



# Food immunotherapy overview

## FAIT Program

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**Food Allergy Immunotherapy  
(FAIT) Program**

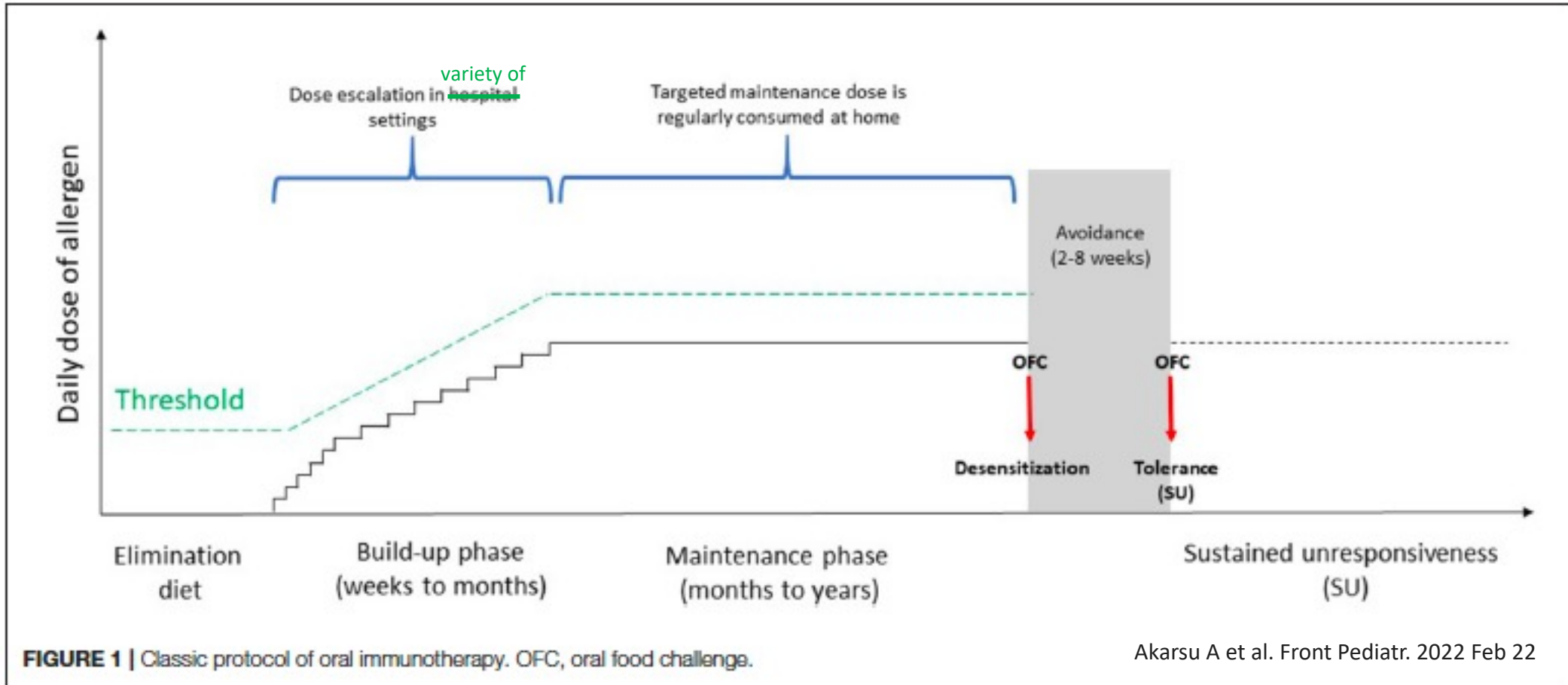


# Oral immunotherapy (OIT)



Eating the allergenic food(s) daily in small amounts, and gradually increasing the amount over time.

# Oral immunotherapy (OIT)



- **Benefits:** protection from accidental exposures, increased reaction threshold, improved quality of life, reduced anxiety, potential for long-term tolerance
- **Risks:** anaphylaxis, eosinophilic esophagitis (EoE) – both are very low in the FAIT program

# OIT safety and effectiveness comparison according to age

<b>Age</b>	<b>Preschool</b>	<b>Older children to adults</b>
Approximate age	Infant to 5yo	6 years and older
Maintenance dose	~ 300mg peanut protein	~ 300mg peanut protein
Anaphylaxis/systemic reaction	0 – 0.7%	~14.2 – 16.5%
Epinephrine	2.7 – 4.1%	8.2 – 14%
Effectiveness	<p>~80-90% had sustained unresponsiveness to 5000mg protein after 29 months of maintenance.</p> <p>~80% tolerated 4000mg protein after 12 months of maintenance.</p>	<p>67.2% tolerated <math>\geq</math> 1043mg protein after 6 months of maintenance.</p> <p>Vickery BP et al. J Allergy Clin Immunol. 2017            Soller L et al. J Allergy Clin Immunol Pract. 2019            Chu DK et al. Lancet. 2019            Soller L et al. J Allergy Clin Immunol Pract. 2021            Soller L et al. J Allergy Clin Immunol Pract. 2022</p>

**TABLE 1.** Comparison of baseline characteristics, and safety and effectiveness outcomes for infants and non-infant (NI)-preschoolers

Patient characteristics	All patients	Infants	NI-preschoolers	P
Baseline data	n = 403	n = 62	n = 341	
Age at entry into OIT, mo (mean [95% CI])	27.6 (26.0-29.2)	9.61 (9.27-9.96)	30.9 (29.2-32.6)	<.001
Male, n (%)	245 (60.8)	43 (69.4)	202 (59.2)	.06
Eczema, n (%)	291 (72.2)	46 (74.2)	245 (71.8)	.71
Grade of initial reaction before entry into OIT, n (%)				
Never exposed, n (%)	14 (3.5)	0	14 (4.10)	.05
Grade 1*	265 (65.8)	49 (79.0)	216 (63.3)	.008
Grade 2*†	110 (27.3)	13 (21.0)	97 (28.4)	.03
Grade 3	1 (0.2)	0	1 (0.30)	
Grade 4	13 (3.2)	0	13 (3.90)	
Baseline OFC and buildup data	n = 403	n = 62	n = 341	
Highest grade of reaction during baseline OFC/buildup, n (%)				
Grade 1*	199 (49.4)	41 (66.1)	158 (46.3)	.002
Grade 2*†	200 (49.6)	21 (33.9)	179 (52.5)	.002
Grade 3	1 (0.3)	0	1 (0.30)	
Grade 4	3 (0.7)	0	3 (0.90)	
Epinephrine administered during buildup, n (%)	21 (5.21)	1 (1.60)	20 (5.90)	.08
Maintenance data	n = 403	n = 62	n = 341	
Highest grade of reaction during maintenance, n (%)				
No reaction during maintenance	367 (91.1)	58 (93.5)	309 (90.6)	.23
Grade 1	24 (6.00)	4 (6.50)	20 (5.90)	.43
Grade 2†	11 (2.70)	0	11 (3.20)	.07
Grade 3	0	0	0	
Grade 4	1 (0.20)	0	1 (0.30)	
Epinephrine administered during maintenance, n (%)	6 (1.49)	0	6 (1.80)	.14
Follow-up OFC data	n = 251	n = 42	n = 209	
Grade of reaction during follow-up OFC, n (%)				
No reaction during follow-up OFC	192 (77.5)	34 (81.0)	158 (75.6)	.23
Grade 1	43 (17.1)	8 (19.0)	35 (16.7)	.36
Grade 2*†	15 (5.00)	0	15 (7.2)	.03
Grade 3	1 (0.40)	0	1 (0.50)	
Grade 4	0	0	0	
Epinephrine administered during follow-up OFC, n (%)	5 (2.00)	0	5 (2.40)	.16

CI, confidence interval; OFC, oral food challenge; OIT, oral immunotherapy.

\*Statistically significant difference ( $P < .05$ ) between infants and NI-preschoolers. All other differences between these groups were not significant.

†For statistical comparisons, grade 2, 3, and 4 reactions were combined into an aggregate category called grade 2+ reactions.

Infants < 12 months have even better safety outcomes than non-infant preschoolers

Soller et al. J Allergy Clin Immunol Pract. 2022 Apr;10(4):1113-1116



# Sublingual immunotherapy (SLIT)



Placing the allergenic food(s) in very tiny amounts under the tongue daily.

# Safety and efficacy of long term peanut SLIT

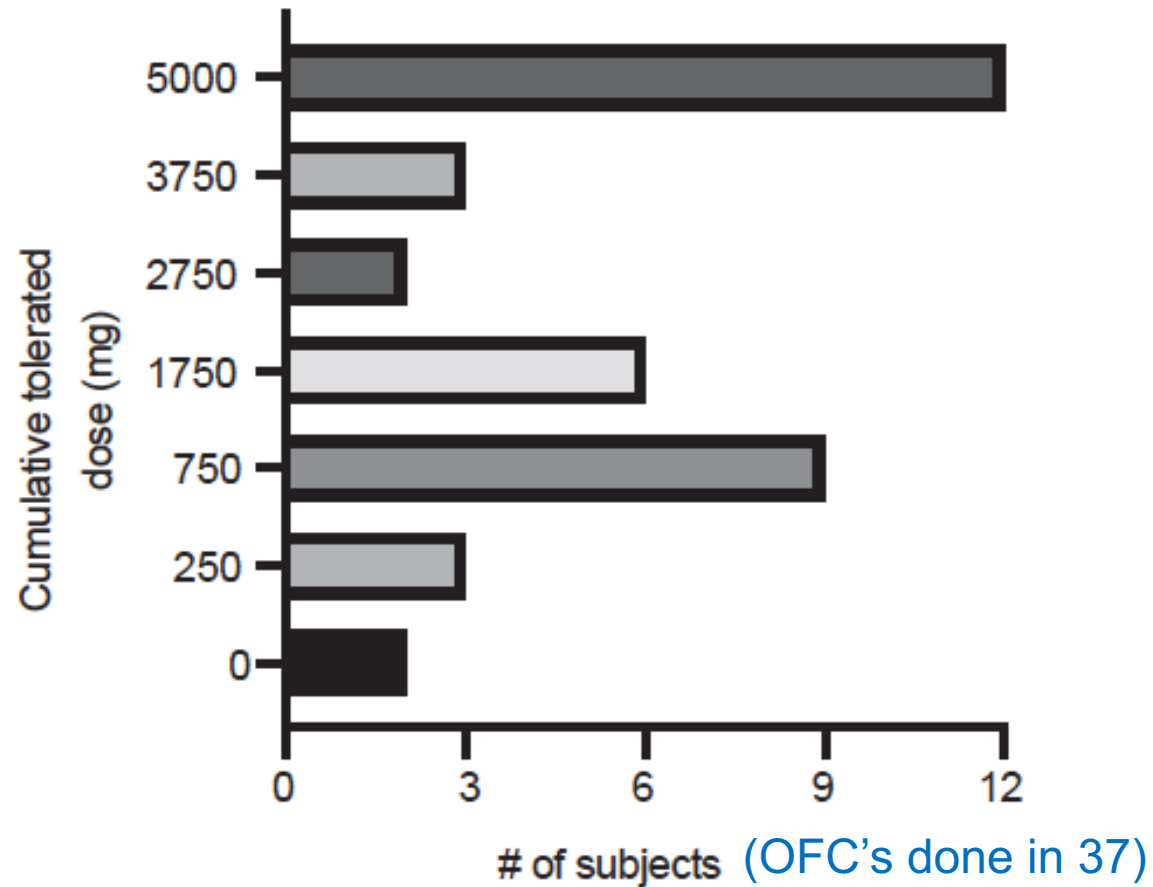


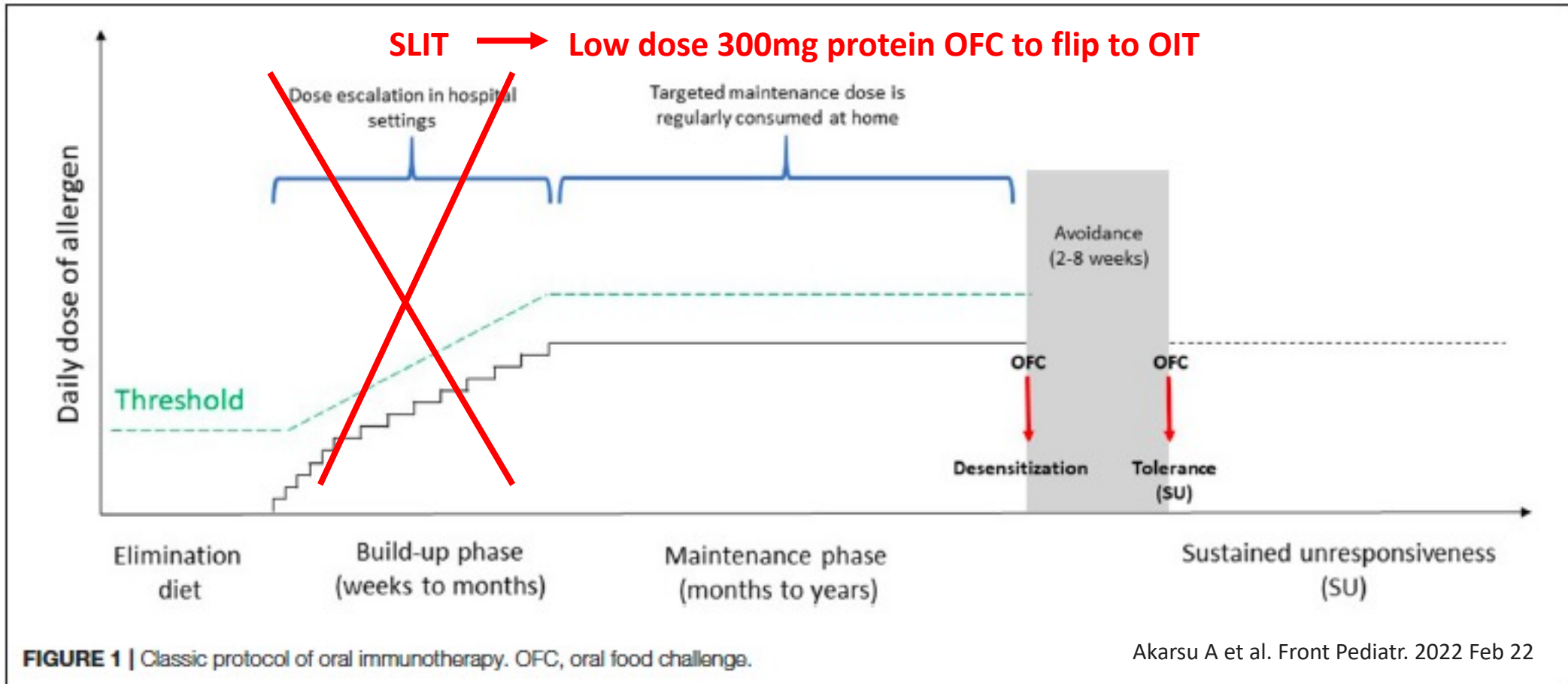
FIG 2. Desensitization thresholds during DBPCFC post-SLIT therapy: Maximum cumulative tolerated dose achieved for each subject during post-SLIT therapy 5000 mg DBPCFC.

- Median age 6.5yo, maintenance dose 2mg protein

37 completed SLIT therapy  
9 after 3 years  
1 after 4 years  
27 after 5 years (73% 5 years)

- Baseline threshold ~85mg peanut protein
- Safety: no anaphylaxis, no epinephrine, ~4.8% doses w. mild symptoms, no EoE
- Efficacy (OFC results after 3-5 years):
  - OFC's done in 37/48 (77%)
  - 32/48 (67%) and 32/37 (86%) consumed at least 750mg peanut protein (at least ~2.5 peanuts)
  - 12/48 (25%) and 12/37 (32%) consumed 5000mg peanut protein (~16 peanuts)

Older children/adolescents: replace OIT build-up with SLIT x 1-2 years, then do low dose OFC in office to flip to OIT

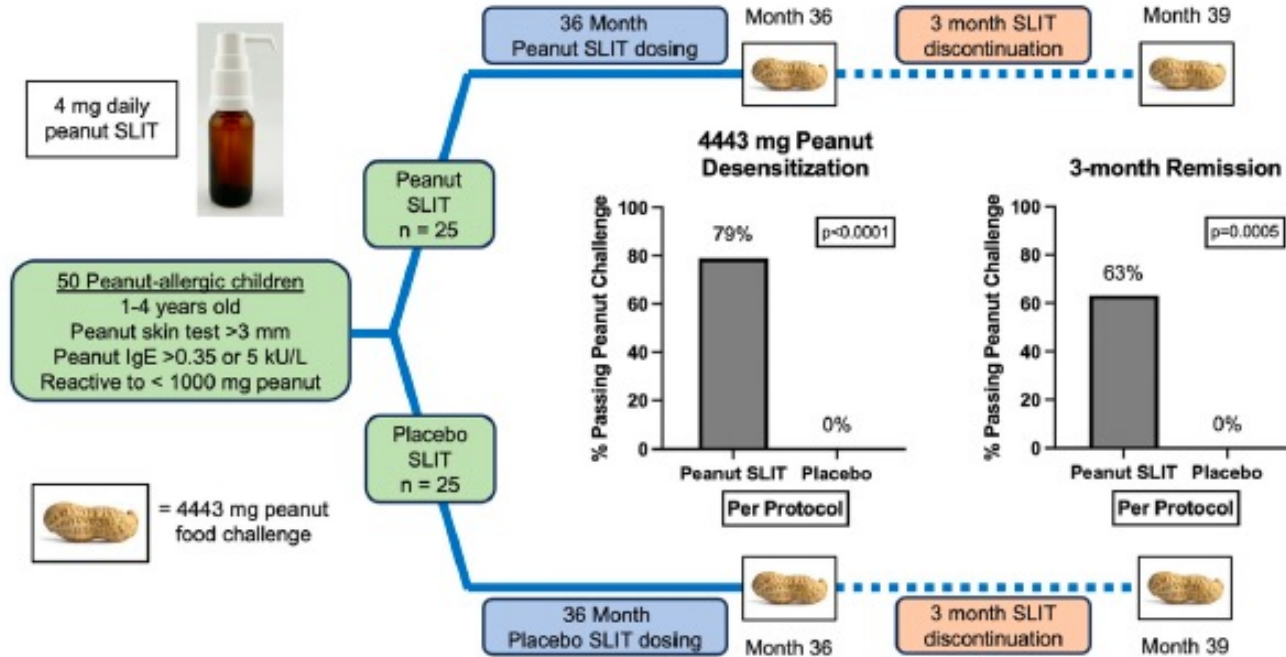


FAIT preliminary real-world UBC/BCCH safety and effectiveness data submitted for publication...



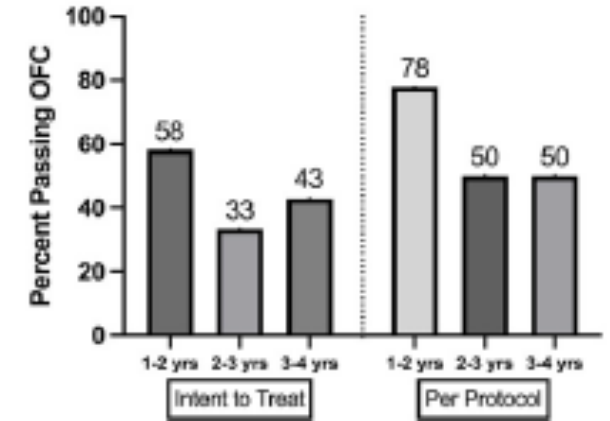


## Desensitization and Remission after Peanut Sublingual Immunotherapy in 1-4 year-old Peanut Allergic Children: a Randomized, Placebo-Controlled Trial



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### Month 39 Remission OFC



### Median age 2.2 years:

- 26% asthma, 80% atopic dermatitis, 74% multiple food allergy
- median peanut SPT 10.3mm
- median baseline threshold 43mg protein

### Safety (median age 2.2 years):

- no anaphylaxis
- no epinephrine
- ~5% doses w. mild symptoms
- no EoE

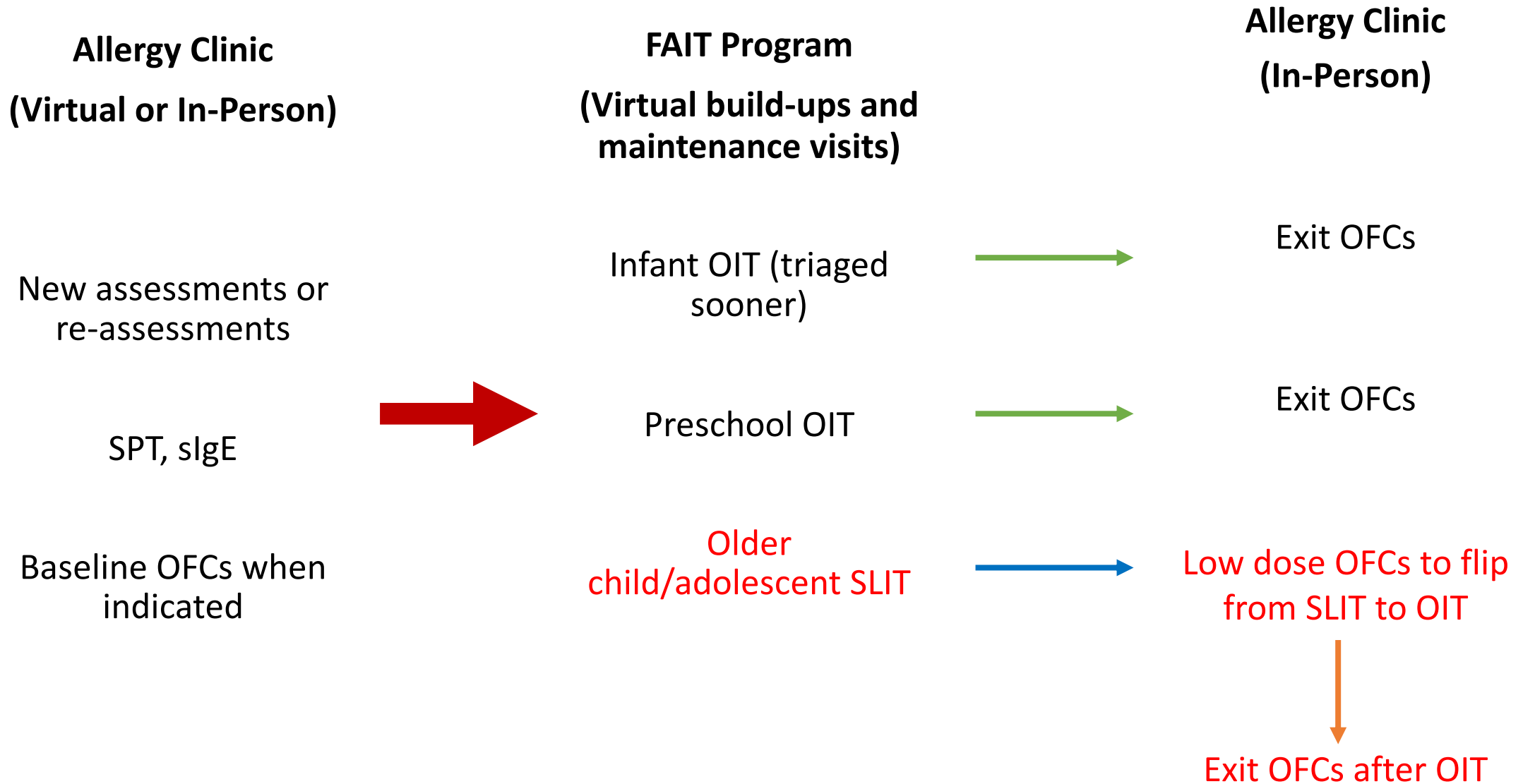
# Summary of FAIT food immunotherapy

Type of FAIT	Current role in my practice	Safety and Effectiveness
Oral immunotherapy (OIT)	Routine use in preschoolers.	Excellent safety. Faster effectiveness.
Sublingual immunotherapy (SLIT)	Initial phase of food immunotherapy in older children/teens (or severe preschoolers).	Outstanding safety. Slower effectiveness.
Hybrid approach for older children/teens	<ol style="list-style-type: none"><li>1. Initial phase of SLIT for ~2 years.</li><li>2. Then, low dose OFC to flip to OIT for 1-2 years.</li></ol>	Comparable safety. Faster effectiveness than SLIT alone.

## Key additional messages:

- 1) Oral food challenges important for confirming diagnosis (when history/testing unclear), and for follow-up to assess effectiveness.
- 2) Long term duration of treatment unclear. *For now, best to continue regular exposure indefinitely until more data available.*

# Summary: 2023 BCCH FAIT Program



# FAIT program: virtual build-up and maintenance visits



Made possible by FAIT choosing the safest protocols for each age group





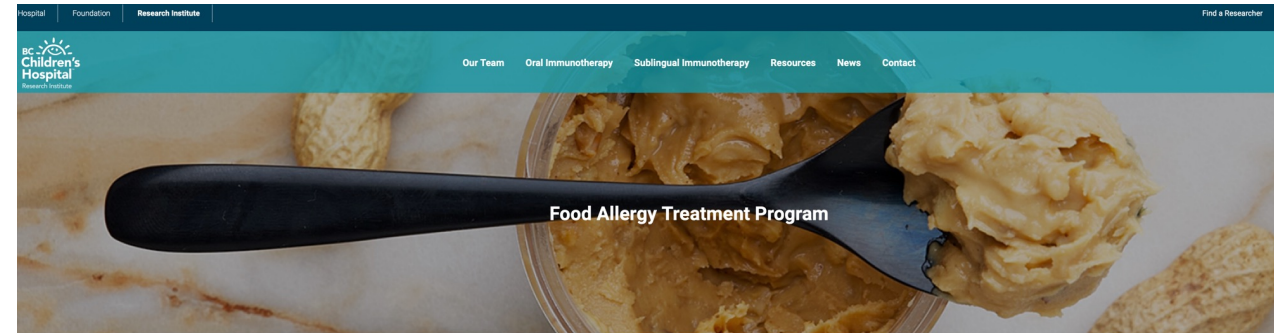
- In Person (Allergists and clinical staff)
  - Skin prick testing
  - Oral food challenges
- Virtual (Research nurses)
  - Orientation
  - OIT build-up visits
  - OIT maintenance visits





# FAIT program

- FAIT program web site:
  - <https://www.bcchr.ca/foodallergy>



Welcome to the Food Allergy Treatment Program  
*Transformative Care for Food Allergies*

- FAIT is a donor funded research program:
  - <https://give.ubc.ca/food-allergy-immunotherapy-program>



**Food Allergy Immunotherapy  
(FAIT) Program**

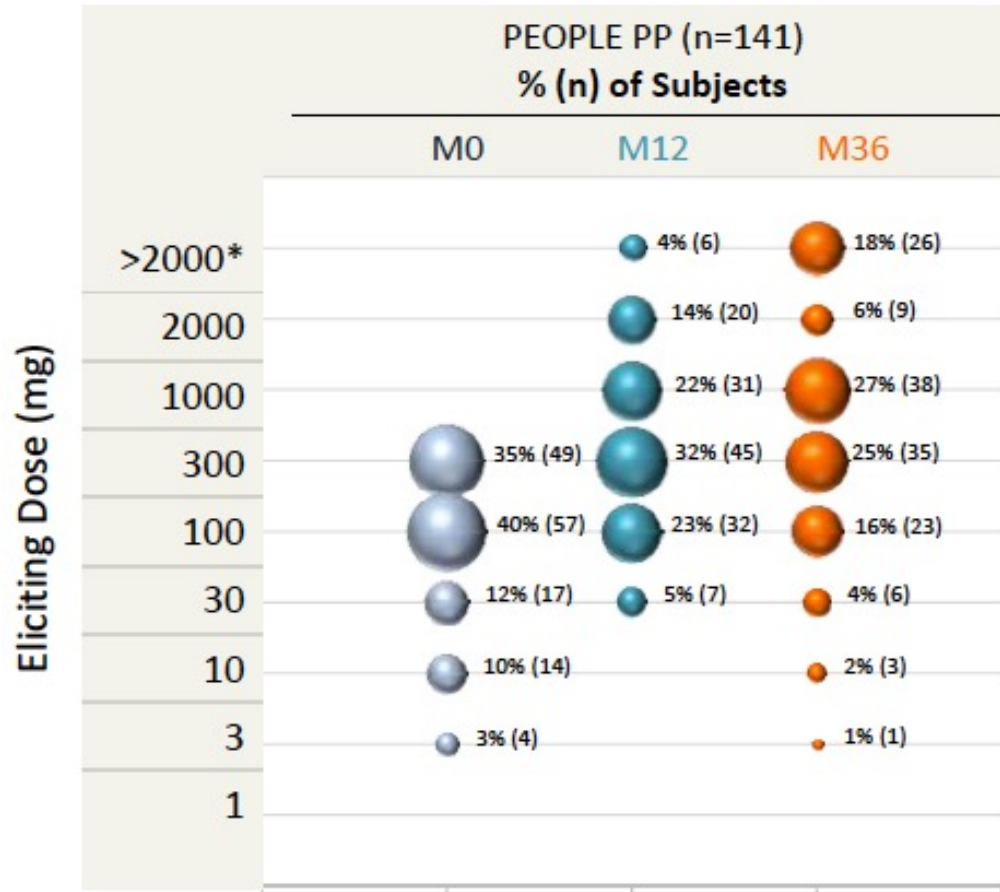
Extra slides

# Epicutaneous immunotherapy (EPIT)



Applying the allergenic food in extremely tiny amounts on the skin daily.

# Long term peanut EPIT (Phase 3 trial)



**FIG 2.** Proportion of subjects from PP data set at each ED (baseline, month 12, and month 36). The percentage of subjects at each ED was determined at baseline (M0), month 12 (M12), and month 36 (M36) in the PP population. For study entry, subjects were required to have an ED at baseline of  $\leq 300$  mg of peanut protein.

- Daily peanut patch (250 mcg protein)
- n=141 of treated subjects had DBPCFC food challenges at 3 years
- Safety: local patch site reactions common (~80%), no treatment-related epinephrine in years 2 and 3
- 51.8% reached eliciting dose 1000mg protein at year 3
  - (vs. 40.4% at year 1)
- Not FDA approved yet