PERINATAL JOURNAL

Original Article

Perinatal Journal 2026; 34(1):1269-1275

https://doi.org/10.57239/prn.26.034100126

# Impact of Oral Food Challenge (OFC) in daily activities and quality of life in children with IGE-Mediated food allergy

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**Abstract**

To analyze the impact of food allergies on daily activities and the quality of life in children with food allergies by OFC. Methods: This study provides an overview of the types of food that because allergies based on the results of the Skin Prick Test, Elimination diet, Oral Food Challenge (OFC) performed to confirm a suspected food allergy diagnosis, Daily activities (The Food Allergy Impact Scale / FAIS), Quality of life (uses the pediatric quality of life inventory/ PedsQL) at the Allergy Polyclinic, Department of Pediatrics, Dr. Soetomo Hospital. In this study, the participants were dominated by boys, 65.6%. Most participants were 0-5 years old, 47.2%. Based on the FAIS pre and post-OFC test, there were significant differences with p-value = .000 in meal preparation, family social activities, caregiver stress and free time, autonomous child social activities, employment and finances, and p-value = .001 in caregiver-supervised child social activities. In assessing PedsQL, there is a significant difference before and after OFC with a p-value = .000 in all health domains. The results of the skin prick test on several types of food, the most positive skin prick test results were found in freshwater fish species was 149 patients (71.3%). In the OFC, the highest positive results for several types of food were cow's milk, 77 children (36.8%), and chocolate, 76 children (36.4%). The OFC procedure is necessary for managing food allergies because it improves daily family activities and the quality of life in children with food allergies.

**Keywords:** Oral food challenges test, IgE-Mediated food allergy, Quality of life, Child health

## Introduction

Food allergies have a very high prevalence and generally occur in children.[1,2] The incidence of food allergies continues to increase.[1,3,4] This is a big problem because it significantly affects the patient's physical and mental well-being, thus impacting individuals' and families' overall quality of life.[5,2] An individual's allergic reaction to certain foods occurs due to a pathological response of the body's immune system triggered by consuming allergens contained in the food protein.[5] Sometimes, minimal exposure to allergenic food can trigger clinical symptoms with mild to life-threatening severity.[2]

Children diagnosed with food allergies requiring an elimination diet are still the main treatment in managing food allergies to date. They can eliminate exposure to food allergens, improving symptoms due to decreased immunological reactions.[6] However, this elimination process is often tedious and time-consuming. It requires extraordinary knowledge, skills, and commitment from individuals, caregivers, and the surrounding environment, so it can negatively impact children's nutritional conditions and family activities, which will affect the child's quality of life.[2,3,5,7]

The Oral Food Challenge (OFC) is the gold standard for confirming a definite diagnosis of a particular food allergen, which will help doctors advise whether to continue avoiding or vice versa, namely reintroducing the food.[8] Performing OFC will allow parents to reintroduce certain essential foods such as milk, eggs, and fish, which were avoided before, thereby reducing family stress and helping to improve children's quality of life and nutritional status.[8,9,5] Based on the explanation above, it is necessary to carry out an analysis to determine the impact of food allergies on daily activities on the quality of life in children with food allergies by OFC.

## Methods

### Skin prick test

The results of the skin prick test were performed with a sterile lancet and commercial food allergens extract in the volar area of the forearm, in the marked area. In this study 10 food allergens were tested: tomatoes,

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oranges, shrimp, sea fish, fresh fish, cow's milk, chocolate, chicken meat, egg whites and yolks. The control specimens used were normal saline (negative) and histamine (positive). The reaction was observed after 20 minutes. Wheal-and flare reactions are measured with a ruler in millimeters (1 mm = 0.001 m). The vertical and horizontal wheal-and-flare diameters are added and divided by 2, yielding the average diameter, which is recorded. Skin prick test results were considered positive if the diameter was >3 mm compared to the negative control. The test results are determined by an allergy-immunology consultant pediatrician.[10,11]

## Elimination diet

Elimination diet is based on history of food allergy response and skin prick tests. Children stop consuming the food that causes allergy and replace the nutritional intake of the food in consultation with a nutritionist. The nutrients obtained from these foods must be replaced with foods that contain the same nutrients. The use of books in elimination diet is very helpful for caregivers and nutritionists to plan a 4-week diet. Elimination diet was declared unsuccessful if the elimination diet was carried out for > 4 weeks and signs of food allergy symptoms were still found. [12,13]

## Oral food challenge

After obtaining specific IgE results either through a skin prick test or serum IgE and the suspected food allergen is known, food elimination is carried out for 3 weeks, after which OFC is performed.[12,13] OFC is performed to confirm a suspected food allergy diagnosis, and is carried out under the supervision of a doctor with adequate equipment and emergency medicines. OFC is started with a minimal/initial challenge dose of allergen followed by gradual increases given at 15-20 minute intervals until the total challenge dose is reached or the child has an adverse reaction.[9,13,14] OFC is said to be positive when the patient experiences an allergic reaction a few minutes-a few hours after consuming the given allergen. The results are said to be negative if no reaction occurs for at least 2 hours after completing the graded challenge, and the food can be consumed at home with a continuous total dose to ensure it is safe for consumption. [13,14,15]

## Daily activities

The Food Allergy Impact Scale (FAIS) is a questionnaire used to evaluate parents' perceptions of the impact of food allergies on eight aspects of daily family activities, with a higher score indicating a greater impact. The scale consists of 32 questionnaire items consisting of 8 aspects of activities, namely meal preparation (six items), family social activities (five items), caregiver-supervised child social activities (two items), family relations (three items), caregiver stress and free time (three items), school or structured activities (six items), autonomous child social activities (three items), and employment and finance (three items). FAIS reliability results obtained Cronbach's alpha value of 0.70, with subscales meal preparation ($\alpha$ = 0.96), family social activities ($\alpha$ = 0.88), caregiver-supervised child social activities ($\alpha$ = 0.73), family relations ($\alpha$ = 79), caregiver stress and free time ($\alpha$ = 0.80), school or structured activities ($\alpha$ = 0.86), autonomous child social activities ($\alpha$ =0.55), and employment and finance ($\alpha$ = 0.60).[16] The Indonesian version of FAIS was declared valid and reliable based on previous research.[3]

## Quality of life

The measurement of children's quality of life uses the pediatric quality of life inventory (PedsQL), which is a questionnaire used to evaluate health-related quality of life (HRQoL) in children. PedsQL is a general health instrument consisting of 23 items that assess five health domains (physical function, emotional function, psychosocial function, social function, and school function) in children and adolescents aged 2 to 18 years. There are 23 questions covering physical function (8 items), emotional function (5 items), social function (5 items), and school function (5 items). The answer to each question was scored on a 5-point Likert scale: never (0), almost never (1), sometimes (2), often (3), and almost always (4). Scores are converted to a scale of 0–100 (0=100; 1=75; 2=50; 3=25; and 4=0). The total score of 23 items is the average of all answers. Value is said to be good if ≥70. This study used the Indonesian version of the PedsQL questionnaire which was obtained from the permit holder and was declared reliable ($\alpha$>0.7). [6,17]

## Statistical analysis

The data were first tested using Kolmogorov-Smirnov. Furthermore, data on participant's characteristics were analyzed using independent t-test or the Mann-Whitney test. In addition, other measurement results were analyzed using independent t-test or Mann-Whitney test and dependent t-test or Wilcoxon test. The statistical test results were declared significant if $p < 0.05$. Data analysis used IBM SPSS Statistics software version 23.0 (IBM Corp., Armonk, NY, USA).

## Ethics approval and consent to participate

This research was approved by the Health Research Ethics Committee of Dr. Soetomo General Academic Hospital Center Surabaya with number 0581/LOE/301.4.2/IX/2021

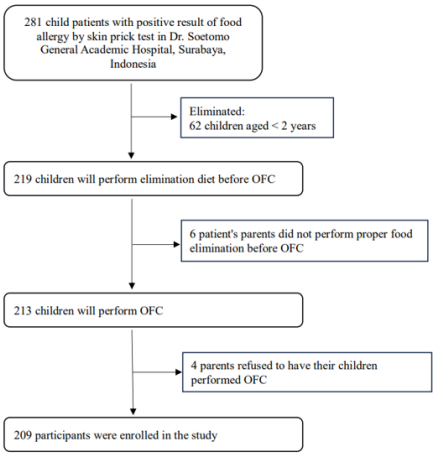


**Figure 1.** Identification flowchart of participants number

## Results

This study's respondents were 209 children, male and female, aged 2 months to 18 years. The Skin Prick Test, Elimination Diet, and Oral Food Challenge were carried out (Figure 1).

**Table 1.** Characteristics of participants

| | n | Percentage |
|---|---|---|
| Sex | | |
| Male | 137 | 65.6% |
| Female | 72 | 34.4 % |
| Total | 209 | 100% |
| Age | | |
| 0-5 years | 98 | 46,2% |
| 6-10 years | 62 | 30,8% |
| 11-14 years | 39 | 18% |
| >14 years | 10 | 5% |
| Total | 209 | 100% |

The characteristics of respondents based on gender were mostly male, namely 137 respondents (65.6%). Based on the age of 98 allergy sufferers who came to the Allergy Department of Children's Hospital, Dr. Soetomo is in the age range of 5-10 years (table 1).

**Table 2.** Participants family history of atopy

| Family History of Atopy | n | Percentage |
|---|---|---|
| Father | 31 | 14.8 % |
| Mother | 50 | 23.9 % |
| Siblings | 13 | 6.2 % |
| Father and mother | 25 | 12.0 % |
| Father mother and siblings | 15 | 7.2 % |
| Denied | 51 | 24.4 % |
| Father and sibling | 11 | 5.3 % |
| Mother and siblings | 13 | 6.2 % |
| Total | 209 | 100 % |

The characteristics of the respondents in Table 2 are based on a family history of atopy. Most of them are mothers, 50 people (23.9%). At least 11 people (5.3%) had a family history of atopy from fathers and siblings (Table 2).

**Table 3.** FAIS Pre and Post OFC test

| FAIS (n=209) | | Mean OFC Test (n=209) | | P value | Z Value |
|---|---|---|---|---|---|
| Aspects of activities | Pre – Post Score (Mean±SD) | Negative | Positive | | |
| Total | (5.35 ± 0.67 - 4.10 ± 0.37) | 109.18 | 29.68 | .000 | -12.162 |
| Meal preparation | (6.22 ± 0.72 - 3.08 ± 0.98) | 105.00 | 0.00 | .000 | -12.536 |
| Family social activities | (5.93 ± 0.92 - 3.69 ± 0.81) | 106.59 | 40.30 | .000 | -12.306 |
| Caregiver-supervised | (4.75±1.91 - 5.33 ± 0.62) | 74.11 | 104.08 | .001 | -3.383 |

| | | | | | | |
|---|---|---|---|---|---|---|
| child social activities | | | | | | |
| Family relations | (5.05 ± 1.50 - 5.03 ± 1.43) | | 88.79 | 101.27 | .816 | -.233 |
| Caregiver stress and free time | (4.85 ± 1.22 - 2.76 ± 1.07) | | 106.44 | 42.04 | .000 | -11.656 |
| School or structured activities | (4.07 ± 1.58 - 4.07 ± 1.61) | | 95.68 | 92.41 | .912 | -.111 |
| Autonomous child social activities | (5.26 ± 1.67 - 6.16 ± 0.69) | | 66.63 | 108.52 | .000 | -6.529 |
| Employment and Finances | (5.32 ± 1.29 - 2.69 ± 1.11) | | 103.77 | 42.00 | .000 | -11.840 |

Based on FAIS pre and post-OFC test, there were significant differences with p value = .000 in meal preparation, family social activities, caregiver stress and free time, autonomous child social activities, employment and finances, and p value = .001 in caregiver-supervised child social activities. Meanwhile, there is no significant difference in family relations and school or structured activities. The highest positive average result was in autonomous child social activities FAIS (108.52) (table 3).

**Table 4.** PedsQL Pre and Post OFC test

| **PedsQL (n=209)** | | **Mean OFC Test (n=209)** | | **P value** | **Z value** |
|---|---|---|---|---|---|
| | | Negative | Positive | | |
| Health Domains | Pre – Post Score (Mean±SD) | | | | |
| Total | (69.13 ± 5.78 – 92.39 ± 4.22) | .00 | 105.00 | .000 | -12.537 |
| Physical Function | (92.44 ± 7.69 – 95.24 ± 5.59) | 20.42 | 36.39 | .000 | -6.525 |
| Emotional Function<br>Psychosocial function | (63.13 ± 10.34 – 91.26 ± 8.41)<br>(61.23 ± 12.23 – 92.31 ± 8.52) | 21.25<br>24.34 | 104.63<br>103.77 | .000<br>.000 | -12.343<br>-12.415 |
| Social Function | (59.42 ± 11.84 – 91.19 ± 8.11) | .00 | 102.50 | .000 | -12.404 |
| School Function | (61.63 ± 12.43 – 91.89 ± 8.29) | 26.50 | 101.87 | .000 | -12.313 |

Based on the results of the PedsQL pre- and post-OFC test, there were significant differences in the total, physical, emotional, social, and school functioning variables, with a p-value of 0.000 for each variable—the most important positive mean result on PedsQL Total (105.00) (Table 4).

**Table 5.** Skin prick test results vs OFC test results

| **Food type** | **Skin prick test** | | **Total** | **Provokasi** | | **Total** |
|---|---|---|---|---|---|---|
| | n | Percent | | n | Percent | |
| Cow's milk | 105 | 50.2% | 100 | 77 | 36.8% | 100 |
| Egg Yolk | 89 | 42.6% | 100 | 35 | 16.7% | 100 |
| Egg White | 109 | 52.2% | 100 | 69 | 33% | 100 |
| Sea food | 98 | 46.9% | 100 | 58 | 27.8% | 100 |
| Fresh fish | 149 | 71.3% | 100 | 33 | 15.8% | 100 |
| Chicken meat | 87 | 41.6% | 100 | 61 | 29.2% | 100 |
| Tomato | 59 | 28.2% | 100 | 43 | 20.6% | 100 |
| Chocolate | 85 | 40.7% | 100 | 76 | 36.4% | 100 |
| Peanuts | 35 | 16.7% | 100 | 26 | 12.4% | 100 |
| Shrimp | 80 | 38.3% | 100 | 73 | 34.9% | 100 |
| Orange | 72 | 34.4% | 100 | 46 | 22% | 100 |

Based on table 5, the results of the skin prick test on several types of food, the most positive skin prick test results were found in freshwater fish species, namely 149 children (71.3%) and egg whites as many as 109 children (52.2%) while the least was found in peanut food types 35 children (16.7%). In the OFC test, the highest positive results for several types of food were cow's milk, namely 77 children (36.8%) and chocolate, 76 children (36.4%), while the least was found in peanut food, namely 26 children (12.4%).

## Discussion

Various burdens arise on sufferers and caregivers of children with food allergies, both financially, physically, and even psychologically.[18,19,20] In sufferers and individual caregivers with food allergies, there is constant vigilance plus anxiety in anticipation of reactions that can occur anytime or anywhere in the future, especially anaphylactic reactions, which can be fatal. This burden has a negative impact and is compounded by the risk of future exposure, which may cause a more severe anaphylactic reaction than before.[18,21] Anxiety is increasing due to the management of food allergies, which still lean towards avoiding exposure and the use of epinephrine and other medications when an anaphylactic reaction occurs, and there is still no cure. [22]

OFC is a gold standard diagnostic procedure to provide evidence of whether an individual is allergic to certain foods.[13,21] Re-introduction of food after OFC with negative results can ideally reduce various burdens, including psychological burdens because it is proven that the individual is not allergic to the suspected food.[21,22,23] This was confirmed in our research, where there was a significant improvement in daily family activities as a whole after OFC, especially in meal preparation activities, family social activities, caregiver-supervised child social activities, caregiver's stress and free time, autonomous child social activities, and employment and finance. However, no differences were found in family relations activities and school or structured activities because in family relations, the caregiver is responsible from the start for providing food intake and observing symptoms that can arise due to food exposure to children accompanied by family support before OFC, as well as in conducting OFC who carry the risk of a severe allergic reaction, the choice for OFC is made with a careful balance of risks and benefits and should always be made in conjunction with the patient or family.[24,25] There was also no difference in school or structured activities because even though OFC is the gold standard for diagnosing food allergies, where negative results are advised to include the tested food in the diet, they often don't. Approximately 25%-30% of food allergy patients continue to eliminate food despite a negative OFC result. Several factors influence this, namely that children end up disliking these types of food, the trauma of allergic reactions occurring, the fear of persistent allergies, and even the food itself eventually not becoming a routine part of the family's diet because it is used to being avoided. In the end, they continued to eliminate various activities outside the supervision of the family. [23]

The quality of life of children with food allergies has increased after OFC, this is in accordance with various previous studies where in our study the same results were obtained.[22,21,26,27,28,29,30] After OFC, the quality of life of food allergy sufferers has increased, and the burden on caregivers and sufferers has been reduced significantly so that it is smoother to carry out various activities, both for families and sufferers.[22,28] The beneficial effect of the OFC procedure that can clarify the severity of food allergies is that it reduces the anxiety of caregivers and sufferers because they can control exposure to the environment after knowing the causes and how to handle reactions in daily practice. [30]

So OFC can improve the activities of sufferers and caregivers in children with food allergies and improve the quality of life for these children, where there is a decrease in the percentage of various food allergens after OFC in our study, so that there are more food choices that children can consume, and this is in accordance with other studies.[12,13,14,15]

## Conclusion

This study concludes that the OFC procedure is necessary for managing food allergies because it improves daily family activities and the quality of life in children with food allergies.

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