PEANUT ALLERGY PREVENTION

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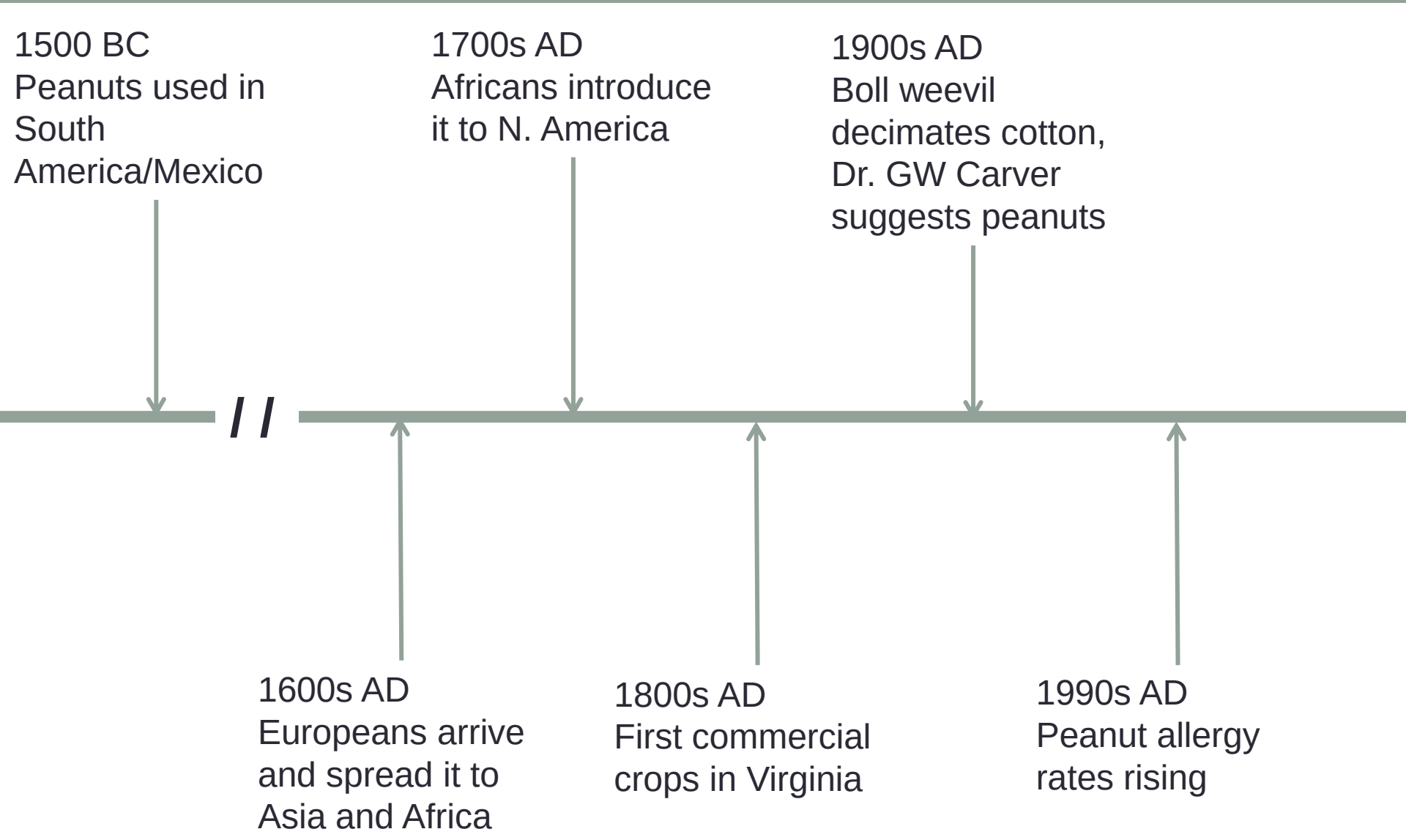
5-13-15

Outline

- Peanut History
- Peanut Prevalence
- AAP Recommendations
- LEAP Study
- Conclusions



http://nationalpeanutboard.org

Peanut allergy (PA) prevalence

TABLE I. Previously reported prevalence estimates of childhood peanut allergy in the US

Study	Criteria for definition	Method	Survey year	Prevalence percent (95% CI)
Sicherer et al[2]	Self-reported reaction and symptoms	Telephone survey	1997	0.4 (0.2-0.7) in <18 y
Sicherer et al[2]	Self-reported reaction and symptoms	Telephone survey	2002	0.8 (0.5-1.2) in <18 y 0.8 (0.4-1.8) in 6-10 y
NHANES 2005-2006[7]	Clinical food allergy based on sIgE criteria*	Nationally representative survey	2005-2006	1.8 (1.5-2.1) in 1-5 y 2.7 (2.4-3.0) in 6-19 y
NHANES 2005-2006[7]	Peanut sIgE ≥ 14 kU/L†	Nationally representative survey	2005-2006	1.0 (0.7-1.3) in 1-5 y 0.9 (0.7-1.2) in 6-19 y
NHANES 2007-2008[6]	Self-reported allergy‡	Nationally representative survey	2007-2008	1.4 (0.9-1.9) in <18 y
Sicherer et al[2]	Self-reported reaction and symptoms	Telephone survey	2008	1.4 (1.0-1.9) in <18 y 2.1 (1.3-3.4) in 6-10 y
NHANES 2009-2010[6]	Self-reported allergy‡	Nationally representative survey	2009-2010	0.9 (0.4-1.4) in <18 y
NHANES 2007-2010[6]	Self-reported allergy‡ excluding those with recent consumption	Nationally representative survey	2007-2010	0.9 (0.7-1.1) in children and adults
Infant Feeding Practices Study II[5]	Self-reported allergy	Mail survey	2009-2010	0.6 (0.3-1.0) in <1 y
Gupta et al[4]	Self-reported allergy and reaction history	Electronic survey	2009-2010	2.0 (1.8-2.2) in < 18 y 1.9 (1.6-2.3) in 6-10 y

J Allergy Clin Immunol. 2014 Sep;134(3):753-5.

Project Viva

TABLE II. Prevalence of peanut allergy among school-age children in a US observational birth cohort not selected for any disease (N = 616)

Criteria for definition	No.	Prevalence percent (95% CI)
Self-reported reaction and symptoms	27	4.6 (2.9-6.3)‡
Clinical food allergy based on sIgE criteria*	31	5.0 (3.5-7.1)
Peanut sIgE ≥ 0.35 kU/L and prescribed epinephrine auto-injector	29	4.9 (3.2-6.7)‡
Peanut sIgE ≥ 14 kU/L†	18	2.9 (1.6-4.3)
Peanut sIgE ≥ 14 kU/L and prescribed epinephrine auto-injector	12	2.0 (0.9-3.2)‡

J Allergy Clin Immunol. 2014 Sep;134(3):753-5.

Why do we care?

- Food allergy is the leading cause of anaphylaxis treated in ERs each year
  - 30,000 anaphylactic reactions
  - 2000 hospitalizations
  - 200 deaths
    - Allergies to peanuts and tree nuts account for the majority of fatal and near-fatal
- 90% US households consume peanuts
  - Found in many products
    - Amounts in Precautionary Allergy Labeling (0.0% to 32.4%)
  - US #3 producer in the world behind China and India

N Engl J Med 2002; 346:1294-1299

2000 AAP Recommendations

- Infants at **high risk** for developing **allergy**, . . . Conclusive studies are not yet available to permit definitive recommendations. However, the following recommendations seem reasonable at this time:
- a) Breastfeeding mothers should continue breastfeeding for the first year of life or longer. . . Mothers should **eliminate peanuts and tree nuts (eg, almonds, walnuts, etc) and consider eliminating eggs, cow's milk, fish, and perhaps other foods from their diets while nursing**. Solid foods . . . introduced …until 6 months of age, with **dairy products delayed until 1 year, eggs until 2 years, and peanuts, nuts, and fish until 3 years of age.**
- b) No maternal dietary restrictions during pregnancy are necessary with the possible exception of excluding peanuts;

2008 AAP Recommendations

- Although solid foods should not be introduced before 4 to 6 months of age, ***there is no current convincing evidence that delaying their introduction beyond this period has a significant protective effect on the development of atopic disease*** . . .
- **. . .** ***there are insufficient data to support a protective effect of any dietary intervention for the development of atopic disease*****.**
- ***Additional studies are needed to document the long-term effect of dietary interventions*** **. . .**

Why didn’t it work?

- Skin sensitization?
  - Eczema and PA correlated
  - Peanut based oils in breast creams and other skin care products
  - Presence of peanut in dust (bed and kitchen)
    - Norwegian adolescents
    - German households
  - Mouse models of cutaneous sensitization
- Lack of oral tolerance?
  - Mouse models with Ovalbumin, Peanut or β-lactoglobulin administration
  - Human study of oral exposure to nickel (braces) prior to ear piercing showed lower rates of sensitization
  - Early egg introduction study in eczema infants

Worldwide differences

- Study of ~4000 children each in Tel Aviv, Israeli and North London, UK Jewish children (recent immigrants)
- Use of Food Allergy Questionnaire
  - Peanut Allergy definition was self report of symptoms within 2 hours of ingestion
    - Subgroup evaluated by sIgE or SPT (95% PPV) or positive Oral food challenge
- Use of Food Frequency Questionnaire
  - Asked when do you introduce foods on weaning
- Peanut Allergy Prevalence: 0.17% Israel vs 1.8% UK (Peanuts)
  - High risk infants: 0.79% vs. 6.46%

George Du Toit (2008) JACI 122:984

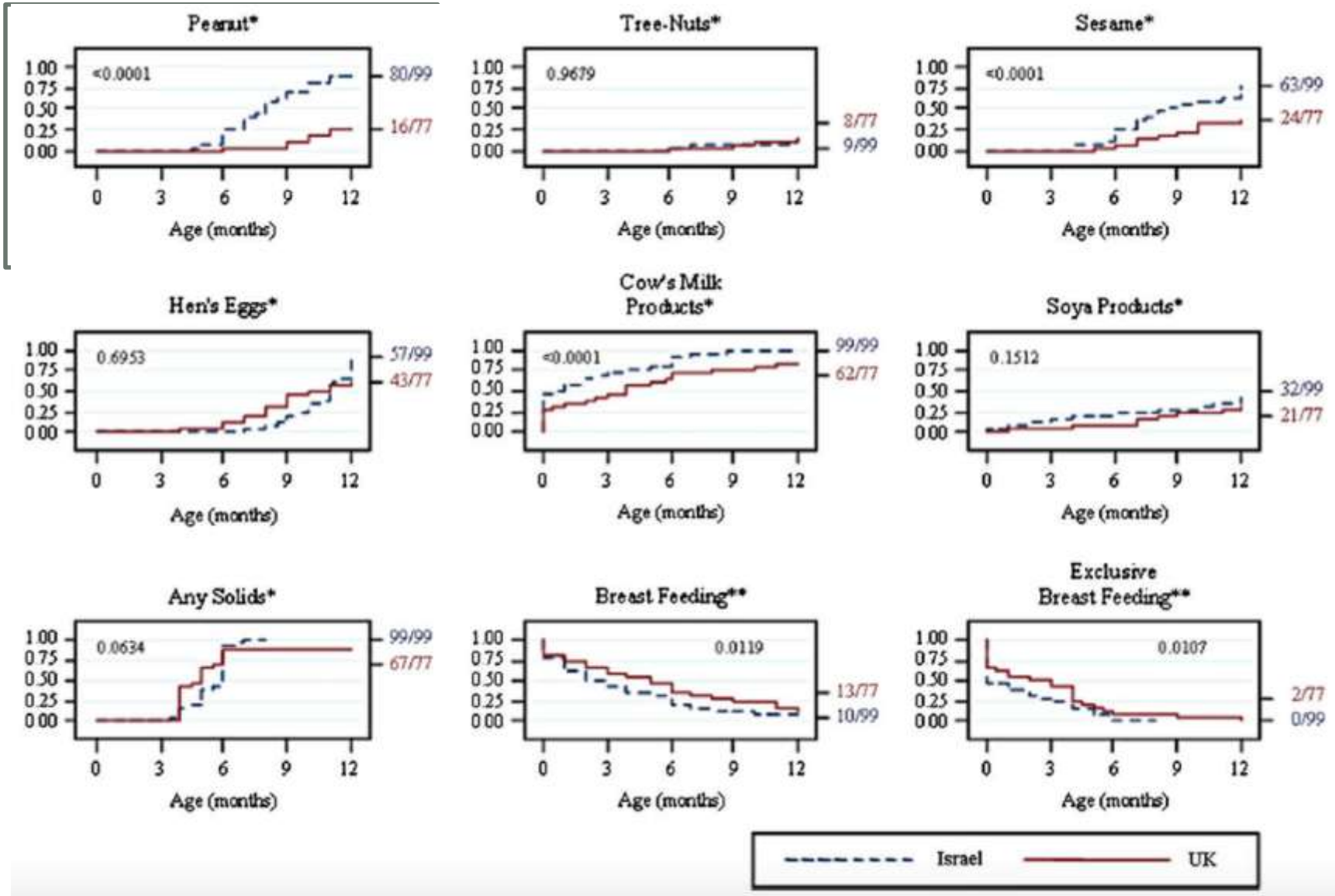
Higher rates in UK vs Israel

TABLE II. The ratio of the risk of food allergies in the UK compared with Israel

	Peanut		Sesame		Tree nuts		Egg		Milk	
	RR (95% CI)	*P* value	RR (95% CI)	*P* value	RR (95% CI)	*P* value	RR (95% CI)	*P* value	RR (95% CI)	*P* value
All individuals										
Unadjusted	10.8 (5.2-22.3)	<.001	6.1 (2.5-14.6)	<.001	15.2 (6.6-34.7)	<.001	3.4 (2.1-5.7)	<.001	1.9 (1.4-2.7)	<.001
Adjusted for age group* and sex§	10.4 (4.8-22.2)	<.001	5.3 (2.2-13.0)	<.001	14.0 (6.0-32.5)	<.001	3.1 (1.8-5.2)	<.001	1.7 (1.2-2.4)	.008
Adjusted for age group,* sex,§ food allergy,‡ and atopy†	5.8 (2.8-11.8)	<.001	2.7 (1.1-7.0)	.057	8.4 (3.6-19.5)	<.001	1.8 (1.0-3.1)	.054	1.3 (0.9-1.9)	.33
Primary school										
Unadjusted	17.4 (5.5-55.6)	<.001	6.3 (2.2-18.0)	<.001	17.4 (5.5-55.6)	<.001	4.8 (2.4-9.4)	<.001	1.7 (1.1-2.5)	.012
Adjusted for sex§	16.9 (5.3-53.5)	<.001	6.1 (2.2-17.6)	<.001	16.5 (5.3-51.8)	<.001	4.6 (2.3-9.0)	<.001	1.6 (1.1-2.4)	.046
Adjusted for sex,§ food allergy,‡ and atopy†	9.8 (3.1-30.5)	<.001	3.6 (1.1-12.1)	.045	9.5 (3.0-29.5)	<.001	2.5 (1.3-4.9)	.011	1.2 (0.8-1.9)	.47

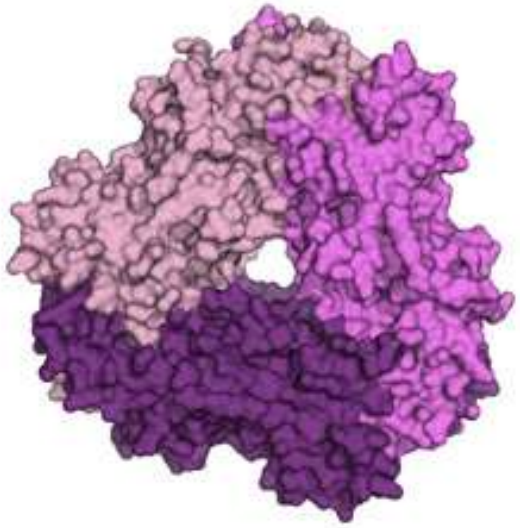
- 47 of 81 of PA clinically evaluate; 36 (77% confirmed PA, rest were tolerant)
  - Adjust for this and worst case scenario then RR 5.4 (2.4-12.2)

Food introduction



Bamba

- 25% of the Israeli snack market
  - Product since 1964
  - Roasted peanut butter flavored puffed maize
- Similar Ara H 1, 2, & 3 content as roasted peanut butter from UK
- 2 grams of peanut protein per 17 grams of Bamba



Learning Early About Peanut Allergy (LEAP) Study

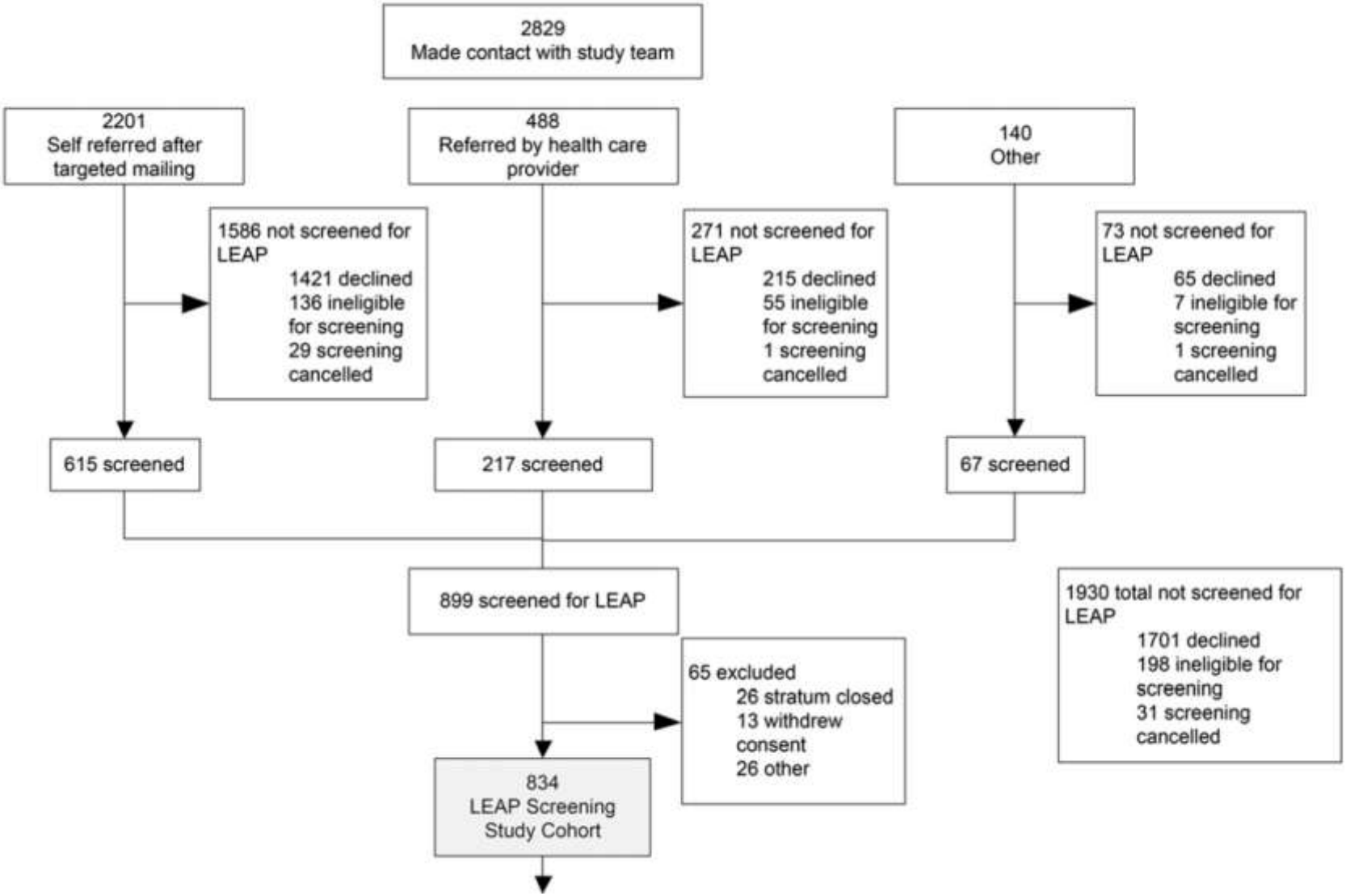
- A randomized controlled trial in high risk infants that aims to determine which is the best strategy for the prevention of PA
  - Early introduction of peanut into the diet
  - Or Complete avoidance
- Recruitment focused on
  - (1) child health professionals such as dermatologists, allergists, and specialist nurses
  - (2) a study flyer posted to parents of young infants in the United Kingdom
  - (3) other avenues, such as written and electronic media and word of mouth

High Risk Population

- Eczema risk factor
  - (1) frequent need for treatment with topical corticosteroids or calcineurin inhibitors
  - (2) parental description of ‘‘a very bad rash in joints and creases’’ or ‘‘a very bad itchy, dry, oozing, or crusted rash,’’
  - (3) a severe SCORAD grade (>40) by a clinician
- Egg allergy risk factor
  - (1) an SPT-induced wheal diameter of 6mm or greater with raw hen’s egg white and no history of previous egg tolerance
  - (2) an SPT-induced wheal diameter of 3 mm or greater with pasteurized hen’s egg white with a history of an allergic reaction to egg

Baseline Testing

- SPTs
  - Egg, Peanut, cow's milk, sesame, soya
- Specific IgE
  - Peanut, Egg, Cow's milk, sesame, brazil nut, hazelnut, cashew, almond, walnut
- SCORAD score


2829
Made contact with study team
2201
Self referred after targeted mailing
488
Referred by health care provider
140
Other
1586 not screened for LEAP
1421 declined
136 ineligible for screening
29 screening cancelled
271 not screened for LEAP
215 declined
55 ineligible for screening
1 screening cancelled
73 not screened for LEAP
65 declined
7 ineligible for screening
1 screening cancelled
615 screened
217 screened
67 screened
899 screened for LEAP
1930 total not screened for LEAP
1701 declined
198 ineligible for screening
31 screening cancelled
65 excluded
26 stratum closed
13 withdrew consent
26 other
834
LEAP Screening Study Cohort

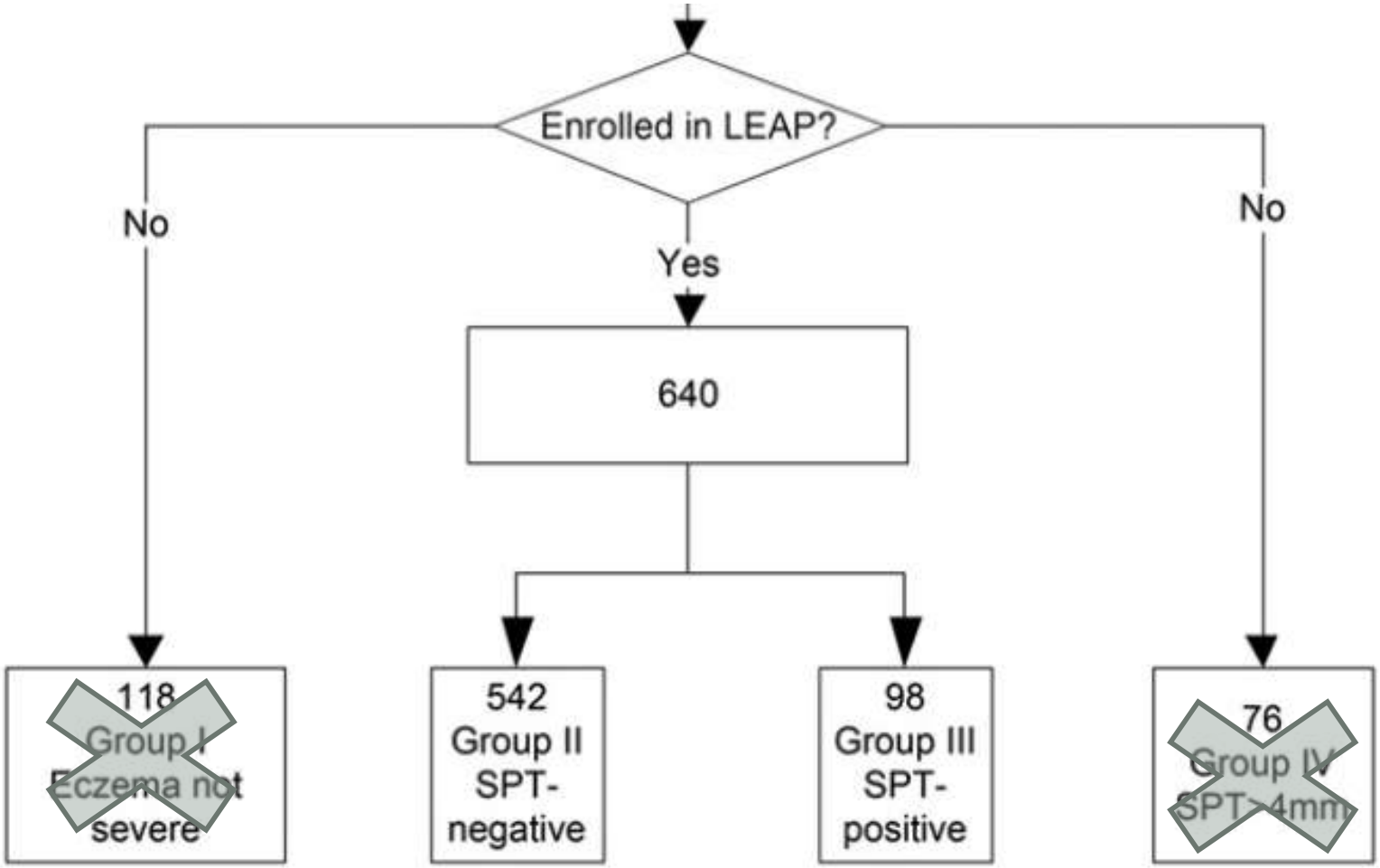

Enrolled in LEAP?
No
Yes
No
640
118
Group I
Eczema not severe
542
Group II
SPT-negative
98
Group III
SPT-positive
76
Group IV
SPT>4mm

TABLE I. Baseline characteristics for the LEAP screening study cohort

	Group I: mild eczema and no egg allergy (n = 118)	Group II: SPT response–negative stratum (n = 542)	Group III: SPT response–positive stratum (n = 98)	Group IV: SPT response >4 mm (n = 76)	*P* value*
Age at screening (mo), mean (SD)	7.5 (1.83)	7.7 (1.74)	8.1 (1.62)	8.3 (1.88)	<.001
Male sex (no.)	65.3% (77)	59.4% (322)	63.3% (62)	57.9% (44)	.552
Race, (no.)					
White	72.0% (85)	74.4% (403)	68.4% (67)	64.5% (49)	
Black	9.3% (11)	7.7% (42)	6.1% (6)	14.5% (11)	
Other					
Mixed	8.5% (10)	13.7% (74)	15.3% (15)	13.2% (10)	
Asian†	7.6% (9)	3.0% (16)	8.2% (8)	5.3% (4)	
Chinese, Middle Eastern, or other	0.8% (1)	1.1% (6)	2.0% (2)	1.3% (1)	
Missing	1.7% (2)	0.2% (1)	0	1.3% (1)	
Severe eczema,‡ (no.)	0	88.9% (482)	90.8% (89)	96.1% (73)	<.001
Definition 1	0	38.6% (209)	52.0% (51)	46.1% (35)	<.001
Definition 2	0	86.2% (467)	88.8% (87)	90.8% (69)	<.001
Definition 3	0	40.2% (218)	42.9% (42)	44.7% (34)	<.001
Age at onset of eczema (mo), mean (SD)	2.6 (1.84)	2.3 (1.63)	2.2 (1.54)	1.6 (1.12)	<.001
Duration of eczema at screening (mo), mean (SD)	4.6 (2.06)	5.4 (2.03)	5.9 (1.89)	6.5 (2.08)	<.001
SCORAD score at screening, mean (SD)	9.9 (6.98)	34.2 (19.12)	35.7 (17.42)	39.3 (18.65)	<.001
Egg allergy‡ (no.)	0	61.4% (333)	76.5% (75)	86.8% (66)	<.001
Definition 1	0	60.7% (329)	74.5% (73)	85.5% (65)	<.001
Definition 2	0	53.1% (288)	72.4% (71)	76.3% (58)	<.001
Percentage eosinophilia, mean (SD)	2.5 (1.30)	4.6 (3.81)	5.6 (3.83)	5.7 (4.12)	<.001
Total IgE (kU/L), mean (SD)	17.9 (34.99)	85.7 (261.0)	211 (482.1)	505 (1263)	<.001
Peanut sensitization					
Specific IgE (kU/L), median (IQR)	0.01 (0.01-0.02)	0.02 (0.01-0.13)	0.55 (0.11-4.42)	8.0 (2.11-20.2)	<.001
SPT 0 mm, median (IQR)	0 (0-0)	0 (0-0)	2.0 (2.0-3.0)	7.5 (6.0-9.0)	<.001

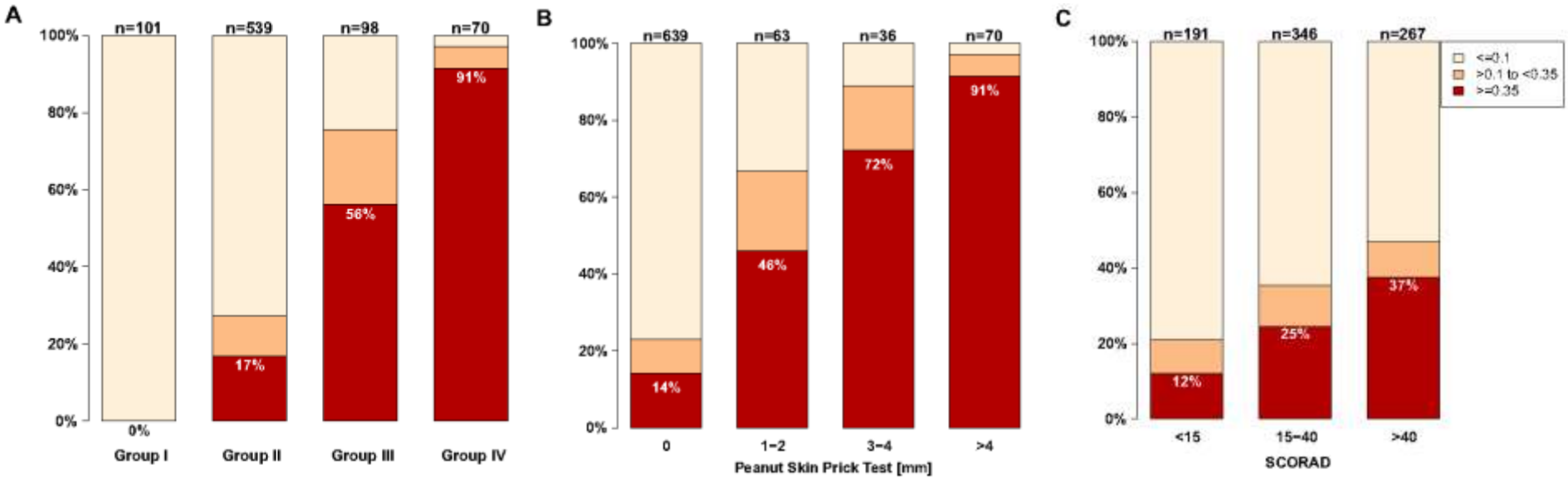

A
n=101
n=539
n=98
n=70
100%
80%
60%
40%
20%
0%
0%
17%
56%
91%
Group I
Group II
Group III
Group IV
B
n=639
n=63
n=36
n=70
14%
46%
72%
91%
0
1−2
3−4
>4
Peanut Skin Prick Test [mm]
C
n=191
n=346
n=267
<=0.1
>0.1 to <0.35
>=0.35
12%
25%
37%
<15
15−40
>40
SCORAD

TABLE II. OR estimates (95% CIs) for predictors of peanut-specific IgE comparing 0.35 kU/L or greater to less than 0.35 kU/L

Variable	Unadjusted	Adjusted for all variables except peanut SPT response	Adjusted for all variables including peanut SPT response
Female (yes vs no)	0.81 (0.58-1.14)	0.82 (0.56-1.19)	0.72 (0.46-1.12)
Race (black vs white)	4.26 (2.49-7.29)	5.30 (2.85-9.86)	7.13 (3.58-14.21)
Egg allergy (yes vs no)	5.97 (3.87-9.21)	4.67 (2.95-7.40)	4.08 (2.45-6.82)
Duration of eczema (quarters)	1.40 (1.10-1.78)	1.31 (0.99-1.75)	1.02 (0.73-1.42)
Severe eczema (yes vs no)	4.35 (2.35-8.06)	3.21 (1.65-6.25)	2.23 (1.09-4.57)
Eosinophilia percentage	1.16 (1.11-1.22)	1.11 (1.06-1.17)	1.12 (1.06-1.18)
Peanut SPT-induced wheal, 1-4 mm (vs 0 mm)	7.35 (4.64-11.64)	—	6.69 (3.97-11.28)
Peanut SPT-induced wheal >4 mm (vs 0 mm)	55.02 (21.30-142.13)	—	51.96 (18.88-142.97)

- Black race, egg allergy or eczema are significantly associated with peanut sensitization assessed by sIgE
- Egg allergy or eczema are significantly associated with SPT also

TABLE III. OR estimates (95% CIs) for predictors of skin test–induced wheal sizes in models comparing 1- to 4-mm and greater than 4-mm wheals with 0-mm wheals

	Unadjusted		Adjusted for all variables except peanut-specific IgE level		Adjusted for all variables including peanut-specific IgE level	
Variable	1-4 vs 0 mm	>4 vs 0 mm	1-4 vs 0 mm	>4 vs 0 mm	1-4 vs 0 mm	>4 vs 0 mm
Female sex (yes vs no)	0.89 (0.57-1.38)	1.29 (0.73-2.27)	0.93 (0.59-1.46)	1.38 (0.76-2.51)	1.06 (0.64-1.75)	2.43 (1.03-5.76)
Race (black vs white)	0.82 (0.34-1.98)	1.83 (0.77-4.33)	0.79 (0.32-1.96)	1.87 (0.75-4.70)	0.26 (0.09-0.72)	0.15 (0.04-0.61)
Egg allergy (yes vs no)	2.86 (1.74-4.69)	5.71 (2.54-12.87)	2.31 (1.39-3.86)	4.03 (2.00-10.57)	1.10 (0.62-1.97)	1.12 (0.36-3.51)
Duration of eczema (quarters)	1.50 (1.09-2.05)	2.29 (1.50-3.50)	1.38 (0.98-1.93)	2.05 (1.31-3.22)	1.40 (0.95-2.04)	1.79 (0.91-3.51)
Severe eczema (yes vs no)	3.07 (1.45-6.49)	14.08 (1.93-102.85)	2.47 (1.14-5.34)	12.53 (1.69-93.14)	1.72 (0.76-3.90)	8.64 (0.92-81.09)
Eosinophilia percentage	1.07 (1.02-1.12)	1.05 (0.99-1.12)	1.04 (0.99-1.09)	1.02 (0.95-1.09)	0.96 (0.91-1.03)	0.88 (0.79-0.99)
Peanut-specific IgE (kU/L), log10	3.17 (2.51-3.99)	8.19 (5.20-12.9)	—	—	3.53 (2.65-4.71)	14.55 (7.61-27.83)

LEAP Study Population

- Inclusion Criteria
  - Ages ≥4 to <11 months old who have had solids successfully introduced into their diet.
  - Egg allergy, severe eczema, or both.
- Exclusion Criteria
  - Chronic illness, except for eczema or recurrent wheeze.
  - SPT >4 mm in the presence of a negative saline control.
  - Previous or current consumption of peanut protein >0.2g
  - Investigator-suspected allergy
  - Diagnosis of persistent asthma.
  - Liver, renal or hematologic abnormalities
- 640 infants (2006-2009), randomized
  - Oral Food Challenge at 5 years of age

Study Protocol

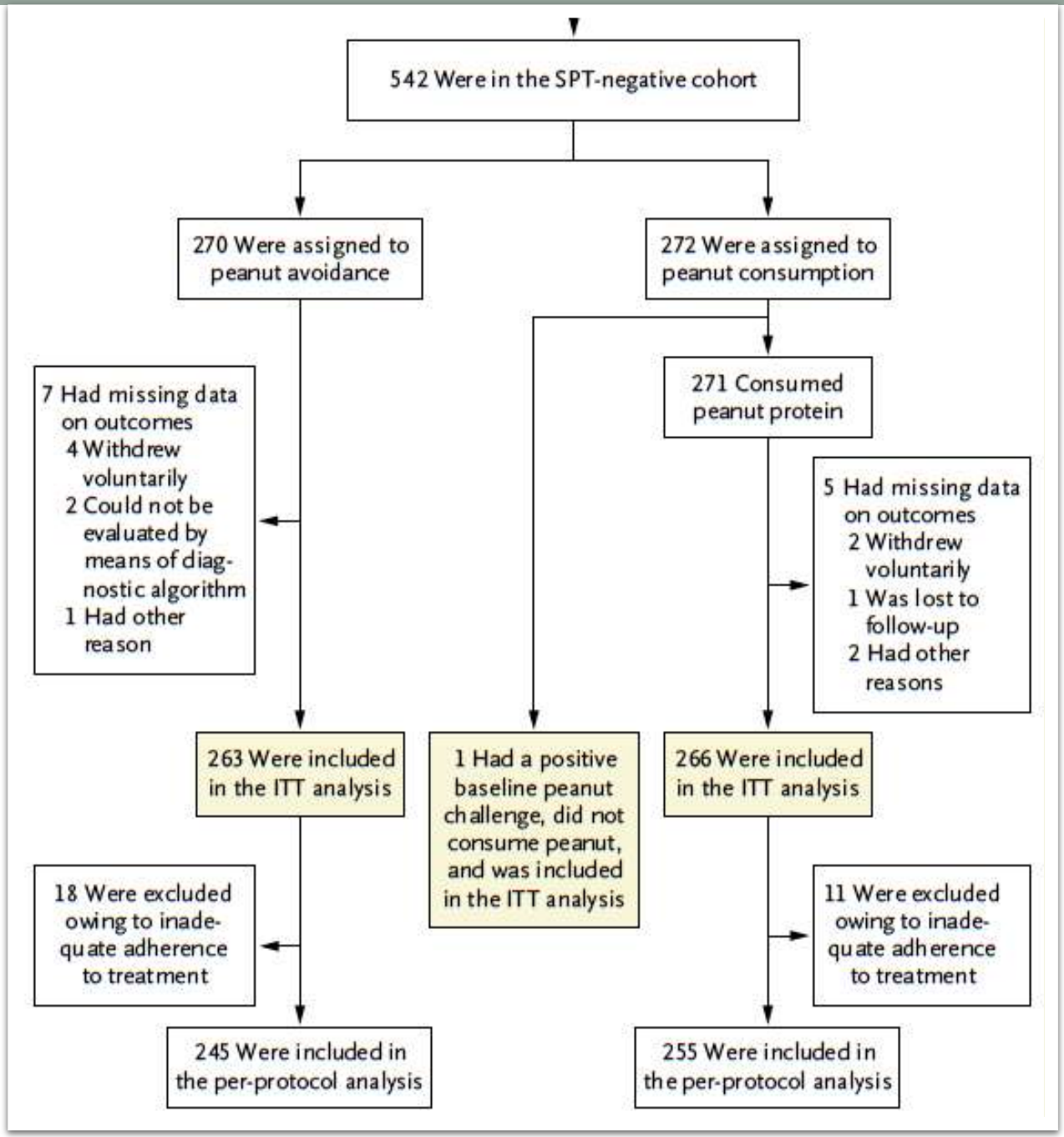
- SPT testing done for primary (0mm) vs secondary intervention
- Randomized to either consumption or avoidance
  - OPEN Label Consumption Arm:
    - At least 2 g of peanut protein 3 times per week until 60 months of age
- Primary Endpoint
  - The proportion of participants with peanut allergy at 60 months of age by DBPCFC or Open Challenge.
- Secondary Endpoints
  - Aeroallergen sensitization and incidence of allergic rhinitis and asthma at 30 and 60 months of age
  - At 60 months of age other food challenges.
  - Incidence of adverse events and laboratory abnormalities
  - Results of cellular and humoral assessments of immune response related to the development of allergy or tolerance to specific allergens.

Demographics

	Negative Stratum (N=542)		Positive Stratum (N=98)		Overall (N=640)	
	Avoidance Group (N=270)	Consumption Group (N=272)	Avoidance Group (N=51)	Consumption Group (N=47)	Avoidance Group (N=321)	Consumption Group (N=319)
Age at screening (mo), mean (SD)	7.7 (1.71)	7.7 (1.77)	8.4 (1.66)	7.9 (1.56)	7.8 (1.72)	7.8 (1.74)
Male sex, no. (%)*	174 (64.4%)	148 (54.4%)	34 (66.7%)	28 (59.6%)	208 (64.8%)	176 (55.2%)
Race, no. (%)						
White	207 (76.7%)	196 (72.1%)	37 (72.5%)	30 (63.8%)	244 (76.0%)	226 (70.8%)
Black	21 (7.8%)	21 (7.7%)	5 (9.8%)	1 (2.1%)	26 (8.1%)	22 (6.9%)
Other						
Mixed	34 (12.6%)	40 (14.7%)	6 (11.8%)	9 (19.1%)	40 (12.5%)	49 (15.4%)
Asian†	6 (2.2%)	10 (3.7%)	3 (5.9%)	5 (10.6%)	9 (2.8%)	15 (4.7%)
Chinese, Middle Eastern or other	2 (0.7%)	4 (1.5%)	0 (0%)	2 (4.3%)	2 (0.6%)	6 (1.9%)
Severe eczema, no. (%)	236 (87.4%)	246 (90.4%)	48 (94.1%)	41 (87.2%)	284 (88.5%)	287 (90.0%)
Age at onset of eczema (mo), mean (SD)	2.2 (1.65)	2.3 (1.61)	2.1 (1.60)	2.4 (1.47)	2.2 (1.64)	2.3 (1.59)
SCORAD, mean (SD)	35.0 (19.87)	33.3 (18.35)	33.7 (16.16)	37.8 (18.64)	34.8 (19.31)	34.0 (18.43)
Total IgE (kU_C/L), mean (SD)	95.1 (321.80)	76.4 (181.39)	125.7 (174.83)	306.4 (666.51)	100.0 (303.24)	109.7 (312.98)
Peanut-specific IgE (kU_A/L), median (IQR)	0.0 (0,0)	0.0 (0,0)	0.4 (0,3)	1.3 (0,5)	0.0 (0,0)	0.0 (0,0)

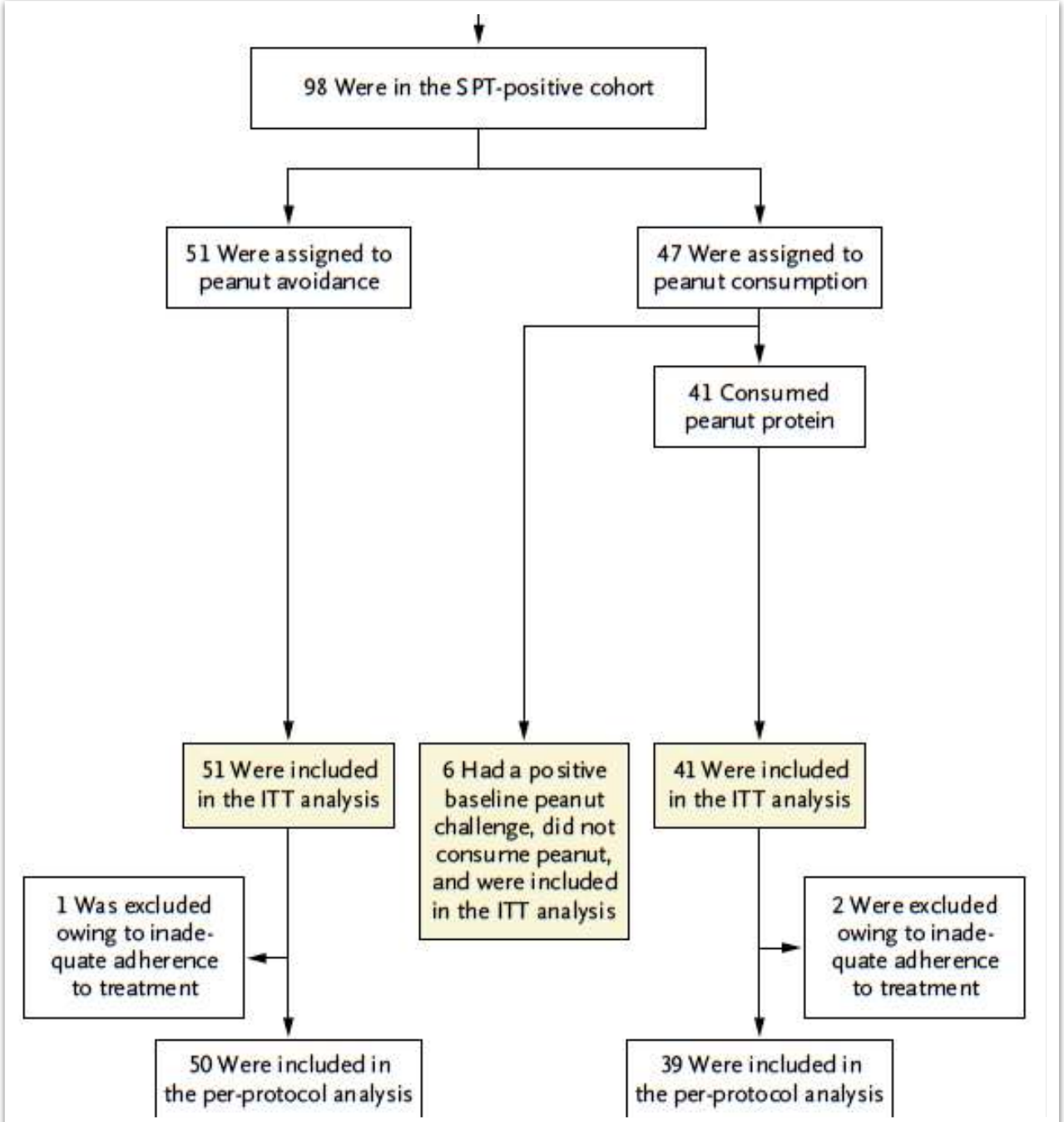
Primary Intervention Outcomes

- Avoidance: 13.7%
- Consumption: 1.9%
- 11.8% (3.4-20.3%)
- 86% reduction



Secondary Intervention Outcomes

- Avoidance: 35.3%
- Consumption: 10.6%
- 24.7% (4.9-43.3%)
- 70% reduction



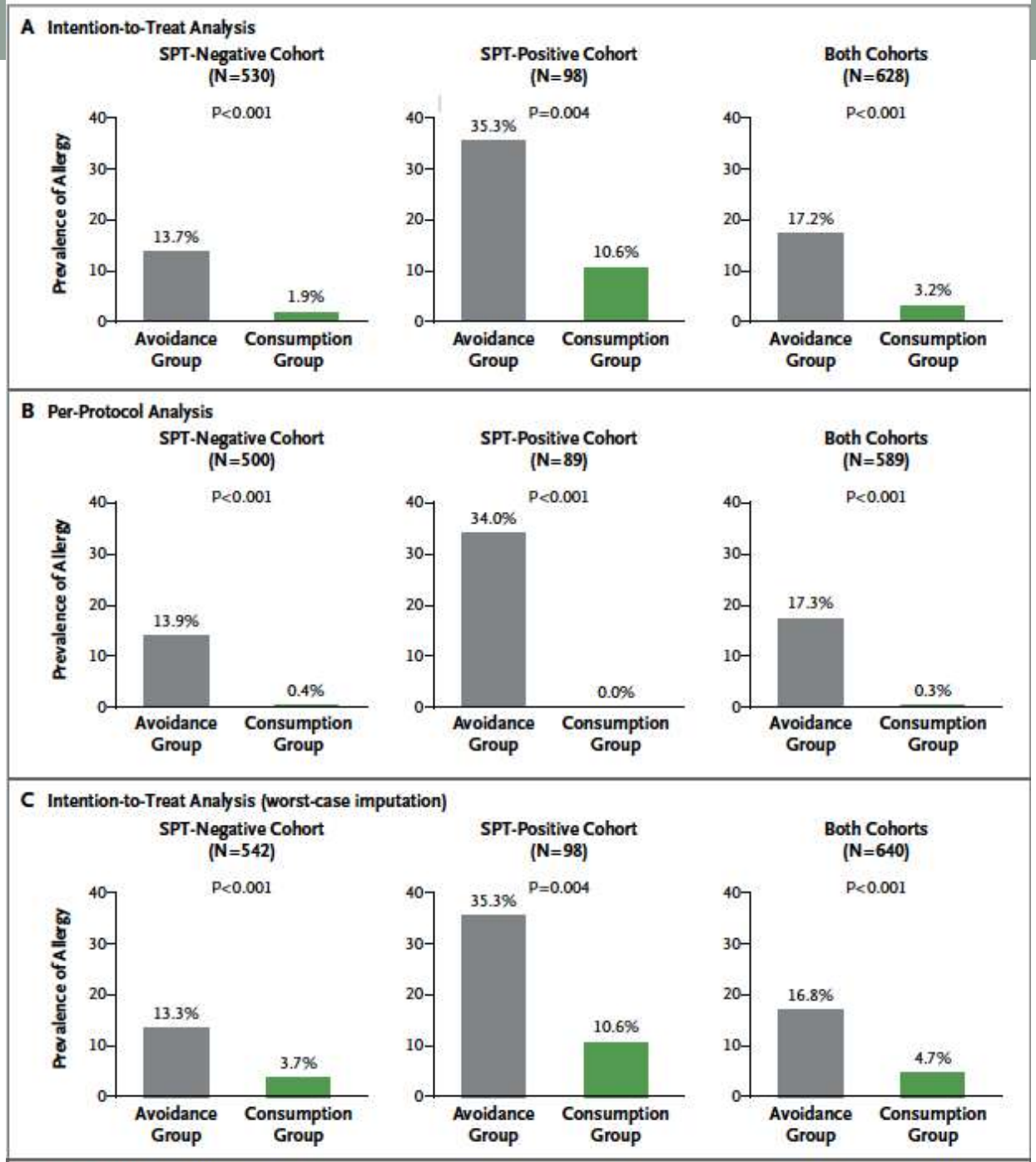


Figure 2. Primary Outcome.

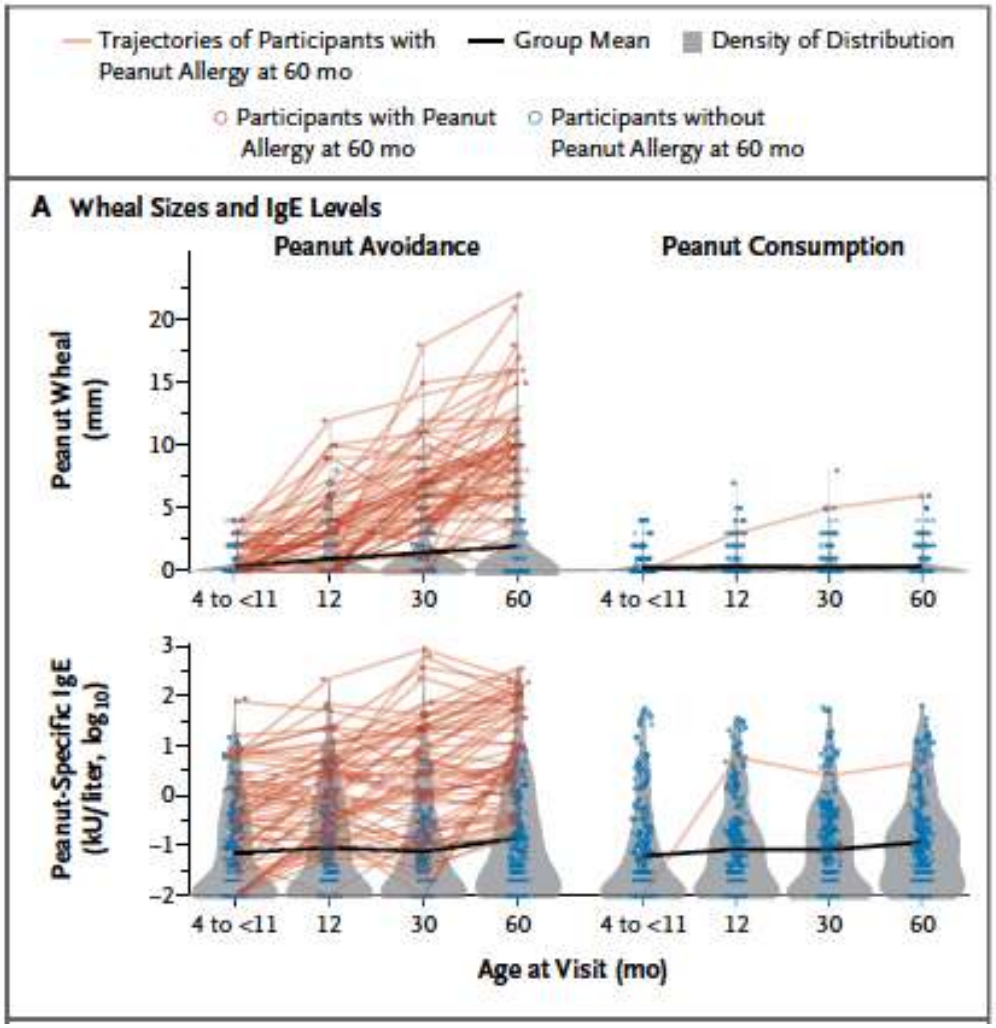
Outcomes of Peanut Consumption

- 4 of the 7 who had positive OFC at baseline had one at 60 months
- 6 of the 9 peanut consumption group who discontinued treatment had positive OFC at 60 months
  - Stopped between 6m to 39m of age due to eczema or Type 1 Hypersensitivity reactions
    - 6m required IM Epinephrine at home
  - 1 patient stopped due to FPIES reaction
- 10 total patients in Peanut consumption group had peanut allergy
  - 4 were positive at baseline
  - 6 stopped consuming because of intolerance

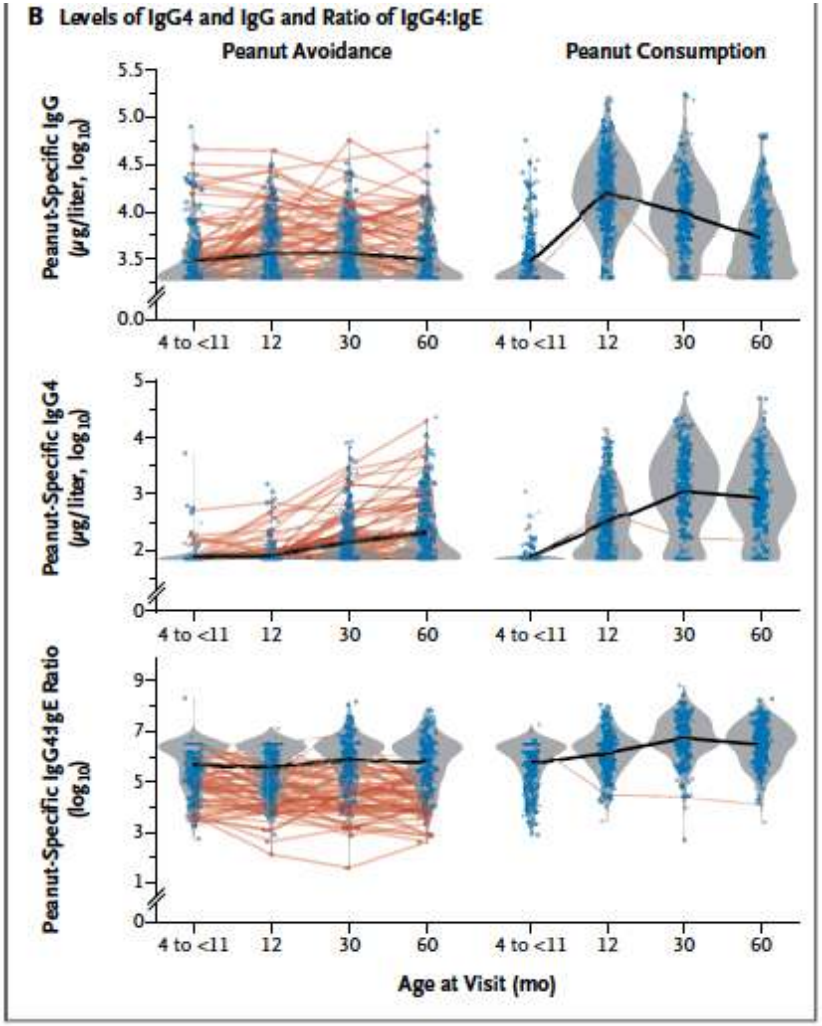
Table S3. Primary and Secondary Prevention for Different Levels of Sensitization

	Peanut Avoidance (N=313)	Peanut Consumption (N=312)	Total (N=625)	p value
Primary Prevention Group				0.0079[1]
Not Allergic	172 (94.0%)	193 (99.0%)	365 (96.6%)	
Allergic	11 (6.0%)	2 (1.0%)	13 (3.4%)	
Secondary Prevention Group				<0.0001[1]
Not Allergic	87 (66.9%)	109 (93.2%)	196 (79.4%)	
Allergic	43 (33.1%)	8 (6.8%)	51 (20.6%)	
SPT-Negative & IgE Positive				<0.0001[1]
Not Allergic	54 (68.4%)	67 (95.7%)	121 (81.2%)	
Allergic	25 (31.6%)	3 (4.3%)	28 (18.8%)	
SPT-Positive & IgE Positive				0.0061[1]
Not Allergic	22 (59.5%)	34 (87.2%)	56 (73.7%)	
Allergic	15 (40.5%)	5 (12.8%)	20 (26.3%)	
SPT-Positive & IgE Negative				0.1589[1]
Not Allergic	11 (78.6%)	8 (100.0%)	19 (86.4%)	
Allergic	3 (21.4%)	0 (0.0%)	3 (13.6%)	

SPT Wheal Size

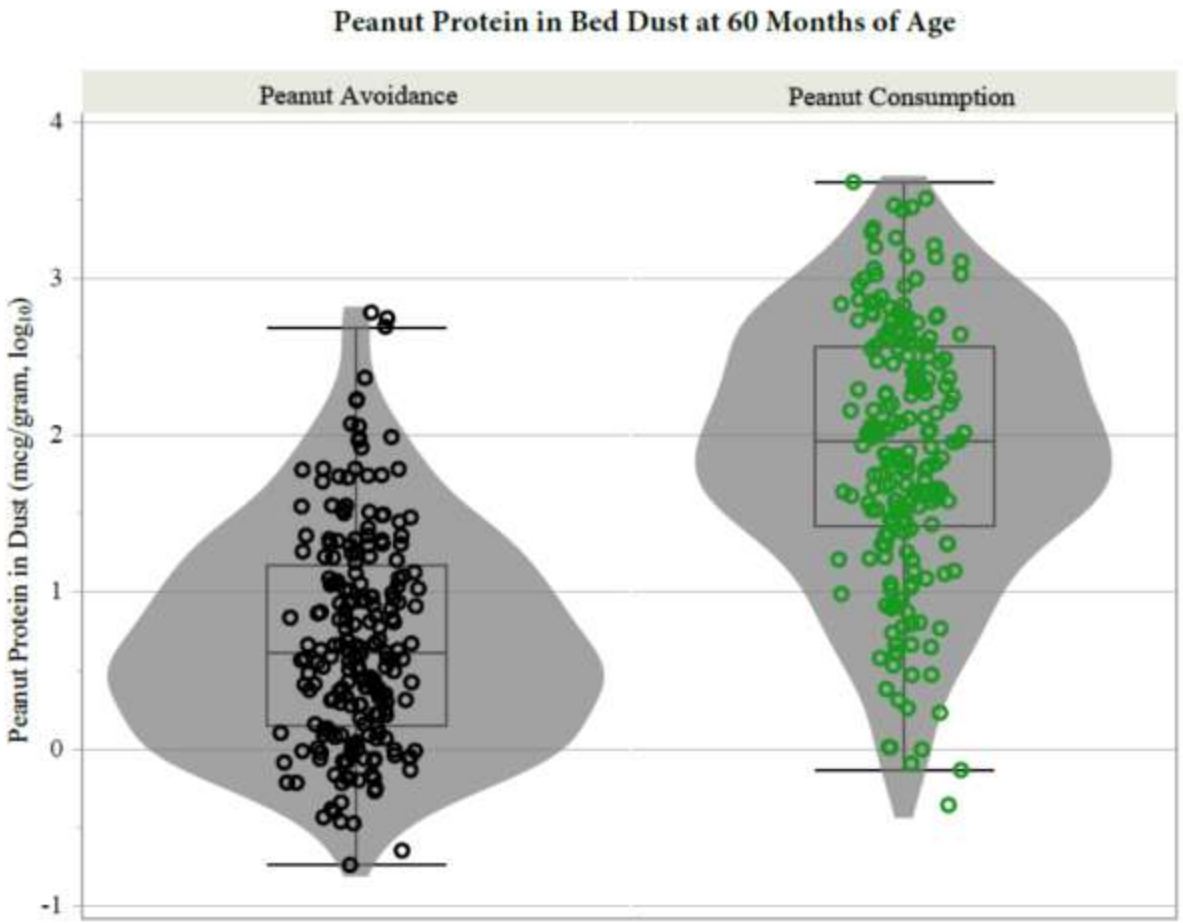


IgG, IgG4, and Ratio



Compliance

Figure S2. Peanut Protein in Bed Dust at 60 Months of Age



Adverse events

- Peanut consumption group
  - URIs
  - Viral skin infections
  - Gastroenteritis
  - Urticaria
  - Conjunctivitis
- 7 positive challenges at baseline required oral antihistamines or glucorticoid
- 57 with positive oral food challenges
  - 9 required IM Epinephrine

Criticisms

- No placebo arm
- Compliance not confirmed throughout study
- 92% Adherence
  - But highly motivated family (2/3 self-enrolled)
- HIGHLY sensitized group or Low Risk group (e.g Group IV and I)
  - No idea if Bamba would prevent Peanut Allergy

Conclusions & Questions

- Early introduction of peanuts for at risk infants leads to decreased rates of peanut allergy.
- Is several years duration needed? Is 2 grams three times a week required?
- What will happen to those who did not do regular consumption after trial? (LEAP-ON study)
- Does the same hold true for other allergenic foods?

La Bamba to Peanut Allergy Prevention!

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