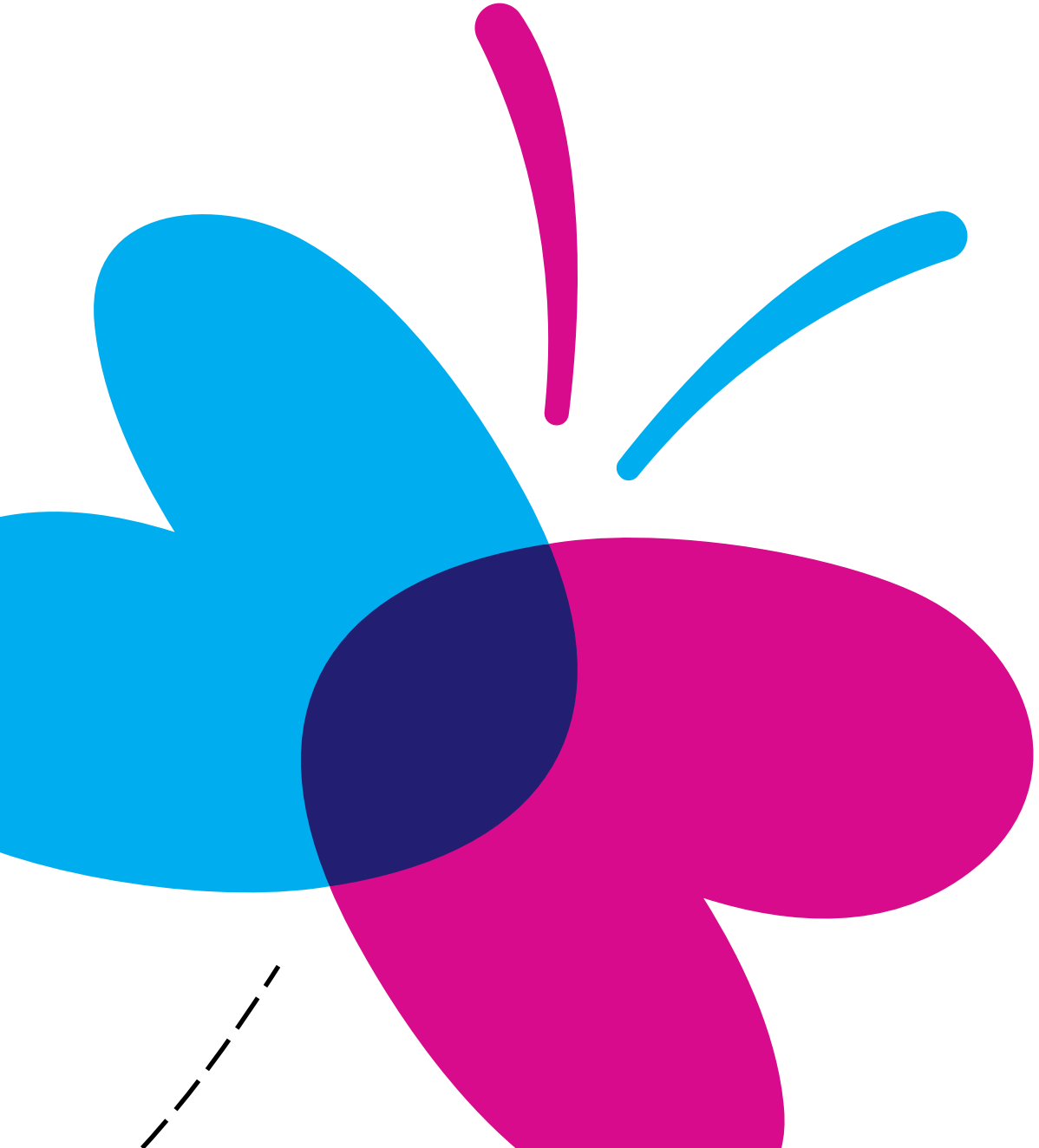


2025 North American Veterinary Dermatology Forum

Food Allergy in Humans – Part 2:

Prevention and Treatment

Amanda Cox, MD

Associate Professor of Pediatrics

Division of Pediatric Allergy / Jaffe Food Allergy Institute

Mount Sinai

Kravis Children's Hospital

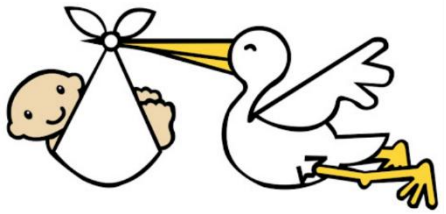
Objectives

1. Consider what is now known about food allergy prevention and review evidence-based early introduction guidelines

2. Discuss therapies for food allergy that are currently available to patients as well as therapies on the horizon

Prevention

Prevention

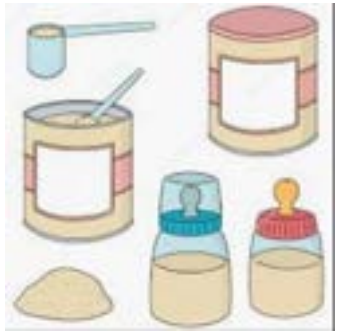


Mode of birth/delivery

Breastfeeding + duration

Timing of complementary food introduction

Maternal diet



Formula selection

Probiotics

Microbiome

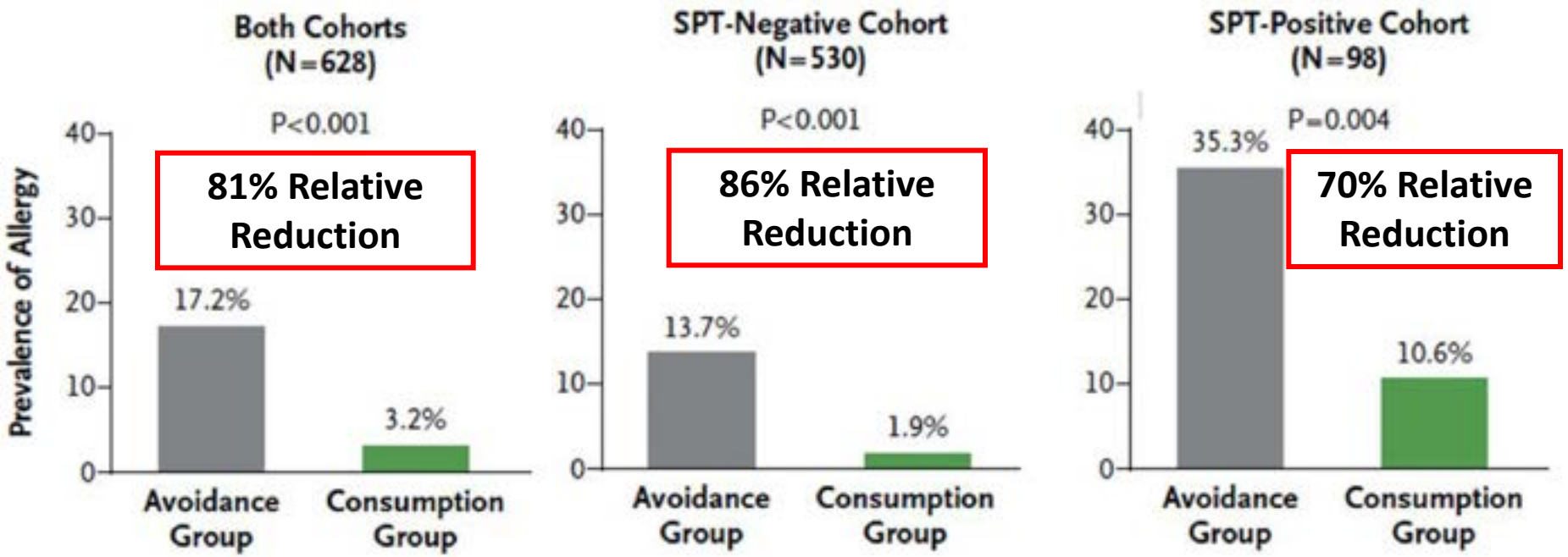
Eczema and skin care

Learning Early About Peanut (LEAP) Allergy Trial

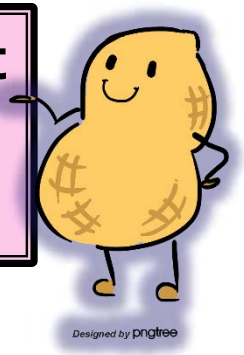
Purpose: Determine whether early introduction of peanut will prevent development of allergy in "high risk" infants

- "**High risk**" defined as young infants with:
  - **Egg allergy**:
    - SPT ≥6 mm to egg white & no history of tolerance
    - SPT ≥3 mm to egg white & history of allergic symptoms
  - **Severe eczema:**
    - Frequent use of topical steroids or calcineurin inhibitors
    - Grade ≥ 40 using the modified SCORAD evaluation

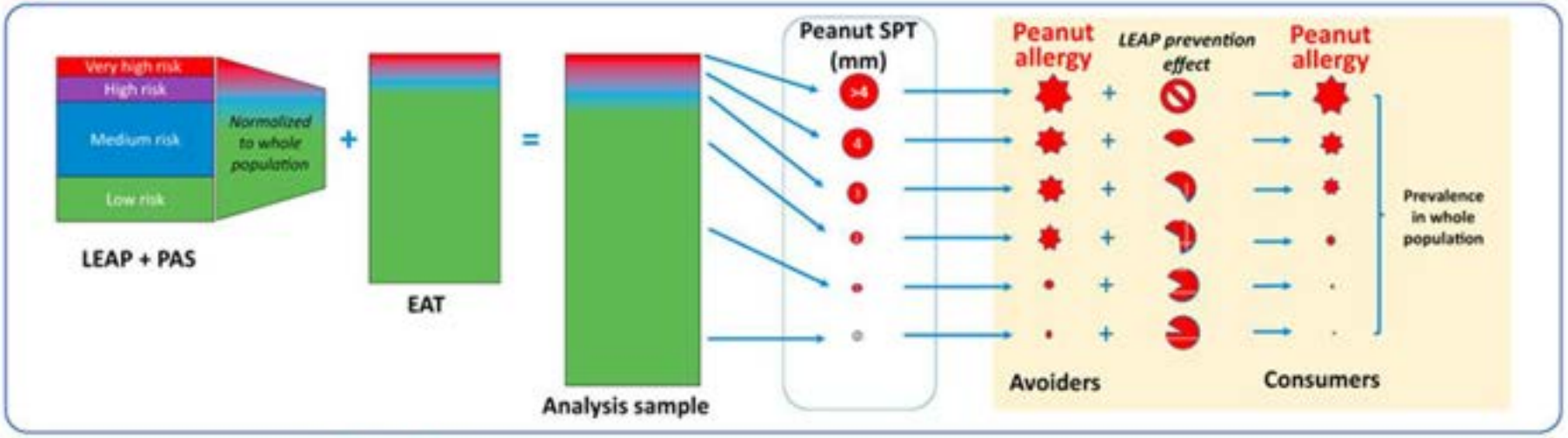
Results from LEAP: Intention to Treat



In infants at high risk of allergy, early peanut introduction in the first 11 months of life resulted in a significant reduction in peanut allergy prevalence at 5 years of age.



Defining the window of opportunity and the target populations to prevent peanut allergy



EAT: Enquiring About Tolerance trial; LEAP: Learning Early About Peanut allergy trial; SPT: skin prick test

Inclusion of a larger number of children with mild and no eczema leads to a greater reduction in peanut allergy if pn intro at 4 mos (eczema) and 6 mos (no eczema)

Reduction in peanut allergy diminishes with every month that introduction is delayed

Duration of eczema is a risk factor

Roberts G, Bhanson H, et al. Defining the window of opportunity and target populations to prevent peanut allergy, JACI, Volume 151, Issue 5, 2023,

JAMA | Original Investigation

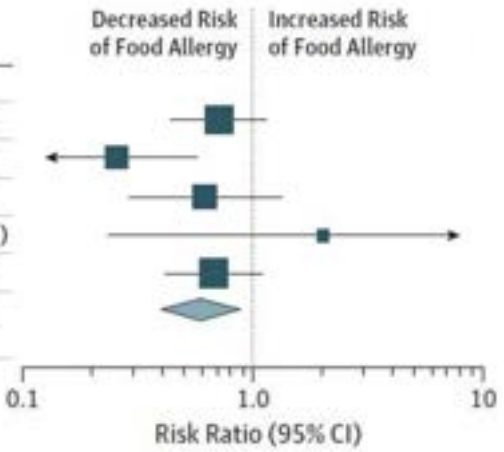
Timing of Allergenic Food Introduction to the Infant Diet and Risk of Allergic or Autoimmune Disease

A Systematic Review and Meta-analysis

Despo Ierodiakonou, MD, PhD; Vanessa Garcia-Larsen, PhD; Andrew Logan, PhD; Annabel Groome, BSc; Sergio Cunha, MD; Jennifer Chivinge, BSc; Zoe Robinson, BSc; Natalie Geoghegan, BSc; Katharine Jarrold, BSc; Tim Reeves, BSc; Nara Tagiyeva-Milne, PhD; Ulugbek Nurmatov, MD, PhD; Marialena Trivella, DPhil; Jo Leonardi-Bee, PhD; Robert J. Boyle, MD, PhD

A Risk of food allergy

Outcome	Dietary Introduction of Allergenic Food: Early, No. of Events	Early, Total No.	Late, No. of Events	Late, Total No.	Risk Ratio (95% CI)
Egg allergy					
Perkin et al,[6] 2016	21	569	32	596	0.69 (0.40-1.18)
Natsume et al,[17] 2016	5	60	23	61	0.22 (0.09-0.54)
Tan et al,[18] 2016	8	130	13	124	0.59 (0.25-1.37)
Bellach et al,[16] 2015	2	142	1	156	2.20 (0.20-23.97)
Palmer et al,[15] 2013	14	42	18	35	0.65 (0.38-1.11)
Random-effects model		943		972	0.56 (0.36-0.87)
Heterogeneity: $I^2 = 35.8\%$; $P = .18$					



Moderate-certainty evidence from 5 trials (n=1915) that early egg introduction at 4 to 6 months was associated with reduced egg allergy (RR 0.56, 95% CI, p=0.009)

Early Introduction of Egg and the Development of Egg Allergy in Children: A Systematic Review and Meta-Analysis

Bandar Al-Saud[a, b] Sigurveig T. Sigurdardóttir[c, d]

[a]Section of Pediatric Allergy/Immunology, Department of Pediatrics, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia; [b]College of Medicine, Alfaisal University, Riyadh, Saudi Arabia; [c]Department of Immunology, Landspitali University Hospital, Reykjavik, Iceland; [d]Faculty of Medicine, University of Iceland, Reykjavik, Iceland

None of these studies provide conclusive evidence that early egg introduction prevents egg allergy, and guidelines for the timing of egg introduction have not yet been published

Of 416 articles identified and screened; 6 RCTs, total of 3,032 participants.

A **low to moderate level of evidence from pooled data** showed a benefit of early egg intro

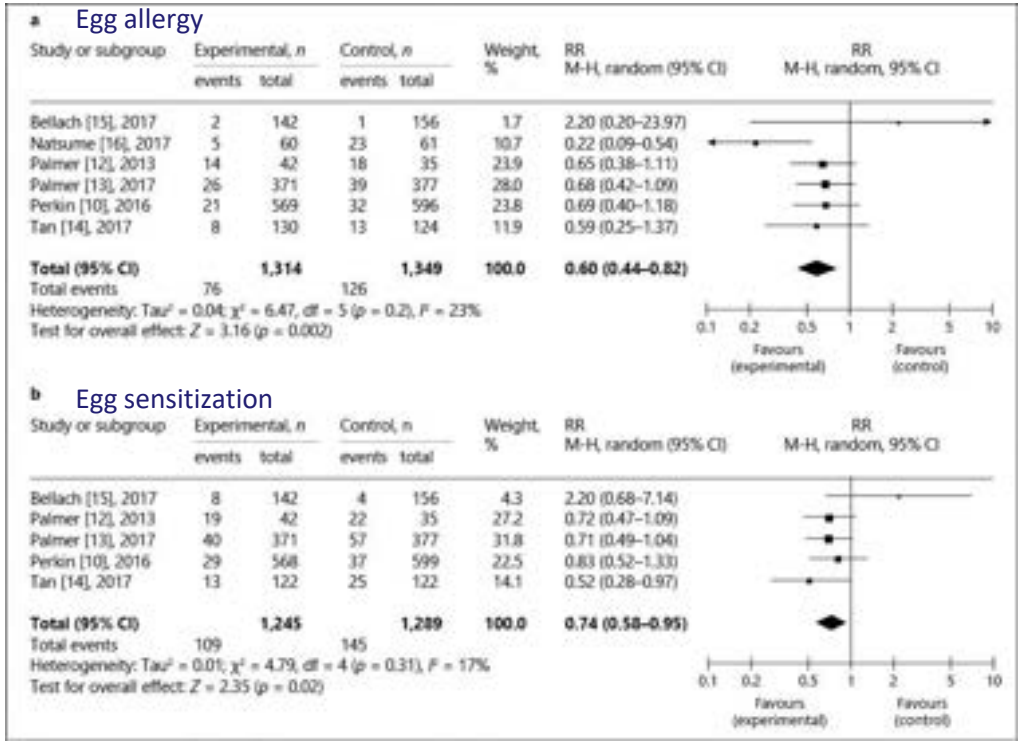
- RR 0.60, 95% CI 0.44–0.82, p = 0.002, mild heterogenity, I^2=23%
- Absolute risk reduction was 37 fewer cases per 1000 people
- Subgroup analysis of high vs low dose egg: Consumption of <4g/wk had a greater preventive effect than higher dose

International Archives of Allergy and Immunology

Int Arch Allergy Immunol 2018;177:350–359
DOI: 10.1159/000492131

Received: March 25, 2018
Accepted after revision: July 16, 2018
Published online: September 5, 2018

Early Introduction of Egg: meta-analysis



Low-moderate level of evidence

- Heterogeneity of study populations
- 4/6 studies included high risk or atopic populations
- Varying amounts and nature of egg protein
  - 2 studies with heated egg
  - 4 studies with raw egg
- Different outcomes measured:
  - clinical egg allergy
  - egg sensitization

No indication to hold allergenic foods beyond 4-6 months

More data needed on early infant introduction of egg before this can be adopted as a guideline for primary prevention of egg allergy

Dietary Intervention
Clinical Trials with Milk

Clinical Trial	Conclusion
SPADE: Sakihara et al. JACI 2020	**Consuming small amounts of CMF daily (≥10cc) between 1 and 2 months of age prevented development of OFC confirmed CMA** in infants from the general population. (Modified ITT, CMA in ingestion group 0.8% vs avoidance 6.8%, P<0.001)
ABC: Urashima et al. JAMA 2019	**Avoidance of cow's milk during the first 3 days of life had a protective effect** against the development of milk sensitization by 2 years. (Relative risk 0.52, 95%CI 0.34-0.81)
EAT: Perkin et al. *NEJM* 2016	**No significant effects** of early milk introduction. (per protocol, P=0.63)
MACS: Lowe et al. JACI 2011	**No significant difference** between early introduction group (CMF) and avoidance group (soy formula). 620 infants with fhx of allergic disease (OR 1.26, 95%CI 0.84-1.88)

Enquiring about Tolerance (EAT) Trial

EAT
Enquiring About Tolerance

1303 exclusively breastfed infants at 3 months

Early Intro Group (n=567)

Continue breastfeeding AND

Between 3-6 months introduce

- Cow's milk (1st)
- Peanut *
- Hard boiled egg *
- Sesame
- Whitefish (cod)
- Wheat (last)

2g of protein twice/week

Standard Intro Group (n=595)

Exclusively breastfed

No allergens introduced until 6 mos

BOTH GROUPS:

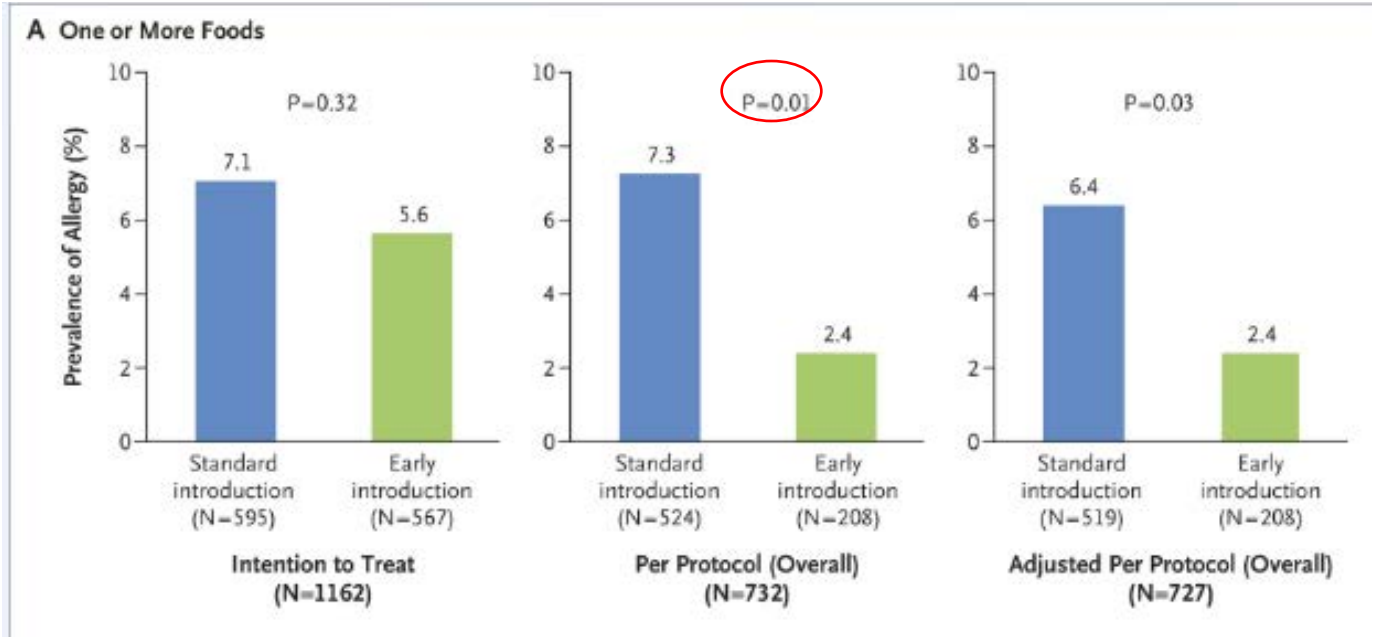
After 6 months of age, consumption of allergenic foods as per parent's discretion.

Primary Outcome:

Food Allergy to 1 of the 6 foods between 1 and 3 years of age

Perkin et al. N Engl J Med. 2016 May 5;374(18):1733-43
Perkin et al. J Allergy Clin Immunol. 2016 May;137(5):1477-1486

EAT
Enquiring About Tolerance



Rate of FA

- 20% decrease in ITT analysis, but not significant
- Significant decrease in prevalence of FA (67%) in per-protocol analysis

- High rate of non-adherence in early introduction group (68.1%)

There were no significant benefits to early introduction of milk, sesame, fish or wheat

Perkin et al. N Engl J Med. 2016 May 5;374(18):1733-43
Perkin et al. J Allergy Clin Immunol. 2016 May;137(5):1477-1486

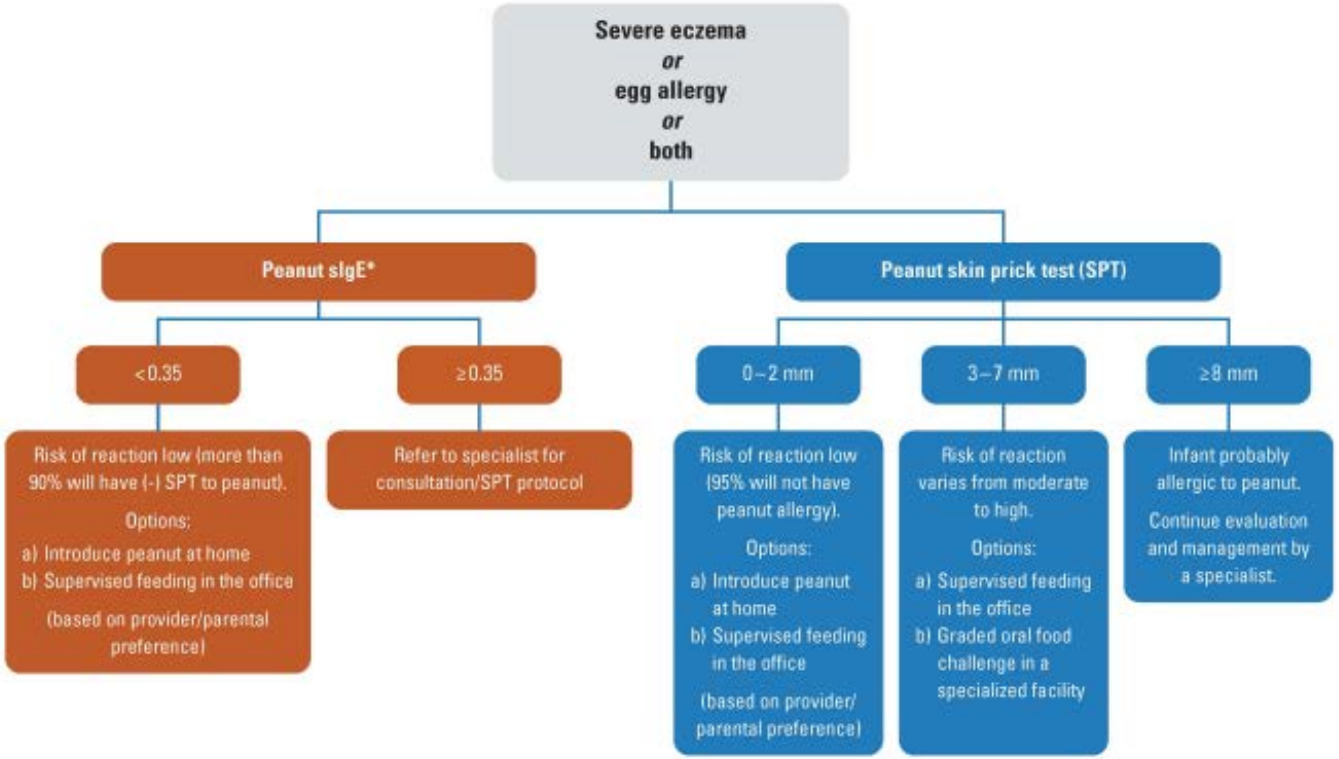
National Institute of Allergy and Infectious Diseases | health information

Addendum Guidelines for the Prevention of Peanut Allergy in the United States

Summary for Clinicians

NIAID

Recommended Approaches for Evaluation of Children With Severe Eczema and/or Egg Allergy Before Peanut Introduction



*To minimize a delay in peanut introduction for children who may test negative, testing for peanut sIgE may be the preferred initial approach in certain healthcare settings. Food allergen panel testing or the addition of sIgE testing for foods other than peanut is not recommended due to poor positive predictive value.

NIAID guidelines for prevention of peanut allergy

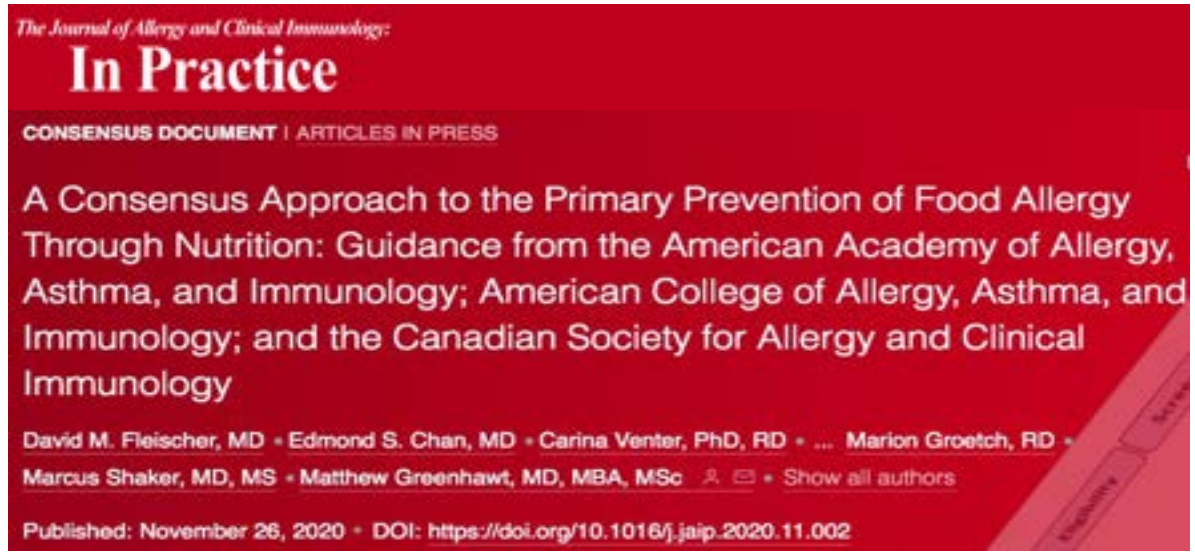
Guidelines

Addendum guidelines for the prevention of peanut allergy in the United States: Report of the National Institute of Allergy and Infectious Diseases–sponsored expert panel

Alkis Togias, MD,[a] Susan F. Cooper, MSc,[a] Maria L. Acebal, JD,[b] Amal Assa'ad, MD,[c] James R. Baker, Jr, MD,[d] Lisa A. Beck, MD,[e] Julie Block,[f] Carol Byrd-Bredbenner, PhD, RD, FAND,[g] Edmond S. Chan, MD, FRCPC,[h] Lawrence F. Eichenfield, MD,[i] David M. Fleischer, MD,[j] George J. Fuchs III, MD,[k] Glenn T. Furuta, MD,[l] Matthew J. Greenhawt, MD, MBA, MSc,[j] Ruchi S. Gupta, MD, MPH,[m] Michele Habich, DNP, APN/CNS, CPN,[n] Stacie M. Jones, MD,[o] Kari Keaton,[p] Antonella Muraro, MD, PhD,[q] Marshall Plaut, MD,[a] Lanny J. Rosenwasser, MD,[r] Daniel Rotrosen, MD,[a] Hugh A. Sampson, MD,[s] Lynda C. Schneider, MD,[t] Scott H. Sicherer, MD,[u] Robert Sidbury, MD, MPH,[v] Jonathan Spergel, MD, PhD,[w] David R. Stukus, MD,[x] Carina Venter, PhD, RD,[y] and Joshua A. Boyce, MD[z]

Bethesda, Md; McLean, Va; Cincinnati and Columbus, Ohio; Ann Arbor, Mich; San Rafael and San Diego, Calif; New Brunswick, NJ; Vancouver, British Columbia, Canada; Aurora, Colo; Lexington, Ky; Chicago and Winfield, Ill; Little Rock, Ark; Rockville, Md; Padua, Italy; Kansas City, Mo; New York, NY; Boston, Mass; Seattle, Wash; and Philadelphia, Pa

J Allergy Clin Immunol 2017



There is strong evidence that **early introduction of peanut and egg** within the first year of life can prevent the development of food allergy to these respective foods.

- Around 6 months but not before 4 months
- Use only cooked forms of egg

Screening infants for evidence of sensitization to peanut and/or egg before initial introduction is NOT required, though this may be a preference-sensitive care choice for some families.

- Encourage home introduction

Skin Barrier

Enhancement of Skin Barrier to Prevent Atopic Dermatitis and Food Allergy

Meta-analysis of 10 studies:

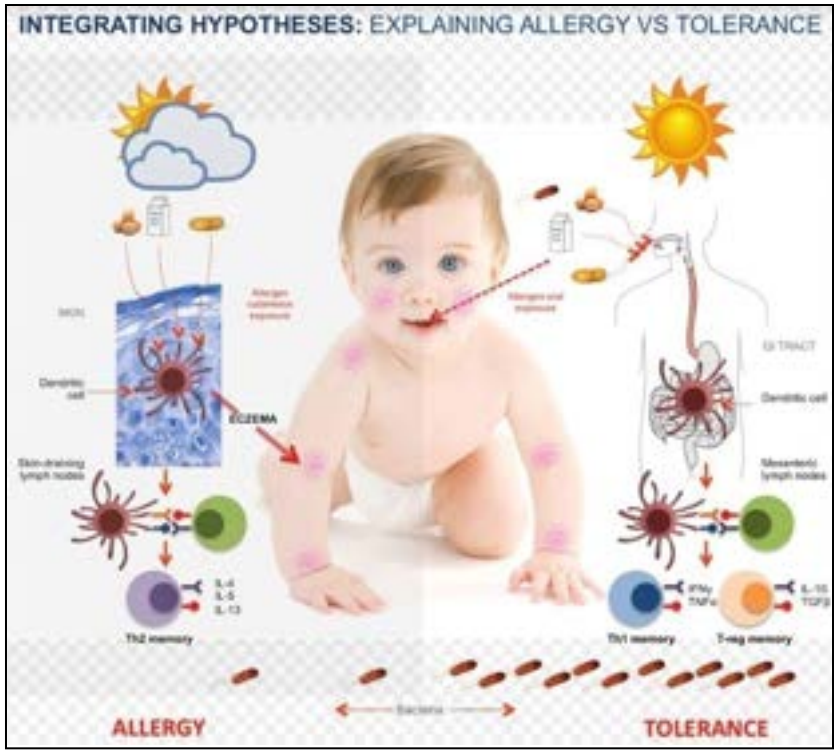
- Did not find that use of daily emollients in early infancy was protective against eczema or food allergy
- Some benefit if high-risk population and emollient used continuously

RCTs planned/underway to assess affect on food allergy development

- PEBBLES (NCT03667651)
- SEAL (NCT03742414)
- PACI (UMIN000028043)

Dual-allergen exposure hypothesis:

Allergic food sensitization occurs through low-dose cutaneous exposures, whereas oral consumption induces tolerance



Diet Diversity

Infants should be fed a diverse diet as this may help foster prevention of food allergy.

AAAAI/ACAAI/CSACI Consensus Document 2020 Increased Diet Diversity within 1st year of life associated with decrease food allergy over first 10 years of life (Roduit et al).

Maternal diet diversity in pregnancy

A maternal diet rich in **vegetables and yogurt** and with **reduced intake of red meat, cold cereal, fried potatoes, rice and grains, and 100% fruit juice** was associated with reduced odds of many allergic outcomes (AR, AD, asthma, wheezing) **but not food allergy**

Breastfeeding and Formula Selection

Exclusive breast feeding – insufficient evidence on food allergy prevention

- di Mauro et al. World Allergy Organ J. 2016 Aug 18;9:28
- Lodge et al. Acta Paediatr. 2015 Dec;104(467):38-53
- **AAAAI/ACAAI/CSACI Consensus Document 2020**

Hypoallergenic infant formulas – no proven benefit

- Boyle et al. Br Med J 2016 (meta-analysis of 37 studies)
- Osborn et al. Cochrane Database Syst Rev. 2018 Oct 19;10:CD003664.
- **AAAAI/ACAAI/CSACI Consensus Document 2020**

Maternal Diet during Pregnancy and Breastfeeding

No evidence that a maternal exclusion diet (cow's milk, egg, peanuts) during pregnancy or during lactation affects the development of atopic disease in infants.

- Kramer et al. Cochrane Database Syst Rev 2012; 9:CD000133.
- Netting et al. Nutrition 2014;30:1225-41.
- **AAAAI/ACAAI/CSACI Consensus Document 2020**

Ongoing RCT, PrEggNut (ACTRN12618000937213)

- Pregnant women to eat 6 eggs and 60 peanuts per week from 22 wks of pregnancy to 4 months of age while BF (compared to 3 eggs and 30 peanuts)
- Outcome: Egg and/or Peanut Allergy (SPT and OFC) at 12 months
- Palmer DJ, BMJ Open. 2022 Jun 13;12(6):e056925.

Supplements

Vitamin D
- no proven benefit

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Probiotics
- possible benefit for prevention of eczema
- inconclusive for food allergy

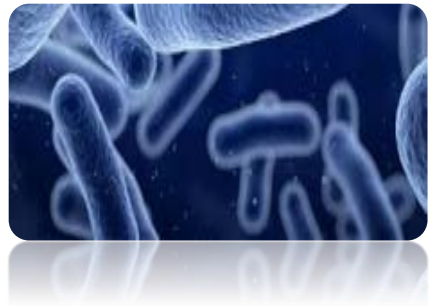
ACAAI/AAAAI: Prenatal or perinatal maternal or infant use of supplements has no clear role in the prevention of food allergy

Siolta Therapeutics

adored
ALLERGIC DISEASE ONSET PREVENTION STUDY

Icahn School of Medicine at Mount Sinai

- Daily administration of a **living bio-therapeutic (STMC-103)** containing three beneficial gut microorganisms for 1 year:
  - *Lactobacillus crispatus*
  - *Akkermansia muciniphila*
  - *Faecalibacterium prausnitzii*
- **Objective:** To assess the **safety, tolerability, and preliminary efficacy** of STMC-103H in infants at risk for allergic disease.
- Enrolling Newborns **14 days or younger** who will be followed for approximately 2 years



Microbiome manipulation

Background studies /rationale: Unexposed C-section delivered infants, lacked vaginal bacteria that were restored by swabbing infants with gauze or that were present in vaginally delivered infants

activate

A study about the infant microbiome and allergy development

Exposure to Vaginal Microbiome in C-section Infants at High-risk for Allergies –

A Pilot Study (NCT03567707)

Intervention: Vaginal Seeding at Birth

Outcome: Food Allergen Sensitization at 12 months

Study sites: Mount Sinai Hospital and Mount Sinai West

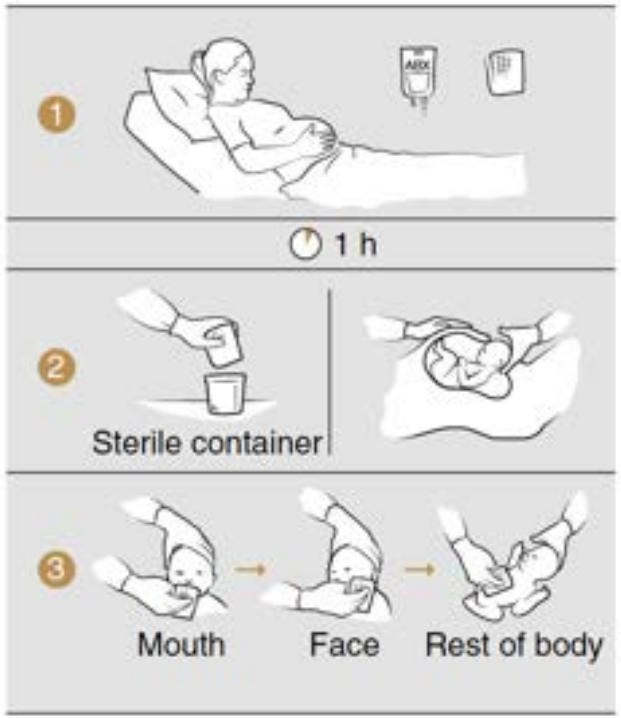


Image: M.J. Schoen

Recently enrolled our last patient

Mount Sinai

SUNBEAM

Systems Biology of Early Atopy

Nationwide, multi-center birth cohort study evaluating for pre-natal and early life determinants of allergic diseases, in particular **food allergy and eczema**

- clinical, environmental, biological, genetic, early-life factors

Recruiting from the general population and must be **delivering at Mount Sinai Hospital**

Enrolling during pregnancy, and infants followed until 3 years of age

CONTACT: SUNBEAM@MSSM.EDU

NOW ENROLLING

CoFAR

CONSORTIUM FOR FOOD ALLERGY RESEARCH

NIH Sponsored

Prevention pearls

- There is currently insufficient evidence that supplements, hypoallergenic formulas, and maternal elimination diets are protective against the development of food allergies.
- Early introduction of peanut in high-risk infants may prevent peanut allergy.
  - Implementation should be evaluated.
- Prevention of other food allergies might be decreased by earlier introduction

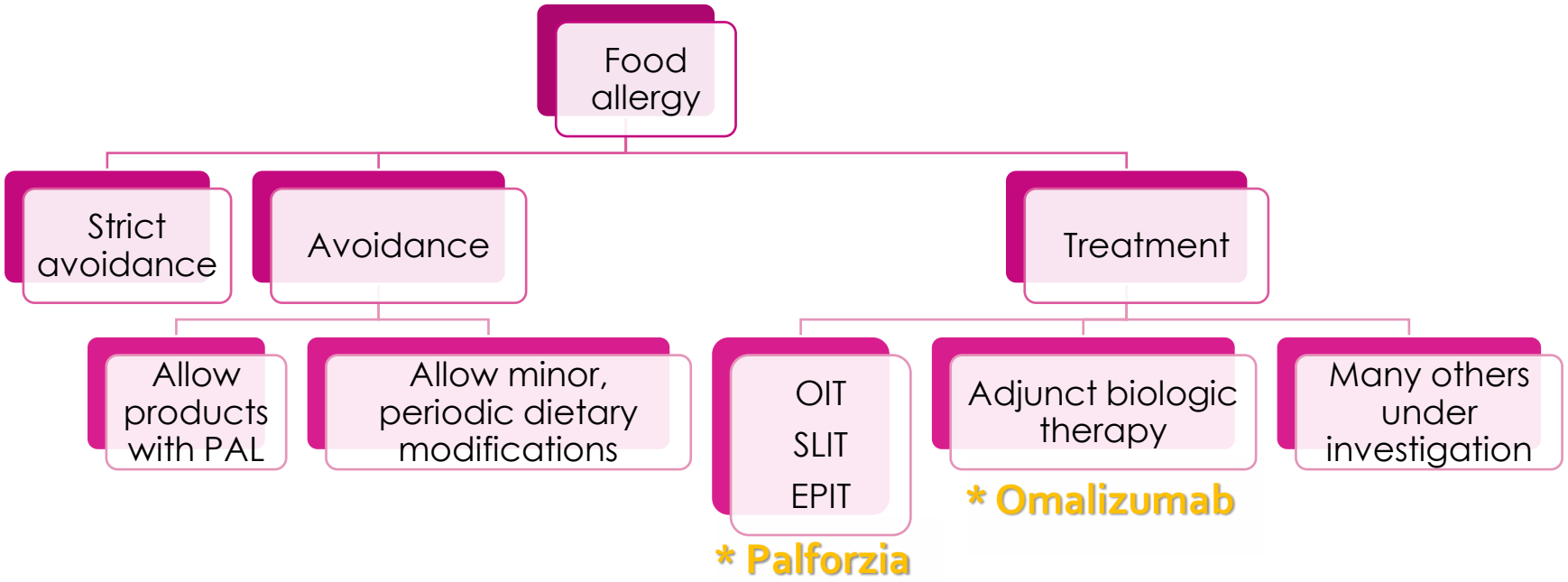
  but additional studies are needed. Guidelines are still being updated.
  - Some data suggesting egg may be beneficial, lacking for other foods
- Data still needed regarding infant emollient skin care and manipulation of microbiome early in life will protect against development of food allergies

Therapeutics

Introduction

- Until recently, the only management option was complete avoidance, preparedness with self-injectable epinephrine, and testing for potential natural resolution
- Oral immunotherapy (OIT) may be the most significant change affecting food allergy clinical care – research is still needed to improve efficacy, safety and accessibility
- A biologic medication (omalizumab) has just been approved for use in food allergy management.
- Other treatment modalities are still being studied / reviewed by the FDA and may be available soon

Food allergy management



Sicherer SH et al. *JACI Pract* 2022;10:46-55.

Goal is desensitization

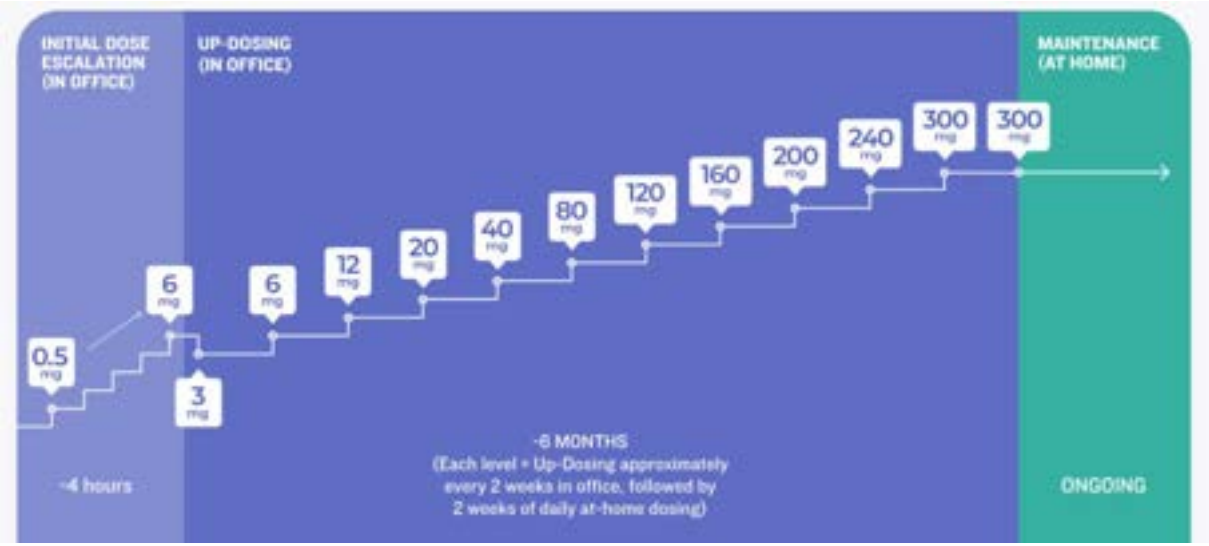
decrease chance for severe allergic reaction due to accidental exposure

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 22, 2018 VOL. 379 NO. 21

AR101 Oral Immunotherapy for Peanut Allergy

The PALISADE Group of Clinical Investigators*



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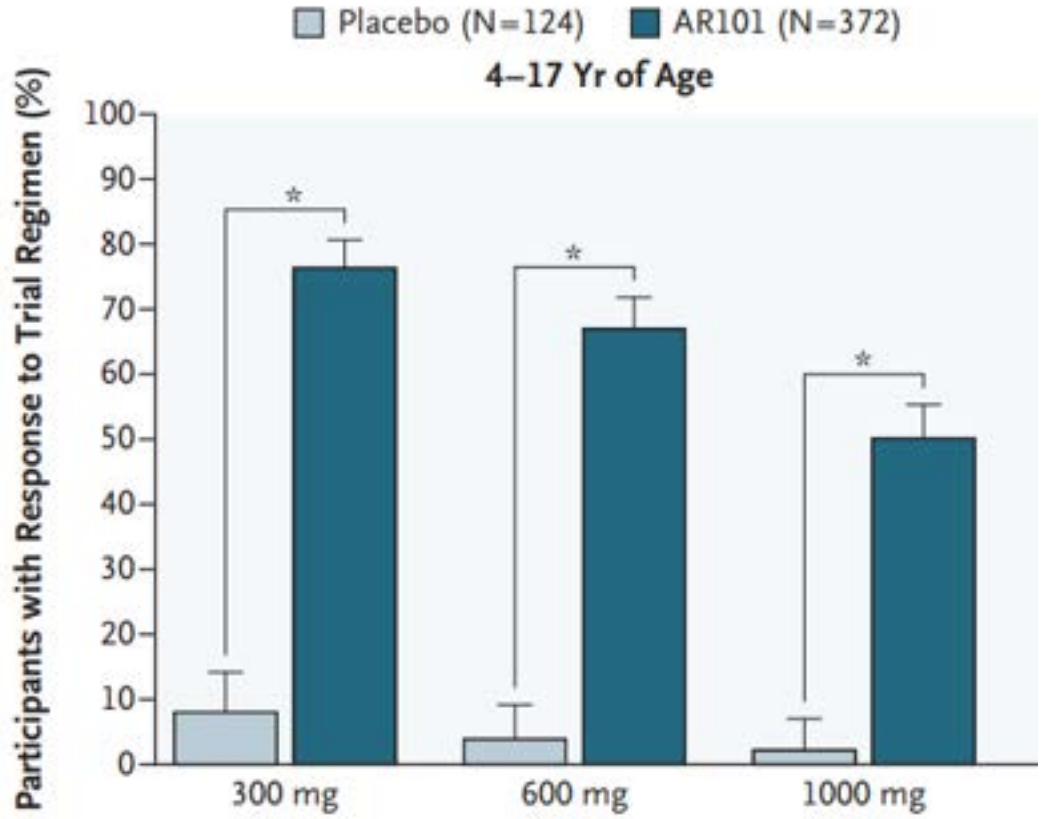


PALISADE Investigator Group. N Engl J Med 2018

Palforzia -- First FDA-approved food allergy treatment

- Approved January 2020 for children aged 4-17 years with confirmed diagnosis of peanut allergy
- Capsules contain set peanut protein dosages, sourced from raw peanuts, processed into 12% defatted, roasted peanut flour
- Used in conjunction with a peanut avoidance diet
- Administered by allergists under a risk evaluation and mitigation strategy (REMS)

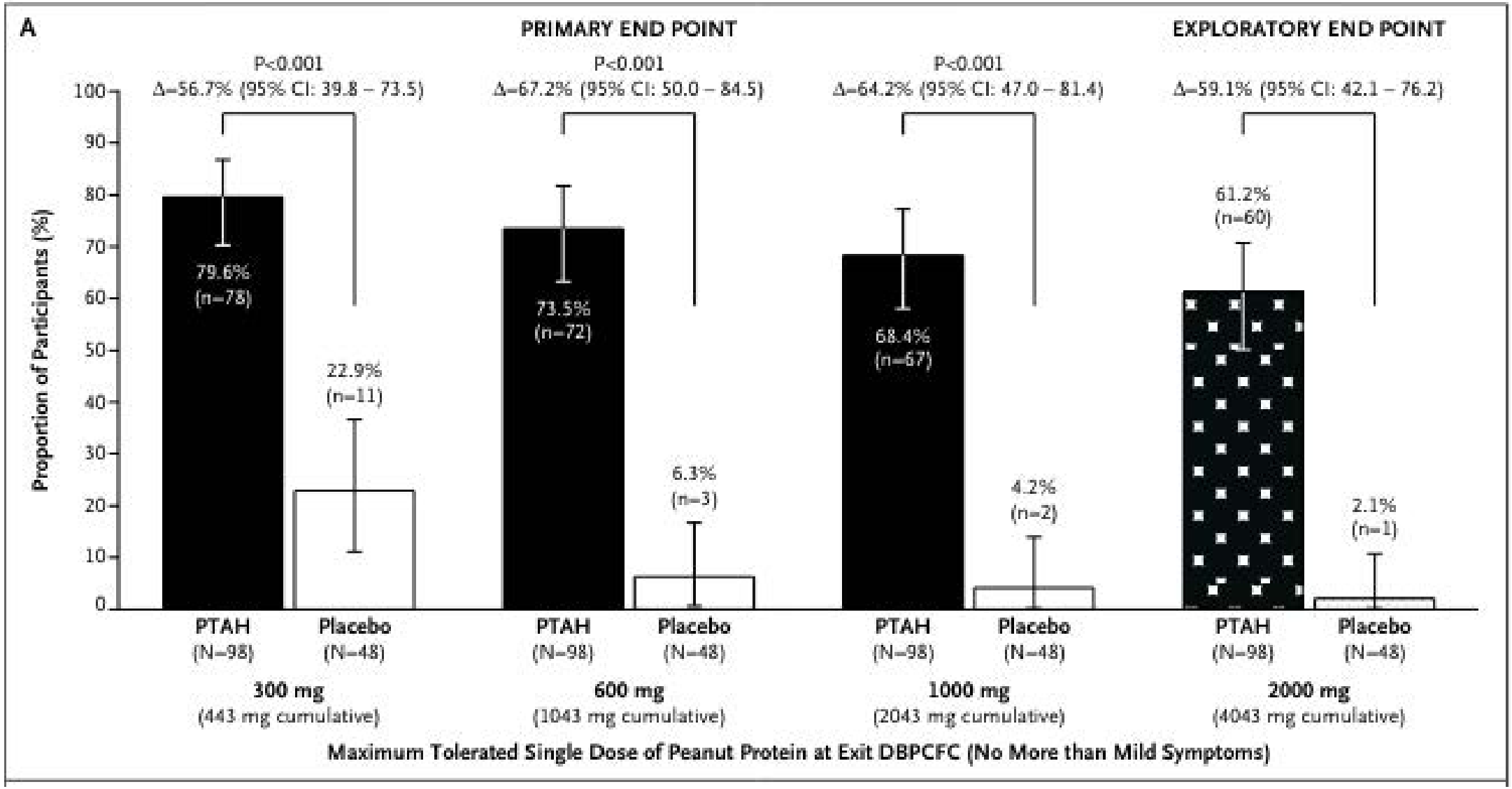
Peanut OIT (AR101) for younger children

Oral Immunotherapy for Peanut Allergy in Children 1 to Less Than 4 Years of Age (POSEIDON study)

- POSEIDON was a phase 3, randomized, double-blind, placebo-controlled trial conducted at 14 study sites in North America (the United States) and 9 study sites in Europe
- PTAH = peanut allergen powder-dnfp OIT
- In peanut-allergic children 1 to 4 years old, treated with PTAH for approximately 12 months, the majority tolerated all peanut protein dose levels assessed.
- 83 in treatment group, 45 in placebo group completed the trial
- PTAH-treated patients had more treatment-related adverse events, which were mild to moderate severity.

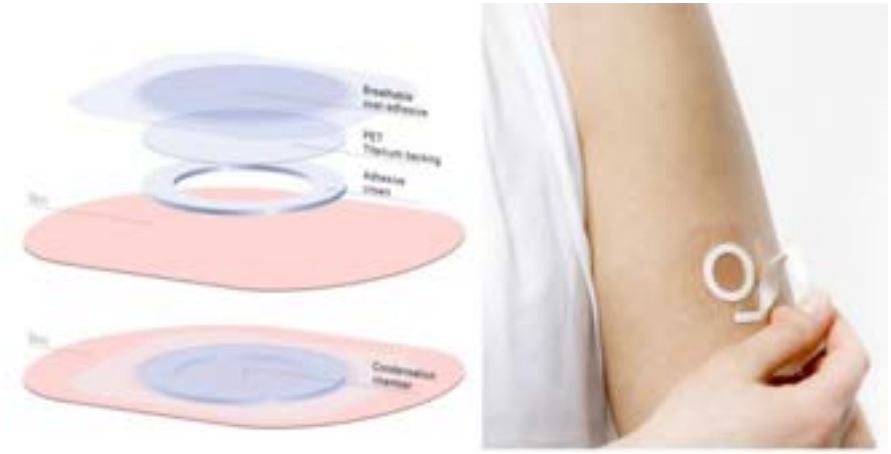
Du Toit, G et al. *NEJM Evidence, 2* (11), October 2023

Peanut OIT (AR101) for younger children



Du Toit, G et al. *NEJM Evidence, 2* (11), October 2023

Epicutaneous Immunotherapy for Foods (EPIT)

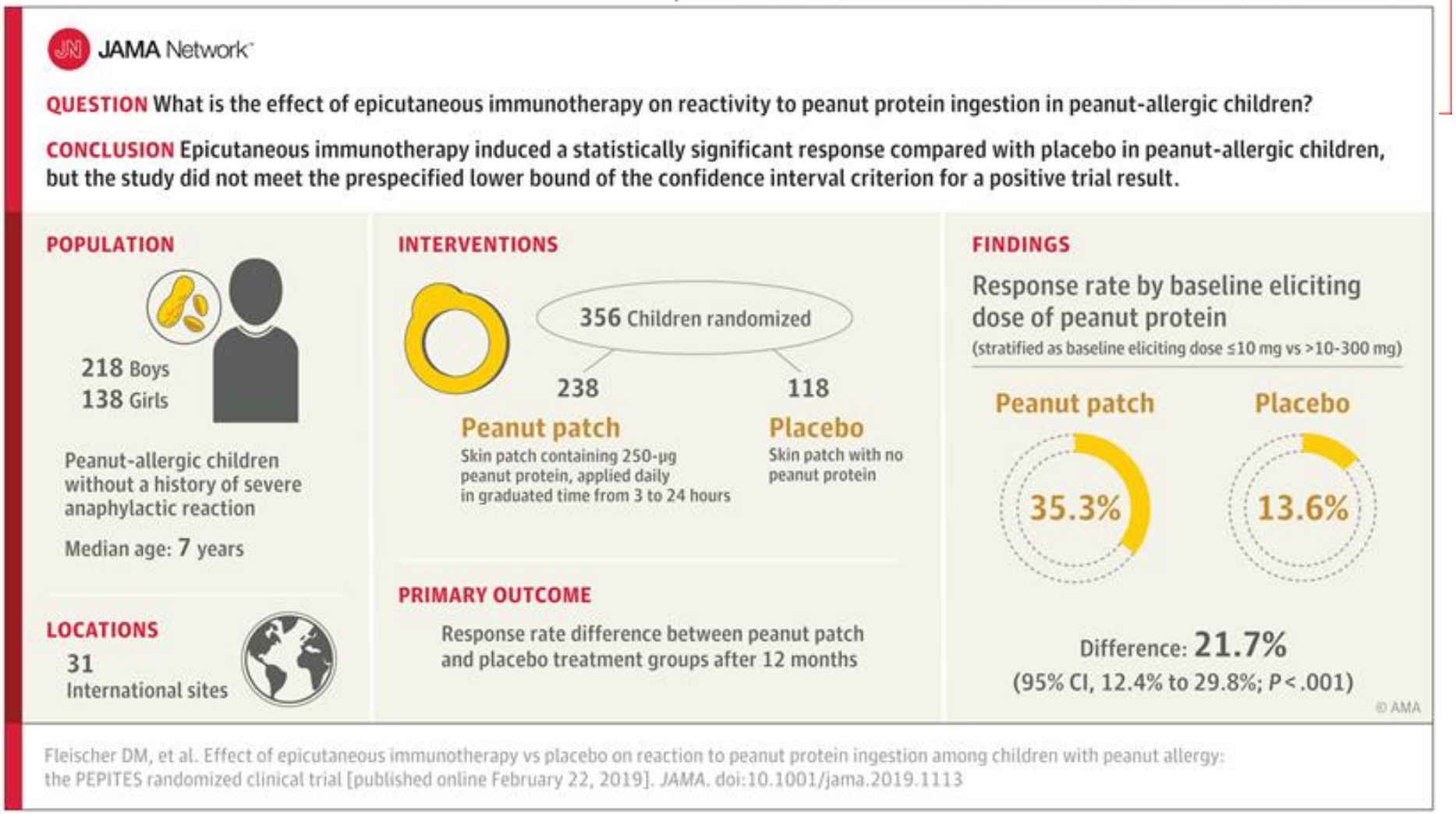


- Novel delivery of allergen to skin
- Allergen-containing patch that facilitates diffusion of allergens into stratum corneum, activates dendritic cells of the epidermis
- Ongoing studies for milk and peanut EPIT

Phase 3 Clinical Trial PEPITES

JAMA | Original Investigation

Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children With Peanut Allergy
The PEPITES Randomized Clinical Trial



Fleischer DM et al. JAMA March 2019

PEPITES Peanut EPIT Phase 3 Trial

89.9% completed the trial
Mean treatment adherence was 98.5%

35.3% response in peanut patch versus 13.6% response in placebo

- 21.7% percentage difference – clinically significant
- **However, the pre-specified lower bound of the CI threshold (>15%) was not met**

Adverse events were primarily patch application site reactions in 95% of active and 89% of placebo patch groups

Discontinuation rate of 10.5% in active versus 9.3% in placebo patch group

Fleischer DM et al. JAMA March 2019

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy

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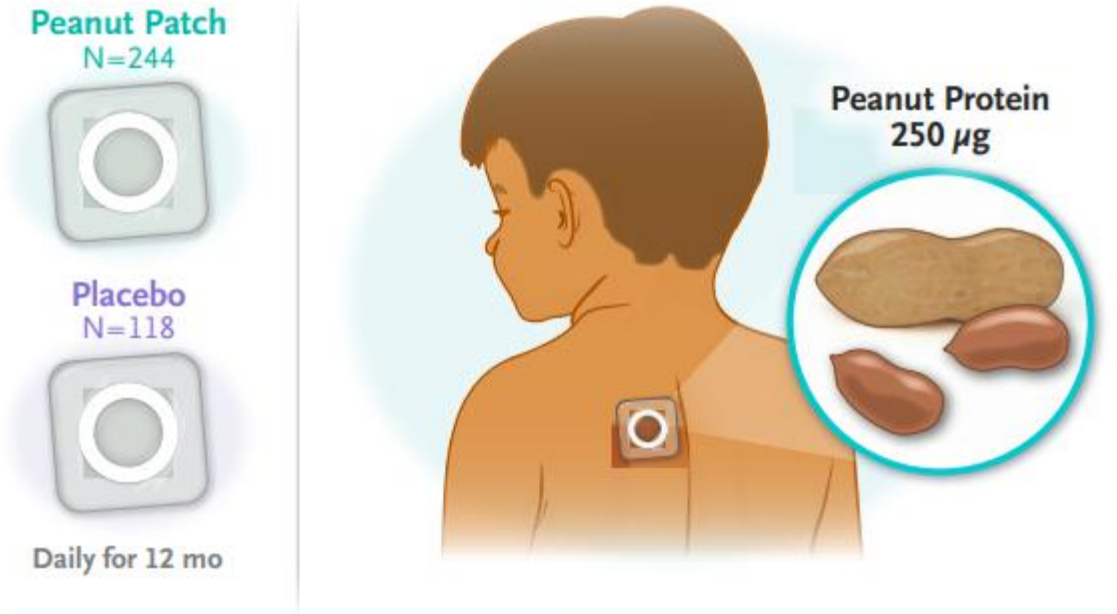
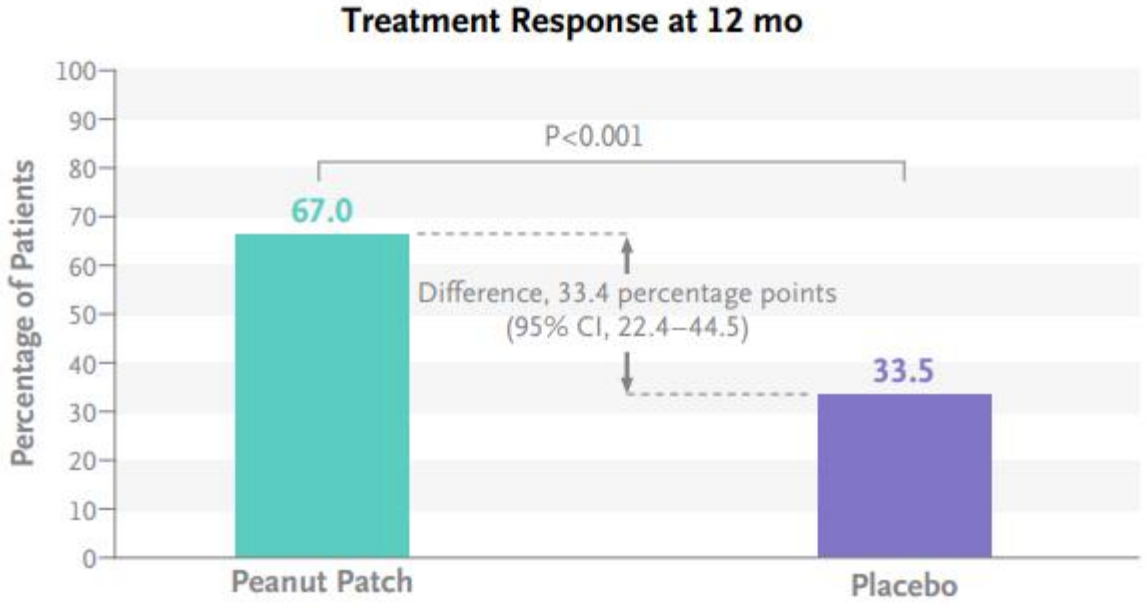
May 2023



Responder endpoint:

- ≥1000mg (if baseline ED >10mg)
- ≥300mg (if baseline ED ≤10mg)



Sublingual Immunotherapy for Foods (SLIT)

- Food protein is delivered sublingually in liquid form,

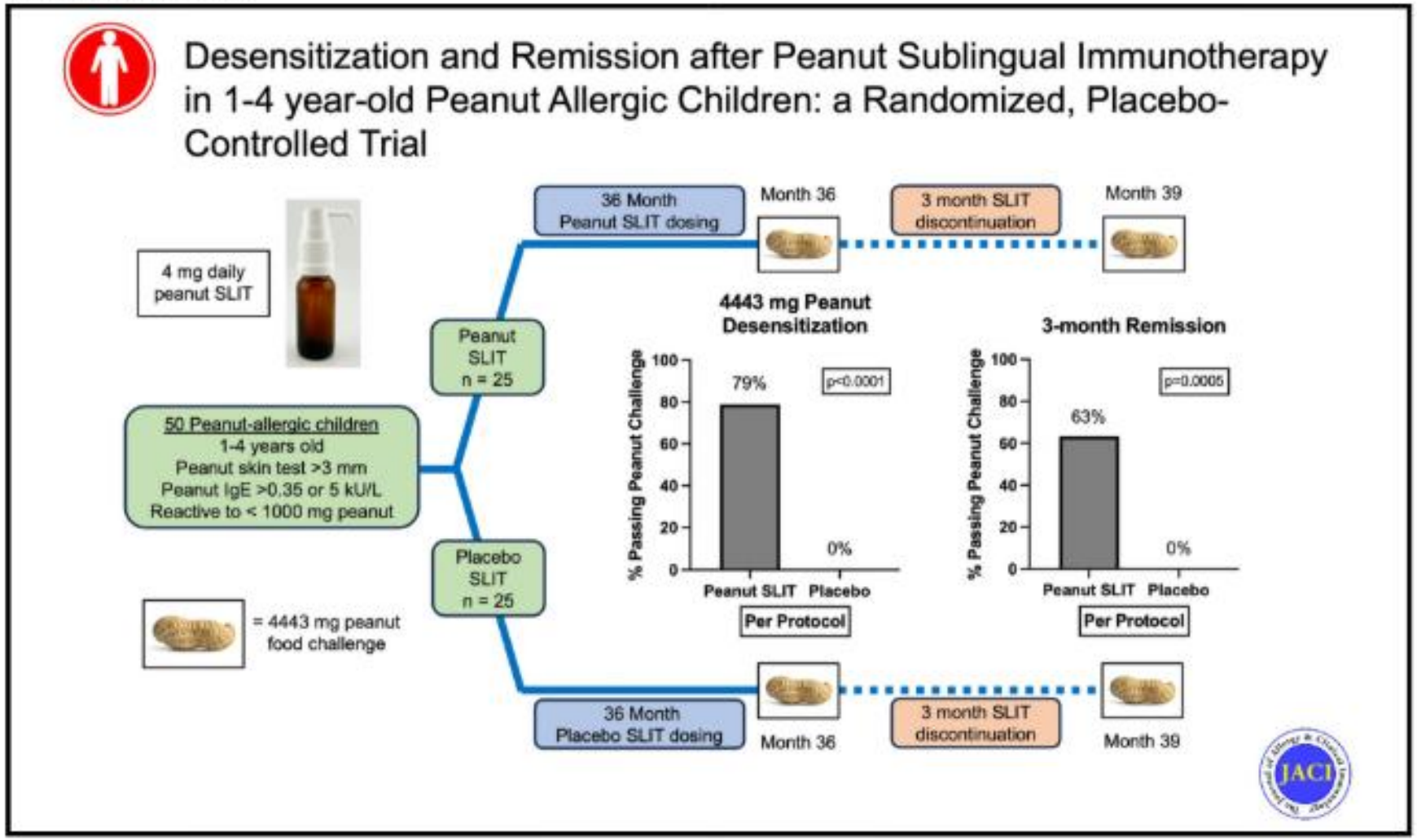
  held for 2 minutes, and swallowed

- Start with microgram levels, increase to 1-10mg maintenance doses
- Thought to activate "tolerogenic" APC's in oral mucosa
- Has shown efficacy for environmental allergies
- Dosing and efficacy limited by the concentration of available extracts, the amount of liquid that can be held under the tongue, and adherence to therapy
- SLIT is safe, with low rate of SE that are primarily mild

  –most common symptoms are transient oral itching

Sublingual immunotherapy (SLIT) for peanut allergy

GRAPHICAL ABSTRACT



Peanut SLIT safely induces desensitization and remission in 1-4 yo

Improved outcomes seen with younger age at initiation

Kim EH, Bird JA, Keet CA, et al. *JACI*. 2023

OUtMATCH: Omalizumab as monotherapy and as adjunct therapy to multi-allergen OIT in food allergic children and adults

CONSORTIUM FOR FOOD ALLERGY RESEARCH
NIH Sponsored

Allergy to peanut and 2 other foods

Stage 1: Omalizumab monotherapy vs placebo

Stage 2: Oma + placebo OIT vs Short Oma + multi OIT

Stage 3: long-term follow-up with food introduction or rescue OIT

Open label extension

(first 60)

ClinicalTrials.gov Identifier: NCT03881696

RESEARCH SUMMARY

Omalizumab for the Treatment of Multiple Food Allergies

Wood RA et al. DOI: 10.1056/NEJMoa2312382

177 children and adolescents

Food challenge-proven allergy to peanut

+ allergy to at least 2 other foods (cashew, egg, hazelnut, milk, walnut, wheat)

DBPCFC at study entry

Baseline reactivity:

≤100 mg of peanut protein

≤300 mg of two other foods

Randomized 2:1

Omalizumab vs placebo Q2-4 weeks

for 16-20 weeks

DBPCFC at study exit

Success:

≥600 mg peanut protein

≥1000 mg of other foods

Wood R, et al. N Engl J Med 2024

RESEARCH SUMMARY

Omalizumab for the Treatment of Multiple Food Allergies

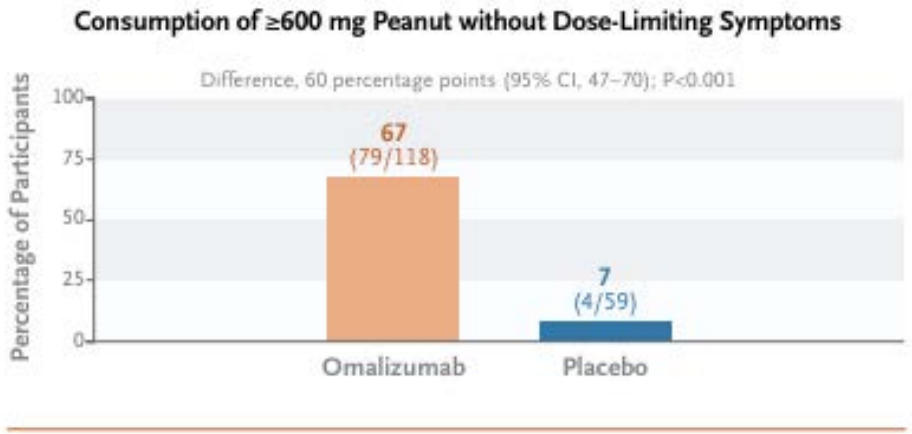
Wood RA et al. DOI: 10.1056/NEJMoa2312382

RESULTS

Efficacy: The percentage of participants who were able to consume ≥600 mg of peanut protein without dose-limiting symptoms was nearly 10 times higher in the omalizumab group than in the placebo group. Key secondary end points (the consumption of cashew, egg, or milk at prespecified threshold doses) also favored omalizumab.

Safety: The incidence of adverse events was similar in the two groups.

Primary endpoint:



Percent of patients able to eat the equivalent of 2 peanuts was almost 10x greater with omalizumab than with placebo

Wood R, et al. N Engl J Med 2024

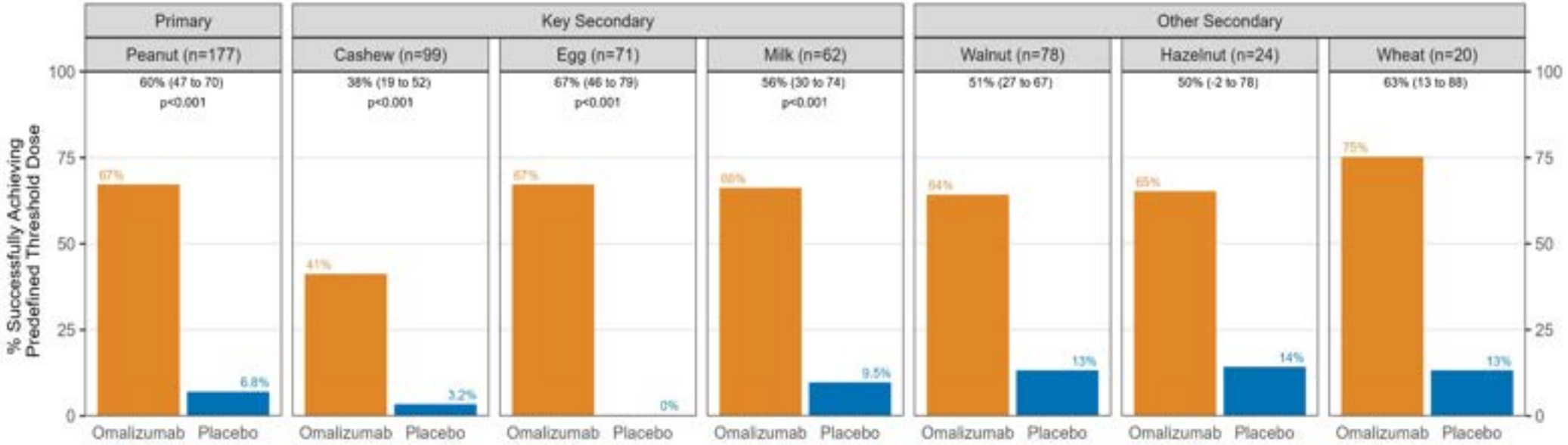
RESEARCH SUMMARY

Omalizumab for the Treatment of Multiple Food Allergies

Wood RA et al. DOI: 10.1056/NEJMoa2312382

Secondary Endpoints

Omalizumab treated group were also better able to tolerate threshold doses of cashew, egg, milk (p<0.001) as well as for walnut, hazelnut and wheat



CONCLUSIONS

In children as young as 1 year of age with multiple food allergies, including peanut allergy, omalizumab was superior to placebo in increasing the reaction threshold for peanut and other common food allergens.

Wood R, et al. N Engl J Med 2024

U.S. FOOD & DRUG ADMINISTRATION

Home / News & Events / F FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure

FDA NEWS RELEASE

FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure

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For Immediate Release: February 16, 2024

Today, the U.S. Food and Drug Administration approved Xolair (omalizumab) injection for immunoglobulin E-mediated food allergy in certain adults and children 1 year or older for the reduction of allergic reactions (Type I), including reducing the risk of anaphylaxis, that may occur with accidental exposure to one or more foods. Patients who take Xolair must continue to avoid foods they are allergic to. Xolair is intended for repeated use to reduce the risk of allergic reactions and is not approved for the immediate emergency treatment of allergic reactions, including anaphylaxis.

Xolair approved

≥ 1 year old

≥ 1 food allergy

*Patients will still need to continue allergen avoidance and carry epinephrine autoinjector

Several therapeutic desensitization strategies have and are currently being investigated for food allergies. (OIT, SLIT, EPIT)

The first FDA approved peanut OIT product has been approved for clinical use (2020).

The first biologic agent (omalizumab) has been approved by the FDA for use in IgE-mediated food allergy.

The treatment of food allergy will likely be very different in the coming years as multiple new therapies become available for peanut and other foods.

Physicians and patient will need to determine if and what specific therapeutic modality is most suitable (shared decision making).

Thank you!

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