

# Learning Early About Peanut (LEAP) Study

A Synopsis of Study Parameters, Outcomes, and Key Takeaways

**Research Question:** The prevalence of peanut allergy among children in Western countries has doubled in the past 10 years. What strategies of peanut consumption and avoidance are most effective in preventing the development of peanut allergy in infants at high risk for the allergy?

**Funding:** Funded by the National Institute of Allergy and Infectious Disease, with additional support from FARE and led by Professor Gideon Lack at Kings College London

**Year Study Began:** Enrollment from December, 2006 to May, 2009.

**Year Published:** originally published 2/23/215 in the New England Journal of Medicine (NEJM). Updated on 2/29/16 at NEJM.org.

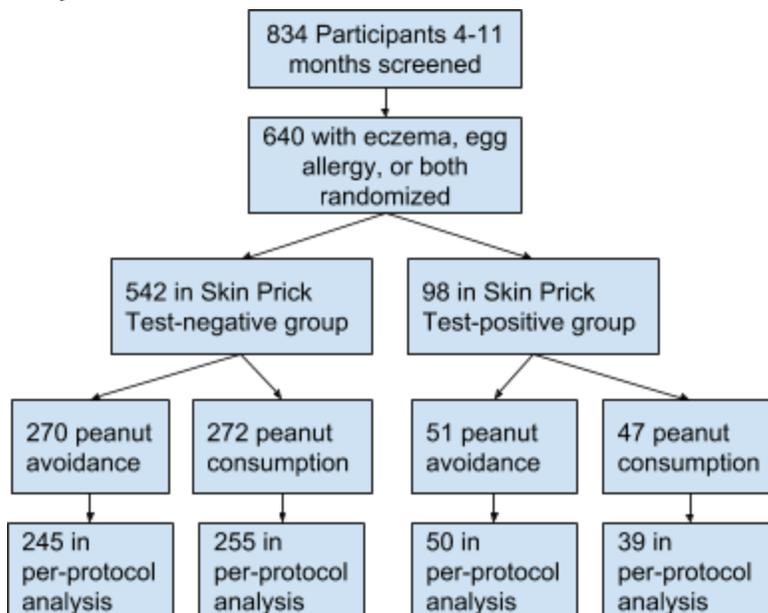
**Study Type:** The LEAP study was a randomized, open-label, controlled trial conducted at a single site in the United Kingdom.

**Who Was Studied:** The study enrolled 640 infants with severe eczema, egg allergy, or both who were between 4 to 11 months old. Overseen by the allergy and asthma data and safety monitoring board of the National Institute of Allergy & Infectious Disease (NIAID)

**Who Was Excluded:** 9.1% of children were already excluded at enrollment due to large wheals on SPT (likely already peanut allergic)

**How Many Patients:** 529 in the intention-to-treat population with negative results on skin-prick test. 92 in the intention-to-treat population with positive results (1mm-4mm wheal) on skin-prick test. Peanut sensitivity determined with the use of a skin prick test. All patients in consumption groups underwent peanut Oral Food Challenges.

## Study Overview



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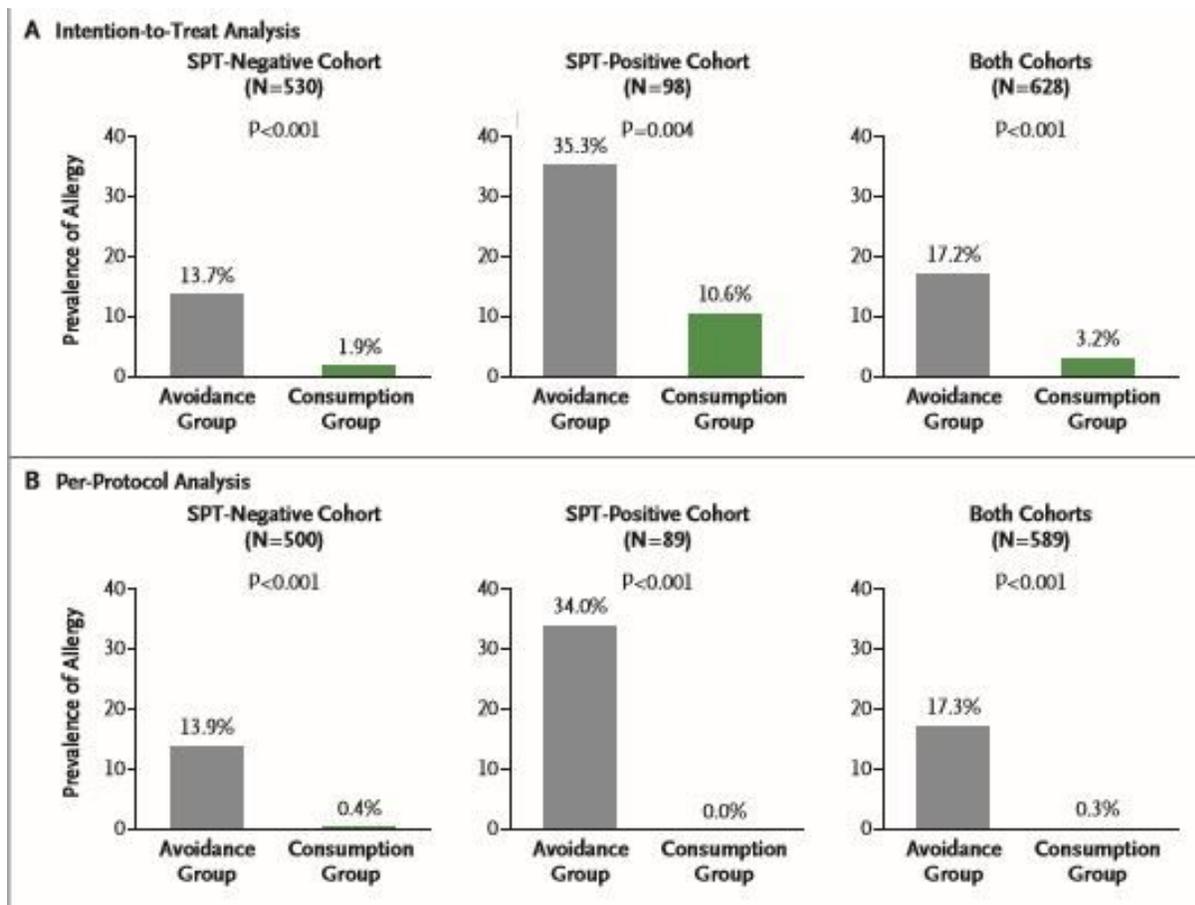
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**Dosing:** At least 6g of peanut protein per week, distributed in 3 or more meals per week, until they reached 60 months of age. Preferred peanut source was Bamba, a snack food manufactured from peanut butter and puffed maize. Smooth peanut butter was provided to infants who did not like Bamba.

Adequate adherence was defined as consumption of at least 2 g of peanut protein on at least 1 occasion in both the first and second years of life and of at least 3 g of peanut protein (25 g of Bamba or 12 g of peanut butter) per week for at least 50% of the weeks.

## Results:

- In the intention-to-treat analysis, 108 or 17.2% of the children who avoided peanut developed peanut allergy by age 5. Only 20 or 3.2% of the children who ate the peanut snack developed peanut allergy by age 5.
- In the per-protocol analysis, 101 or 17.3% of the children who avoided peanut developed peanut allergy by age 5. Only 1 or 0.3% of the children who ate the peanut snack developed peanut allergy by age 5.
- Therefore, in high-risk infants, sustained consumption of peanut beginning in the first 11 months of life was highly effective in preventing the development of peanut allergy.
- In the consumption group, 13 participants were excluded due to non-adherence to treatment protocol.



**Criticisms and Limitations:** The main weakness of the study was that it did not include low-risk infants and those who had large wheals (>4 mm in diameter) after the skin-prick test. A further limitation was the failure to collect

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dust samples to validate peanut consumption or avoidance at earlier time points in the study (peanut protein levels were measured in dust collected from participant's beds 2 to 4 weeks before the final visit)

**Summary and Implications:** Among infants with eczema, sustained peanut consumption beginning in the first 11 months of life, as compared with peanut avoidance, resulted in a significantly smaller proportion of children with peanut allergy at the age of 60 months. This intervention was safe, tolerated, and highly efficacious. The LEAP study showed that early oral introduction of peanuts could prevent allergy in high-risk, sensitized infants and in non-sensitized infants.

## References:

- 1) <http://www.leapstudy.com/leap-study-results#.WvCFsUxFzb0>
- 2) <https://www.nejm.org/doi/full/10.1056/NEJMoa1414850>