

## Clinical Communications

### Guided introduction after negative double-blind placebo-controlled peanut challenges in children

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#### Clinical Implications

- Introduction after negative peanut challenge at home fails in 38% of children and is indispensable to exclude or diagnose peanut allergy accurately. Introduction should be monitored closely to detect peanut-related problems early.

#### TO THE EDITOR:

A diagnostic double-blind placebo-controlled food challenge (DBPCFC) is the gold standard to confirm or exclude a peanut allergy.<sup>1</sup> After a negative food challenge, parents and children report less fear of an allergic reaction and better quality of life.<sup>2</sup> Moreover, a negative food challenge usually results in the introduction of peanut at home and when successful no restrictions when eating out or buying and cooking food related to peanut. Nevertheless, previous studies show that introduction at home often fails.<sup>3-8</sup> Reasons are refusal, behavioral or psychological factors, and having symptoms during introduction. Failure of introduction (especially when symptoms occur) could indicate lack of diagnostic accuracy of the food challenge. Results of most previous studies were based on retrospective questionnaires up to multiple years after food challenges.<sup>3,4,6,7</sup> This results in recall bias and in lack of data about the timing and start of introduction, amount of food eaten, symptoms, and difficulties during introduction. The current study is part of a prospective diagnostic study on peanut allergy performed in the Wilhelmina Children's Hospital, a tertiary referral center for food allergy in the Netherlands. It evaluates the course and success rate of standardized introduction at home with careful monitoring after double-blind and open food challenges. The study was reviewed and approved by the ethical committee of the University Medical Centre Utrecht and written informed consent was obtained from parents and children before enrolment in the study. Children with a negative DBPCFC subsequently underwent an open challenge with whole peanuts. Children with a negative or inconclusive open challenge were instructed to introduce peanut at home during a peanut introduction period of 1 month. This introduction consisted of a 7-day introduction schedule, telephonic counseling with a physician (once a week), a diary for the child and parents, and a follow-up questionnaire after the introduction period. Successful introduction in to the diet was defined as parents reported that the child ingested at least 5 g of whole peanuts or an equivalent at home during the introduction period and was eating products containing peanut

as an ingredient on a regular basis ( $\geq 2$  times a month) without peanut allergic symptoms at the time of the follow-up questionnaire. The complete procedure of inclusion and exclusion of patients, food challenges, introduction, and statistical methods are presented in the [Methods](#) section in this article's Online Repository at [www.jaci-inpractice.org](http://www.jaci-inpractice.org).

In the original study, we included 83 children with suspected peanut allergy.<sup>9</sup> Baseline characteristics of 37 of the 83 (45%) children passing the DBPCFC and open challenge are shown in [Table 1](#). All those children started the introduction period. In 19 of the 37 (51%) children, the use of alternative products (ie, M&Ms, peanut snacks) during introduction was necessary due to aversion for peanut butter or whole peanuts. The introduction schedule was extended beyond 7 days due to practical reasons in 14 of the 37 (38%) children. Symptoms after the ingestion of peanut during introduction were reported in 11 of the 37 (30%) children. Of the 37 children, 3 (8%) reported repetitive and persistent oral itch within 5 minutes after all peanut ingestions in their diary and during telephonic consults. Those children were considered peanut allergic and their introduction was defined as failed ([Table IIa](#)). Other reported symptoms were an exacerbation of eczema for several days ( $n = 2$ ), (peri-) oral symptoms ( $n = 3$ ), abdominal pain ( $n = 2$ ), and wheezing ( $n = 1$ ). These symptoms occurred only once or were transient and therefore were not considered peanut allergy related.

The introduction of peanut in diet failed in 14 of the 37 (38%) children ([Table IIa](#)). The reported reasons for failure were aversion ( $n = 5$ ), aversion and fear ( $n = 2$ ), oral symptoms ( $n = 4$ ), an exacerbation of eczema that was considered peanut related by parents ( $n = 1$ ), uncertainty of parents about the challenge outcome ( $n = 1$ ), and insufficient peanut ingestion during follow-up ( $n = 1$ ). The introduction period was more often extended in children with failure of introduction compared with children with successful introduction (71% and 17%,  $P = .002$ ). Although differences were not significant, parents of children with failed introduction tended to be more often worried about a peanut allergic reaction compared with children with successful introduction (50% and 23%,  $P = .091$ ) and less often changed their habits with respect to buying and preparing meals (43% and 73%,  $P = .073$ ). A fair amount of parents in both the failure and the success group reported that they continued with checking food labels for peanut during follow-up (70% and 50%,  $P = .204$ ). Inconclusive open challenge outcomes or subjective symptoms during the DBPCFC were not seen significantly more in children with introduction failure compared with children with introduction success ([Table I](#)).

To our knowledge, this is the first prospective study that investigates the course and success rate of standardized, carefully monitored introduction of peanut after the DBPCFC. The introduction failure rate in our study is even higher than that of studies not applying a standardized guided introduction (19%-32% failure).<sup>3,4,6,7</sup> In both the failure and the introduction group, a fair amount of parents reported that they did not change their shopping and cooking habits and continued to check food labels. This suggests that even extensive counseling during 1 month after the DBPCFC is not effective in changing

**TABLE 1.** Characteristics of children with and without introduction failure in the diet, n = 37

	Total (n = 37)	Success (n = 23)	Failure (n = 14)	P value
<b>Baseline characteristics</b>				
Mean age (SD), y	8.46 (3.84)	8.66 (3.61)	8.13 (4.33)	.394
Gender (male)	27 (73)	16 (70)	11 (78)	.550
History of asthma	14 (38)	11 (48)	3 (21)	.108
History of allergic rhinitis	19 (51)	11 (48)	8 (57)	.582
History of eczema	21 (57)	15 (65)	6 (43)	.183
Elimination diet for >1 other allergen	21 (58)	15 (68)	6 (43)	.133
Nut-free diet	17 (47)	13 (59)	4 (29)	.074
<b>Sensitization, median (IQR)</b>				
Skin prick test, index	1.36 (0.70-2.00)	1.25 (0.00-1.93)	1.42 (1.00-2.11)	.344
sIgE Peanut, kUA/L	0.76 (0.12-2.73)	1.33 (0.13-2.16)	0.46 (0.10-5.50)	.745
sIgE Ara h2, kUA/L	0.10 (0.10-0.39)	0.10 (0.10-0.39)	0.10 (0.10-0.94)	.467
sIgE Ara h8, kUA/L	0.62 (0.10-7.34)	0.62 (0.10-4.18)	0.66 (0.10-10.89)	.889
<b>History of peanut allergy</b>				
No (traces of) peanut in diet	13 (35)	6 (26)	7 (50)	.139
Lifelong elimination in history	14 (38)	12 (52)	6 (43)	.745
Severe reaction in history	13 (35)	8 (35)	5 (36)	.954
<b>Food challenge</b>				
Subjective symptom during DBPCFC (verum)	7 (19)	3 (13)	4 (29)	.242
Subjective symptom during DBPCFC (placebo)	8 (22)	6 (26)	2 (14)	.398
Subjective symptom during open challenge	15 (41)	8 (35)	7 (50)	.361
Open challenge inconclusive	9 (24)	4 (17)	5 (36)	.208
Convinced about challenge outcome*	28 (78)	17 (77)	11 (79)	.927
<b>Introduction</b>				
Alternative products used	19 (51)	13 (57)	6 (43)	.420
Refusal during introduction	11 (30)	6 (26)	5 (36)	.713
Introduction schedule extended (>7 d)	14 (38)	4 (17)	10 (71)	<b>.002</b>
Peanut-related symptoms during introduction	11 (30)	5 (22)	6 (43)	.173
Parents worried about an allergic reaction after exposure to peanut at home*	12 (33)	5 (23)	7 (50)	.091
Parents worried about an allergic reaction after exposure to peanut outdoors*	16 (44)	8 (36)	8 (57)	.221
Buying and cooking different products*	22 (61)	16 (73)	6 (43)	.073
Reading food labels for peanut*	21 (58)	11 (50)	10 (71)	.204

DBPCFC, Double-blind placebo-controlled food challenge; IQR, interquartile range.

Bold P value indicates significant difference between failure and success group ( $P < .05$ ).

\*The follow-up questionnaire was completed in all but one child, in a median time of 42 (IQR 35-105) days after the last day of food challenge.

peanut allergy-related habits nor in preventing introduction failure. The high rates of parents who worry about exposure in both the failure and introduction group suggest that families still have fear for a possible allergic reaction. Another explanation is that the struggle of children to incorporate peanut in their diet (and lengthening of the introduction period) leads to parental worry that the allergy is not really gone. Aversion was also a common problem despite the offering of alternative products with hidden peanut. It could not be excluded that the aversion was due to underlying subjective symptoms (such as a sensation of oral pruritus). The usefulness of the longer duration of professional support, provision of psychological guidance, or repeating (open) food challenges to reduce fear, encourage parents, and introduce peanut after food challenge should be further investigated. Introduction was standardized, and the procedure and the importance of peanut consumption at home after a negative challenge were explained to all parents before the food challenge. We therefore did not investigate the willingness by the

patient and family of introducing the food, whereas this could also be an important predictor for the success of introduction in daily practice.

Subjective symptoms were common during the DBPCFC (46%) and open challenge (32%). These subjective symptoms were no reason to stop the challenge or consider the child allergic as they were mild and transient. In 3 of those children, peanut allergy was confirmed during follow-up. However, the majority of children were able to successfully reintroduce peanut to their diets despite subjective symptoms during the challenge. These results indicate that challenges should not be stopped and considered positive based on occasional subjective symptoms. Instead, a standardized peanut introduction protocol with professional guidance could be considered for these patients.

A limitation of this study is that the follow-up time was relatively short. Parents and children could need more time to get used to the introduction of peanut. Given that the risk of recurrence of peanut allergy after its resolution is unknown, follow-up

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