

The role of dietitians and psychologists to promote optimum patient related outcomes in oral immunotherapy

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ABSTRACT

Although research in oral immunotherapy for food allergy is perceived primarily as a biomedical endeavor, the involvement of multiple disciplines is required to ensure optimum outcomes for patients and their caregivers. This is a narrative review of research in which we also provide expert opinion due to the small number of studies addressing the role of dietitians and psychologists in oral immunotherapy to foods. Dietitians support patient education with instructions on how to measure and prepare the immunotherapy dose, incorporate the dose into the daily diet, and transition to equivalent foods to meet dosing needs. Dietitians play an important role in assessing the impact of oral immunotherapy on nutritional health. Psychological distress in food allergy is largely driven by the persistent fear of an adverse reaction, therefore the principal objective of food allergy treatment is to improve patient outcomes, e.g., quality of life. Psychologists must be involved in the design of patient related outcome measures in clinical trials to inform clinical decision-making and health-care policy; an important step in selecting and supporting patients who will benefit most from a particular treatment. Psychologists and dietitians can play a critical role during all phases of oral immunotherapy to foods.

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Food allergy is a common problem, is increasing in prevalence, and places a substantial burden on the patient, caregivers, and the health-care system. Patients with food allergy must adhere to individualized allergen avoidance; however, this is not a simple endeavor, with ~40% of patients reporting allergic reactions due to accidental exposure.^{1,2} Psychological distress and poor food allergy quality of life (FAQL) are largely driven by persistent fear of an adverse reaction, which affects emotional and social aspects of

everyday life for patients of all ages and their families.³ Food allergy management typically involves social and dietary restrictions, which are interrelated. Oral immunotherapy (OIT) to foods involves gradually ingesting increasing quantities of a food allergen in an attempt to achieve some level of desensitization. When considering the psychological distress caused by fear of reactions and the consequent social and dietary restrictions incurred, OIT has garnered much attention and interest from both the health professional and patient communities.

Although research in OIT is perceived as primarily a biomedical endeavor, the involvement of multiple disciplines can ensure optimum treatment outcomes for patients and their caregivers. The Canadian Society for Allergy and Clinical Immunology guidelines⁴ for the ethical, evidence-based, and patient-oriented clinical practice of OIT in immunoglobulin E-mediated food allergy states, “A multidisciplinary approach adapted to patient needs should be promoted, and should include nurses, registered dietitians, psychologists, and peer supporters, when possible to ensure optimal delivery of quality care.” The role of nurses is covered elsewhere in this manual by Russell *et al.*⁵ In this article, we focus on the role of dietitians and psychologists to promote optimum patient-related outcomes to achieve the full potential of OIT in improving patient health and well-being.

THE ROLE OF PSYCHOLOGY AND BEHAVIORAL SCIENCES IN OIT

Health-related quality of life is a multidimensional, patient-centered concept, influenced by individual

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experiences, beliefs, expectations, and perceptions, in addition to age, gender, culture, and socioeconomic factors.⁶ FAQL measures impacts that are specific to food allergy, including food anxiety, emotional distress, fear of reactions, and social and dietary restrictions. Food allergy-specific patient-reported outcome measures (PROM), *e.g.*, the Food Allergy Quality of Life Questionnaires (FAQLQ), have been shown to have high validity and reliability, and ensure that the patient perspective is emphasized in research and in practice.³ FAQL has been found to be significantly influenced by a negative expectation of adverse outcomes in relation to allergic reactions in patients and caregivers.³ Therefore, an important objective of OIT is to improve patient-important outcomes, *e.g.*, improved FAQL.

Few studies have evaluated FAQL outcomes with peanut OIT. However, both the Peanut Allergy Oral Immunotherapy Study of AR101 for Desensitization in Children and Adults (PALISADE) and ARC004, the open-label follow-on study to PALISADE showed that OIT improves FAQL and that this improvement is sustained and may be enhanced with longer duration of treatment.⁷⁻⁹ Similarly, the Probiotic and Peanut Oral Immunotherapy (PPOIT) the PPOIT-003 study¹⁰ assessed FAQL by using the FAQL parent proxy form.¹¹ Analysis of the data suggests that PPOIT provides substantial improvement in FAQL compared with placebo to 1-year after treatment and, more importantly, establishes that sustained unresponsiveness (SU) and/or remission provides greater FAQL improvement than desensitization (without SU and/or remission) or remaining allergic. More research is urgently needed to understand the influence of patient-related factors such as these on outcomes.

With regard to the use of OIT in clinical practice, PROMs, *e.g.*, FAQLQ, can be valuable. In clinical practice, the decision to offer OIT should be based not only on evaluation of safety, efficacy, and tolerability but on the potential benefits to FAQL. Treatment success may be defined not only by desensitization or SU but by improved FAQL, and screening may help in this regard. For example, if a child and/or caregiver is satisfied with managing a food allergy with selective avoidance and has integrated self-management strategies well (perhaps for an extended period of time), then even SU after treatment may result in little or no improvement, or perhaps even a worsening in FAQL. In contrast, raising the threshold for an individual reaction even mildly in an anxious child and/or the caregiver may significantly improve FAQL for that child and/or the caregiver. FAQLQs¹²⁻¹⁶ (Proxy or Self-Report, short forms) or other food allergy specific outcomes measures (Food Allergy Self-Efficacy,¹⁷ Food Allergy Coping and Emotions Scales¹⁸) are available.

OIT in food allergy is an exciting development, with the potential to change the course of food allergy management and everyday lives of the patients and their families. However, further patient-related factors

should be considered to ensure optimal FAQL outcomes. Psychologists and patient partners must be involved in the design of PROMs in clinical trials to ensure that scientific, logistic, and resource considerations are addressed with high-quality complete data collection in mind to inform clinical decision-making and health-care policy.¹⁹ This will represent an important step in selecting and supporting those patients for whom a therapy is appropriate and who will benefit most from a particular treatment. It can also help us tailor and support treatment to the characteristics and needs of the patient. Further discussion on patient and/or parent counselling and consent in the shared decision-making process for OIT is discussed by Greenhawt *et al.*²⁰ in this manual.

THE ROLE OF THE DIETITIAN

Food Equivalents

Patients frequently prefer a variety of foods to meet their OIT dosing needs; however, determining the appropriate equivalent dosing can be challenging.²¹ Options for peanut OIT include whole peanuts, peanut flour, peanut butter, peanut candies, and peanut puffs. There are a variety of tree nut butters, vegan beverages, yogurts, and cheeses made from tree nuts. Liquid pasteurized egg can easily be measured with household measurements and added to a recipe. Milk and dairy products come in a variety of protein contents. In single-ingredient foods, one must read the nutrition facts label and ingredient list to ensure that the protein content is appropriate for the desired dose. Also, the protein content listed on the product label is rounded, which may lead to over- or underestimating the dose, especially at lower dosing levels. Consider checking nutrient data bases such as the *FoodData Central* from the United States Department of Agriculture for more information on the protein content of a specific food.

The product label does not always provide sufficient information to determine allergenic protein content, particularly in composite foods. A recent study aimed to estimate the amount of allergenic protein from milk, egg, peanut, and hazelnut in composite and noncomposite foods, and found that the amount of allergenic protein could be estimated in only 47 of 70 foods (67%).²¹ In addition, items such as whole peanuts or peanuts in candies come in variable sizes, and it is difficult to determine the exact protein content by visual assessment.^{22,23} The peanuts contained in candies are generally much smaller than whole roasted peanuts,²² and adjustments must be made for equivalent dosing. Mack *et al.*²³ assessed peanut protein content of 294 peanut M&Ms (Mars Chocolate, Hackettstown, NJ) from two lots. Fourteen (4.8%) candies contained either no, partial, or multiple peanuts, and one contained an almond.²³

Leroux *et al.*²² reported that visual assessment essentially eliminated candies with two peanuts but not

Table 1 Shelf life of food items

Food Item	Average Shelf Life		
	Pantry	Refrigerator	Freezer
Peanut butter, unopened*	6–9 mo	Not needed	Do not freeze
Peanut butter, opened*	2–3 mo	6–9 mo	Do not freeze
Peanut flour, opened*	2–3 mo	6* to 12# mo	9–12 mo
Tree nut flour, opened§	2–3 mo	6 mo	Not provided
Tahini, opened§	6 mo	8 mo	Not provided
Powdered eggs, opened	Typically 6 mo; store according to specific product brand instructions	Not provided	Not provided
Powdered milk, opened§	2 wk to 3 mo; store according to specific product brand instructions	Does not extend the shelf life	Not provided

*Information from the National Peanut Board, Atlanta, Georgia.

#Adapted from Ref. 24.

§E-mail communication from companies.

Table 2 In-office preparation summary

Procure safe and appropriate food products
At minimum, store food products according to the manufacturer’s recommendations
Refrigeration may extend the shelf life of certain products
Label products with the date of opening; hold products no longer than recommended by the manufacturer after opening
Create a protocol and train the staff about safe food handling
Have a dedicated oral immunotherapy dose preparation area
Clean and sterilize food contact surfaces and equipment in the preparation area
Wash hands and don single-use gloves before preparation
Carefully measure the dose and the label with the food item’s name, dose, and patient’s name
Clean the food preparation area and equipment, wash hands, and wear new gloves when changing from one allergen dose preparation to another

those with partial or no peanut. The coefficient of variation decreased with higher peanut protein doses, which indicated that using equivalent foods may be more practical at higher target doses than at very low doses. Also, it is important to review product labels (ingredients, serving size, and total protein content) with every purchase because ingredients, recipes, and allergenic protein content can change without notice. When developing food equivalent protocols consider factors such as total versus allergen protein content, size and variability of food items, processing of the food item (baked versus unbaked) ingredients, and rounding of protein content on food product labels.²¹ Providing food equivalent dosing protocols or teaching patients to calculate the dose if literacy allows is imperative to compliance with daily dosing.

In-Office Preparation Strategies

The role of in-office preparation of OIT doses often falls to nursing or dietetic professionals. Preparing OIT

dosing in the office requires procuring appropriate foods, following standard operating protocols for safe food preparation, using a designated food preparation area, and using measuring and serving equipment.

Procuring and Handling Food Product

In general, flours (e.g., tree nut or peanut flour, pasteurized milk and/or egg powder) as opposed to the whole foods (e.g., peanut, whole egg) have been used during OIT up dosing. In the research setting, flours are frequently evaluated for food safety (bacterial, yeast, mold analysis) and allergen safety (reduced risk of cross-contact), may undergo testing for microbial load and allergenic protein stability, and are dated for expiration in a central good manufacturing procedure facility. The good manufacturing procedure also provides safe storage instructions.

In a clinical setting, the safety of the food item provided is the responsibility of the clinical site. Foods should be chosen, stored, and prepared so as to protect

Table 3 Vehicles and masking*

Vehicle
Applesauce
Other fruit purees
Yogurt
Pudding
Mashed potatoes
Smoothie, milk, plant-based beverages
Tolerated infant or toddler formula
Oatmeal
Soups
Salsa
Ground meat
Chili
Masking flavor or texture
Flavored syrups (vanilla, chocolate, strawberry), maple syrup
Jam or jelly
Condiments (ketchup, mustard, soy sauce, coconut aminos)
Herbs and spices (cinnamon, nutmeg, chili powder, curry powder, cocoa powder)
Flavor extracts (mint, orange, raspberry extract)
Grain flakes or cookie crumbs for added texture

*Some items listed may serve as both vehicle and masking ingredients.

against contamination from other allergens and pathogens. Foods will spoil more quickly, and pathogenic bacteria can multiply rapidly and cause foodborne illness when foods are mishandled (consider ServSafe Food Handler and ServSafe Allergen training programs for staff). Importantly, food items should be purchased in a package size that will reasonably meet the short-term needs of the allergy practice rather than hold and handle a larger amount of a food item for extended periods. Although most manufacturers state that peanut butter, tree nut, and peanut flours may be stored in a “cool, dry place,” storage in the refrigerator may be preferable because it can extend shelf life threefold.

Berglund *et al.*,²⁴ evaluated the peanut allergen stability of 12% fat, light roast, peanut flour purchased from Golden Peanut Company, Alpharetta, Georgia. They found that Ara h 1 and 2 levels remained constant and that little to no microbial growth occurred when the flour was kept at 2–8°C over a 12-month period.²⁴ Peanut flour companies typically report that their products are safe to use for up to 1 month if stored in the pantry and 4–6 months if stored in the refrigerator after the package is opened, although it is likely that some specific brands may last longer (based on Berglund *et al.*²⁴) if properly handled. No such study has been conducted for tree nut flours, and it is

Table 4 Considerations when choosing a vehicle or masking food

Previous consumption and tolerance of the “masking” food
The cumulative volume of the vehicle plus the dose
Age-specific textures, volume, and food safety
Specific-food aversions and/or phobias
Specific-food preferences

safest to use these products according to the manufacturer’s specification, typically no longer than 6 months after opening if properly stored in the refrigerator.

The “use by” date may be listed on the package, and this is the last recommended date for use of the product while at peak quality. However, once a product is opened, the shelf life quickly decreases. The shelf life, after opening the package, may not be listed on the package, and practices should contact the company for further information on proper storage and product shelf life. After the manufacturer-recommended storage time, the remaining product should be discarded even if it is before the “use by” date. See Table 1 for more product storage information. There is little information available on the shelf life for egg and milk powders. We recommend adhering closely to brand-specific recommendations. Food handling and hygiene is important to prevent bacterial contamination and cross-contact. See Table 2 for in-office preparation summary.

Educating Families

During initial OIT visits, patients and/or caregivers receive information from multiple health-care providers. Allergists and/or allergy nurses often provide information, such as timing of the dose feeding, activity restrictions about dosing, when to hold or reduce a dose, and what to do if an allergic reaction occurs. Patients and/or caregivers must also learn how to safely prepare the dose. For instance, tree nut, peanut, and seed butters, should be diluted when offered to children ages < 5 years to reduce the risk of choking. These foods can also be mixed with food purees or a suitable soft, moist food such as oatmeal or yogurt. Caregivers must understand how to measure the daily dose. Even a simple dose, measured by using a measuring spoon, requires instruction on measuring. The difference between a packed or an unpacked measure, a rounded or level measure can be twofold.

Describing, demonstrating, and having the patient and/or caregiver practice measuring the dose under observation (teach back) will help to assess the effectiveness of the teaching method and help build patient confidence in the technique. This is important, whether

Table 5 Nutrient content of 10 g of the allergenic food

Amount: 10 g per Nutrition Data System for Research	Calories	Protein, g	Fat, g	Carbohydrate, g
Cow's milk yogurt	7	0.397	0.372	0.534
Egg white	5	1.09	0.017	0.073
Boiled egg	16	1.258	1.061	0.112
Peanut butter	59	2.435	4.966	2.126
Cashew butter	59	1.756	4.941	2.757
Walnut butter (nutrition fact)	69	1.6	6.5	0.69
Tahini	60	1.7	5.376	2.119
Almond butter	61	2.096	5.55	1.882
Soy yogurt (flavored)	9	0.475	0.233	1.404
Soy yogurt (plain)	5	0.388	0.191	0.511

Table 6 The food form, matrix, and nutrient content*

Amount, per 2g peanut protein	Kcal	Protein, g	Fat, g	CHO, g
Peanut butter	50	2	3	1.76
Defatted peanut flour	20	2	0.5	1.6
Reese's regular size peanut butter cup (not mini, miniature, snack size, or king size)	105	2	6	12
Whole peanut (8 cocktail peanuts)	48	2	4	1.5
Bamba (Osem Bamba 12 oz pack)	60	2	3.3	5.6

*This table is for nutrition purposes only and the protein content is rounded and may vary by brand. The information should not be used to calculate doses.

weighing a dose on an electronic scale or measuring a dose by using a level measurement, or counting out doses in pieces of food. Written materials for medical information are known to lead to better adherence in recommendations,²⁵ so providing written instructions on measuring and taking the daily OIT dose will give the patient and/or caregiver a way to review instructions after the visit. Leroux *et al.*²⁶ demonstrated the efficacy of a dietitian-led counseling program with written instructions, which significantly increased knowledge compared with no dietitian intervention ($p < 0.0001$).

Practical Aspects of OIT and Continued Ingestion

OIT requires regular dosing of the allergen, and children and adults alike may not prefer the food. Flavor masking and tips for serving the OIT dose are provided in Table 3. Flavor masking can help with dosing at any dose level, although it is easier to mask a smaller dose (Table 4), and smaller maintenance dosing may be more practical with multifoed OIT. In a clinical setting, it is reasonable to individualize a target maintenance dose based on the patient's goal, tolerance, and his or her willingness to consume the daily dose. Consider, however, that removing the need for allergen avoidance and that the ability to stop

maintenance OIT drives FAQL improvement beyond what is offered from protection against accidental exposure, so these discussions may be part of the shared decision-making in OIT, which is discussed further by Greenhawt *et al.*²⁰ in this manual.

Flours and powders can be added to a small amount of any moist food, such as a fruit puree, yogurt, pudding, oatmeal, or ice cream. Flours can also be mixed into and cooked in a small meatball or made into a small chocolate button by stirring into melted chocolate that is then hardened. Powders may be added to a single pancake (sprinkle on top or stirred into 2 tablespoons of batter), and served with cinnamon. Although peanut flour typically used in OIT is roasted, milk, egg, and some tree nut flours (cashew for instance) are not previously "cooked," and cooking the dose may impact the desired allergenicity.

Nutrition Impact

The nutrient panel of the dosing food should be scrutinized for additional ingredients, such as sugar and fat, which may unnecessarily increase the volume required, calories, and fat content. Using a variety of products can help to reduce the monotony of dosing; however, the overall nutritional composition and the individual

nutritional needs should be considered. During OIT, it is important to monitor dietary intake and the impact on nutritional health because OIT for peanut and milk allergy have been reported to lead to overweight and obesity.^{27,28} In a small study from Brazil, 3 of 18 participants (17%) had gained excessive weight 12 months after OIT.²⁷ Interestingly, >50% of the children reported preference to ultraprocessed foods for dosing.

In another small study, from Italy, in 16 individuals with milk allergy, the investigators reported a non-significant reduced intake of calories, protein, carbohydrate, fiber, and calcium, and an increased intake of fat.²⁸ Despite the advice to consume milk daily, only 25% of the individuals consumed milk. Food preferences included hard cheese (94%), soft cheese (75%), pizza (62%), yogurt (56%), with a lower preference of sweet foods, such as chocolate (12%), ice cream (12%), and deserts (6%).²⁶ It has been reported that > 70% of commercial products contain precautionary advisory labeling, which advises about the potential for unintentional allergen content.²⁹ If the individual has been advised that foods that contain precautionary advisory labeling are safe to consume after OIT, then there is a possibility that food intake may change to a great extent, which could affect nutritional intake.

Foods used for OIT and their matrices add additional calories and other nutrients to the diet. The nutrient content of foods that contain food allergens are summarized in Table 5. The effect of the food form and matrix on nutrient intake are summarized in Table 6. As a simple example, peanut butter candy or chocolate contains twice as many calories than peanut butter and five times the amount in defatted peanut flour per 2-g peanut protein dose. These factors should be considered to balance the goals of continued consumption with healthy eating.

CONCLUSION

A multidisciplinary approach is key to the concept of integrated care, which aims to improve the patient experience and health outcomes, particularly in the context of chronic diseases. OIT benefits from such a multidisciplinary approach. We must continue to measure patient outcomes to ensure an approach that is effective in treating food allergy, improving FAQL, and optimizing and maintaining nutritional health.

CLINICAL PEARLS

- OIT to foods benefits from a multidisciplinary approach.
- In clinical practice, the decision to offer OIT should be based not only on an evaluation of safety, efficacy, and tolerability but also on the potential benefits to FAQL.

- FAQLQs are available for clinical practices. For guidance on using these FAQLQs, please contact A. DunnGalvin at a.dunngalvin@uss.ie
- FAQLQs may help assess the benefits and harms of OIT for individual patients.
- When developing food equivalent protocols, consider factors such as total versus allergen protein content, size and variability of food items, processing of the food item (baked versus unbaked) ingredients, and rounding of the protein content on food product labels.
- Education for OIT dosing benefits from a systematic approach with demonstration, teach back, and written instructions to support patient competency.
- Provide serving suggestions and masking ideas to improve dosing compliance.
- Consider the nutritional contribution of the OIT food and matrix to avoid negative nutritional consequences.

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