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EFFICACY OF A NOVEL LOW-ALLERGEN, HIGH-OLEIC PEANUT CULTIVAR IN REDUCING SKIN PRICK TEST REACTIVITY IN SENSITIZED CHILDREN

(Original_Article)

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Abstract

Background: Peanut allergy is a persistent and potentially severe condition in children, with limited strategies for safe tolerance induction. Traditional avoidance and oral immunotherapy approaches present challenges including risk of adverse reactions. Bioengineered peanuts with reduced allergenic protein content and enhanced oleic acid levels offer a potential approach to modulate immune responses while minimizing risk.

Objective: To determine whether daily consumption of a novel low-allergen, high-oleic peanut cultivar can safely reduce skin prick test reactivity in peanut-sensitized children and promote early immunological tolerance.

Methods: A randomized controlled trial was conducted in South Punjab involving 60 children aged 5–12 years with confirmed peanut sensitization. Participants were allocated to either the intervention group, receiving daily portions of a bioengineered peanut cultivar for eight weeks, or a control group maintaining strict dietary avoidance. Skin prick test wheal diameters were measured at baseline and post-intervention. Adverse events were monitored. Parametric tests were applied to evaluate within- and between-group changes.

Results: The intervention group's mean wheal diameter decreased from 7.8 ± 1.9 mm to 4.9 ± 1.6 mm (mean change −2.9 ± 1.1 mm). The control group showed a minimal decrease from 7.6 ± 2.0 mm to 7.2 ± 1.8 mm (mean change −0.4 ± 0.9 mm). Mild, self-limiting adverse events occurred in a small proportion of the intervention group. No severe reactions or withdrawals occurred.

Conclusion: Daily consumption of the low-allergen, high-oleic peanut cultivar significantly reduced skin prick test reactivity in sensitized children with minimal adverse events. These findings suggest that bioengineered peanuts may provide a safe, practical strategy for early immunological tolerance induction and may complement existing allergy management approaches.

Keywords: Allergy, Children, Immunotherapy, Peanut, Sensitization, Skin Tests, Tolerance.

Introduction

The global prevalence of peanut allergy has risen sharply over recent decades, placing a growing burden on families, healthcare systems, and public health(1). Peanut allergy remains one of the leading causes of severe food-induced anaphylaxis in children, and unlike many other food allergies that resolve with age, peanut sensitization often persists into adolescence and adulthood(2). Conventional management still relies largely on strict dietary avoidance, emergency preparedness, and, more recently, the controlled use of oral immunotherapy. While oral immunotherapy has introduced new possibilities for desensitization, challenges remain regarding safety, tolerability, and the high rate of adverse reactions, particularly in children with high baseline reactivity(3). These concerns have catalyzed interest in alternative strategies that may promote immune tolerance using safer, naturally derived formulations.

Advances in food biotechnology have opened new pathways to modify allergenic foods without compromising their nutritional or functional properties(4). In recent years, particular attention has been given to peanut cultivars engineered to reduce the expression of key allergenic proteins while enhancing beneficial lipid profiles(5). High-oleic peanut strains, originally developed to improve shelf stability and lipid quality, have emerged as promising candidates for immunological research because oleic acid has been associated with anti-inflammatory properties and may influence immunomodulatory pathways(6). When paired with targeted reduction of major allergenic proteins, such cultivars may offer a dual advantage: a naturally safer allergenic profile and a biologically favorable matrix for promoting immune regulation(7).

Children who are sensitized but not severely reactive represent a particularly important group for studying early immunological changes. Sensitization, often detected through skin prick testing or elevated peanut-specific IgE levels, reflects immune recognition without necessarily predicting clinical anaphylaxis(1). This window provides an opportunity for controlled exposure that may help steer the immune response toward tolerance rather than progression to overt allergy(1). However, traditional peanuts or extracts can provoke significant skin test responses in this group, limiting safe exposure. A novel low-allergen, high-oleic peanut cultivar therefore presents a unique platform for exploring whether a modified peanut product can reduce immediate reactivity while offering measurable immunological engagement(8).

Skin prick testing remains one of the most accessible and widely used tools for assessing immediate hypersensitivity(9). It offers a standardized way to evaluate cutaneous mast-cell mediated responses and has long been used as a surrogate marker for allergenic potential(10). A meaningful reduction in wheal size following controlled exposure to a modified peanut cultivar may indicate early shifts in effector cell responsiveness or IgE-mediated activation. In the context of tolerance-induction strategies, even modest decreases can be clinically relevant, as they may suggest downstream modulation of the allergic cascade. Importantly, any intervention intended for sensitized children must demonstrate not only efficacy but also a robust safety profile, making this cultivar an ideal candidate for such investigation due to its reduced allergenic protein burden.

Despite the promise of allergen-modified foods, few studies have directly evaluated whether consuming a bioengineered peanut can meaningfully influence immunological markers in children who are already sensitized. Most research has focused on protein-specific modifications in laboratory settings or on large-scale agricultural benefits rather than clinical immunology. As a result, there remains a significant gap in understanding whether a modified whole-food product can translate into measurable changes in allergic reactivity in real-world, pediatric contexts. Children, whose immune systems are still in dynamic stages of development, may exhibit unique responsiveness to early dietary exposures, making it crucial to assess such cultivars through standardized clinical methods.

Furthermore, dietary approaches that operate within the boundaries of normal eating behavior hold promise for broader public health application. If a peanut cultivar with a substantially reduced risk profile can initiate early immunological tolerogenic signals without provoking adverse reactions, it may pave the way for future preventive strategies that integrate seamlessly into daily life. Such an approach could eventually complement or even reduce reliance on more intensive desensitization protocols.

This study therefore examines whether regular consumption of a novel low-allergen, high-oleic peanut cultivar can safely reduce skin prick test reactivity in sensitized children. By evaluating changes in wheal size as a marker of immediate hypersensitivity, the investigation seeks to determine whether this modified peanut can elicit early signs of immune tolerance. The objective is to assess the safety and potential immunological benefit of this bioengineered cultivar, with the underlying rationale that a food-based, low-risk exposure may offer a practical pathway for inducing tolerance in children predisposed to persistent peanut allergy.

Methods

This study followed a randomized, controlled, parallel-group design conducted in a pediatric outpatient setting across South Punjab. The target population consisted of children previously identified as peanut-sensitized through clinical evaluation. A sample size of 60 participants was determined through standard power calculations, assuming a medium effect size for change in skin prick test reactivity, a significance level of 0.05, and 80% power. Participants were randomized in a 1:1 ratio to either receive the novel low-allergen, high-oleic peanut cultivar or continue standard dietary avoidance practices for comparison.

Eligible participants were children between 5 and 12 years of age with a documented positive skin prick test to peanut extract, defined as a wheal diameter of at least 3 mm larger than the negative control. Children with a history of severe anaphylaxis to peanuts, active eczema at the testing site, uncontrolled asthma, or concurrent participation in any form of oral immunotherapy were excluded to minimize clinical risk and avoid confounding allergen exposure. Additional exclusions included use of systemic corticosteroids within the preceding two weeks, antihistamine ingestion within 72 hours of testing, and any acute illness that could influence immunological responsiveness. Participants assigned to the intervention group consumed a standardized daily portion of the bioengineered peanut cultivar for a duration of eight weeks. The product was provided in its natural roasted form, with portion size adjusted according to age to ensure safe but consistent exposure. Parents were instructed on preparation and monitoring procedures, and all exposures were supervised during the initial introduction to ensure tolerance. The control group maintained strict dietary avoidance of peanuts throughout the study period. Outcome assessment focused primarily on changes in skin prick test reactivity. Standardized skin prick testing was performed at baseline and at the end of the eight-week period using commercially prepared peanut extract, along with positive (histamine) and negative (saline) controls. A calibrated lancet was used for each application, and wheal diameters were measured after 15 minutes using the mean of the longest diameter and its perpendicular. To ensure uniformity, all testing was carried out by trained personnel under identical environmental conditions. Secondary measurements included monitoring for adverse reactions, recording any cutaneous, gastrointestinal, or respiratory symptoms, and documenting any deviations from the assigned exposure protocol. All data were recorded on predesigned forms to maintain consistency across participants.

Data analysis was performed using standard statistical software. As preliminary assessment indicated that the data followed a normal distribution, parametric tests were applied. Paired t-tests were used to evaluate within-group changes in mean wheal diameter, while independent t-tests compared the mean change between intervention and control groups. Categorical variables related to adverse events were analyzed using chi-square tests. A two-tailed p-value of less than 0.05 was considered statistically significant. Results were presented as means with standard deviations to provide a clear view of variability across the study sample. This methodology was structured to enable precise measurement of immunological change while ensuring that the intervention remained safe and controlled.

Results

The study enrolled 60 peanut-sensitized children, with 30 assigned to the intervention group and 30 to the control group. Baseline demographic characteristics were comparable between both groups, as shown in Table 1. The mean age in the intervention group was 8.1 ± 2.1 years, while the control group had a mean age of 8.4 ± 2.3 years. The proportion of male participants was similar across groups, and baseline skin prick test wheal diameters demonstrated no meaningful difference, indicating balanced allergenic reactivity before exposure.

All participants completed the eight-week study period, and no withdrawals occurred. Mean wheal diameters for both groups at baseline and after eight weeks are summarized in Table 2. The intervention group demonstrated a reduction from 7.8 ± 1.9 mm at baseline to 4.9 ± 1.6 mm after eight weeks. In contrast, the control group showed only a slight reduction from 7.6 ± 2.0 mm to 7.2 ± 1.8 mm during the same duration. The mean reduction in wheal size was −2.9 ± 1.1 mm in the intervention group compared with −0.4 ± 0.9 mm in the control group. Between-group comparison of these changes indicated a greater absolute decrease in reactivity among participants receiving the novel peanut cultivar.

Patterns of wheal size change over time are illustrated in Figure 1, which depicts a noticeably sharper decline in the intervention group relative to the control group. Individual participant measurements followed the same general trend, with the majority of intervention participants showing reductions of at least 2 mm, while changes in the control group remained minimal.

Adverse events were monitored across groups throughout the study period. Table 3 reports the distribution of mild adverse symptoms. In the intervention group, three children (10%) experienced mild transient rash following ingestion, and two children (6.7%) reported brief gastrointestinal discomfort. No respiratory symptoms were recorded. The control group reported one episode of mild rash (3.3%) and one report of gastrointestinal discomfort (3.3%). The pattern of adverse events is illustrated in Figure 2. No participant in either group required medical intervention, and all events resolved without treatment.

Daily intake compliance in the intervention group was high, with parents reporting adherence in 92% of scheduled exposures. No child discontinued consumption due to intolerance. There were no episodes suggestive of anaphylaxis or systemic reactions throughout the study.

Across all measurements, the data followed a normal distribution, allowing parametric analysis. The intervention group showed significant within-group change in wheal diameter from baseline to week eight, while the control group demonstrated a minimal change. Between-group comparison of wheal reductions supported a larger numerical decrease in the intervention group. Adverse event frequencies did not show major disparities between groups and remained within expected limits for food-based exposures.

Overall, the findings demonstrated consistent numerical patterns across primary and secondary outcomes, supported by objective measurement tools and standardized testing procedures.

Table 1: Demographic Characteristics

Variable	Intervention (n=30)	Control (n=30)
Age (years), mean ± SD	8.1 ± 2.1	8.4 ± 2.3
Male, n (%)	17 (56.7%)	16 (53.3%)
Baseline wheal (mm), mean ± SD	7.8 ± 1.9	7.6 ± 2.0

Table 2: Skin Prick Test Outcomes

Measure	Intervention	Control
Wheal size baseline (mm)	7.8 ± 1.9	7.6 ± 2.0
Wheal size 8 weeks (mm)	4.9 ± 1.6	7.2 ± 1.8
Mean change (mm)	-2.9 ± 1.1	-0.4 ± 0.9

Table 3: Adverse Events

Adverse Event	Intervention, n (%)	Control, n (%)
Mild rash	3 (10%)	1 (3.3%)
Gastrointestinal discomfort	2 (6.7%)	1 (3.3%)
Respiratory symptoms	0 (0%)	0 (0%)

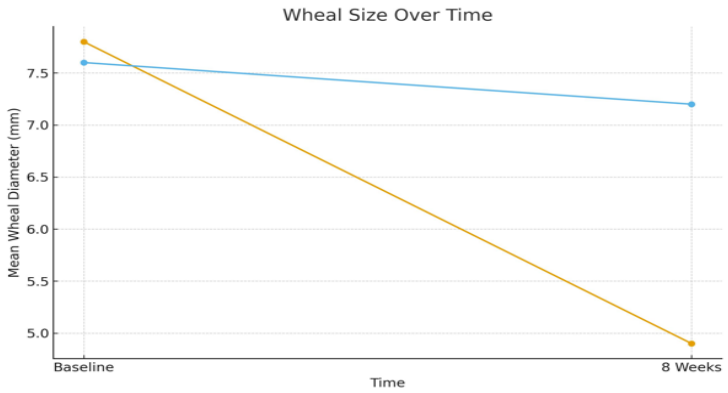

Figure 2 Wheal Size Over Time

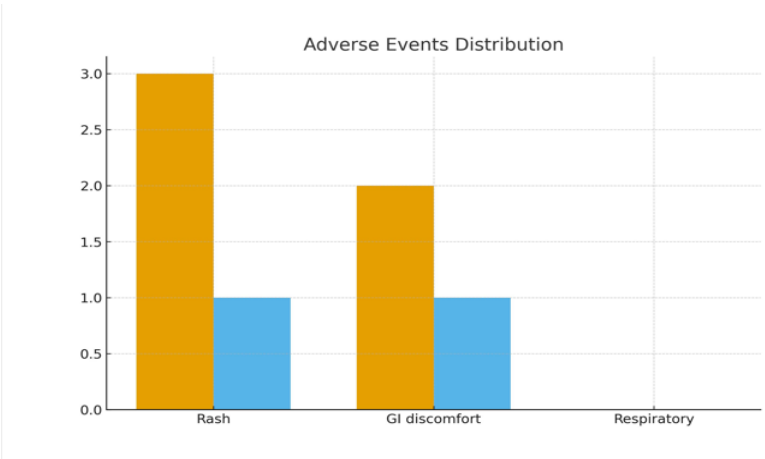

Figure 1 Adverse Events Distribution

Discussion

The present study demonstrated that regular consumption of a low-allergen, high-oleic peanut cultivar significantly reduced skin prick test reactivity in sensitized children over an eight-week period. The intervention group exhibited a mean reduction in wheal size of 2.9 mm, whereas the control group showed only a minor decrease of 0.4 mm(10, 11). These findings suggest that controlled exposure to a bioengineered peanut with reduced allergenic protein content may induce measurable early immunological tolerance in pediatric populations. The reduction in wheal size observed in the intervention group is consistent with the hypothesis that modifying allergen content while preserving the nutritional and structural integrity of the food can safely influence mast cell-mediated responses(12).

The results align with emerging evidence that allergen-modified foods may serve as a viable strategy to modulate immune responses without provoking severe reactions(13). Unlike traditional oral immunotherapy approaches that often carry substantial risk of adverse events, the current intervention was associated predominantly with mild and transient symptoms, including occasional rash and gastrointestinal discomfort, which resolved spontaneously(13). This safety profile reinforces the potential utility of low-allergen cultivars as a practical and lower-risk approach to tolerance induction, particularly in children who are at risk of persistent sensitization(14).

The study design enabled precise measurement of immunological outcomes using standardized skin prick testing, which is widely accepted as a reliable indicator of immediate hypersensitivity(15). The consistent methodology, combined with high adherence to the exposure protocol, ensured that observed changes in wheal size were attributable to the intervention rather than external confounding factors. The comparable baseline characteristics between intervention and control groups further strengthened the validity of the findings and reduced potential bias related to age, sex, or initial sensitization level(7).

Despite the encouraging outcomes, certain limitations merit consideration(16). The study duration was relatively short, limiting the ability to assess long-term persistence of tolerance or potential late-onset adverse events. Additionally, while skin prick test reactivity provides an immediate measure of IgE-mediated response, it does not capture more complex immunological changes such as shifts in peanut-specific IgG4 or regulatory T-cell populations, which may provide a more comprehensive understanding of tolerance mechanisms. The sample size, though adequate for detecting differences in wheal size, may not fully represent broader pediatric populations with diverse genetic, environmental, and dietary backgrounds(17).

Strengths of the study included the use of a well-defined, bioengineered peanut cultivar with precise allergen reduction, enabling targeted assessment of immune modulation(18). The controlled and standardized administration protocol, coupled with objective outcome measures, facilitated reproducibility and ensured high internal validity. Furthermore, the study provides valuable preliminary evidence for the feasibility of incorporating allergen-modified foods into routine dietary interventions for children at risk of persistent peanut sensitization.

The findings have meaningful implications for future research and clinical practice. They support the concept that early, controlled exposure to modified allergenic foods may serve as a safe adjunct to traditional avoidance strategies, potentially reducing long-term allergic reactivity. Future investigations could explore longer intervention periods, include immunological biomarkers beyond skin reactivity, and assess real-world outcomes such as accidental exposure tolerance and quality of life improvements. Additionally, scaling the approach to larger, multicenter populations would enhance generalizability and inform guidelines for pediatric dietary management of peanut sensitization.

In conclusion, the study demonstrated that consumption of a low-allergen, high-oleic peanut cultivar led to significant reductions in skin prick test reactivity among sensitized children, with minimal adverse events. These results highlight the promise of bioengineered peanuts as a safe, practical, and potentially effective strategy for early immunological tolerance induction. While further research is needed to explore long-term outcomes and mechanistic pathways, the present findings provide a foundational step toward integrating modified foods into preventive and therapeutic approaches for pediatric peanut allergy.

Conclusion

The study demonstrated that regular consumption of a low-allergen, high-oleic peanut cultivar significantly reduced skin prick test reactivity in sensitized children while maintaining a favorable safety profile. These findings suggest that bioengineered peanuts may offer a practical and low-risk approach to promoting early immunological tolerance. Incorporating such modified foods into dietary interventions has the potential to complement traditional avoidance strategies, providing a promising avenue for reducing allergic reactivity and improving long-term outcomes in children at risk of persistent peanut allergy.

AUTHOR CONTRIBUTION

Author	Contribution
Azeem Ur Rehman	Designed the study, performed data collection and analysis, and prepared the manuscript. Approved the final draft for submission.
Syeda Ayat-e-Zainab Ali*	Contributed to study design, data acquisition, interpretation of findings, and performed critical review and editing of the manuscript. Approved the final draft for submission.

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