

Initiating peanut oral immunotherapy in peanut-allergic children under age four may be more effective: long term study

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The majority of young children treated with peanut immunotherapy achieved desensitization after two and a half years of treatment, and one

in five remained in remission 26 weeks after treatment ended, according to a randomized controlled trial published in *The Lancet*.

Achieving [remission](#) was more common the younger the child was at the start of therapy: 71% (5/7) of those aged one year old, 35% (7/20) of those aged two years old, and 19% (8/43) of those aged three years old achieved remission.

Peanut allergy affects 2% of [children](#) in Western countries and most remain allergic across their lifetime. Current standard of care for children with [peanut allergy](#) is dietary avoidance and access to self-injectable epinephrine, but the risk of [peanut](#)-induced anaphylaxis from accidental exposures persists, highlighting the need for safe and effective therapies.

Immunotherapy involves repeated exposure over time to gradually increasing doses of the allergen, to reduce [allergic reactions](#). Previous studies in [school-aged children](#) and young adults have demonstrated that peanut oral [immunotherapy](#) can achieve desensitization (an increased allergic reaction threshold while on therapy) in most participants, but success in achieving remission (lack of reactivity after discontinuing therapy over a prolonged period) has been limited. Therefore, the observation that one in five children achieved remission is the most novel outcome in this study, and it provides a better indication of a lasting treatment effect than desensitization.

Dr. Stacie Jones, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, U.S., says, "As a developing therapy, researchers are looking for ways to improve and prolong effects of peanut oral immunotherapy. It has been suggested that intervening in early life when the immune system is still developing may prove more effective than intervening in later life. As the first large study in a preschool age group to test earlier interventions, we found that the

treatment induced desensitization in a majority of peanut-allergic children and around one in five achieved remission. We also saw an additional one in five children whose peanut tolerability did not reach our threshold for remission but still increased significantly after treatment."

Dr. Jones adds, "Interestingly, we also observed that those children who did achieve remission were more likely to be at the younger end of the age group, with the best outcomes in children aged one year old, suggesting that very early interventions may provide the best opportunity to achieve remission. However, there were only small numbers of children aged one year old enrolled in our study, so more studies are needed to investigate this finding."

The study recruited 146 one- to three-year-olds, whose average tolerated dose of peanut protein was 25mg at study entry, as assessed by blinded food challenge, across five medical centers in the United States. Ninety-six children were randomly assigned to peanut oral immunotherapy treatment and 50 children were randomly assigned to a placebo group. The treatment lasted two and a half years (134 weeks). Children received a daily dose of peanut protein powder that was gradually increased from 0.1mg to 2,000 mg (equivalent to roughly six peanuts), while the placebo group received the same treatment regime but with an oat flour substitute. Dosing was mainly administered at home by parents, but each time the dosing level was increased, this was done in medical centers under observation.

At the end of treatment, desensitization was tested by a supervised blinded food challenge to see if children could safely consume 5,000 mg peanut protein powder, equivalent to approximately 16 peanuts, without experiencing significant symptoms. To test remission, the food challenge was repeated after 26-weeks after treatment ended. The children were asked to avoid peanut consumption in between the two food challenges.

Throughout the trial, adverse reactions were recorded, and clinical tests were taken to measure immunologic biomarkers known to correspond with peanut allergy.

71% (68/96) of children treated with peanut oral immunotherapy achieved desensitization, compared to 2% (1/50) in the placebo group. 21% (20/96) of children treated with peanut oral immunotherapy achieved remission compared to 2% (1/50) in the placebo group.

An additional 20 children who did not achieve the threshold for remission could still tolerate 1,755-3,755 mg (roughly 6-12 peanuts) 26 weeks after the end of treatment. Therefore, a total of 57% (40/70) of children who completed treatment could safely consume 1,755-3,755mg peanuts, compared to 4% (1/23) in the placebo group.

Most participants experienced at least one dosing reaction, which were predominantly mild to moderate and more frequent in peanut oral immunotherapy participants (98% peanut oral immunotherapy versus 80% placebo). The most common reactions were skin-related including hives, skin rashes, skin flushing (88% peanut oral immunotherapy group versus 58% placebo); gastrointestinal including stomach pain, itching in the mouth (78% peanut oral immunotherapy group versus 54% placebo); and respiratory including rhinitis, coughing and wheezing (75% peanut oral immunotherapy group versus 44% placebo). Epinephrine was used to treat 21 participants for 35 allergic reactions to the peanut oral immunotherapy over the two and a half years daily dosing period.

Dr. Wesley Burks, University of North Carolina at Chapel Hill, U.S., says, "The serious and unpredictable nature of food allergic reactions can be worrisome for affected children and their parents. Other than avoidance and medication to treat allergic reactions or anaphylaxis, there are no treatment options, resulting in a considerable burden on allergic children and their caregivers to avoid accidental exposure. In severe

cases, this can restrict peanut-allergic children's freedoms, particularly when it comes to navigating daycare or schools and public spaces where a access to a safe diet is in jeopardy for young children. Exploring safe and effective therapy options for children with peanut allergy is crucial to improving quality of life for this group of patients, particularly as most children remain allergic for their lifetime."

The authors note that direct comparisons between this study and other studies looking at oral peanut immunotherapy in older aged children cannot be made because lengths of treatment vary, as do the thresholds used to measure desensitization and remission. However, they do note that a previous study has suggested that roughly 20% of peanut-allergic children may develop tolerance without treatment, but that study included children who were less sensitive to peanuts compared to this trial.

The authors note some limitations of their study. The food challenges were conducted under supervised study conditions, so while they provide an indication of tolerability, they may not reflect how participants will react to consuming peanuts in real-world settings. There was a high dropout rate between the end of treatment and the remission test after 26 weeks of avoidance, which differed substantially between the placebo and treatment group and could have impacted the accuracy of the treatment efficacy results. Furthermore, 27% (22/81) of children in the treatment group and 20% (7/35) in the [placebo group](#) did not reach the 2000mg maximum dose of treatment, potentially leading to an underestimation of the treatment response.

Writing in a linked Comment, lead author Dr. Matthew Greenhawt, Children's Hospital Colorado, University of Colorado School of Medicine, U.S., (who was not involved in the study), says, "IMPACT data advance our understanding of peanut oral immunotherapy, showing that peanut oral immunotherapy can produce desensitization in very

young children with good safety. Although peanut oral immunotherapy at any age is not without some risk of an allergic reaction, this is a reasonable treatment consideration for very young children with peanut allergy, guided by an allergy specialist, in the context of shared decision making. Oral immunotherapy has the potential to help manage disease through [treatment](#), not fear and avoidance."

More information: Efficacy and safety of oral immunotherapy in children aged 1–3 years with peanut allergy (the Immune Tolerance Network IMPACT trial): a randomised placebo-controlled study, *The Lancet* (2022). DOI: [10.1016/S0140-6736\(21\)02390-4](https://doi.org/10.1016/S0140-6736(21)02390-4) , [www.thelancet.com/journals/lan ... \(21\)02390-4/fulltext](https://www.thelancet.com/journals/lan.../fulltext)

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