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Linguistic Ratification and Evaluation of Psychometric Properties of the Specialized FLIP Questionnaire in Russian for Assessing Quality of Life of a Food-Allergic Child's Family Members: the First Results

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Assessment of quality of life of a food-allergic child's family members requires developing special instruments or adapting the existing ones. ***The study was aimed*** *at developing a specialized questionnaire "The Food hypersensitivity family ImPact "(FLIP) in Russian for assessing quality of life a food-allergic child's family members and evaluating its psychometric properties.* ***Methods:*** *linguistic and cultural adaptation of the FLIP questionnaire in Russia involving parents / legal representatives of children with food allergies was performed prospectively. We confirmed reliability and constructive validity of the questionnaire in Russian.* ***Results:*** *polling involved parents / legal representatives of 131 children with food allergies aged 1-18 months. Results of evaluation of the questionnaire's psychometric properties demonstrated an average level of internal consistency of the questionnaire (Cronbach's $\alpha > 0.72$ in different age groups). The questionnaire evaluation results depend on the degree of manifestation of disease symptoms ($p = 0.033$), pharmacotherapy duration ($p = 0.033$), breastfeeding for 6 months or more ($p = 0.033$), time or diet broadening and strictness of elimination diet observation ($p = 0.033$), number of foods eliminated from the diet ($p = 0.010$) and number of diagnostic events ($p = 0.033$). Conclusion: the FLIP questionnaire in Russian was developed; it underwent assessment of psychometric properties. We demonstrated dependence of quality of life of food-allergic children's family members on disease characteristics and therapy effectiveness.*
Keywords: *children, early age, food allergy, quality of life, questionnaire.*

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Rationale

Food allergy in children is a significant socio-economic issue [1]. According to EAACI, the European Academy of Allery and Clinical Immunology, some 17% of European population report manifestations of food allergies over the lifetime [1]. In infants and toddlers, allergies are mostly caused by cow milk protein (CMP). According to ESPGHAN, the European Society for Pediatric Gastroenterology Hepatology and Nutrition, the prevalent of CMP allergy peaks at 2 to 3 percent among infants [2]. Further (by age o 5), 80% of patients develop tolerance; by age of 6, the prevalence of this allergy drops below 1% [2].
According to a number of studies, CMP-allergic children has a far lower quality of life than children with allergy to other foods [3, 4]. The most frequent clinical manifestation of food

allergy is atopic dermatitis; the quality of life of children with moderate-severe and severe clinical manifestations of this disease is far lower than that of children with diabetes, psoriasis, or bronchial asthma [5]. This obviously has a negative effect on the quality of life of the child's family members. As a rule, this "effect" is about socioeconomic restrictions as well as changed in the psychoemotional status of the family members. It should be noted that the severity of the disease in the child does not always correspond to how strongly it affects the family members' quality of life. That is why it is urgent to develop a method to assess how the disease affects the child as well as their family members.

Our research was aimed at developing the Russian version of the Food Hypersensitivity FamiLy ImPact (FLIP) questionnaire, which is targeted at assessing the quality of life of a food-allergic child's family members (referred to as ИВС-ПА in Russian, hereinafter referred to as IVS-PA to distinguish the Russian version from the original FLIP - *translator's note*). Another goal was to assess the psychometric properties of the questionnaire.

Methods

STUDY DESIGN

We have carried out a prospective cohort study with surveying.

FITTING CRITERIA

Inclusion criteria:

- outpatients and inpatients aged 1 to 18 months, with confirmed food allergy diagnosis.

Non-inclusion criteria:

- the child's record mentions anaphylactic responses to foods.

Exclusion criteria:

- parents' or legal representatives' refusal to take part in this study;
- rebuttal of food allergy diagnosis.

RESEARCH CONDITIONS

Research was carried out on the grounds of the consultation and diagnosis center of Research Institute for Preventive Pediatrics and Recovery Treatment of the Scientific Center of Children's Health, Moscow, Russia.

RESEARCH DURATION

Research was carried out from October 2014 till May 2015.

ABOUT THE QUESTIONNAIRE

Within the framework of this study, we developed the Russian version of the specialized questionnaire, FLIP [6]. The questionnaire is designed to assess the quality of life of a food-allergic child's family.

The original version of this questionnaire consists of 19 questions and is designed to assess the quality of life of a family where a child aged 6 months to 7 years is food-allergic. In consultation with Andrea Mikkelsen, the maker of the original questionnaire, we modified questions 4 and 14 for the Russian version, whilst questions 10, 13, 15 were removed and substituted with two questions that are more appropriate for such linguistic and cultural adaptation. Thus, the Russian

version consists of 18 questions that are, like in the original version, divided into 3 groups based on the aspect of life concerned:

- nutrition (Questions 4, 12, 13);
- emotions and health (Questions 6, 7, 9 to 11, 15, 16);
- daily life (Questions 1 to 3, 5, 8, 14, 17, 18).

Responses were evaluated using Likert scales with the following gradation of answers: all the time (7 points); almost all the time (6 points); often (5 points); sometimes (4 points); a little (3 points); almost never (2 points), never (1 point); not relevant (0 points). For a simpler data analysis, we used the arithmetic mean of these grades for all the 3 aspects. Total of 7 points indicated maximum effect; 0 points meant the patient's condition did not affect the family's quality of life at all. For question 16, answers were inverted. Thus, the format, the evaluation, and the transcoding of our questionnaire were identical to those of FLIP [6].
The Russian version of the questionnaire was filled by children's parents or legal representatives. Each participant filled the questionnaire only once, upon a visit to the outpatient hospital.

VALIDATION OF THE QUESTIONNAIRE

Validation of the Russian version of the FLIP consisted of linguistic and cultural adaptation as well as determination of psychometric properties, i.e. reliability and construct validity.

Linguistic and Cultural Adaptation

For the first adaptation stage, the original version of the questionnaire was translated into Russian by two independent native speakers of the Russian language. Further, during the consultation stage, the preliminary version was discussed by an expert panel consisting of a translator who had not translated the document, and a group of pediatricians from the SCCH Laboratory of Social Pediatrics. Their suggestions were taken into account to correct the Russian version of the questionnaire in accordance with the linguistic peculiarities so as to ensure the patient's adequate interpretation of the questions whilst preserving their original sense. The first stage included a reverse Russian to English translation of the preliminary questionnaire. Both Russian and English versions were reviewed again. As a result, we created a test version of the IVS-PA questionnaire.
The questionnaire was adapted by interviewing parents or legal representatives of 52 families, each of which had at least one food-allergic child aged 1 to 18 months. This part of our study was carried out so as to make textual adjustments in case some questions were misunderstood or not understood at all. All the participants were native Russian speakers. They answered all the questions on their own. All the questions were comprehensible and did not cause any trouble. Based on the interviewing results, we concluded there was no need to make corrections in the question texts.
After the questionnaire was adapted for Russians, the author of the original FLIP questionnaire received from us a report in English, where we had specified the total number of respondents, the total time to fill the questionnaire (8 minutes on the average), and the age of patients. We also specified what member of the family was interviewed in each case (the mother in 39 cases, the father in 1 case, both parents in 12 cases). The author then sent to us an instruction on how to transcode the answers. He also approved the IVS-PA questionnaire (Russian version) for use, see the Appendix.

Psychometric Properties of the Questionnaire

When testing this [1]tool for reliability, we studied its internal consistency by calculating Cronbach α. The reliability of the questionnaire was deemed satisfactory if Cronbach α equaled or exceeded 0.7 [7].
Construct validity[2] was determined using the "known groups" method[3]. We formulated a number of hypotheses on how the quality of life indicators depended on: 1) the severity of clinical manifestations of food allergy, 2) the type of feeding, 3) the duration of the elimination diet and how strictly the child adhered to it, 4) the parents' compliance with doctoral recommendations. The latter was assessed with the doctor's assistance after the prescribed treatment was over. We also took into account the number of diagnostic tests and other diagnostic events that involved check-ups by specialists in dietetics, allergology, immunology, and dermatology. Results of laboratory and instrumental studies were drawn into consideration was well.

ADDITIONAL DATA

Food allergy was diagnosed in accordance with the EAACI Recommendations on Food Allergy and Anaphylaxis on the basis of allergy record, the clinical picture of the diseases, sIgE test results (per UniCAP), and dietetic diagnosis [1]. The intensity of atopic dermatitis in children was assessed per SCORAD [8]. To assess the severity of gastrointestinal symptoms, we used CoMiSS, a tool designed for assessing CMP allergy symptoms in infants and toddlers [9]. We assessed how much time children cried or whined during a day, how frequently and how much they posseted; we also analyzed the frequency and quality of stool per the Bristol stool scale. Each of these CoMiSS parameters was evaluated and assigned a score of 0 to 6 points. The final assessments were grouped together per the following criteria: 0 to 6 points total stood for mild gastrointestinal manifestations; 7 to 12 stood for moderate-severe manifestations; 13 to 18 stood for severe manifestations.

ETHICAL EXPERTISE.

Since this research did not imply an analysis of experimental medical intervention, it did not require parents' or legal representatives' informed consent for enrollment. Questioning was voluntary. The research protocol was approved by the Local Committee for Ethics of Sechenov Moscow State Medical University, no. 27 dd. November 26th, 2013.

STATISTICAL ANALYSIS

Sample size was not calculated preliminarily. Data were processed using STATISTICA v. 6.0 by StatSoft Inc., USA. Quantitative data are described with reference to the median (25^{th} and 75^{th} percentile). We calculated Spearman rho correlation coefficient (r), Cronbach α was used to assess the internal consistency of the questionnaire. Difference in values and/or the values themselves were considered significant if $p < 0.05$.

Results

STUDY ENROLLMENT

[1]**Reliability of a questionnaire is its ability to return consistent and accurate measurements [7].**

[2]**Validity of a questionnaire is its ability to make accurate measurements of the primary parameter that it is designed to measure [7]. Construct validity has to be determined so that you can find out whether the construction of the questionnaire allows for accurate measurements of what it is designed to measure.**

[3]**When assessing the construct validity by the "known groups" method, all the participants are divided into groups based on whether they have or do not have a certain factor. Then the research makes a maximum likelihood assumption on how this factor will be distributed and analyzies the interrelations of parameters depending on this factor [7].**

We have surveyed the parents or legal representatives of 131 food-allergic children aged 1 to 18 months, with median age of 8 months (3; 18). The person to survey was the mother in 93 cases (71.0%), the father in 2 cases (1.5%), both parents in 36 cases (27.5%). Table 1 describes the leading pathology in differently-aged food-allergic children. 62 children (47.3%) had cutaneous manifestations, 61 (46.7%) had both cutaneous gastrointestinal manifestations, and 8 children (6.1%) had isolated gastrointestinal manifestations.

Speaking of patients with atopic dermatitis, more than a half of them (67, or 54.5%) had mild symptoms (less than 20 SCORAD points); 46, or 37.4%, had moderate-severe symptoms (20 to 60 SCORAD points), and 10, or 8.1%, had severe manifestations (more than 60 points). As for children with gastrointestinal symptoms of food allergy, 36 children (52.2%) had mild symptoms (less than 6 points per CoMiSS), 25 (36.2%) had moderate symptoms (7 to 12 points), 8 (11.6%) had severe symptoms (13 to 18 POINTS).

Table 1. Clinical Characteristics of Food-Allergic Children Under Study

Nature of Clinical Symptoms	Age (in months)		
	1–6 (*n* = 59)	7–12 (*n* = 41)	13–18 (*n* = 31)
Cutaneous manifestations of allergy (atopic dermatitis L 20; food-triggered dermatitis L 27.2), abs. (%)	23 (17.5)	20 (15.7)	19 (14.5)
Cutaneous and gastrointestinal manifestations (L 20, L 27.2, K 52.2), abs. (%)	31 (23.7)	18 (13.7)	12 (9.2)
Gastrointestinal manifestations (allergic and alimentary gastroenteritis and colitis K 52.2), abs. (%)	5 (3.8)	3 (2.3)	0

70 children (53.4%) were breastfed at least until the age of 6 months; 27 (20.6%) received both formulas and breastfeeding; 34 (26%) were bottle-fed exclusively. In most (107, or 81.7%) children, the first food allergy symptoms manifested during the infancy (until the age of 12 months); in half of all cases (63, or 48.1%), they manifested during the first 6 months of life.

We analyzed the etiological structure of food allergies in children under research and found out that all the patients had allergy to CMP and its fractions. 26 children, or 19.8%, had food allergy to chicken eggs; 43, or 32.8%, had allergy to two or more allergens.

We also analyzed the duration of pharmacotherapy of food allergies and found out that for the preceding 3 months, 42 children (32%) had received no permanent drug therapy; 69 (52.7%) had been treated for less than a month; 14 (10.7%) had been treated for a month to two; 6 (4.6%) had been exposed to nearly permanent pharmacotherapy.

By the beginning of our research, 5 patients (3.8%) had been on the elimination diet for a month or less; 4 (3%) for three months; 52 (39.7%) for six months; 70 children (53.4%) had been on such diet for more than six months. 39, or 29.8% children (or lactating mothers) adhered to the diet strictly; 54, or 41.2%, abided by the diet with rare deviations; 34, or 26%, abided partially.

We analyzed the parents' compliance and found out that in 12 (9.2%) cases doctoral instructions were followed strictly; in 54 (41.2%) cases, they were followed with rare deviations; and there were 65 (49.6%) cases of complete non-compliance.

SURVEY RESULTS

This study collected had 131 participants from 131 families answer the questionnaire. No question was skipped, which means that the questions are not difficult to understand. Table 2 presents averaged statistical values we obtained using the IVS-PA questionnaire.

Table 2. IVS-PA used to assess the quality of life of food-allergic children's family members: the assessment results

Parameter	Points on average	Dispersion of scores, min-max
Total IVS-PA score	3.04 (1.38; 4.12)	1 to 5.52
Nutrition scale	3.51 (1.40; 4.36)	1.25 to 5.75
Emotions and health scale	2.74 (1.10; 4.01)	0.88 to 5.13
Daily life scale	3.24 (0.90; 4.47)	0.7 to 5.86

EVALUATION OF RELIABILITY AND CONSTRUCT VALIDITY OF THE QUESTIONNAIRE

The reliability of questionnaire (Cronbach α) when filled by parents / legal representatives of children aged 6 months or less (n = 59) was 0.72; for parents / representatives of children aged 7 to 12 months (n = 42), it was 0.78; for the group aged 13 to 18 months13–18 (n = 30), it was 0.83. That being said, the questionnaire offers a satisfactory reliability.

When determining the construct validity of the IVS-PA questionnaire, we found out that the quality of life of food-allergic children's family members was associated with the intensity of clinical manifestations, the duration of pharmacotherapy of food allergy, the duration and strictness of the elimination diet in the child and/or the mother; the duration of breastfeeding, the number of foods excluded from the child's and /or the mother's nutrition, the number of diagnostic events, and the parents' compliance (Table 3).

Table 3. How IVS-PA Values of Researched Parameters Correlate: Results of Analysis

Parameter	*r**	*p*
Age	-0.16	0.150
Strictness of adherence to diet	0.47	0.033
Severety of clinical manifestations of food allergy	0.68	0.010
Duration of pharmacotherapy	0.60	0.010
Breastfed or not?	0.51	0.033
Diet expansion timeline	0.32	0.033
Number of excluded foods	0.57	0.010
Number of diagnostic events in the record	0.34	0.033
Parental compliance	-0.23	0.05

Note. * r is Spearman rho correlation coefficient

Discussion

Allergic diseases have a significant social impact on the patient and his or her family members. This is particularly true for allergic diseases in childhood. For instance, one of the recent studies of allergic impact on the child's behavior showed that the allergic pathology is associated with anxiety, depression, and disturbance. The study enrolled children aged 4 to 7 years [11]. It was also shown that behavioral disorders are associated with the number of allergies in children aged 4. This allows suggesting that allergic diseases can affect not only the child's psychoemotional status, but also their family members' quality of life. This is why researching both the patient's and their family members quality of life is still a topical pediatric problem.

This study was aimed at creating the Russian version of FLIP, a questionnaire for assessing the quality of life of a food-allergic child's family members. It is shown that the Russian version of the questionnaire has a satisfactory reliability of 0.72 to 0.83. IVS-PA values were found to be dependent on the intensity of clinical manifestations of food allergies in children, the duration of pharmacotherapy, the elimination diet and how strictly it was adhered to, the number of foods excluded from the diet, and for how the child had been breastfed.

The original FLIP questionnaire features better reliability (0.95) and shows a great effect of food allergy on different life aspects of an allergic child's family [6]. It is most likely that the lower reliability of the Russian version is due to the specificities of linguistic and cultural adaptation.
From a practical point of view, the most significant parameters are the duration of the elimination diet and consequently, the time when the food-allergic child develops tolerance. So, a prospective monitoring of dynamic FLIP values for CMP-allergic children helped find out that family members assess their quality of life differently depending on whether the child manages to develop food tolerance over the six-month course of research [12]. Our research has identified the statistically significant correlation of IVS-PA values to the duration of the elimination diet, which reflects the tolerance development, as a strict elimination diet is only needed where the child cannot develop food tolerance to cause-significant allergens.
The assessment of the psychometric properties of the IVS-PA questionnaire shows, albeit indirectly, that food allergy has a negative impact on the quality of life of the child's family member, mostly because of the socioeconomic restrictions that it imposes. The results we obtained will probably help correct the currently employed strategies of food-allergic patient management so as to reduce the negative socioeconomic impact of food allergies on the families of children with this pathology. That is why the Russian version of our making requires further validation.

RESEARCH LIMITATIONS

This paper only presents the first results of validation of the Russian-language FLIP. That is why the analysis of the psychometric properties of the IVS-PA questionnaire was limited to construct validity and reliability. Besides, this research was not representative, a factor that might have affected the results. Research results are extrapolated to all the family members of food-allergic children. However, the questionnaire was mostly filled by mothers. Comparability of the food-allergic child's impact on the quality of life of other family members (in particular, the father) is something that requires further research. The results of our research on the correlation of IVS-PA values to a number of the child's disease parameters and disease-related factors do require a multifactor analysis so as to identify the independent predictors of life quality of food-allergic children's family members.

Conclusion

The IVS-PA questionnaire we have developed has shown mid-level internal consistency. We have found out that the questioning data are affected by most of the parameters under research; the severity of clinical manifestations of food allergy, the duration of pharmacotherapy, and the adherence to breastfeeding are the factors to have the strongest impact on the values the questionnaire returns. The tool we have developed to assess the quality of life of food-allergic children's family members, IVS-PA, can become a useful addition to the existing tools for assessing the quality of life of the patient's family as well as the efficiency of treatment.

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Conflict of Interest

The authors declared they have no competing interests to disclose.

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Appendix IVS-PA questionnaire: index of food-allergic child's impact on family

Questions and answers
1. If you and your family were planning a holiday/vacation, how much would your choice be limited by your child's food hypersensitivity?
2. If you and your family were planning to go to a restaurant, how much would your choice be limited by your child's food hypersensitivity?
3. Do you limit your participation in public events involving food because of your child's food hypersensitivity?
POSSIBLE ANSWERS (Questions 1 to 3): extremely limited, very limited, quite limited, moderately limited, somewhat limited, hardly limited, not limited, not relevant.
4. How often do you have difficulties explaining your family members that your child and/or you (if you are a lactating mother) SHOULD NOT eat some foods?
5. In the past month, how often have you been troubled by your need to spend extra time preparing meals (i.e. label reading, extra time shopping, cooking extra meals, etc.) due to your child's food hypersensitivity?
6. In the past month, how often have you been worried that your child will have a reaction due to the food hypersensitivity?
7. In the past month, how worried have you been that your child may not outgrow the food hypersensitivity?
8. In the past month, how often have you felt unsafe when leaving your child at the kindergarten/babysitter because of the food hypersensitivity?
9. In the past month, how often have you had difficulties making others appreciate the importance of avoiding the food items your child does not tolerate?
10. In the past month, how often have you felt sad because of your child's food hypersensitivity?
11. In the past month, how often have you felt worried that your child will not have a normal upbringing because of the food hypersensitivity?
12. In the past month, how often have you been able to make your child's or your diet (if you are a lactating mother) more diverse?
13. In the past month, how often have you felt concerned about the nutritional content in your child's diet?
14. In the past month, how troubled have you been about increased costs of food for your child?*
15. In the past month, how troubled have you been by comments from others concerning your child's food hypersensitivity?
16. In the past month, how often have you experienced that your child is happy and satisfied?
17. How often do you have to impose dietary restrictions on the entire family because of your child's food hypersensitivity?
18. In the last month, how often have you felt worried your child (or you, if you are a lactating mother) might eat allergenic foods?
POSSIBLE ANSWERS (Questions 4 to18): all the time, almost all the time, often, sometimes, a little, almost never, never, not relevant.

Note. * signifies questions that were added to the questionnaire for linguistic and cultural adaptation.

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