

Peanut allergy oral immunotherapy increases allergic reactions, compared with avoidance or placebo

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A systematic review including 12 studies with more than 1,000 patients who were followed for a year finds that, compared with allergen avoidance or placebo, current oral immunotherapy treatments result in a large increase in anaphylaxis and other allergic reactions, rather than preventing them as intended.

The findings, published in *The Lancet*, highlight the gap between outcomes measured in the clinic and the [allergy](#) relief outcomes that [patients](#) desire after oral [immunotherapy](#) for [peanut](#) allergy.

Studies of oral immunotherapy currently measure treatment success by whether a treated patient can pass a supervised [food challenge](#), but this cannot predict a patient's future risk and frequency of [allergic reactions](#) in the real world. The study authors call for a new approach to food allergy research to focus on real-world outcomes and everyday exposures.

"Numerous studies of varying quality have been published on oral immunotherapy, but its effectiveness and reliability remains unclear. Our study synthesises all randomized [clinical trials](#) comparing peanut oral immunotherapy to no immunotherapy in order to generate the highest quality evidence to inform decision making. It shows that current peanut oral immunotherapy regimens can achieve the immunological goal of desensitisation, but that this outcome does not translate into achieving the clinical and patient-desired aim of less allergic reactions and anaphylaxis over time. Instead, the opposite outcome occurs, with more allergic and adverse reactions with oral immunotherapy compared

with avoidance or placebo," says lead author Dr. Derek Chu, McMaster University, Canada. "Our results do not denounce current research in oral immunotherapy, but the method needs to be more carefully considered, improvements in safety made, and measures of success need to be aligned with patients' wishes."

Food allergy is a growing global problem. In Europe and North America, more than 6 million people are affected, including up to 8% of children and 2-3% of adults. Although allergy to milk and egg are commonly outgrown by the age of 5-10 years, allergies such as to peanut are lifelong in 80-85% of cases and affect 2% of children and 1% of adults in high-income countries.

The unpredictable and potentially life-threatening nature of food allergic reactions is associated with substantial anxiety and impaired quality of life for patients. There is no treatment for allergies, other than avoidance and medication to treat allergic reactions or anaphylaxis.

Immunotherapy is an investigational therapy for allergies that involves repeated exposure over time to gradually increasing doses of the allergen, with the aim of reducing allergic reactions. While other forms of immunotherapy (sublingual or subcutaneous) for other allergies appear safe and effective in randomised controlled trials, the outcomes of oral immunotherapy are debated.

The authors combined results from 12 randomised controlled trials from the USA, UK, Europe and Australia (including three unpublished trials) including 1,041 patients to compare outcomes after oral immunotherapy with those after no oral immunotherapy. The trials compared oral immunotherapy against placebo, avoidance or other types of immunotherapy, and used different peanut products and doses.

The average age of participants in the studies was around 9 years of age

(between 5-12 years), and participants were followed for a year on average. The study measured anaphylaxis (data for this was available in nine trials), allergic or adverse reactions (10 trials), epinephrine use (nine trials), and quality of life (three trials).

The results suggest with high and moderate quality evidence that, compared with no oral immunotherapy, peanut oral immunotherapy increases the risk and frequency of anaphylaxis (by around three times, from 7.1% without oral immunotherapy to 22.2% with oral immunotherapy), epinephrine use (by around two times, from 3.7% without to 8.2% with), and serious adverse events (by around two times, from 6.2% without to 11.9% with) to a similar extent during build-up and maintenance. Allergic reactions involving the gastrointestinal tract (vomiting, abdominal pain, mouth itching), skin and mucous membranes (hives or urticaria and swelling or angioedema), nose (congestion or rhinitis), and lungs (wheeze or asthma) also increased.

However, they found that quality of life was no better in people receiving oral immunotherapy compared to those that did not. The authors note that this is in contrast to observational studies, and this may be due to those studies not being controlled for confounding and bias. They note that large, well done randomised controlled trials are required to clarify the effect, if any, of peanut oral immunotherapy on quality of life.

The authors say that their findings favour avoidance over current forms of oral immunotherapy if a patient wishes to avoid peanut-induced anaphylaxis and allergic reactions, and that the increased risk of reactions associated with these regimens might be a substantial barrier to widespread adoption by patients with peanut allergies.

In future research, it will be important to clarify patient values and preferences regarding food allergy therapies in general—understanding

what patients expect from treatment, and what outcomes are desirable and undesirable. The measures to estimate health benefits and harms of food allergy interventions should be patient-centred outcomes, such as a risk and rate of allergic and anaphylactic reactions over time, as recommended by GRADE, the US National Institute of Allergy and Infectious Diseases, the FDA, and other organisations.

"Considering the current view of peanut allergy oral immunotherapy as a model for other food allergies, and the increasing global prevalence of food allergies, these findings are significant and important to the ongoing development of food allergy treatments," concludes Dr. Chu.

The authors note some limitations, including that although the study included all available evidence in this area, the number of patients is small, and some studies in the analysis did not report all data for all patients despite requests from the authors. Whether longer term oral immunotherapy or treatment in adults has a different efficacy and safety profile than observed in this study requires further investigation.

Writing in a linked Comment, Graham Roberts, University of Southampton, UK, says: "Although oral immunotherapy undoubtedly reduces the likelihood of reacting to peanuts in a controlled clinic setting, its overall side-effect profile means that patients seem to have more allergic reactions while on therapy. Trading treatment-related side-effects at home for allergic reactions to accidental exposures out of the house (ie, in social situations) might be beneficial for some patients. However, it is not clear which patients might benefit most and the relative balance of reactions in and out of patients' homes. It would also be useful to compare oral with epicutaneous immunotherapy. Although epicutaneous immunotherapy is less effective, it has a better safety profile than [oral immunotherapy](#), which some patients might find more acceptable. Finally, we should not forget that we now know that the early introduction of peanut products into the infant diet can prevent most

cases of peanut allergy. Moving forward we need to develop implementation strategies to reduce number of patients with [peanut allergy](#)."

More information: Derek K Chu et al, Oral immunotherapy for peanut allergy (PACE): a systematic review and meta-analysis of efficacy and safety, *The Lancet* (2019). [DOI: 10.1016/S0140-6736\(19\)30420-9](#)

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