Translation, Adaptation and Initial Validation of the Food Allergy Quality of Life Questionnaire – Child Form (8 – 12 Years) in Ukrainan Language

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Abstract

Food allergy affects quality of life of children and their families. In the current context of the COVID-19 pandemic, when a physician has to consult a patient remotely, the introduction of a disease-specific health-related quality of life questionnaire has become particularly important for assessing the course of the disease and the effectiveness of treatment interventions. Our study involved 60 children aged 8 to 12 years and was conducted at the Communal Nonprofit Organization "City Children's Clinical Hospital of Lviv" (Ukraine). After the linguistic validation, both the Ukrainian FAQLQ-CF and Food Allergy Independent Measure (FAIM) were used for interviewing children with diagnosed food allergy during the visit to the allergist. The prevalence of allergies, the proportion and the correlation between different allergens were analyzed in the children involved in the study. Reliability of FAQLQ-CF was evaluated by calculating Cronbach's alpha. A factor analysis was performed to assess construct validity and to reveal an underlying structure of four factors that explain a total of 55% percent of the variance. The significant strong positive correlation was between the total FAQLQ-CF and the total FAIM ($r=0.81$, $p>0.05$). Each of the FAQLQ-CF subscales correlated significantly with at least one of the FAIM scale questions. The internal consistency of the Ukrainian FAQLQ-CF was sufficient (Cronbach's alpha 0.73). The Ukrainian FAQLQ-CF is acknowledged as a suitable, reliable and valid tool to be self-completed by food allergic children aged 8-12 years. The information obtained from this questionnaire can be used in clinical trials, aiming at outcome assessment.

Key words 1

food allergy, quality of life, validation, children.

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1. Introduction

Urbanization, environmental pollution and modern lifestyle have led up to an increase in allergic diseases in children around the world over the past 30 years. In particular, nowadays food allergy remains a fairly common problem, affecting between 6-8% [1] to 10 % [2] of children living in industrial areas. Recent data illustrate that about 2.4% of children suffer from multiple food allergies, and anaphylactic reactions may occure in about 3% of children [3]

A food allergy is an immunological reaction to the protein contained in food, mediating the rapid onset of clinical symptoms [4]. The increased predisposition of children to food allergies can be explained by the imperfection of the barrier between the environment and internal tissues, which include skin, mucous membranes of the respiratory tract and gastrointestinal tract, as well as immaturity of the immune system, T-cell tolerance dysfunction [5]. The foods that are most often associated with the development of IgE-mediated allergic reactions include: cow's milk, hen's egg, peanut, tree nuts, fish, shellfish, wheat, soybeans and seeds [[6], [7]]. And while immunological tolerance to milk and chicken egg protein often develops, nut allergy tend to last a lifetime [8].

Unpredictability of reactions to foods, and in some cases the development of a life-threatening condition of anaphylaxis, cause fear and anxiety in parents or people involved in the care for an allergy child [9]. Strict avoidance of food allergens is the only effective treatment for food allergies. Therefore, a careful control of food composition, precautions when cooking to avoid cross-contact of the allergen with safe foods, as well as the ability in recognizing life-threatening symptoms in a child in a timely way and to provide emergency care remain important today [4]. However, mortality from food allergies is relatively low, patients with this disease constantly face up to the possibility of potentially severe reactions and the need to follow a diet. This undoubtedly cannot but affect the quality of life of both patients and their parents. Bollinger et al. [10] found that 41% of parents indicated an increase in stress levels since the diagnosis of their child with allergies due to the risk of an accidental allergen consumption and fear of an allergic reaction. It becomes the responsibility of parents to explain to the child in an accessible form that certain foods must not be consumed, thereby not causing the food disgust in general. It is also important to avoid nutritional deficiencies by providing the necessary nutrients at the expense of the other safe for allergy products. A frequent complaint of modern parents is also the labor intensity of the process of cooking and ready meals choosing. In particular, they are forced to spend more time in the store, facing difficulties with product labeling.

Therefore, childhood food allergies currently are not only a medical but also a social problem. According to a number of studies, the quality of life of schoolchildren with food allergies is much lower than that of their healthy peers [[11], [12]]. There are undoubtedly age differences among allergy children from the feeling of some discomfort due to the inability to eat certain foods consumed by their peers to depression and negativism in adolescents, in particular, including bullying [13]. Some parents try to minimize their anxiety about their child by avoiding certain social activities, such as attending children's organized activities, parties, and recreations. Considering the fact that the Health-Related Quality of Life (HRQL) of allergy patients is usually worse than in the general population, it may be the only important indicator for assessing the effectiveness of various therapeutic interventions [[1], [14]].

Generic or disease-specific questionnaires are commonly used to assess the patient's quality of life. Generic questionnaires allow to compare the life quality of patients with different diseases, but more sensitive are questionnaires designed for specific diseases (disease-specific questionnaires), as the latter are usually based on potentially clinically important differences for a particular disease [15]. All researchers who evaluated the impact of food allergies in children on HRQL in different countries with the use of generic questionnaires [[12], [16]] and some non-validated disease-specific questionnaires [17] noted a deteriorated HRQL. The amount of food allergens and the presence of anaphylaxis in the case history correlated with the poorer quality of life of patients and their relatives [16].

Nowadays, the Food Allergy Quality of Life Questionnaire (FAQLQ) is most commonly used questionnaire to measure the quality of life of children with allergies. This disease-specific questionnaire was developed and validated in Europe as a part of the multi-center research project

(EuroPrevall). The questionnaire includes forms created for different age-groups of children (ages 8-12 and 13-17), as well as parents of 0-12 year old children with food allergies [18]. In order to assess the real state and consequences of the disease, the ability of children to answer questions on their own is very important, because their vision of the problem, their feelings are often different from those felt by adults who take care of them. Assessing the quality of life of a child with allergies, it is possible to identify problems in a certain age group, to compare the effectiveness of different treatment approaches to the quality of life of a young patient, to choose the best treatment regimen and further to evaluate its effectiveness taking into account the quality of life of a child with food allergies. The original FAQLQ-CF questionnaire was developed in the Dutch language and has an excellent internal consistency (Cronbach's alpha 0.94). Nowadays it has been translated and validated in several languages, including English, French and Greek. It is extremely important to adapt the translation of the questionnaire to the linguistic and cultural characteristics of patients living in different countries and even in different regions of the same country.

The aim of the study was to conduct a translation, adaptation and initial validation of Food Allergy Quality of Life Questionnaire – Child Form (FAQLQ-CF) for children aged 8–12 years in the Ukrainian language.

2. Methods

2.1. Participants

The study, conducted at the Communal Nonprofit Organization "City Children's Clinical Hospital of Lviv" (Ukraine), involved 60 children aged 8 to 12 years on condition of the informed parental consent. Parents were provided with comprehensive information on the conditions of the study. The diagnosis of food allergy was established by a pediatric allergist on the basis of clinical symptoms and skin prick tests with the use of the most common allergens such as milk, eggs, fish (hake), soy, wheat, chicken, citrus, strawberries, cocoa, and others (grapes, veal, carrot, apple). The prick-prick method was used with nuts (peanuts, cashews, hazelnuts, walnuts) and sesame. The test was considered as positive (the child was allergic to one or another food product) if the size of the papule was ≥ 3 mm. Oral provocation tests and serological diagnosis were not performed.

The exclusion criteria from study were: autoimmune diseases, episode of anaphylaxis in the history, as well as the inability to conduct skin prick tests.

As it is known, depending on the affected target organ, the patient may have different symptoms of food allergy. The pathological process may involve the skin (rash, swelling of the lips and eyelids), digestive tract (dysphagia, vomiting, constipation, diarrhea, abdominal pain, refusal to eat, rapid satiety), respiratory organs (cough, runny nose, wheezing). A combination of allergy symptoms from different organs is also quite common. In the most severe cases (anaphylactic shock and food-dependent cofactor-induced anaphylaxis) systemic signs are evident [4]. Therefore, collecting a medical history, a comprehensive assessment of complaints and general condition of the child was conducted.

2.2. Procedure

During the visit to the allergist, the children were asked to fill in the questionnaires. Parents or medical staff could read the questions aloud or explain to the child if something was not clear, but it was monitored that the child answered the questions on his own.

2.3. Questionnaires

Two questionnaires: FAQLQ-CF and Food Allergy Independent Measure (FAIM) were used in the study. Both mentioned questionnaires were previously translated into the Ukrainian language in accordance to the World Health Organization guidelines and combined in one package of papers [19]. The translation included the following steps: preliminary English to Ukrainian translation, followed by the group of experts review, a native speaker translation backward into English from Ukrainian, pretesting and interviewing, final questionnaires approval.

FAQLQ-CF includes 24 questions, divided into four subscales (Table 1): allergen avoidance (AA), risk of accidental exposure (RAE), emotional impact (EI) and dietary restrictions (DR). The answers to the questions were evaluated on a 7-point scale (0-not: 1-barely, 2-a little bit; 3- fairly; 4-quite; 5-very; 6- extremely). The highest score rated for FAQLQ-CF is associated with the worst quality of life. In addition, the Food Allergy Independent Measure (FAIM) measures the perceived disease-severity. The FAIM consists of six questions [20]. Four of those questions are related to expectation of outcome (EO) in patient with food allergy (accidental exposure, chance of severe reaction in case of unintentional eating of something, risk to pass away when accidentally being exposed to allergen, and hazard of not acting effectively after exposure). Other two remaining questions concern the independent measure (IM) accordingly they reflect severity of the disease (number of products that should be avoided and the impact of food allergy on social life). Children have to indicate their answer on a seven-point scale which range from 0-never (0% chance) to 7-always (100% chance). The highest score rated for FAIM is associated with the worst perceived disease-severity. The FAIM is a reliable and successfully applied tool for the cross-sectional validation of the FAQLQ-CF. Consequently, we compare the results of FAQLQ-CF with the six questions listed in FAIM to determine the correlation.

Table 1
Distribution of questionnaire questions on subscales

Subscales			
Allergen avoidance (AA)	**Risk accidental exposure (RAE)**	**Emotional impact (EI)**	**Dietary restriction (DR)**
4 - read labels	11 - beware of touching foods	19 - allergic reaction terrifies you	1 - always watch
6 - less easily stay for a meal	13 - the ingredients change	20 - eating wrong food by accident	2 - limit yourself in some products
7 - try fewer thing	14 - the label warns	21 - eat food you have not eaten	3 - can't buy food you like
8 - warn in advance	16 - people always forgetting about…	22 - food allergy never goes away	5 - refuse treats
9 - control yourself on allowed food	17 - others can eat	23 - people have no regard for…	12 - refuse food
10 - hesitate to eat certain food		24 - makes you frustrated	18 - don't know taste
15 - inform the people around			

2.4. Ethics issue

Ethical Committee or Institutional Animal Care and Use Committee Approval: Nonprofit Communal Enterprise "City Children's Clinical Hospital of Lviv"; 16. Nov. 2018 № 6.

Written information was given to children and their parents, indicating that participation in the study was voluntary.

2.5. Statistical analyses

Principal component analysis (PCA) was applied to determine whether the items form one overall scale or more than one. Since the factor structure has been determined in similar investigations, the confirmatory factor analysis was performed. The internal consistency was evaluated by calculating Cronbach's alpha (α), a widely used measure of variability. An item-total correlation test was performed to check the contribution of each item to instrument consistency as determined by the ability to discriminate between high- and low-scoring children.

For the statistical analysis FAQLQ-CF and FAIM scores 0 to 6 were recoded as 1 to 7. Non-parametric tests were used for the not normally distributed dataset. Spearman's correlation coefficient was calculated in order to estimate the construct validity of the FAQLQ-CF comparing it with a FAIM.

3. Results

3.1. Description of the study group

The study involved 29 (48.3%) boys and 31 (51.7%) girls. The mean age of patients was 10.12 years (SD 1.58 year), the median total duration of food allergy symptoms was 7.5 years (interquartile range 6.0-10.0 years).

One questionnaire was excluded because the descriptive characteristics of allergy prevalence were missing, and the statistical analysis was performed with data from the questionnaires of 59 patients.

The most common manifestations of food allergy in children aged 8-12 years were skin reactions 33 (55%) (95% CI: 42.41-67.59). However, distinguishing the patients, who reported a combination of allergy symptoms from different organs (multi-organ reaction for instance, skin and gastrointestinal tract, or skin and respiratory system) into a separate group, the combined manifestations of allergy 22 (37.3%) (95% CI: 24.95-49.63) became dominant and displaced the isolated skin lesions into a second place 15 (25.4%). Gastrointestinal and respiratory symptoms were hence observed in 12 (20.3%), (95% CI: 10.06-30.61) and 10 (16.90%) (95% CI: 7.37-26.52) children respectively.

The products that most often caused allergic reactions in our patients according to the results of the skin prick test (positive test ≥ 3 mm) included; chicken 23 (38.3%) (95% CI: 26.7-51.0), soy 19 (31.7%) (95% CI: 20.8-44.4), wheat 18 (30%) (95% CI: 19.4-42.4). Strawberries had the lowest specific weight among allergens 5 (8.3%) (95% CI: 3.0-17.3).

A significant correlation was observed between the reported allergies by the patient and the presence of a positive skin prick test for peanuts and other nuts (walnut r = 0.606), cashews (r = 0.680), and hazelnuts (r = 0.431)) and chicken egg (r = 0.631).

3.2. Cross-sectional validation

Comparing the correlation of all 24 questions included in FAQLQ-CF with 6 questions of FAIM, a strong positive correlation was found between these two questionnaires (r = 0.81, p <0.05). Each of the FAQLQ-CF subscales (AA, RAE, EI, DR) correlated significantly with at least one of the FAIM scale questions (Table 2). The top row in the Table 2 shows Spearman's correlation between the overall FAQLQ scale and five of six FAIM questions.

Table 2
Spearman correlation coefficients for the FAQLQ-CF with the FAIM

				FAIM			
FAQLQ-CF	Q1*	Q2*	Q3*	Q4*	Q5*	Q6*	Total
Total	0.47	0.54	0.6	0.58	0.05	0.49	0.81
Allergen avoidance	0.88	0.11	0.52	0.43	-0.21	0.19	0.62
4. importance of reading food labels	0.7	0.09	0.28	0.39	-0.11	0.19	0.46
6. Less easily staying for a meal with someone	0.7	0.18	0.56	0.4	-0.35	0.2	0.56
7. Tasting or trying fewer things when you eat out	0.64	0.17	0.42	0.34	-0.23	0.22	0.5
8. Must warn in advance against forbidden food consumption when you eat out	0.72	-0.06	0.39	0.25	-0.09	0.04	0.45
9. Must control yourself on allowed food when eating out	0.41	0.29	0.3	0.27	-0.1	0.14	0.44
10. Hesitate to eat certain food if you don’t know whether it is safe	0.66	0.12	0.29	0.26	-0.2	0.13	0.43

15 Inform the people around you about your food allergy	0.7	0.04	0.38	0.4	-0.23	0.23	0.47
Risk of accidental exposure	0.14	0.78	0.5	0.35	0.02	0.49	0.66
11. Beware of touching definite foods	0.17	0.57	0.42	0.26	-0.1	0.39	0.5
13. Food ingredients change	0.16	0.65	0.48	0.41	-0.03	0.39	0.62
14. The label warns: “May contain traces of…“	-0.03	0.64	0.37	0.16	0.12	0.35	0.42
16. People around you are always forgetting about your food allergy	0.02	0.49	0.33	0.28	0.12	0.36	0.44
17. When you deal with the other people, they can eat food which is allergic for you	0.18	0.64	0.37	0.27	-0.001	0.47	0.54
Emotional impact	-0.06	0.33	0.35	0.29	0.03	0.59	0.31
19. A possible allergic reaction terrifies you	0.007	0.26	0.18	0.22	-0.14	0.29	0.18
20. Frightened of eating the wrong food by accident	-0.07	0.39	0.31	0.16	0.002	0.49	0.29
21. You are afraid to eat food you have not eaten before	-0.08	0.19	0.09	0.03	-0.24	0.24	0.07
22. Worried about the fact that your food allergy never goes away	0.08	0.24	0.15	0.28	0.01	0.47	0.29
23. Makes you disappointed if people have no regard for your food allergy	-0.03	0.12	0.1	0.05	0.15	0.26	0.09
24. The food allergy makes you frustrated	-0.11	0.09	0.4	0.21	0.13	0.34	0.18
Dietary restriction	-0.3	-0.04	-0.11	0.07	0.6	-0.14	-0.08
1. Must always watch what you eat	-0.12	0.06	0.003	-0.13	0.2	0.03	0.05
2. Have to limit yourself in some products	-0.17	-0.09	-0.19	0.04	0.48	-0.18	-0.12
3. Can’t buy food you like	-0.23	-0.09	-0.22	-0.14	0.36	-0.13	-0.19
5. Must refuse treats when doing something with other people	-0.15	0.08	0.07	0.16	0.37	-0.05	0.07
12. Must refuse food when someone offers it at school	-0.11	0.11	-0.1	0.16	0.47	0.06	0.13
18. Don`t know the taste of food which you can`t try	-0.16	-0.12	-0.02	0.26	0.07	-0.08	-0.03

*FAIM scale questions: Q1- How big is the chance of an accidental exposure; Q2 - Chance of a severe reaction development if you consumed something accidentally; Q3 - Chance of dying when accidentally exposed; chance to die if consumed something accidentally; Q4 - Chance to fail in effective help when you consumed something accidentally; Q5 - Foods number you have to avoid; Q6 - Impact on your social life which food allergy makes.

Italics – $p > 0.05$. **In bold type** - key pairs between specific FAQLQ-CF scales and specific FAIM questions, significant correlation ($p < 0.05$).

Principal component analysis of the 24 items of the FAQLQ-CF revealed 7 factors. To clarify the relationship among factors Varimax rotation was performed and some factors were excluded afterwards. Considering that in the original study Flokstra-de Blok et al. [15] as well as in a similar study of Greek colleagues, 4 factors were identified, the preference was also given to a four-factor model. The analysis of the main components indicates that these 4 factors explain a total of 55% percent of the variance. The obtained 4 factors were similar to the original factors highlighted by Flokstra-de Blok et al. [15] and were called F1 - allergen avoidance (AA), F2 - risk of accidental exposure (RAE), F3 - emotional impact (EI), and F4 - dietary restrictions (DR). Questions that were lost with the reduction of factors, have been added to the most appropriate factor by our expert group.

When conducting a factor analysis with the 4 factors distinguishing (according to the results of the previous subdivision with the inclusion of all questions), the third group of questions (EI scale) was not separated into the common factor during the statistical processing of data provided in the questionnaires. In terms of the influence on the variance in the selection of 4 factors, other issues dominated (Table 3).

Table 3

Confirmatory factor analysis for four factors and all questions from FAQLQ-CF(Ukrainian)

QN*	Questions **	F 1***	F 2	F 3	F 4	SSº
4	Importance of reading food labels		0.678	0.368		AA
6	Less easily staying for a meal with someone	0.393	0.570	0.525		AA
7	Tasting or trying fewer things when you eat out		0.979			AA
8	Must warn in advance against forbidden food consumption when you eat out		0.504	0.541		AA
9	Must control yourself on allowed food when eating out	0.340	0.441			AA
10	Hesitate to eat certain food if you don’t know whether it is safe			0.665		AA
15	Inform the people around you about your food allergy		0.312	0.672		AA
11	Beware of touching definite foods	0.642				RAE
13	Food ingredients change	0.797				RAE
14	The label warns: “May contain traces of…“	0.738				RAE
16	People around you are always forgetting about your food allergy	0.569				RAE
17	When you deal with the other people, they can eat food which is allergic for you	0.667				RAE
19	A possible allergic reaction terrifies you					EI
20	Frightened of eating the wrong food by accident					EI
21	You are afraid to eat food you have not eaten before					EI
22	Worried about the fact that your food allergy never goes away					EI
23	Makes you disappointed if people have no regard for your food allergy					EI
24	The food allergy makes you frustrated					EI

1	Must always watch what you eat			-0.469		DR
2	Have to limit yourself in some products				0.398	DR
3	Can’t buy food you like				0.353	DR
5	Must refuse treats when doing something with other people	0.310			0.871	DR
12	Must refuse food when someone offers it at school			-0.418		DR
18	Don`t know the taste of food which you can`t try				0.444	DR

* Question number from the original questionnaire.
**Original question formulation in the questionnaire FAQLQ-CF.
***F1 (AA), F2 (RAE), F3 (EI), F4 (DR).
ºSubscales (SS).

Questions 1 (must always watch what you eat) and 12 (must refuse treats when doing something with other people) from the DR subscale had demonstrated a negative relationship (loads negatively) with the corresponding factor instead, and therefore they were removed and the factor analysis was conducted repeatedly. As a result, a better distribution of factors was obtained, which coincided with our previously selected subscales (Table 4). And even though the first group of questions (AA scale) tended to be divided into two sub-factors, these questions also clearly fit into the general factor with the questions of their scale.

After the two questions had been excluded, factors F1, F2, F3 demonstrated strong loadings from 0.401 to 0.853 (AA, 0.823-0.401; RAE, 0.817-0.578; EI, 0.853-0.414) and minimally acceptable one for F4 (DR, 0.511-0.304).

Table 4
Confirmatory factor analysis for four factors after the 1 and 12 question exclusion from FAQLQ-CF (Ukrainian)

QN*	Questions**	F 1***	F 2	F 3	F 4	SSº
4	Importance of reading food labels	0.823				AA
6	Less easily staying for a meal with someone	0.800	0.352			AA
7	Tasting or trying fewer things when you eat out	0.748				AA
8	Must warn in advance against forbidden food consumption when you eat out	0.737				AA
9	Must control yourself on allowed food when eating out	0.401	0.309			AA
10	Hesitate to eat certain food if you don’t know whether it is safe	0.580				AA
15	Inform the people around you about your food allergy	0.624				AA
11	Beware of touching definite foods		0.633			RAE
13	Food ingredients change		0.817			RAE
14	The label warns: “May contain traces of…“		0.711			RAE
16	People around you are always forgetting about your food allergy		0.578			RAE
17	When you deal with the other people,		0.630			RAE

	they can eat food which is allergic for you				
19	A possible allergic reaction terrifies you			0.411	EI
20	Frightened of eating the wrong food by accident			0.483	EI
21	You are afraid to eat food you have not eaten before			0.369	EI
22	Worried about the fact that your food allergy never goes away			0.500	EI
23	Makes you disappointed if people have no regard for your food allergy			0.304	EI
24	The food allergy makes you frustrated			0.511	EI
2	Have to limit yourself in some products		0.414		DR
3	Can't buy food you like	-0.335	0.458		DR
5	Must refuse treats when doing something with other people		0.853		DR
18	Don`t know the taste of food which you can`t try		0.420		DR

* Question number from the original questionnaire.
** Original question formulation in the questionnaire FAQLQ-CF .
***F1 (AA), F2 (RAE), F3 (EI), F4 (DR).
ºSubscales (SS): AA (allergen avoidance), RAE (risk of accidental exposure), EI (emotional impact), DR (dietary restrictions).

The obtained results of the statistical analysis allow us to state that the total Ukrainian FAQLQ-CF have sufficient internal consistency since Cronbach α was 0.73, although the corrected item total correlations were between 0.067-0.67. All subscale DR questions tended to correlate negatively with the total FAQLQ-CF scale, on condition that all questions were included. Subscales AA (Allergen avoidance) and RAE (Risk of accidental exposure) showed good consistency both within the scale and in general (Cronbach α index was 0.86 and 0.81, respectively). For the EI (Emotional impact) subscale, the Cronbach α index was 0.57 with fluctuations in the adjusted correlation "parameter-total" of 0.28-0.53. One this subscale question („How disappointed are you if people have no regard for your food allergy?") had α below 0.3.

However, in the factor analysis on the impact on the dispersion the domination belonged to other groups of questions, during the EI subscale questions selection into a separate group, they revealed good consistency. After the 1 and 12 question excretion from the factor analysis, Cronbach α for the Dietary Restrictions (DR) subscale was 0.61 and the corrected item total correlations were 0.45-0.59 (Table 5).

Table 5
Cronbach's alpha, corrected item-total correlation for FAQLQ-CF (Ukrainian language**)**

Scale/subscale	NoQ	Cronbach's alpha	Corrected item-total correlation
FAQLQ-CF Ukrainian (total scale)	24	0.73	0.067-0.67
Allergen avoidance (AA)	7	0.86	0.44-0.83
Risk of accidental exposure (RAE)	5	0.81	0.59-0.80
Emotional impact (EI)	6	0.57	0.28-0.53
Dietary restrictions (DR)	6 (4)*	0.56 (0.61)	0.18-0.61 (0.45-0.59)

* Number of questions
* *All questions (after the 1 and 12 question exclusion)

4. Discussion

The prevalence of food allergies in children nowadays requires the development of effective preventive and curative interventions. There is no doubt that in the food allergies prophylaxis an important place is given to the exclusion of products to which hypersensitivity has been detected.

At the same time, young patients together with their parents face a number of difficulties related to this straightforward, at first glance, task: safe food obtainment in the retail network, a daily menu planning, eating in organized groups (school, kindergarten), participation in cultural activities, which foresee food consumption (school trips, children's parties), etc. All this beyond question cannot but affect the quality of life of both the patient and his family members. Parents are often disturbed that food allergies may be life-threatening and a source of teasing done by peers. However, children with food allergies may perceive this problem quite differently, and therefore it is necessary to consider first of all the assessment of the patient's quality of life.

In the current context of the COVID-19 pandemic, it is important to limit patient visits to healthcare facilities to the greatest degree, since scheduled visits may increase the risk for infection. At the same time, it is necessary to carry out the remote control over the course of the disease and the effectiveness of the prescribed treatment. In this regard, the introduction of appropriate questionnaires into the practice of allergists, aiming to assess the patient's quality of life, becomes relevant. To date, no food allergy-specific questionnaire has been validated in Ukraine.

The original Food Allergy Quality of Life Questionnaire - Child Form was developed and validated by B. Flokstra-de Blok et al. [15] measures the most important problems that allergy children face with every day, and which can consequently affect their quality of life. In order to preserve the content validity of the original questionnaire, an important task was not only to translate it into Ukrainian, but also to carry out a cultural adaptation.

Construct validity is the degree to which a test measures what it claims and is verified by comparing the implemented questionnaire to the existing independent ones. Comparing the Ukrainian version of FAQLQ-CF to FAIM, which in turn proved its ability to measure a child's perception of the condition severity, statistical analyses revealed the strong positive significant correlation between these two questionnaires total-total ($r=0.81$, $p> 0.05$). In the original study by Flokstra-de Blok et al. the total FAQLQ-CF score correlated significantly with the mean FAIM ($r=0.60$, $p <0.001$). With one question of the six individual FAIM questions (Number of foods one needs to avoid) we did not find a significant correlation as well as Greek researchers who were validating an identical questionnaire in Greek [21]. At the same time, the results of our study showed that each of the FAQLQ-CF subscales significantly correlated with at least one of the six FAIM questions, and therefore we consider the Ukrainian version of FAQLQ-CF suitable to measure the impact of food allergies on a child's quality of life.

The total Ukrainian FAQLQ-CF has sufficient internal consistency since Cronbach α was 0.73. The DR (Dietary Restrictions) subscale, including two questions affecting the internal consistency of FAQLQ-CF, proved to be problematic. Cronbach α for DR was 0.56 and corrected item total correlations 0.18-0.61. Excluding two questions, "Must always watch what you eat" and "Must refuse food when someone offers it at school" solved this problem to some extent, improving both the consistency of this scale ($\alpha = 0.61$) and the overall consistency of the questionnaire.

According to the results of the statistical analysis, the subscale EI (Emotional impact) turned out to be insipid. The average final score value was 2.17 with fluctuations from a minimum of 1.17 to a maximum of 3.33 (e.g. the fluctuation of the final score on the AA subscale was from 0.29 to 4.29). Therefore, low Cronbach's alpha - 0.57 with fluctuations in the adjusted correlation "parameter-total" 0.28-0.53, reflects the poor correlation of the subscale EI. And although this subscale has a clear factorial separation, vagueness of complaints led to mediocre indicators.

Analyzing the results of the study, some statistical inconsistency of separate questions with existing scales can be detected. There are several reasons to explain why these questions did not work in our patients. First, probably these are the features of sample formation. In contrast to the studies of Flokstra-de Blok et al. and Morou et al. [[15], [21]] we did not include children with anaphylaxis for whom dietary restrictions are essential. Patients with mild food allergies have a simpler attitude toward a diet and usually do not refuse if someone treats them, since it does not threaten their lives.

Another important factor is hyper-parenting, caused by parents' fear for the life of an allergic child. The desire to protect the child from all possible risks deprives him or her of the opportunity to make independent choices and independent decisions, which provokes indifference to the surroundings. As an example, a child does not need to pay attention to the inscriptions on the label, because it is done by the parents. Since the questionnaire was filled in during the visit to the doctor, children may have felt anxiety about it, hence the child could not focus on some questions, understand their content, and therefore chose a picture rather than gave a real answer.

Although some questions did not work in our patients, they cannot be removed from the questionnaire because they may be important for the patients with severe food allergies, including anaphylaxis in the medical history.

We did not determine the discriminatory ability of the questionnaire among the children with different levels of life quality, in particular due to the small sample size and the absence of children with severe food reactions.

5. Conclusions

In summary, according to the results of the statistical analysis, the Ukrainian Food Allergy Quality of Life Questionnaire - Child Form is valid and reliable, able to measure the most important problems faced by children with food allergies. Despite the fact that some questions did not work in our sample, a possible explanation for this is the lower severity of the disease in children involved in the study, hence some extent of careless attitude to the risk of accidental consumption and avoidance of allergens in children with food restrictions.

The issues covered by this questionnaire are designed to improve the quality of life of children with food allergies and should be taken into account not only by healthcare professionals and researchers studying food allergies, but also by food manufacturers and regulators (including clear labeling and ingredient list of ready-made products).

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