

Original article

Development and validation of the Food Allergy Quality of Life Questionnaire – Adult Form

Background: Health-related quality of life (HRQL) may be affected by food allergy. Presently, no disease-specific HRQL questionnaire exists for food allergic adults. Therefore, we developed and validated the Food Allergy Quality of Life Questionnaire – Adult Form (FAQLQ-AF) in the Dutch language.

Methods: Twenty-two food allergic patients (≥ 18 years) were interviewed and generated 180 HRQL items. The most important items were identified by 54 food allergic patients using the clinical impact method resulting in the FAQLQ-AF containing 29 items (score range 1 'not troubled' to 7 'extremely troubled'). The FAQLQ-AF, the Food Allergy Independent Measure (FAIM) and a generic HRQL questionnaire (RAND-36) were sent to 100 other food allergic adults for cross-sectional validation of the FAQLQ-AF.

Results: Cross-sectional validity was assessed by the correlation between FAQLQ-AF and FAIM ($\rho = 0.76$, $P < 0.001$). The FAQLQ-AF had excellent internal consistency (Cronbach's $\alpha = 0.97$). The FAQLQ-AF discriminated between patients who differ in severity of symptoms (anaphylaxis vs no anaphylaxis, total FAQLQ-AF score 4.9 vs 4.1; $P = 0.041$) and number of food allergies (> 3 food allergies vs ≤ 3 food allergies, total FAQLQ-AF score 5.2 vs 4.2; $P = 0.008$). The total FAQLQ-AF score was correlated with one RAND-36 scale (convergent/discriminant validity).

Conclusions: The FAQLQ-AF is the first disease-specific HRQL questionnaire for food allergic adults and reflects the most important issues that food allergic patients have to face. The questionnaire is valid, reliable and discriminates between patients with different disease characteristics. The FAQLQ-AF is short and easy to use and may therefore be a useful tool in clinical research.

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Food plays an important role in our social and cultural life. In patients with food allergy, the ingestion of a particular food may provoke an allergic reaction, which may be fatal for some patients (1–3). The only proven form of treatment is strict avoidance of the food(s) involved and medications for emergency treatment (4). Food allergic patients thus need to be continuously alert as to what they are eating in numerous situations and settings. Consequently, daily life of these patients may be seriously disrupted by the required continuous vigilance, the threat of accidental exposure and fear of an allergic reaction and this may have a negative impact on their quality of life.

A few studies have investigated the impact of food allergy on health-related quality of life (HRQL) (5–11), but all these studies investigated children or adolescents

with food allergy or parents with a food allergic child. Only one study investigated HRQL in adults with food allergy and reported that daily life was significantly more disrupted in peanut allergic adults than in adults with a rheumatological disease (12). However, in that study, a generic HRQL questionnaire was used, which may be not as sensitive as a disease-specific HRQL questionnaire (13). At present, no validated food-allergy-specific HRQL questionnaire exists for use in adults.

Therefore, we here report the development and cross-sectional validation of the first disease-specific HRQL questionnaire for adults with food allergy, the Food Allergy Quality of Life Questionnaire-Adult Form (FAQLQ-AF). This questionnaire is the last HRQL questionnaire in a series of questionnaires developed in the EuroPrevall project, a European multi-centre research

project on food allergy, to cover all age groups of patients with food allergy. It complements the recently developed FAQLQ-PF for parents of food allergic children aged 0–12 years and the two self-administered questionnaires; the FAQLQ-CF for children aged 8–12 years and the FAQLQ-TF for adolescents aged 13–17 years (14–16).

Methods

Participants and procedure

During all stages of questionnaire development, only patients 18 years or older with a physician-diagnosed food allergy were included. All common food allergies and different types and severities of symptoms were represented. Patients with only oral allergy syndrome were excluded. During the item generation, patients were recruited only from our outpatient allergy clinic. During the item reduction and cross-sectional validation, patients were recruited when attending our outpatient allergy clinic or recruited through food allergy support organizations (the Dutch Foundation for Food Allergy and the Dutch Anaphylaxis Network) and by advertisement in local news papers.

Before the cross-sectional validation, the questionnaire was pretested in three patients. No major problems emerged during this pretest. Thereafter, the FAQLQ-AF, the Food Allergy Independent Measure (FAIM) and the RAND-36, a generic quality of life questionnaire, were sent to 100 food allergic patients by post. These questionnaires are described in more detail later on. A subset of these patients were previously asked to participate in the item generation ($n = 20$) or item reduction phase ($n = 59$), but were eligible to participate in the validation process as it is independent of the development phase. Descriptive characteristics were elicited regarding age, gender, type and number of food allergies, type of symptoms and diagnosis. For the patients recruited from our clinic, we checked the patient records to determine whether or not the food allergy was diagnosed by a double-blind placebo-controlled food challenge (DBPCFC).

This study was approved by the local medical ethics review commission (METc 2005/051) who deemed that permission from the commission was not required, as this study does not fall under the Medical Research Involving Human Subjects Act.

Development

Item generation. The development and validation of the FAQLQ-AF was based on the methodology used for the development and validation of the FAQLQ-CF and FAQLQ-TF (15, 16). Potential items for the new adult questionnaire were generated by interviewing 22 food allergic patients, reviewing literature and consulting expert opinion. This procedure resulted in an 'extended item questionnaire' of 180 items.

Item reduction. The clinical impact method was used for identifying the most important items of the extended item list (17, 18). The 'extended item questionnaire' was sent to a different group of 63 food allergic patients, who were asked to indicate the importance to them of each applicable item, rated on a 5-point scale. The overall importance (OI) of each item was calculated by multiplying the frequency with which an item was identified as being important (%) with the mean importance using the 5-point scale. The maximal possible OI was 5.0 (19, 20). The items with the greatest OI were selected for the FAQLQ-AF, except one of any pair of items with

overlapping content (face validity) and/or an inter-item correlation > 0.85 . The selected items were worded as questions with a 7-point response scale (ranging from 'not troubled' to 'extremely troubled') (18, 20). A psychologist and a linguist reviewed the FAQLQ-AF for clarity and ease of use.

Cross-sectional validation

Construct validity. Construct validity is usually evaluated by comparing the HRQL questionnaire with an objective measurement of the extent or severity of the disease. However, in disorders not characterized by chronic symptoms, as in food allergy, such an independent measure (IM) is not available. It has been shown that the perceived expectation of what will happen following exposure can be used as an IM to evaluate construct validity and instruments developed in this way have proved to be useful and consistent in measuring HRQL (8, 14–16, 20, 21). Therefore, to investigate construct validity of the FAQLQ-AF, correlation coefficients were calculated for the FAQLQ-AF with the FAIM. The FAIM, which has previously been used to validate the FAQLQ-PF, -CF and -TF (14–16), contains four expectation of outcome (EO) questions (8, 20, 21) and two additional IM questions (15, 16). The EO questions are based on the perceived expectation of patients of what will happen following exposure, which is likely to be a driving force of quality of life (21). The IM questions are based on the same principle and query about the perceived number of foods one needs to avoid and perceived impact on social life. We expected moderate correlation coefficients (0.40–0.60) (22) for the FAQLQ-AF with the FAIM. The validation of the FAQLQ-AF was carried out in the Dutch language. The Dutch FAQLQ-AF and the FAIM were translated into English following the guidelines of the World Health Organization (23). The English version of the FAQLQ-AF and the FAIM may be found as Appendices S1 and S2.

Convergent and discriminant validity. Additionally, construct validity was further investigated by convergent and discriminant validity. To investigate convergent and discriminant validity, a generic HRQL questionnaire was administered, the RAND-36 (24). This health profile measure is the Dutch version of the MOS 36-item Short-Form Health Survey (SF-36) (25) and consists of 36 items divided into nine scales: physical functioning, social functioning, role functioning-physical, role functioning-emotional, mental health, vitality, bodily pain, general health and change in health (single item). Because the FAQLQ-AF is a disease-specific questionnaire and the RAND-36 a generic questionnaire, we expected no to weak correlations (0.20–0.40) for the total FAQLQ-AF score with the RAND-36 scales (i.e. discriminant validity). When looking at the FAQLQ-AF domains, we expected that food allergy related health (FAH) would correlate better with the RAND-36 scales than the other FAQLQ-AF domains, as this is the most 'generic' FAQLQ-AF domain (i.e. convergent validity).

Discriminative ability. To investigate the discriminative ability of the FAQLQ-AF, we compared the total FAQLQ-AF score of patients who reported anaphylaxis (i.e. two or more of the following cardiovascular symptoms: dizziness, palpitations, loss of vision, inability to stand, light headedness, collapse, loss of consciousness) vs patients who did not, for men vs women, for patients who were recruited from our clinic vs patients who were recruited by advertisement and for patients who reported many food allergies vs patients who reported few food allergies. We investigated which cut off in number of reported food allergies revealed a significant difference in the total FAQLQ-AF score.

Reliability. The test–retest reliability of the FAQLQ-AF was assessed by administering the questionnaire to 36 patients on two occasions 10–14 days apart.

Statistical analyses

The raw FAQLQ-AF and FAIM scores 0–6 were recoded as 1–7. The total FAQLQ-AF score is the mean score of all items with a range of 1 ‘no impairment’ to 7 ‘maximal impairment’. Cross-sectional validity was assessed by calculating Spearman’s correlation coefficients between the FAQLQ-AF and the FAIM (individual FAQLQ-AF items with individual FAIM items, individual FAQLQ-AF items with mean FAIM, total FAQLQ-AF score with mean FAIM and total FAQLQ-AF score with individual FAIM items). Domains were created by performing factor analysis (principal component analysis with Varimax rotation) (26) and face validity determined by a clinical expert panel (BMJFdB, JNGOE and AEJD) (27). The internal consistency was measured by calculating Cronbach’s α . An $\alpha > 0.70$ indicates good internal consistency (28). Convergent and discriminant validity was assessed by calculating Spearman’s correlation coefficients between the FAQLQ-AF and the RAND-36 scales. The discriminative ability was measured by using the Mann–Whitney test. The test–retest reliability was assessed by calculating the intraclass correlation

coefficient of the repeated FAQLQ-AF measurement (29). Statistical analyses were performed with SPSS for Windows 14.0 (SPSS Inc., Chicago, IL, USA).

Results

Development

Descriptive characteristics of the patients involved in the item generation and item reduction are shown in Table 1. The ‘extended item questionnaire’ was returned by 54 of the 63 adults (response rate 86%). The OI scores of all 180 items of the extended item list ranged from 0.00 to 3.19. The item reduction resulted in the selection of 29 items (OI ≥ 1.61) for the FAQLQ-AF (Table 2).

Cross-sectional validation

Participants. The FAQLQ-AF with the FAIM and the RAND-36 were returned by 80 of the 100 adults (response rate 80%). The questionnaire of one patient was excluded from the analysis because no current food allergies were reported and the questionnaires of seven patients were excluded because no physician-diagnosed food allergy was reported. Thus, 72 questionnaires were assessable for the cross-sectional validation. Forty-two patients (58%) were recruited from our clinic of which 11 (15%) had a food allergy confirmed by a DBPCFC and three (4%) with an open food challenge (OFC). The other patients from our clinic had a physician-diagnosed food allergy with a positive history and positive skin prick and/or blood test. All patients recruited by advertisement (42%) reported physician-diagnosed food allergies. Descriptive characteristics of the patients involved in the cross-sectional validation are shown in Table 1. There were no significant differences in descriptive characteristics between men and women (not shown). Patients who were recruited by advertisement reported significantly more food allergies than patients who were recruited from our clinic ($P = 0.001$). Patients with a DBPCFC or OFC diagnosis reported significantly fewer food allergies ($P = 0.046$) and reported significantly more severe symptoms ($P = 0.046$) than patients with a physician-diagnosed food allergy.

Construct validity. All items of the FAQLQ-AF correlated significantly with at least one of the FAIM questions and all items correlated significantly with the mean of the FAIM questions. Therefore, all 29 selected items were included in the final version of the validated FAQLQ-AF. The total FAQLQ-AF score correlated significantly with the mean FAIM ($\rho = 0.76$, $P < 0.001$) and with the individual FAIM questions (Table 3). The correlation coefficients for the FAQLQ-AF with the FAIM were the same for patients with a food allergy diagnosed by DBPCFC or OFC and patients with a

Table 1. Descriptive characteristics of the patients involved in the item generation, item reduction and cross-sectional validation

	Item generation	Item reduction	Cross-sectional validation
Patients (<i>n</i>)	22	54	72
Gender (m/f)	6/16	20/34	18/54
Age, mean in years (SD)	36.4 (16.5)	39.1 (16.4)	37.2 (14.3)
Food allergy, <i>n</i> (%)			
Peanut	10 (45)	32 (59)	42 (58)
Tree nuts	6 (27)	36 (67)	42 (58)
Egg	4 (18)	13 (24)	16 (22)
Milk	6 (27)	17 (32)	19 (26)
Fish	3 (14)	9 (17)	11 (15)
Shell fish	2 (9)	16 (30)	12 (17)
Wheat	4 (18)	14 (26)	12 (17)
Sesame	3 (14)	12 (22)	13 (18)
Soy	2 (9)	14 (26)	13 (18)
Celery	3 (14)	10 (19)	11 (15)
Number of food allergies, <i>n</i> (%)			
1 food	7 (32)	11 (20)	21 (29)
2 foods	4 (18)	10 (19)	19 (26)
3 foods	5 (23)	15 (28)	14 (19)
>3 foods	6 (27)	18 (33)	18 (25)
Type of symptoms, <i>n</i> (%)			
Cardiovascular*	6 (27)	20 (37)	32 (44)
Respiratory tract†	7 (32)	21 (39)	29 (40)
Gastrointestinal tract‡	7 (32)	5 (9)	4 (6)
Skin§	2 (9)	8 (15)	4 (6)
Other¶	0	0	3 (4)

*Dizziness, feeling your heartbeat fast, loss of vision, inability to stand, light headedness, collapse, loss of consciousness/passing out.

†Tightening throat, difficulty swallowing, hoarseness/hoarse voice, difficulty breathing in, shortness of breath, wheezing, cough.

‡Sick to your stomach, stomach cramps, vomiting, diarrhoea.

§Itchy skin, red rash, hives, worsening eczema, swelling of the skin.

¶Oral allergy, swollen tongue or lips, symptoms of the nose or eyes.

Table 2. Selected items for Food Allergy Quality of Life Questionnaire–Adult Form (FAQLQ-AF)

Item	%	MI	OI
Always be alert as to what you are eating	89	3.58	3.19
Change of ingredients of a product	80	3.91	3.11
Able to eat fewer products	96	3.21	3.09
Limited as to the products you can buy	87	3.36	2.93
Frightened of an allergic reaction	81	3.48	2.83
Labels are incomplete	65	3.94	2.56
Feel discouraged during an allergic reaction	69	3.70	2.54
Having to read labels	94	2.65	2.50
Frightened of accidentally eating the wrong food	69	3.62	2.48
Hesitate eating a product when you have doubts about it	91	2.73	2.48
Troublesome for your host or hostess should you have an allergic reaction	67	3.64	2.43
Have the feeling that you have less control of what you eat when eating out	72	3.31	2.39
Apprehensive about eating something you have never eaten before	69	3.38	2.31
Refuse many things during social activities	69	3.24	2.22
The lettering on labels is too small	61	3.61	2.20
Less able to accept spontaneously an invitation to stay for a meal	57	3.77	2.17
Worried that the allergic reactions to foods will become increasingly severe	57	3.65	2.09
Less able to taste or try various products when eating out	72	2.79	2.02
Sometimes frustrate people when they are making an effort to accommodate your food allergy	54	3.72	2.00
People underestimate your problems caused by food allergy	72	2.72	1.96
Label states: 'May contain (traces of)...'	48	3.96	1.91
Unclear to which foods you are allergic	46	4.00	1.85
Frightened of an allergic reaction when eating out despite the fact that your dietary restrictions have been discussed beforehand	59	3.09	1.83
Worried about your health	54	3.21	1.72
Ingredients are different in other countries (e.g. during vacation)	50	3.41	1.70
Eating out less often	44	3.79	1.69
Have to explain to those around you that you have a food allergy	91	1.86	1.69
Check personally whether you can eat something when eating out	67	2.42	1.61
Feel you are being a nuisance because you have a food allergy when eating out	48	3.35	1.61

MI, mean importance; OI, overall importance.

physician-diagnosed food allergy (total FAQLQ-AF score with the mean FAIM, $\rho = 0.78$, $P = 0.001$ and $\rho = 0.78$, $P < 0.001$, respectively). These results support the construct validity of the FAQLQ-AF, i.e. the FAQLQ-AF is measuring quality of life that is affected by food allergy.

Domain structure and internal consistency. Factor analysis (principal component analysis) was performed on the

29 items of the FAQLQ-AF and revealed five components with eigenvalues > 1 . To aid in the interpretation of these components, Varimax rotation was performed for 5, 4 and 3 factors. An expert panel reviewed these groupings and based on face validity the grouping of four domains made the most sense. This grouping revealed the following domains: allergen avoidance and dietary restrictions, emotional impact, risk of accidental exposure and FAH. All factors showed a number of strong loadings and were > 0.300 which is regarded as an acceptable criterion (26). Based on face validity, the expert panel allocated a few items to a more appropriate domain. The FAQLQ-AF and the domains had excellent internal consistency which is shown by the Cronbach's α that are all exceeding 0.70 (Table 3).

Convergent and discriminant validity. The total FAQLQ-AF score was weakly correlated with one RAND-36 scale (mental health) and the correlations with the other RAND-36 scales were not significant (Table 4). Given the fact that the FAQLQ-AF is a disease-specific questionnaire, whereas the RAND-36 is a generic questionnaire, these results were expected (discriminant validity). The domains of the FAQLQ-AF showed weak correlation with a few RAND-36 scales. As expected, most correlations with the RAND-36 scales were found for the domain FAH, as this is the most general domain of the disease-specific FAQLQ-AF (convergent validity).

Discriminative ability. Patients who reported anaphylaxis (i.e. cardiovascular symptoms) reported a significantly more impaired HRQL than patients who did not report anaphylaxis (total FAQLQ-AF score 4.9 vs 4.1; $P = 0.041$). In addition, the total FAQLQ-AF score of patients who reported more than three food allergies was significantly higher, indicating more impairment in HRQL, than patients who reported three or less food allergies (5.2 vs 4.2; $P = 0.008$). The impairment of HRQL did not differ significantly between men and women (total FAQLQ-AF score 4.1 vs 4.6; $P = 0.060$) and did not differ significantly between patients who were recruited by advertisement and patients who were recruited from our clinic (4.8 vs 4.2; $P = 0.054$).

Reliability. The total FAQLQ-AF score intraclass correlation coefficient was 0.95 (95% CI: 0.91–0.98), indicating excellent test–retest reliability.

Discussion

We here report the development and cross-sectional validation of the first disease-specific HRQL questionnaire for adults with food allergy, the FAQLQ-AF. Our analysis showed that the FAQLQ-AF has good construct validity (Table 3) and excellent internal consistency. In addition, the FAQLQ-AF discriminates

Table 3. Spearman's correlation coefficients for the FAQLQ-AF with the FAIM and internal consistency (Cronbach's α) of the FAQLQ-AF

	FAIM							α
	EO1	EO2	EO3	EO4	IM1	IM2	Mean	
Total FAQLQ-AF score	0.54	0.59	0.49	0.75	0.56	0.56	0.76	0.97
Allergen avoidance and dietary restrictions (AADR)								0.95
Eating out less often	0.29	0.56	0.40	0.53	0.49	0.48	0.60	
Limited as to the products you can buy	0.38	0.35	0.22	0.56	0.68	0.62	0.56	
Check personally whether you can eat something when eating out	0.39	0.45	0.32	0.75	0.53	0.51	0.57	
Able to eat fewer products	0.25	0.18	0.08	0.49	0.67	0.60	0.40	
Less able to taste or try various products when eating out	0.27	0.45	0.26	0.70	0.45	0.48	0.51	
Having to read labels	0.35	0.51	0.40	0.63	0.27	0.29	0.48	
Always be alert as to what you are eating	0.38	0.45	0.36	0.54	0.52	0.48	0.57	
Hesitate eating a product when you have doubts about it	0.44	0.43	0.30	0.78	0.30	0.29	0.48	
Refuse many things during social activities*	0.37	0.40	0.35	0.54	0.48	0.40	0.55	
Less able to accept spontaneously an invitation to stay for a meal*	0.28	0.35	0.25	0.57	0.62	0.52	0.51	
Having to explain to those around you that you have a food allergy*	0.38	0.28	0.23	0.66	0.49	0.52	0.51	
Emotional impact (EI)								0.90
Frightened of accidentally eating the wrong food	0.42	0.58	0.53	0.77	0.22	0.23	0.61	
Frightened of an allergic reaction	0.33	0.55	0.45	0.75	0.08	0.16	0.49	
Frightened of an allergic reaction when eating out despite the fact that your dietary restrictions have been discussed beforehand	0.39	0.54	0.53	0.83	0.29	0.35	0.60	
Apprehensive about eating something you have never eaten before	0.34	0.57	0.37	0.59	0.25	0.34	0.55	
Feel discouraged during an allergic reaction	0.29	0.32	0.32	0.64	0.15	0.17	0.37	
Have the feeling that you have less control of what you eat when eating out†	0.45	0.58	0.49	0.68	0.47	0.47	0.68	
Feel you are being a nuisance because you have a food allergy when eating out†	0.42	0.38	0.34	0.51	0.49	0.50	0.59	
Risk of accidental exposure (RAE)								0.88
Sometimes frustrate people when they are making an effort to accommodate your food allergy	0.33	0.36	0.28	0.50	0.55	0.46	0.54	
People underestimate your problems caused by food allergy	0.40	0.33	0.28	0.45	0.30	0.39	0.47	
Change of ingredients of a product‡	0.35	0.44	0.41	0.44	0.53	0.48	0.62	
Labels are incomplete‡	0.37	0.42	0.27	0.44	0.36	0.39	0.50	
Ingredients are different in other countries (e.g. during vacation)‡	0.29	0.25	0.22	0.77	0.50	0.38	0.41	
Label states: 'May contain (traces of)...'§	0.30	0.33	0.23	0.69	0.23	0.30	0.34	
Troublesome for your host or hostess should you have an allergic reaction§	0.38	0.45	0.48	0.63	0.15	0.29	0.53	
The lettering on labels is too small§	0.35	0.23	0.27	0.55	0.04	0.14	0.30	
Food allergy related health (FAH)								0.77
Worried about your health	0.52	0.38	0.28	0.54	0.37	0.37	0.55	
Unclear to which foods you are allergic	0.36	0.20	0.23	0.28	0.45	0.48	0.43	
Worried that the allergic reactions to foods will become increasingly severe	0.54	0.35	0.34	0.51	0.27	0.47	0.59	

The values given in bold are $P < 0.05$.

FAQLQ-AF, Food Allergy Quality of Life Questionnaire-Adult Form; FAIM, Food Allergy Independent Measure; EO1, chance of accidental exposure; EO2, chance of severe reaction when accidentally exposed; EO3, chance of dying when accidentally exposed; EO4, chance of not acting effectively when accidentally exposed; IM1, number of foods one needs to avoid; IM2, impact of food allergy on social life.

Based on face validity, the expert panel allocated:

*Items from RAE to AADR.

†Items from AADR to EI.

‡Items from AADR to RAE.

§Items from 5th factor to RAE.

between patients with and without anaphylaxis and between patients who differ in the number of food allergies. Finally, the FAQLQ-AF showed convergent/discriminant validity (Table 4). This supports the need for a disease-specific quality of life questionnaire in food allergic adults.

The content of the FAQLQ-AF reflects the most important issues that food allergic patients have to deal with in their daily life and impairs their quality of life. Consequently, these issues are likely to be important targets for interventions by healthcare providers, catering industries, food manufacturers and governments

Table 4. Spearman's correlation coefficient of the total FAQLQ-AF score and domains of the FAQLQ-AF with the RAND-36 (SF-36) scales

RAND-36 scales	Total FAQLQ-AF	Domains of the FAQLQ-AF			
		AADR	EI	RAE	FAH
Physical functioning	0.10	0.04	0.22	0.03	0.02
Social functioning	-0.22	-0.26	-0.09	-0.18	-0.35
Role functioning-physical	-0.10	-0.14	-0.02	-0.15	-0.21
Role functioning-emotional	-0.20	-0.18	-0.12	-0.19	-0.25
Mental health	-0.27	-0.25	-0.18	-0.21	-0.35
Vitality	-0.18	-0.19	-0.07	-0.14	-0.27
Bodily pain	0.01	-0.05	0.16	-0.09	-0.09
General health	-0.06	-0.06	0.12	-0.16	-0.27
Change in health	0.10	0.16	0.06	0.01	0.07

The values given in bold are $P < 0.05$. Correlation coefficients are negative because a high score on the FAQLQ-AF indicates maximal impairment of quality of life, whereas a high score on the RAND-36 indicates better health status.

FAQLQ-AF, Food allergy Quality of life Questionnaire-Adult Form; AADR, allergen avoidance and dietary restrictions; EI, emotional impact; RAE, risk of accidental exposure; FAH, food allergy-related health.

aimed at improving quality of life in food allergic patients (30). An example is the item 'Change of ingredients of a product'. In the item reduction phase, it turned out that this was one of the most important items (Table 2). This item indicates that food allergic patients find it very frustrating when a product that was safe to eat, which in some cases are very few, turned out to be unsafe. The impact of this item may be reduced to some extent if, for example, manufacturers would place a warning on the product indicating changed ingredients.

Another notable item of the FAQLQ-AF is 'Unclear to which foods you are allergic'. The inclusion and validation of this item emphasizes the fact that if uncertainty is left about foods that may cause allergic reactions, this consequently impairs quality of life. Therefore, this item demonstrates the need for proper diagnosis for all suspected food allergies and it stresses the need for education on proper management of food allergy in order to prevent unnecessary impairment of quality of life.

In the discriminative analysis, it turned out that patients who reported anaphylaxis had a significantly more impaired quality of life than patients who did not report anaphylaxis. The difference in total FAQLQ-AF score between these two groups was 0.8. It is known from the literature that the minimal importance difference (MID) of HRQL questionnaires with a 7-point scale is approximately 0.5. The MID is the smallest difference in score which patients perceive as beneficial and which would mandate, in absence of troublesome side-effects and excessive cost, a change in the patient's management (31). Therefore, the difference in total FAQLQ-AF score between patients who reported anaphylaxis and patients who did not was not only a statistically significant difference but also a clinically

significant difference. The same was true for the difference in total FAQLQ-AF score of patients who reported more than three food allergies vs patients who reported three or less food allergies. Although the MID of 0.5 is a robust estimate for HRQL questionnaires with a 7-point scale, the specific MID of the FAQLQ-AF remains to be estimated in a longitudinal survey.

When looking at the discriminative ability of the previously developed questionnaires for children (FAQLQ-CF) and adolescents (FAQLQ-TF), it turned out that there was no significant difference in quality of life between young patients who reported anaphylaxis and those who did not (15, 16). At that time, we speculated that these patients may be too young to realize the potentially life-threatening consequences of severe anaphylactic reactions to food. This hypothesis is confirmed when considering the present results in adults. The difference in total FAQLQ score between patients who reported anaphylaxis and patients who did not increases with age (0.3 in children, 0.5 in teenagers and 0.8 in adults, respectively) and this difference was significant in adults. This suggests that as individuals age, they become more aware of the severity of symptoms in the past and the possibly life-threatening effect of food allergy. Consequently, these patients may judge their quality of life to be more impaired than patients with less severe food allergic reactions.

Finally, this study may have some limitations. The validation of the FAQLQ-AF was carried out in the Dutch language. The FAQLQ-AF was carefully translated into English using the guidelines of the World Health Organization. The validity of the English language version of this questionnaire is currently being investigated as well as versions in several other European languages. Our experience with the Dutch Vespider Allergy Quality of Life Questionnaire was that the English translation validated well (25). It is possible, however, that cultural differences may influence the ability of our questionnaire to identify the most important items for food allergic patients in different cultural or linguistic settings. Another limitation may be that we did not independently verify the food allergy diagnosis of patients recruited through advertisement who reported a physician-diagnosed food allergy. However, all these patients reported an allergy to a common/known food allergen, they reported symptoms that are common/known in food allergy, and they reported strict avoidance of the food to which they think they were allergic. Additionally, this report describes only the cross-sectional validation of the FAQLQ-AF. Currently, the longitudinal validation of the questionnaire is being investigated (i.e. the capacity of the FAQLQ-AF to measure differences in HRQL over time).

In summary, we presented here the first disease-specific HRQL questionnaire for food allergic adults, the FAQLQ-AF with very good to excellent measurement

properties. Moreover, the questionnaire is short and easy to use. The FAQLQ-AF is thus suitable for studies of adult food allergic patients in which HRQL is the outcome of interest. Examples include investigation of the effect of emerging treatments such as oral immunotherapy and anti-IgE therapy on quality of life. The FAQLQ-AF complements the recently developed FAQLQ-TF (for adolescents aged 13–17 years), the FAQLQ-CF (for children aged 8–12 years) and the FAQLQ-PF (for parents of food allergic children aged 0–12 years) (14–16). Hence, validated disease-specific

HRQL questionnaires are now available for food allergic patients of all age groups.

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Appendix 1. Food Allergy Quality of Life Questionnaire – Adult Form (≥18 years)

The following questions concern the influence your food allergy has on your quality of life. Answer every question by marking the appropriate box with an 'x'. You may choose from one of the following answers.

	0	1	2	3	4	5	6
	Not	Barely	Slightly	Moderately	Quite	Very	Extremely
How <u>troublesome</u> do you find it, because of your food allergy, that you...	0	1	2	3	4	5	6
1 must always be alert as to what you are eating?	☐	☐	☐	☐	☐	☐	☐
2 are able to eat fewer products?	☐	☐	☐	☐	☐	☐	☐
3 are limited as to the products you can buy?	☐	☐	☐	☐	☐	☐	☐
4 must read labels?	☐	☐	☐	☐	☐	☐	☐
5 have the feeling that you have less control of what you eat when eating out?	☐	☐	☐	☐	☐	☐	☐
6 must refuse many things during social activities?	☐	☐	☐	☐	☐	☐	☐
7 sometimes frustrate people when they are making an effort to accommodate your food allergy?	☐	☐	☐	☐	☐	☐	☐
8 are less able to accept spontaneously an invitation to stay for a meal?	☐	☐	☐	☐	☐	☐	☐
9 are less able to taste or try various products when eating out?	☐	☐	☐	☐	☐	☐	☐
10 can eat out less?	☐	☐	☐	☐	☐	☐	☐
11 must personally check whether you can eat something when eating out?	☐	☐	☐	☐	☐	☐	☐
12 hesitate eating a product when you have doubts about it?	☐	☐	☐	☐	☐	☐	☐
How <u>troublesome</u> is it, because of your food allergy...	0	1	2	3	4	5	6
13 that the ingredients of a product change?	☐	☐	☐	☐	☐	☐	☐
14 that labels are incomplete?	☐	☐	☐	☐	☐	☐	☐
15 that the lettering on labels is too small?	☐	☐	☐	☐	☐	☐	☐
16 that the label states: 'May contain (traces of)...'?	☐	☐	☐	☐	☐	☐	☐
17 that ingredients are different in other countries (e.g. during vacation)?	☐	☐	☐	☐	☐	☐	☐
18 that people underestimate your problems caused by food allergy?	☐	☐	☐	☐	☐	☐	☐
19 that it is unclear to which foods you are allergic?	☐	☐	☐	☐	☐	☐	☐
20 that you must explain to those around you that you have a food allergy?	☐	☐	☐	☐	☐	☐	☐
21 for your host or hostess should you have an allergic reaction?	☐	☐	☐	☐	☐	☐	☐
How <u>worried</u> are you because of your food allergy...	0	1	2	3	4	5	6
22 about your health?	☐	☐	☐	☐	☐	☐	☐
23 that the allergic reactions to foods will become increasingly severe?	☐	☐	☐	☐	☐	☐	☐
How <u>frightened</u> are you because of your food allergy...	0	1	2	3	4	5	6
24 of an allergic reaction?	☐	☐	☐	☐	☐	☐	☐
25 of accidentally eating the wrong food?	☐	☐	☐	☐	☐	☐	☐
26 of an allergic reaction when eating out despite the fact that your dietary restrictions have been discussed beforehand?	☐	☐	☐	☐	☐	☐	☐

Appendix 1. Continued

0	1	2	3	4	5	6
Not	Barely	Slightly	Moderately	Quite	Very	Extremely

Answer the following questions:

		0	1	2	3	4	5	6
27	to what degree do you <i>feel you are being a nuisance</i> because you have a food allergy when eating out?	☐	☐	☐	☐	☐	☐	☐
28	how <i>discouraged</i> do you feel during an allergic reaction?	☐	☐	☐	☐	☐	☐	☐
29	how <i>apprehensive</i> are you about eating something you have never eaten before?	☐	☐	☐	☐	☐	☐	☐

Appendix 2. Food Allergy Independent Measure – Adult Form (≥18 years)

The following four questions are about the chance that you think you have of something happening to you because of your food allergy. Choose one of the answers provided. This is followed by two more questions about your food allergy. Answer every question by putting an 'x' in the box next to the appropriate answer.

0	1	2	3	4	5	6
Never (0% chance)	Very small chance	Small chance	Fair chance	Great chance	Very great chance	Always (100% chance)

How great do you think the chance is that you...

		0	1	2	3	4	5	6
a.	will accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐
b.	will have a severe reaction if you accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐
c.	will die if you accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐
d.	cannot effectively deal with an allergic reaction should you accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐

e. How many products must you avoid because of your food allergy?

- ☐ Almost none
☐ Very few
☐ A few
☐ Some
☐ Many
☐ Very many
☐ Almost all

f. How great is the impact of your food allergy on your social life?

- ☐ Negligibly small
☐ Very small
☐ Small
☐ Moderate
☐ Great
☐ Very great
☐ Extremely great