Food immunotherapy overview

FAIT Program

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Feb 2026

Oral immunotherapy (OIT)

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

Oral immunotherapy (OIT)

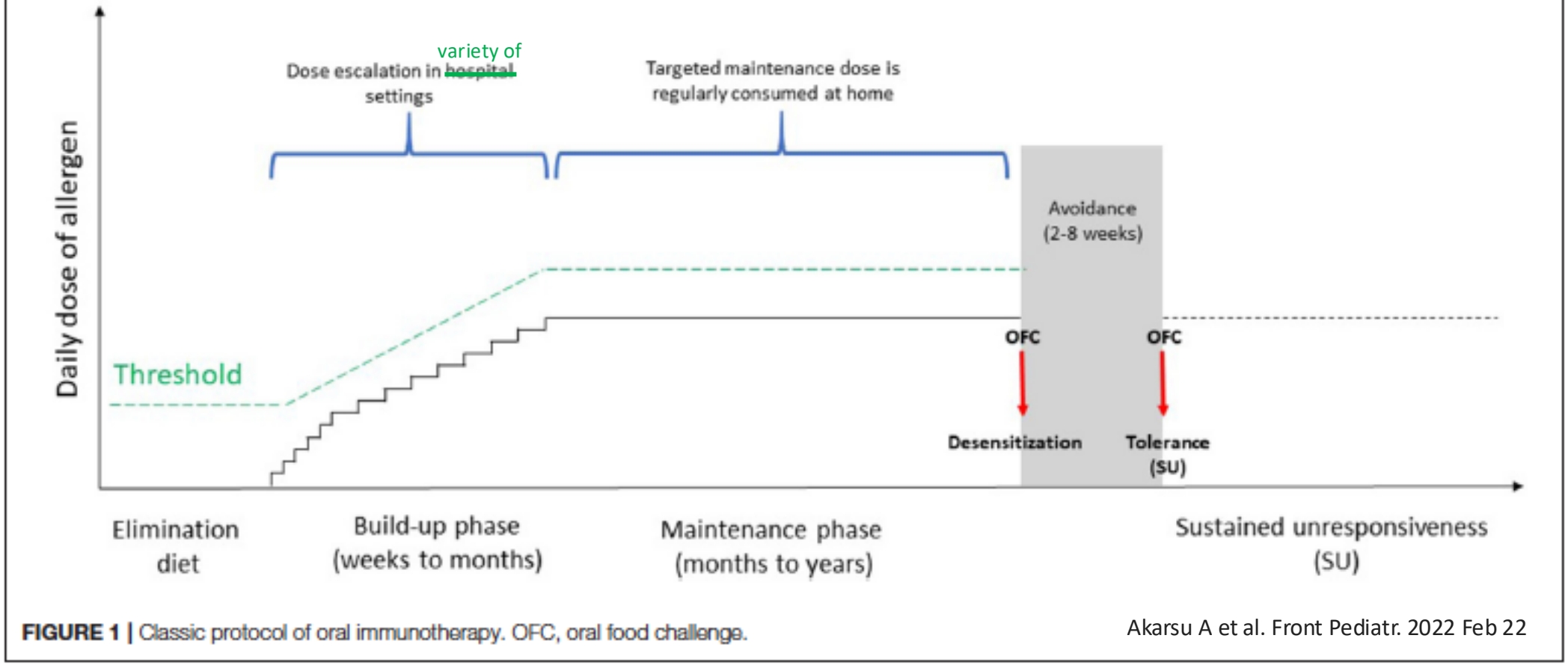


FIGURE 1 | Classic protocol of oral immunotherapy. OFC, oral food challenge.

Akarsu A et al. Front Pediatr. 2022 Feb 22

- *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, e.g.) EoE ~0.5-0.7%

OIT safety and effectiveness: preschoolers vs older children

Age	Preschool	Older children to adults
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	~80-90% had sustained unresponsiveness to 5000mg protein after 29 months of maintenance. ~80% tolerated 4000mg protein after 12 months of maintenance.	67.2% tolerated ≥ 1043mg protein after 6 months of maintenance.

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
Soller L et al. Clin Exp Allergy. 2025

TABLE I. 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.

Long term peanut SLIT (3-5 years)

37 completed SLIT therapy
9 after 3 years
1 after 4 years
27 after 5 years

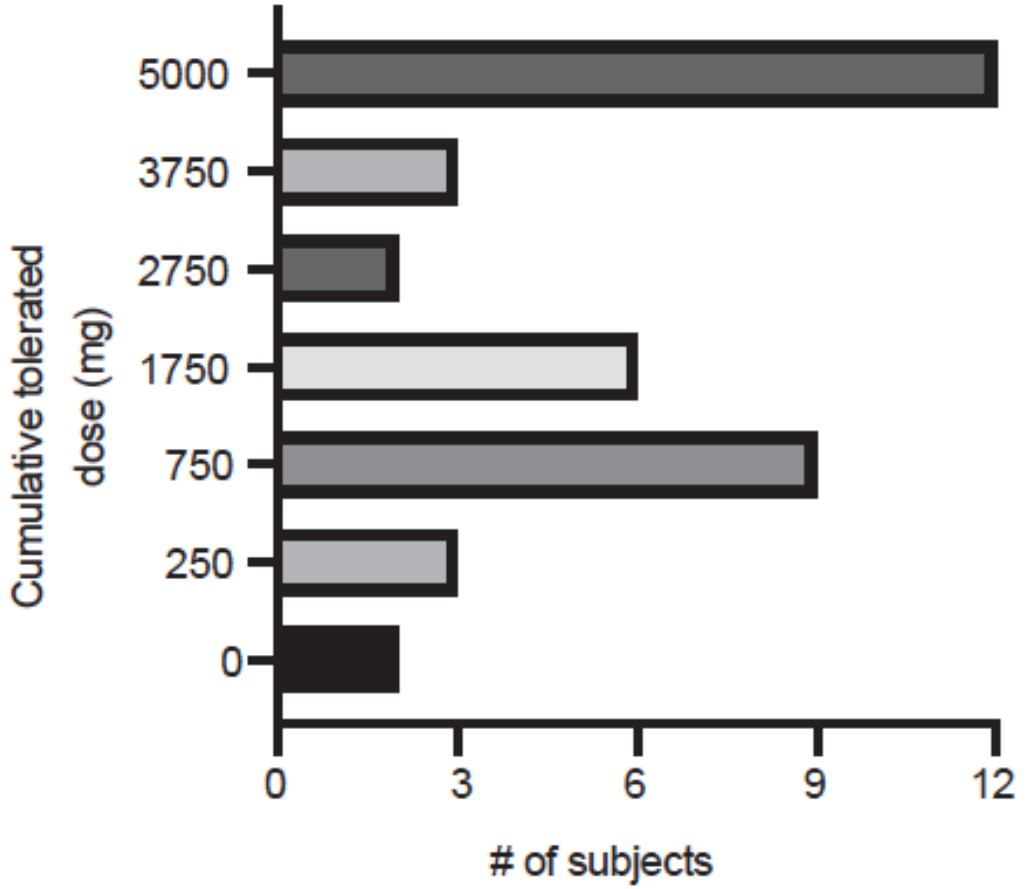


FIG 2. Desensitization thresholds during DBPCFC post-SLIT therapy: Maximum cumulative tolerated dose achieved for each subject during post-SLIT therapy 5000 mg DBPCFC.

- Median age 6.5yo, maintenance dose 2mg protein
- 13 buildup visits
- Baseline threshold ~85mg peanut protein
- Safety: no anaphylaxis, no epinephrine, ~4.8% doses w. mild symptoms, no EoE
- Efficacy (exit OFCs after 3-5 years):
  - OFC's done in 37/48 (77%)
  - 32/48 (67%) ITT and 32/37 (86%) PP consumed at least 750mg peanut protein (at least ~2.5 peanuts)
  - 12/48 (25%) ITT and 12/37 (32%) PP consumed 5000mg peanut protein (~16 peanuts)

Kim EH et al. *J Allergy Clin Immunol*. 2019 Nov

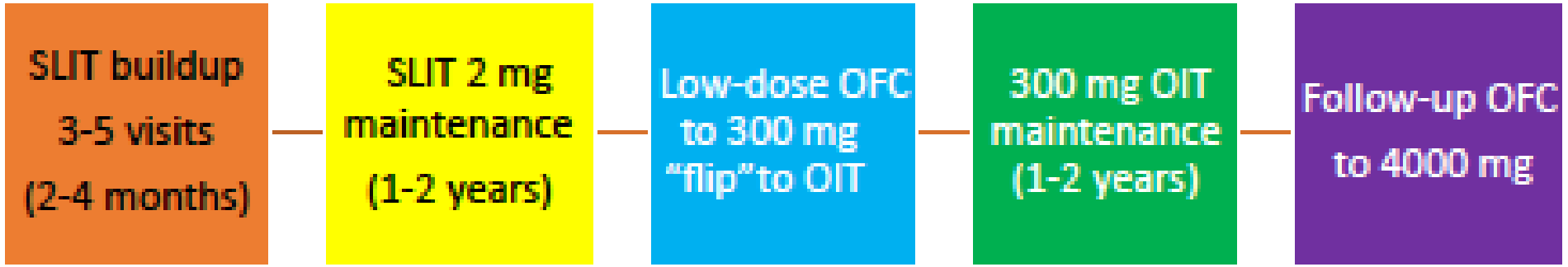


FIGURE E1. The entire food SLIT journey at BC Children's Hospital.

Soller L et al. J Allergy Clin Immunol Pract. 2024 Feb 27

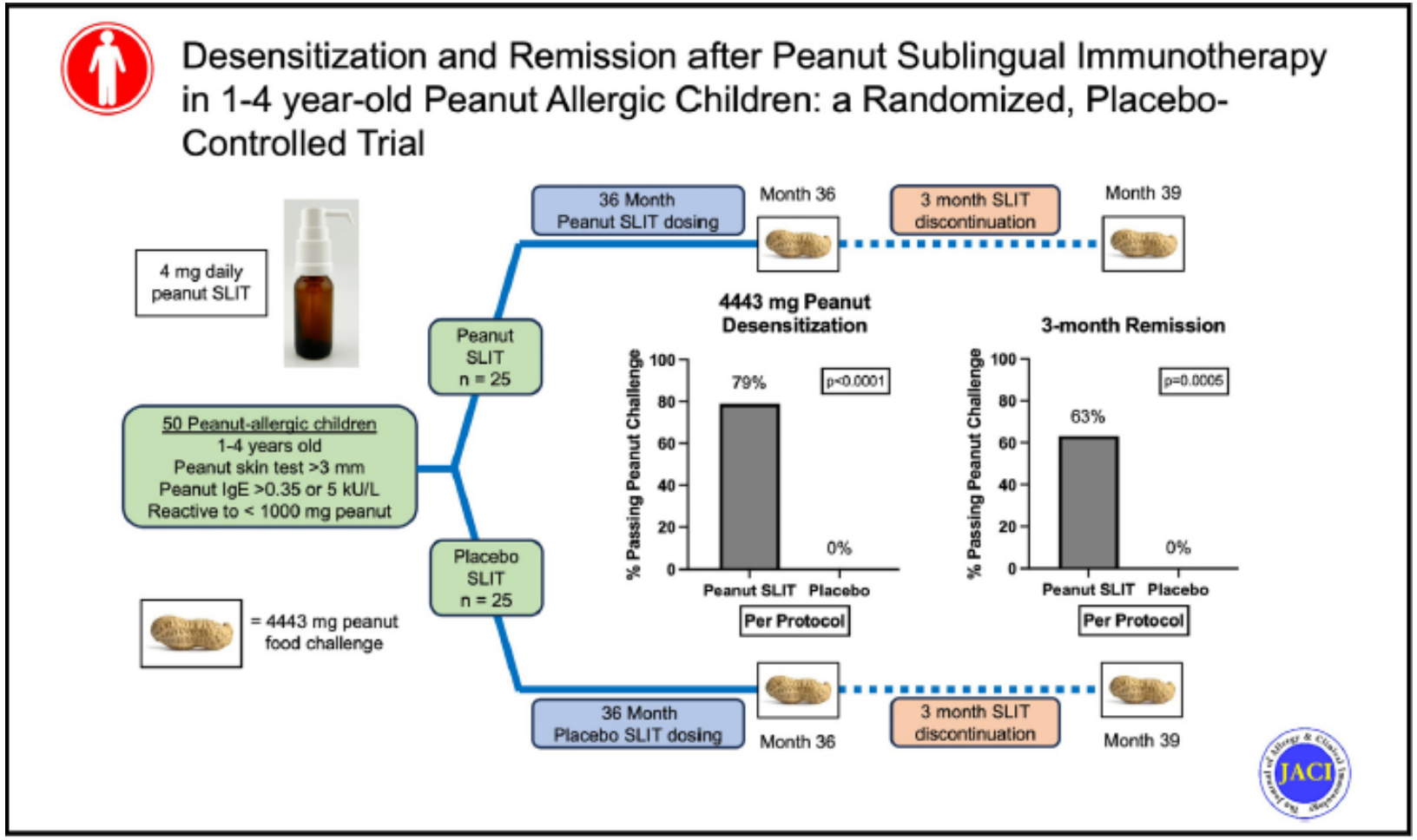
Original Article

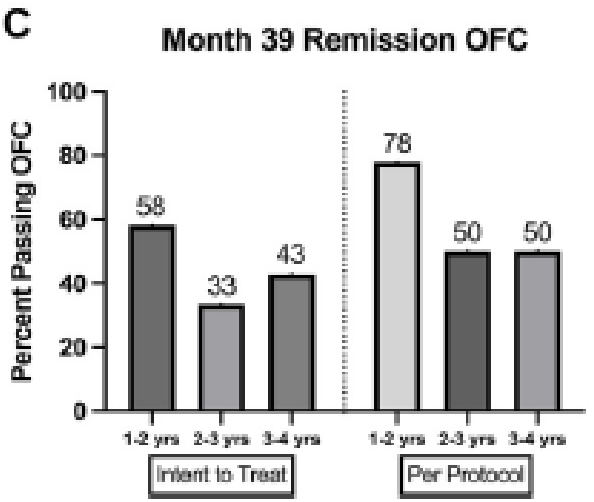
Safety and Effectiveness of Bypassing Oral Immunotherapy Buildup With an Initial Phase of Sublingual Immunotherapy for Higher-Risk Food Allergy

Lianne Soller, PhD, Brock A. Williams, PhD, Raymond Mak, MD, Tiffany Wong, MD, Stephanie C. Erdle, MD, Alanna Chomyn, MD, Brittany Tetreault, BScN, Kelly Morrison, BScN, Lisa Gaudet, BScN, and Edmond S. Chan, MD
Vancouver, BC, Canada

J Allergy Clin Immunol Pract. 2024 Feb 27

- **188 patients, median 11yo:**
  - 75% classified as higher-risk
  - Over 20 different foods treated
- **Safety:**
  - No patients had Grade 4 (severe) reactions during SLIT buildup
  - 4 pre-existing controlled EoE didn't have worsening
  - 1 (0.5%) with vomiting declined endoscopy, reduced dose temporarily, and then successfully completed SLIT
- **Effectiveness:**
  - 50 low dose (300mg protein) OFCs completed in a subset of 20 patients after 1-2 years of SLIT
  - 70% OFCs passed, allowing those patients to bypass OIT buildup and proceed straight to OIT maintenance dosing





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

Kim EH et al. *J Allergy Clin Immunol*. 2024 Jan

Summary of food immunotherapy

Type of food immunotherapy	**Current role in my practice**	**Safety and Effectiveness**
Oral immunotherapy (OIT)	Routine use in infants and preschoolers.	Excellent safety. Faster effectiveness.
Sublingual immunotherapy (SLIT)	Long term daily treatment in older children/teens (or severe preschoolers).	Outstanding safety. Slower effectiveness.
Hybrid approach for older children/teens	1. Initial phase of SLIT for ~2 years. 2. Then, low dose oral challenge to flip to OIT for 1-2 years.	Safer than OIT alone. Faster effectiveness than SLIT alone.

Key additional messages:

1) Due to excellent safety, preschool OIT and older child/teen SLIT compatible with home-based initiation and dose increases.

2) After sufficient duration of the maintenance phase, options include oral food challenge or home-based dietary liberalization to full servings.

3) Long term duration of treatment after reaching full servings is unclear. *For now, best to continue regular exposure indefinitely until more data available.*

FAIT program

- FAIT research program web site:
  - https://faitprogram.org

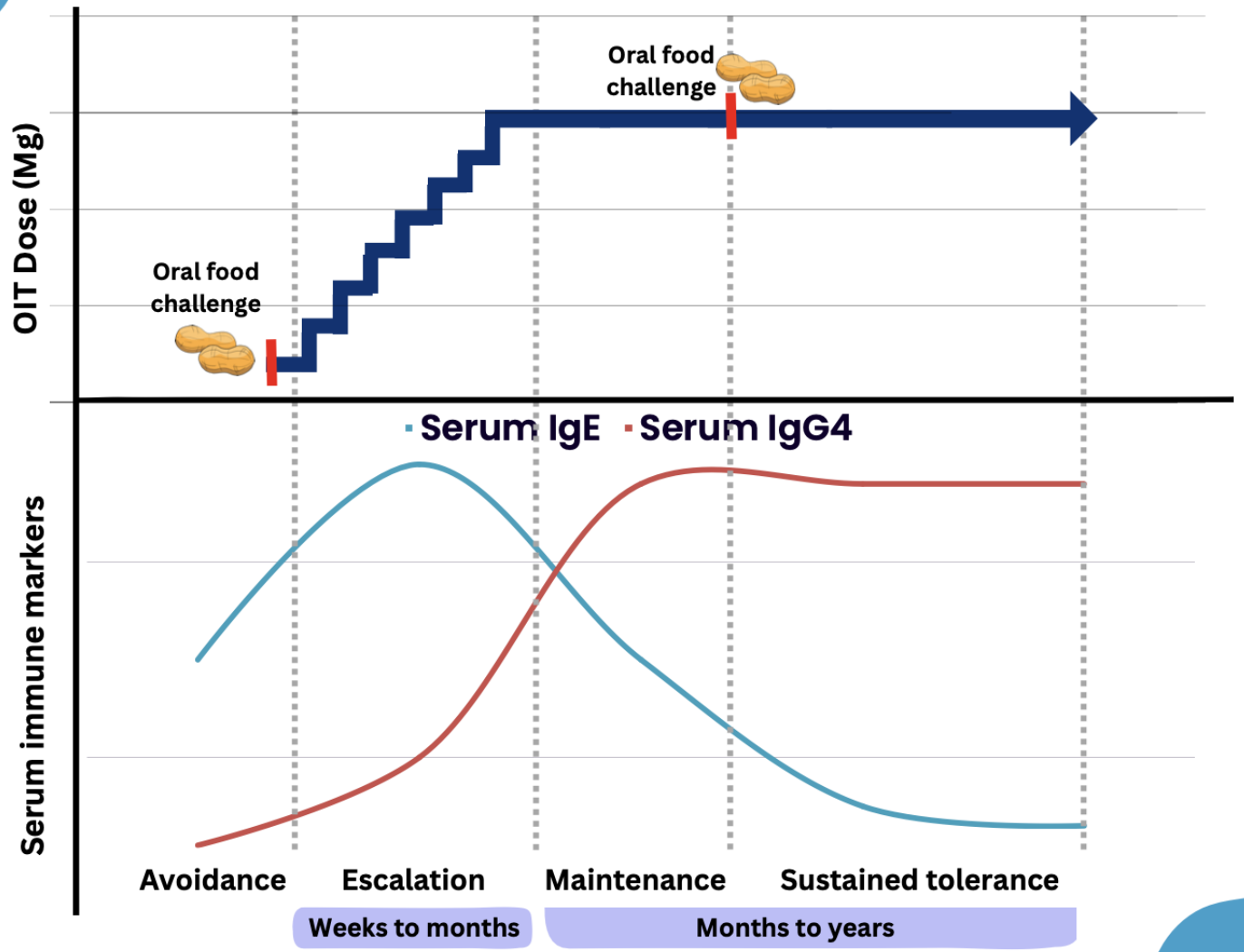
- FAIT is a donor funded research program:
  - https://www.canadianfaitfoundation.org
  - http://www.bcchf.ca/foodallergy

FAIT PROGRAM

Food Allergy Immunotherapy

Extra slides

OIT TIME COURSE AND IMMUNOLOGIC CHANGES



Jeimy S, Yu N, Chan ES, Cook V. CMAJ. 2024 Jun 16

SICK PROTOCOL

MILD SYMPTOMS

Mild cough
Runny nose/Congestion
Mild headache
Mild stomach ache

No change in behavior
No change in appetite
No change in energy

PROCEED with OIT Dose

- ❑ Ensure dose taken dose with SNACK
- ❑ RESTRICT activity for 2 hours after dose
- ❑ Pre-medicate with non-drowsy antihistamine [optional]

General reminders:
Always be CAUTIOUS
It is OK to miss a dose and reschedule next visit
SAFETY is always a priority
Email FAIT Nurse before reducing doses
Keep in mind:

- ✓ MUST be on dose for 3-5 days BEFORE next build-up visit after illness
- ✓ MUST have a minimum of 12 doses total in order to be eligible for build-up visit

SEVERE SYMPTOMS

Sore throat
Persistent cough
Vomiting or Diarrhea
Severe stomach ache
Fatigue or Lethargy
Muscle aches
Poor appetite
Poor sleep

Fever [requiring treatment at any time during the day]

Asthma exacerbation [requiring more than 1 dose of rescue inhaler in the day]

HOLD OIT Dose

Symptoms resolve **3+ missed days consecutively**

Follow safe restart plan (next page of document)

Symptoms resolve **1-2 missed days consecutively**

No need to contact FAIT team. **RESUME** same dose

Table 4 Generic sample protocol for buildup of any food OIT allergen to ~ 300-mg maintenance dose. Eight to 11 visit buildup schedule

Dose number	Protein (mg)	Actual weight or volume of food	Interval (weeks)
Optional	1		2–4
Optional	2.5		2–4
Optional	5		2–4
1	10		2–4
2	20		2–4
3	40		2–4
4	80		2–4
5	120		2–4
6	160		2–4
7	240		2–4
8	300		2–4

Abrams EM et al. Curr Allergy Asthma Rep. 2021

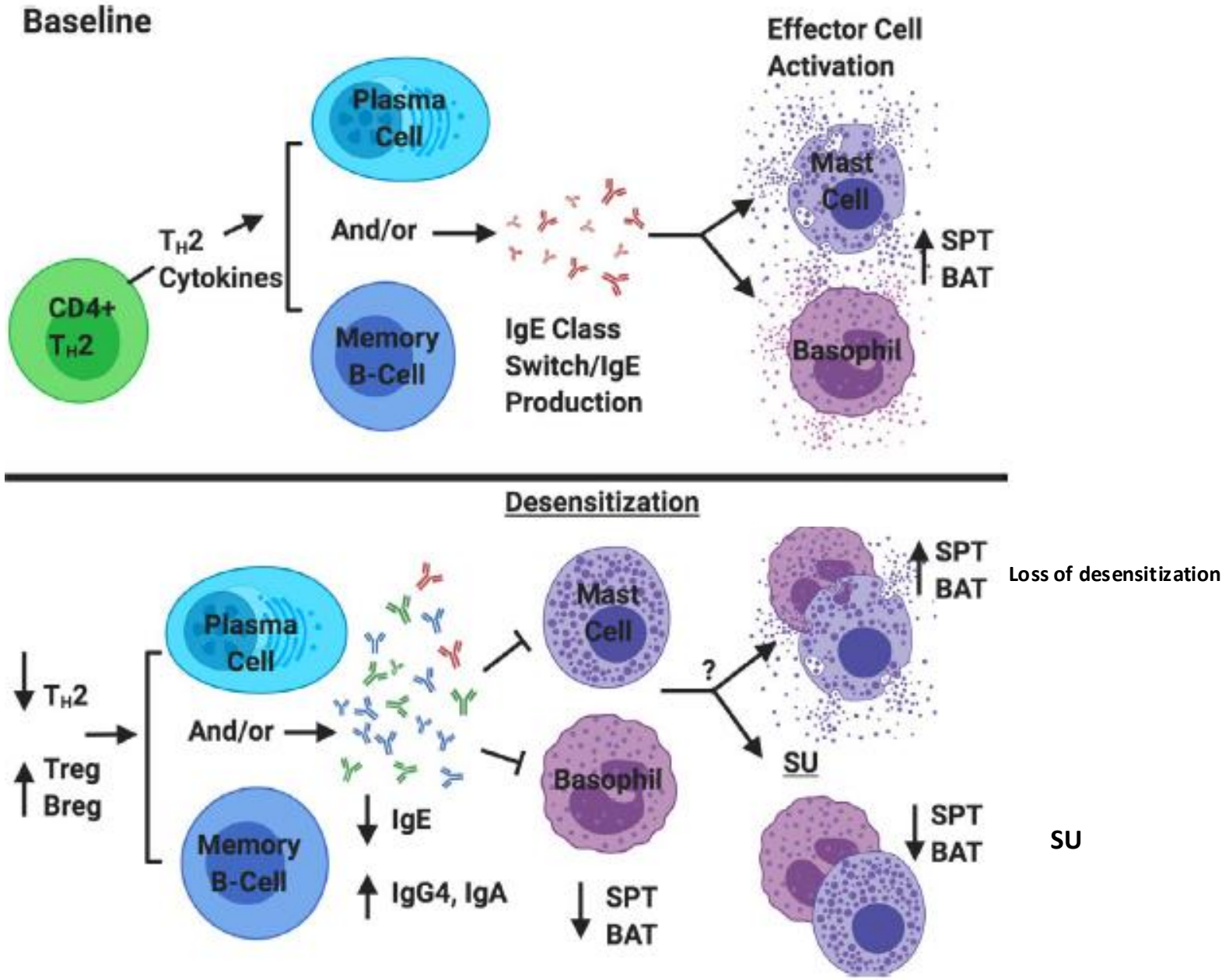
SLIT terminology

- Sublingual immunotherapy (SLIT)
  - Food allergen is placed under the tongue daily (e.g. 1 min). Can swallow saliva after 1 min. No eating or drinking for 5 min, to prevent dilution and maximize absorption.
  - Start at a dose which will cause minimal symptoms. Increase the dose over time (buildup phase), and then maintain (maintenance phase).
  - E.g. of a common maintenance dose = 2mg or 4mg protein daily
- Desensitization
  - Not reacting to the food while exposed to it regularly (threshold increase)
- Sustained unresponsiveness (SU)
  - Absence of clinical reactivity after SLIT has been stopped for weeks or months
- Tolerance
  - Absence of clinical reactivity regardless of the length of time since SLIT has been stopped
  - Disease modification

Bohle B. J Allergy Clin Immunol. 2023 Jun
Barshow SM et al. Clin Exp Allergy. 2021 Apr
McHenry M et al. Allergy Asthma Clin Immunol. 2025 Feb 12

Untreated food allergy:

SLIT: uptake of daily dose of allergen by dendritic cells (Langerhan cells) in the oral mucosa, resulting in T-cell modulation and antibody shift.



Barshow SM et al. Clin Exp Allergy. 2021 Apr

Epicutaneous immunotherapy (EPIT)

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

Long term peanut EPIT (Phase 3 trial)

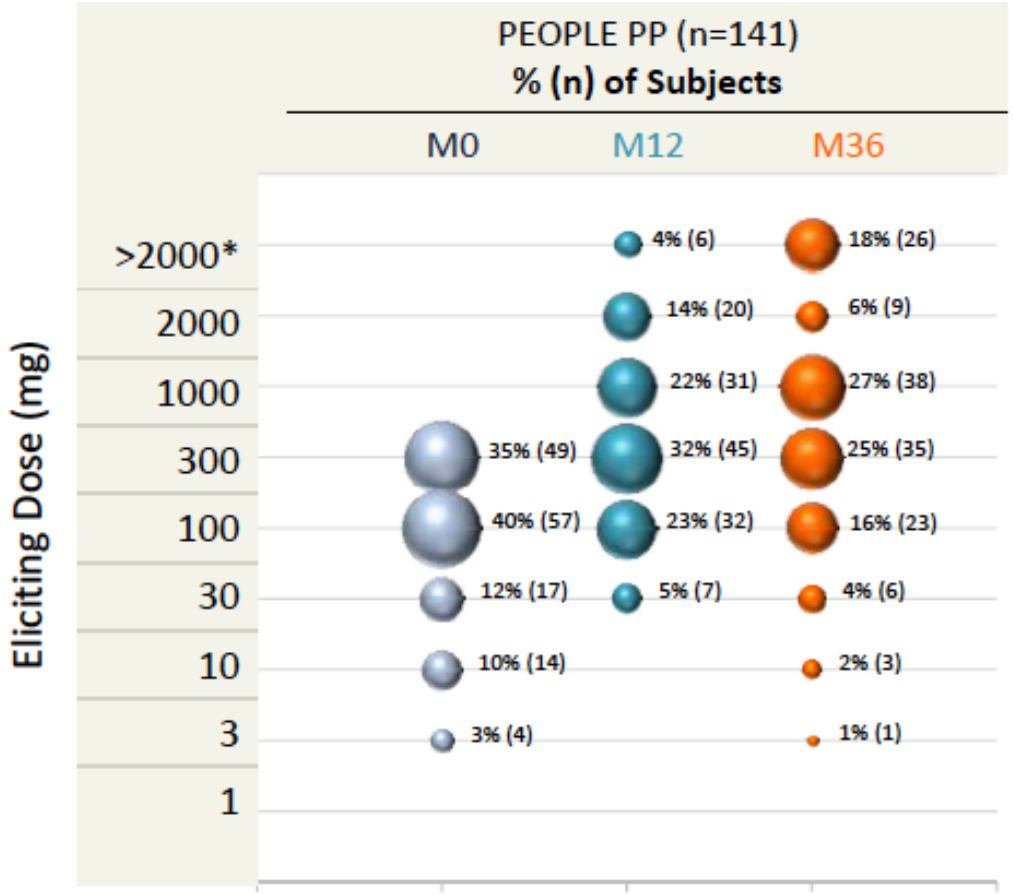


FIG 2. Proportion of subjects from PP data set at each ED (baseline, month 12, and month 36). The percentage of subjects at each ED was determined at baseline (M0), month 12 (M12), and month 36 (M36) in the PP population. For study entry, subjects were required to have an ED at baseline of ≤300 mg of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

Fleischer DM et al. *J Allergy Clin Immunol*. 2020 July