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# **Oral Immunotherapy (OIT)**



You have been told that you have a food allergy, and the current standard of care is simply avoidance of the food(s) you are allergic to along with the use of an EpiPen in the case of an adverse reaction. Food allergies not only pose high risk and danger for potential life-threatening reactions known as anaphylaxis, but people have also reported a decreased quality of life and social isolation from the constant fear and anxiety of eating outside the home due to possible cross-contamination or accidental exposure. More traditionally, subcutaneous immunotherapy ("allergy shots") have been used for patients diagnosed with environmental triggers of allergic rhinitis including but not limited to grass, dust mite, pollen, insect venom, cat, and dog. However, subcutaneous immunotherapy is not widely used for food allergies due to frequent bouts of systemic reactions in prior trials. Thus, novel treatment options including oral, sublingual, and epicutaneous immunotherapy are emerging and being explored to help offer some relief for people with food allergies.

### WHAT IS OIT?

Oral immunotherapy (OIT) is an exciting, innovative approach to help induce desensitization and potentially build tolerance to food allergens by ingesting increasingly small amounts of the allergen in a timely fixed schedule. The primary objective of OIT is decrease your sensitivity to the food allergen, so that accidental exposure or cross-contamination with the offending food (peanut, tree nuts, milk, etc.) will result in fewer and less severe symptoms. This does not mean that OIT is a substitute for avoidance of large amounts of direct consumption of known food allergens, but rather it is a supplement to those treatment measures.

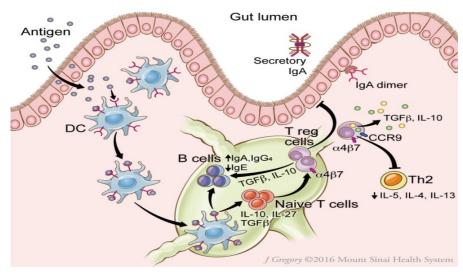
## WHAT WOULD OUALIFY ME FOR OIT?

Due to the still ongoing research regarding OIT, this treatment option is not yet widely offered to everyone. In order to qualify as a good candidate for OIT, you must have a convincing clinical history or diagnosed with a food allergy confirmed by a positive skin test, and/or test for IgE antibody in the blood. The skin test is typically performed first; however, since it is highly sensitive, blood work can be ordered to test for overall and food component IgE antibodies in the blood. It is important to note that the diagnostic tools that we have are not perfect and not always completely specific; however, strongly positive tests are often seen in individuals who are truly allergic. Due to the highly sensitive diagnostic tools that can produce false positives, we do not perform random food testing. Rather, we test you according to your clinical history of any itching, rash, or hives upon exposure or ingestion of food. If you have tolerated a certain food in the past well with no problems, then it is highly unlikely that you have a food allergy. True food allergies often lead to immediate reproducible symptoms of itching, rash, or hives typically within 15 minutes of consumption, since it follows an IgE mediated pathway.

OIT is not yet offered for patients who have been intubated or admitted into the ICU from severe or systemic reactions including but not limited to anaphylaxis. This treatment is also not ideal for patients with uncontrolled asthma or GERD. It is not recommended to start OIT while also simultaneously building up for subcutaneous allergy shots.

# **HOW DOES IT WORK?**

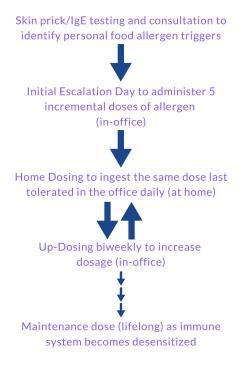
The immune mechanism is still being researched; however, the proposed mechanism behind OIT food tolerance is that small amounts of the food protein are introduced and passes through the epithelial barrier of the gut. The food protein ("antigen") is then taken up by dendritic cells, which present the antigen and travel to the mesenteric lymph node where B cells decrease specific IgE and secrete of IgA and IgG4. Regulatory T cells also are also activated to help suppress the food allergy pathway by secreting Th1-type (immunosuppressive)

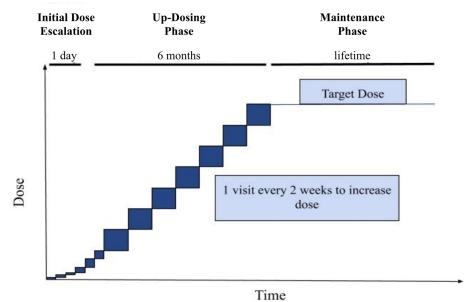


cytokines and decreasing Th2-type cytokines responsible for strong IgE production. For peanut allergies particularly, IgG4 is thought to suppress the reactivity of peanut-induced basophils and mast cell activation by competing with IgE and binding to an inhibitory receptor.

#### WHAT WOULD THE TREATMENT LOOK LIKE?

Oral immunotherapy is begun at a very low dose. This dosage is then gradually increased on a regular interval basis until a therapeutic dose (often called the "maintenance dose") is reached. The first round of doses is given in our medical office and, as long as this initial dosing is well tolerated, that same dose is repeated daily at home. Every two weeks, the dosage is then increased in our office and again subsequent daily doses are taken at home if well tolerated. After the maintenance dose is reached, the treatment should still be continued and taken daily at home.





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## WHAT IS THE EFFICACY AND RISK?

Improvement in your symptoms will not be immediate, but there have been studies showing both the efficacy and safety of OIT in both children and adults. However, with all forms of immunotherapy, there are some associated risks to be aware of. It is not uncommon for you to experience some local reactions in your mouth consisting of minor itching and discomfort. Other symptoms include oral paresthesia, throat irritation, rhinorrhea, and sneezing. These symptoms, should they occur, are typically brief and go away without any special treatment. Gastrointestinal reactions including abdominal pain and cramps are also common. Other systemic reactions, while rare, can occur at any time during treatment including but not limited to hives all over the body, chest tightness, trouble swallowing, angioedema, or anaphylaxis. If present, reactions are likely on the Initial Dose Escalation day in our medical office, which is why a 30 minute waiting period is required following each dosage administered. There have been very small occurrences of any adverse reactions occurring during the home dosing phase; therefore, you must have a self-injectable epinephrine auto injector on hand with each dose of treatment.

## WHAT ARE SOME IMPORTANT THINGS TO CONSIDER?

- OIT requires large patient responsibility and compliance as it is a time commitment.
  - Consultation to discuss candidacy and details of OIT (~30 minutes in office)
  - o Initial Dose Escalation day (~2.5 hours in office) to incrementally increase in dose
  - Biweekly office visits for the *Up-Dosing* phase (~30 minutes in office)
  - Repeat the same dose last tolerated in the office at home DAILY
    - Must be consumed around the same time per day within 4 hours
    - Must avoid strenuous exercise 2-3 hours post dose
    - Recommend taking the dose in the evening after dinner
    - Cannot take the dose right before bedtime to allow for sufficient observation
  - Log the date, time, and any associated symptoms of doses taken daily
  - o Communicate with Dr. Zheng & staff of any of the following:
    - Missed dose or deviances in protocol, adverse reactions, symptoms
- You must adhere to all medication instructions for doses both in our office and at home.
  - The following pre-treatments may be supplemented as indicated by Dr. Zheng:
    - Probiotics (i.e. Culturelle)
    - Antihistamines (i.e. Zyrtec, Allegra, Xyzal)
    - Antacids (i.e. Pepcid AC)
  - NSAIDs (i.e. aspirin, ibuprofen, etc.) and beta-blocker medications are contraindicated during the build-up desensitization phase as they can increase one's susceptibility to allergic reactions.
- This is still an ongoing field of study.
  - OIT has been widely researched in clinical trials, some of which suggest induced desensitization and a higher threshold of tolerance after reaching the maintenance dose
  - A caveat of the results so far, however, is that the treatment and approach in research studies are much more vigorous and aggressive due to the nature and time constraints of clinical trials
  - There is no wide standardized protocol for OIT in a community setting
  - The FDA recently approved the first peanut allergy drug, Palforzia
    - <a href="https://www.washingtonpost.com/health/2020/01/31/first-peanut-allergy-drug-approved-by-fda/">https://www.washingtonpost.com/health/2020/01/31/first-peanut-allergy-drug-approved-by-fda/</a>