

YOUR HEALTH

A Controversial Treatment for Peanut Allergies

Patients get increasing doses of peanuts until they no longer suffer allergic reactions



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Peanut M&M dispensers stand in the waiting room of the New England Food Allergy Treatment Center. Hundreds of drawings plaster the walls, almost all done by children with peanut allergies. One shows a picture of a boy holding hands with Mr. Peanut. “Now

we're friends!" reads the caption.

The children coming to the center are openly flouting rules drilled into their heads for most of their lives: Avoid peanuts and potentially contaminated products at all costs. Instead, the children here eat carefully measured doses of peanut protein, usually mixed into yogurt, pudding or apple sauce, in a treatment known as oral immunotherapy. The idea is to gradually increase the doses to desensitize their bodies to peanuts so they no longer suffer allergic reactions. Immunotherapy is a popular treatment for people with environmental allergies, such as hay fever. But it is less common, and is a controversial practice, for treating food allergies.

"We've treated about 750 to 760 patients so far with a 90 to 92% success rate," says Jeffrey Factor, founder and medical director of the center, which opened in 2010. Nearly all the patients, most of whom are children, come because of peanut allergies. But the center also has treated about 50 patients who have milk, egg or tree-nut allergies.

Matthew Sullivan, 12, of Longmeadow, Mass., in a treatment room at the New England Food Allergy Treatment Center. Earlier in February, Matthew passed a food challenge, in which he ate the equivalent of 46 peanuts in one sitting, and is now considered peanut tolerant. He no longer has to carry an EpiPen and can eat as many peanuts, and peanut M&M's, as he wants. *PHOTO: JULIE BIDWELL FOR THE WALL STREET JOURNAL*



Oral immunotherapy, often called OIT, isn't approved by the U.S. Food and Drug Administration or endorsed by any professional organization of allergists. Some of the country's leading allergists say that, despite promising evidence, more research and regulatory approval are needed before the process should be recommended as a treatment for food allergies. Studies have shown about 80% to 85% of patients who undergo oral immunotherapy are successfully desensitized to their allergen. But questions remain about its long-term effectiveness, and there are concerns some patients could have adverse reactions, these allergists say.

The therapy is a frequent topic of debate at medical conferences and in academic journals. Many academic institutions offer oral immunotherapy for food allergies, but only as part of ongoing clinical trials. Some trials are being sponsored by Aimmune Therapeutics, a biopharmaceutical company near San Francisco that is in Phase 3 clinical trials for its pharmaceutical-grade peanut formulation, the final stage needed for FDA approval.

“We absolutely don’t do OIT for treatment,” said Robert Wood, division chief for pediatric allergy and immunology at Johns Hopkins School of Medicine, in Baltimore, which is participating in about a dozen OIT trials for different foods. “In my mind doing so is pushing the envelope beyond the appropriate level of safety,” Dr. Wood says.

Some 15 million people in the U.S. have a food allergy, including nearly 8% of children, a rate that has jumped by half in recent decades. Peanut allergies are the most common and dangerous, with reactions ranging from skin rashes to anaphylactic shock, which can be fatal. About 80% of children don’t outgrow peanut allergies. There is no approved treatment for food allergies except avoidance.

NUTS ABOUT PEANUTS

Matthew Sullivan, 12, has gone from severe peanut allergy to eating a peanut butter and jelly sandwich for school lunch.

- **May 2004:** At 13 months old, Matthew develops hives on his arms and legs after biting into a peanut-butter cracker.
- **June 2004:** An allergist confirms Matthew has an allergy to peanuts. His parents decide to avoid exposing him to peanuts, fearing a possible anaphylactic reaction.
- **November 2010:** At age 7, Matthew begins immunotherapy treatment. He gradually increases his intake of peanut protein over several months, suffering occasional headaches and stomachaches.
- **July 2011:** Matthew eats three peanut M&M’s at the clinic, after two weeks of ingesting the equivalent amount of peanut-protein powder.
- **October 2013:** Skin tests continue to show Matthew is allergic to peanuts. But he continues to eat three or so peanut M&M’s daily.
- **January 2016:** Tests indicate Matthew is no longer allergic to peanuts. He passes a food challenge at the clinic, eating the equivalent of 46 peanuts in one sitting.
- **Feb. 4, 2016:** Matthew brings a peanut butter and strawberry jelly sandwich to school for lunch.

A growing number of allergists in private practice offer OIT for food allergies, though the numbers are still low—about 50 across the country, according to a popular Facebook group of parents interested in the therapy. The West Hartford center is the only one in New England and patients drive from as far as Ohio, Pennsylvania and Maryland for appointments.

Dr. Factor, of the New England center, says his patients typically start with a 0.1-milligram dose of peanut protein—just a few flecks of peanut flour that look like grains of sand. Over the next five hours or so, the dose is gradually increased to about 6 milligrams. If the peanut protein is tolerated, patients are sent home with a plastic bin holding individual containers of the dose, which they take daily. They return to the center every two weeks for ever-larger doses until they graduate to whole peanuts or peanut M&M's. They are considered desensitized when they can tolerate about 10 peanuts daily and then must continue a maintenance dose indefinitely. Treatment usually lasts 10 to 12 months and is often covered by private insurance, he says.

Precautions include avoiding exercise for two hours after a dose, calling the center for advice if a patient is sick or has asthma, and avoiding hot showers and NSAIDs, like Advil, at the time of a dose, Dr. Factor says. While it isn't uncommon to have some symptoms during treatment, most are minor, such as itchy mouth or stomachaches. Systemic or anaphylactic reactions have occurred in less than 10% of patients, Dr. Factor says. "So it's not without any risk at all," he says.

Matthew Sullivan, now 12, started oral immunotherapy for a peanut allergy at the New England center in 2010. The first picture he drew there was of him and a peanut, with the caption: "Can we be friends?" The boy had his first allergic reaction to peanuts, including hives on his arms and legs, at 13 months old.

His mother, Heather Sullivan, drove them to appointments from their Longmeadow, Mass., home every other week. After nine months Matthew was successfully desensitized and has been on a maintenance dose of three to four peanut butter or peanut M&M's a day. He no longer carries an EpiPen in case of an anaphylactic reaction, Ms. Sullivan says. And earlier in February, Matthew passed a food challenge at the treatment center, in which he ate the equivalent of 46 peanuts in one sitting.

"On Tuesday he brought a Reese's peanut butter cup to school and the whole lunch table applauded," Ms. Sullivan says. For his lunch two days later, Matthew brought a peanut butter and jelly sandwich.

"It was totally worth it," Matthew says. "It worked!"

Laura Donoghue has been bringing her 6-year-old son, Michael, to the center for more than a year from their home in Oceanside, N.Y., about three hours away. Before he began



Michael Donoghue, 6, with parents Christopher and Laura, in the waiting room at the New England Food Allergy Treatment Center, where the boy is being treated for peanut allergy. The family has been coming to the center from their home in Oceanside, N.Y., about three hours away, for more than a year. Michael completed his treatment in December and is now eating 10 peanuts a day as part of his posttreatment maintenance diet. *PHOTO: JULIE BIDWELL FOR THE WALL STREET JOURNAL*

treatment, Michael had several anaphylactic reactions after being exposed to food containing peanut products. The quiet kindergartner completed his treatment in December and is now eating 10 peanuts a day as part of his posttreatment maintenance diet. The family hopes Michael will be ready to do a food challenge by the summer.

There is no uniform protocol for OIT for food allergies, which is a reason critics say it shouldn't be recommended for treatment. At the Dallas Food Allergy Center in Texas patients come in every week for about 6½ months, on average, says Richard L. Wasserman, the center's director. At home they take twice-daily doses. The center, which opened 8½ years ago, has begun treatment on more than 400 patients, mostly children, with about 62 dropping out before completion. More than half have peanut allergies; the rest come in mostly for milk and egg allergies. Systemic reactions have occurred. About one in 1,000 doses of food has resulted in an epinephrine-treated anaphylactic reaction.

A study published last year in the journal *Lancet* found that 84% of children could safely eat the equivalent of five peanuts a day after six months of OIT compared with none in a control group. The study included 99 children between the ages of 7 and 16.

Whether the treatment lasts is the subject of research by some prominent allergists.

Kari Nadeau, director of the Sean N. Parker Center for Allergy and Asthma Research at Stanford University, oversees about 15 clinical trials involving OIT and food allergies around the country. Her team at Stanford has performed clinical research on more than 700 patients using OIT and she has a wait list of 4,000 people interested in joining the trials.

So far the researchers have followed patients as long as nine years and found that as many as 90% of the participants become desensitized, though for some patients that can take a few years. Nearly a third of those reach the point of “sustained unresponsiveness,” meaning they appear to be allergy-free, according to skin and blood tests.

Given the level of demand for OIT, and because private physicians are already practicing it, researchers should be “sharing what we’ve learned so that people get treated effectively and safely,” Dr. Nadeau says.

Mark Weinstein, an allergist in Belleville, N.J., plans to open an office using OIT for food allergies this summer. He says about 40 patients have already signed up for treatment.

Natalie Hower, 5 years old, will be one of Dr. Weinstein’s patients. Her mother, Cynthia Hower, says the girl was diagnosed as allergic to peanuts and tree nuts when she was 2. Ms. Hower, of Rutherford, N.J., says she is hoping for a day when she doesn’t have to scrutinize labels and call companies to ask if a product was made in a facility with peanuts.

“I know it’s a risk. I know it’s not a cure. I’ve heard of some children not being able to continue with the process. But I’ve also heard of many success stories,” Ms. Hower says.

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