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Validation of the Finnish version of the food allergy quality of life questionnaire–parent form (F-FAQLQ-PF)

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Abstract

Aim: Specific questionnaires about food allergy and health-related quality of life (HRQoL) have been developed and validated in several languages, but not Finnish. We aimed to validate the Finnish Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF) for children under age 13 years.

Methods: The original FAQLQ-PF and Food Allergy Independent Measure (FAIM) were translated into Finnish per World Health Organisation guidelines and tested by 72 parents of children under age 13 years with suspected severe peanut or tree nut allergy who were recruited at Allergy Centre in Tampere University Hospital in Tampere, Finland. We calculated the construct validity of the questionnaire by calculating the coefficients between the two measures and used Cronbach's alpha to establish the internal consistency.

Results: The FAQLQ-PF showed strong correlations with domain structure and internal consistency, based on Spearman's correlations (ρ) for the HRQoL questions, FAIM questions and FAIM mean values. The total questionnaire score correlated

Abbreviations: FAIM, Food Allergy Independent Measure; FAQLQ, Food allergy quality of life; FAQLQ-PF, Food Allergy Quality of Life Questionnaire–Parent Form; HRQoL, Health-related quality of life; ρ , Spearman's correlation coefficient; SD, Standard deviation; WHO, World Health Organisation.

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significantly with the mean FAIM ($\rho = 0.95, p < 0.001$) and individual FAIM questions. The FAQLQ-PF and domains had good or excellent internal consistency (Cronbach's alpha > 0.70).

Conclusion: The Finnish FAQLQ-PF demonstrated good construct validity and excellent internal consistency for measuring food allergy HRQoL in children under age 13 years.

KEYWORDS

food allergy, food allergy quality of life questionnaire–parent form, health-related quality of life, validation

1 | INTRODUCTION

Previous studies have shown that food allergy poses a substantial burden in many countries, and the prevalence of food-induced anaphylaxis is increasing.^{1–3} While food-triggered anaphylaxis fatalities are rare, some documented cases exist.^{4–6} Currently, sensitisation therapies are being developed, and, in carefully selected patient groups, implemented to treat severe food allergies. However, for most people living with food allergy, strict avoidance of the culprit food(s) and use of emergency medications remain main management tools for severe food allergies.^{4,7} Unsurprisingly, food allergy is associated with poorer quality of life among affected children and their families.^{8,9}

Families managing food allergy need to focus their attention to eating, and handling of foods at all times, including social gatherings, in a constant attempt to minimise risk of exposure to known allergens. Previous studies have shown that patients with food allergy generally have poorer health-related quality of life (HRQoL) than the general population. Moreover, the impact of food allergy on HRQoL is intermediate in magnitude between diabetes mellitus type 1, rheumatoid arthritis, irritable bowel syndrome and asthma.¹⁰

Several studies have provided evidence of associations between food allergy on HRQoL in adults and children, in different countries.^{11–14} While food allergy-specific HRQoL questionnaires have been validated in several languages, no such questionnaire has previously been developed and validated in the Finnish language.

Finland is known for the long research traditions in the field of allergic diseases and asthma; Finnish Allergy and Asthma Programmes have been successful in cutting health care costs, making changes in policy and being cited widely internationally.^{15,16} Yet, studies on the HRQoL of Finnish families managing food allergy are scarce. This knowledge gap represents the limited understanding about the burden of food allergy on Finnish families, but which could be addressed through the translation and validation of existing, and widely cited, Food Allergy Quality of Life Questionnaires (FAQLQ).^{17–19} Therefore, both the cultural and linguistic adaptation and validation of the original FAQLQ-Parent Form (FAQLQ-PF) in

Key Notes

- The Food Allergy Quality of Life Questionnaire (FAQLQ) exists in several languages and is commonly used in research but to date, no Finnish language version has been validated.
- We translated the FAQLQ-Parent Form and Food Allergy Independent Measure into Finnish per World Health Organisation guidelines.
- Among Finnish parents of young children with suspected severe nut allergy, the translated Finnish FAQLQ-Parent Form had good construct validity and internal consistency.

Finnish is important to later assess the impact of food allergy on the quality of life of Finnish child patients.

To this end, we aimed to adapt and validate the FAQLQ-PF in Finnish, for children under age 13 years.

2 | METHODS

2.1 | Translation and language validation of the FAQLQ-PF and FAIM in Finnish language (F-FAQLQ-PF and F-FAIM)

The validation of the FAQLQ-PF was performed in Finnish. The original FAQLQ-PF and Food Allergy Independent Measure (FAIM) were translated into Finnish following World Health Organisation (WHO) guidelines.²⁰ These guidelines include six steps. First, a forward translation must be performed by a health-care professional who has a same mother tongue as target culture. Second, an expert panel fluent in both English and the target language for translation, composed of the original translator, health professionals and experts with experience in instrument development and translation review the forward translation. Third, back-translation performed

by an independent translator, whose mother tongue is English and who has no knowledge of the questionnaire. Fourth, pre-testing and cognitive interviewing to pre-test the instrument on the target population need to be performed. We performed this fourth step at the Allergy Centre in Tampere University Hospital, Finland. Fifth, the final version needs to be approved by the original authors. Sixth, and finally, the initial forward version, as well as recommendations by the expert panel and the back-translation, are documented.

The FAQLQ-PF consists of 30 questions that are divided into three domains: Emotional Impact, Food Anxiety, and Social and Dietary Limitations. As part of this questionnaire, respondents are asked to rate the impact of each item on a six-point scale from not at all, to extremely in which the higher score indicates the larger clinical impact or worse FAQLQ. Depending about the child development stage, some of the questions deal with emotions or activities that cannot be observed among younger children. Thus, the parents of children aged 0–3 years answer only 14 questions, the parents of children aged 4–6 answer 26 questions and the parents of children aged 7–12 answer all 30 questions. The FAIM consists of four questions, also rated on a 6-point scale, and assesses the parents' expectation of the outcome for the child with food allergy. The senior investigator of this study (JEK) requested and received consent from the developers of original FAQLQ series of instruments to develop Finnish versions of these documents.

2.2 | Participants

Patients under age 13 years with a suspected severe peanut or tree nut allergy and their parents were recruited at Allergy Centre in Tampere University Hospital in Tampere, Finland. Consent was provided by all parents. Children aged 6 years or older also provided assent to participate in the study.

All patients were referred to Tampere University Hospital due to suspected severe food allergy defined as immediate allergic symptoms and or positive component levels to the culprit food(s). Basic descriptive characteristics, such as sex and age, were recorded. All patients completed the questionnaires after their parent/legal guardian provided written informed consent.

2.3 | Validation

The construct validity of HRQoL questionnaires is generally evaluated through comparison with an objective measurement or tool that characterises the extent or severity of the particular disease being assessed. The FAIM has been developed for this purpose. The FAIM is comprised of six questions, of which four are expectations of outcome questions and two are independent measure items, has been shown to be valid, relevant and reliable in adults, adolescents and children. Thus, in order to investigate the construct validity of the FAQLQ-PF, we calculated the correlation coefficients between the FAQLQ-PF and the FAIM.^{21–23}

2.4 | Statistical analysis

The internal consistency of the questionnaire was evaluated using Cronbach's alpha.

Concurrent validity was examined using Spearman correlation coefficients (ρ) between the FAQLQ-PF and FAIM scale scores. Statistical analyses were performed using SPSS Statistics version 28 (IBM Corp).

The Tampere University Hospital Ethics Committee approved the study design (18/05/2021 code R21024).

3 | RESULTS

In total, 72 patients under age 13 years were recruited to the study from Allergy Centre in Tampere University Hospital between June 2021 and March 2023. They all had suspicion of severe peanut or tree nut allergy, defined as immediate allergic symptoms and or positive component levels to the culprit food(s). The FAQLQ-PF were returned by all 72 parents and which were thus used for cross-sectional validation. The mean (standard deviation [SD]) age of the children was 7.0 years (SD 2.2, range 3.8–12.5 years), and 51% were females.

Domain Structure and Internal Consistency based on Spearman's correlations for HRQoL questions, FAIM questions and FAIM mean values had strong correlations in all age groups: 0–3, 4–6 and 7–12 years. (Tables 1–4).

3.1 | Construct validity

All items on the Finnish FAQLQ-PF correlated significantly with FAIM questions, and they all correlated significantly with the mean of the FAIM questions. The total FAQLQ-PF score correlated significantly with the mean FAIM ($\rho=0.95$, $p<0.001$) and with the individual FAIM questions. The FAQLQ-PF and the domains had good or excellent internal consistency (Cronbach alpha >0.70).

3.2 | Health-related quality of life

The reliability of Emotional Impact questions of Finnish FAQLQ-PF was approved to be good. Cronbach's alpha for all variables among ages 7–12 years was 0.946. Cronbach's alpha for all variables among ages 4–6 years was 0.952 and 0.903 among children ages 0–3 years.

3.3 | Emotional impact

The reliability of Emotional Impact questions of Finnish FAQLQ-PF was approved to be good. Cronbach's alpha for all variables among age 7–12 years was 0.862. Cronbach's alpha for all variables among ages 4–6 years was 0.850 and 0.824 among children ages 0–3 years.

TABLE 1 Domain structure and internal consistency: Spearman's correlations for HRQoL questions, FAIM questions and FAIM mean values.

Spearman's correlations	HRQoL summary score	Emotional impact	Food anxiety	Social and dietary limitations	Mean FAIM questions	FAIM 1	FAIM 2	FAIM 3
Emotional impact	0.873 $p < 0.001$							
Food anxiety	0.693 $p < 0.001$	0.693 $p < 0.001$						
Social and dietary limitations	0.871 $p < 0.001$	0.762 $p < 0.001$	0.647 $p < 0.001$					
Mean FAIM questions	0.587 $p < 0.001$	0.608 $p < 0.001$	0.431 $p < 0.001$	0.621 $p < 0.001$				
FAIM 1	0.495 $p < 0.001$	0.491 $p < 0.001$	0.343 $p = 0.003$	0.519 $p < 0.001$	0.713 $p < 0.001$			
FAIM 2	0.272 $p = 0.022$	0.363 $p = 0.002$	0.119 $p = 0.322$	0.371 $p < 0.001$	0.747 $p < 0.001$	0.418 $p < 0.001$		
FAIM 3	0.332 $p = 0.005$	0.371 $p < 0.001$	0.289 $p = 0.015$	0.311 $p = 0.008$	0.765 $p < 0.001$	0.418 $p < 0.001$	0.604 $p > 0.001$	
FAIM 4	0.221 $p = 0.064$	0.268 $p = 0.024$	0.165 $p = 0.169$	0.246 $p = 0.039$	0.519 $p < 0.001$	0.232 $p = 0.051$	0.123 $p = 0.306$	0.382 $p < 0.001$

TABLE 2 Domain structure and internal consistency among 0–3-year-old age group: Spearman's correlations for HRQoL questions, FAIM questions and FAIM mean values.

Spearman's correlations	HRQoL summary score	Emotional impact	Food anxiety	Social and dietary limitations	Mean FAIM questions	FAIM 1	FAIM 2	FAIM 3
Emotional impact	0.900 $p = 0.037$							
Food anxiety	0.821 $p = 0.089$	0.667 $p = 0.219$						
Social and dietary limitations	0.821 $p = 0.089$	0.718 $p = 0.172$	0.395 $p = 0.511$					
Mean FAIM questions	1.000 $p < 0.001$	1.000 $p < 0.001$	0.949 $p = 0.051$	0.632 $p = 0.368$				
FAIM 1	0.775 $p = 0.225$	0.775 $p = 0.225$	0.544 $p = 0.456$	0.816 $p = 0.184$	0.775 $p = 0.225$			
FAIM 2	0.316 $p = 0.684$	0.316 $p = 0.684$	0.056 $p = 0.944$	0.500 $p = 0.500$	0.316 $p = 0.684$	0.816 $p = 0.184$		
FAIM 3	0.800 $p = 0.200$	0.800 $p = 0.200$	0.949 $p = 0.051$	0.105 $p = 0.895$	0.800 $p = 0.200$	0.258 $p = 0.742$	-0.211 $p = 0.789$	
FAIM 4	0.800 $p = 0.200$	0.800 $p = 0.200$	0.949 $p = 0.051$	0.105 $p = 0.895$	0.800 $p = 0.200$	0.258 $p = 0.742$	-0.211 $p = 0.789$	1.000 $p < 0.001$

TABLE 3 Domain structure and internal consistency among 4–6-year-old age group: Spearman's correlations for HRQoL questions, FAIM questions and FAIM mean values.

Spearman's correlations	HRQoL summary score	Emotional impact	Food anxiety	Social and dietary limitations	Mean FAIM questions	FAIM 1	FAIM 2	FAIM 3
Emotional impact	0.896 $p < 0.001$							
Food anxiety	0.889 $p < 0.001$	0.699 $p < 0.001$						
Social and dietary limitations	0.862 $p < 0.001$	0.765 $p < 0.001$	0.625 $p < 0.001$					
Mean FAIM questions	0.570 $p < 0.001$	0.573 $p < 0.001$	0.382 $p = 0.020$	0.652 $p < 0.001$				
FAIM 1	0.434 $p = 0.007$	0.445 $p = 0.006$	0.275 $p = 0.099$	0.473 $p = 0.003$	0.759 $p < 0.001$			
FAIM 2	0.221 $p = 0.188$	0.256 $p = 0.125$	0.060 $p = 0.725$	0.397 $p = 0.015$	0.770 $p < 0.001$	0.526 $p < 0.001$		
FAIM 3	0.430 $p = 0.008$	0.435 $p = 0.007$	0.346 $p = 0.036$	0.436 $p = 0.007$	0.823 $p < 0.001$	0.620 $p < 0.001$	0.681 $p > 0.001$	
FAIM 4	0.364 $p = 0.027$	0.386 $p = 0.018$	0.201 $p = 0.232$	0.444 $p = 0.006$	0.492 $p = 0.002$	0.307 $p = 0.064$	0.059 $p = 0.730$	0.267 $p = 0.110$

TABLE 4 Domain structure and internal consistency among 7–12-year-old age group: Spearman's correlations for HRQoL questions, FAIM questions and FAIM mean values.

Spearman's correlations	HRQoL summary score	Emotional impact	Food anxiety	Social and dietary limitations	Mean FAIM questions	FAIM 1	FAIM 2	FAIM 3
Emotional impact	0.826 $p < 0.001$							
Food anxiety	0.955 $p < 0.001$	0.714 $p < 0.001$						
Social and dietary limitations	0.885 $p < 0.001$	0.797 $p < 0.001$	0.798 $p < 0.001$					
Mean FAIM questions	0.454 $p = 0.012$	0.550 $p = 0.002$	0.481 $p = 0.007$	0.433 $p = 0.017$				
FAIM 1	0.494 $p = 0.006$	0.457 $p = 0.011$	0.465 $p = 0.010$	0.472 $p = 0.008$	0.601 $p < 0.001$			
FAIM 2	0.198 $p = 0.293$	0.421 $p = 0.020$	0.208 $p = 0.270$	0.244 $p = 0.194$	0.725 $p < 0.001$	0.190 $p = 0.315$		
FAIM 3	0.056 $p = 0.770$	0.190 $p = 0.316$	0.118 $p = 0.534$	0.000 $p = 0.999$	0.652 $p < 0.001$	0.239 $p = 0.203$	0.534 $p = 0.002$	
FAIM 4	0.022 $p = 0.909$	0.135 $p = 0.478$	0.060 $p = 0.753$	-0.026 $p = 0.893$	0.597 $p < 0.001$	0.152 $p = 0.424$	0.285 $p = 0.127$	0.475 $p = 0.008$

3.4 | Food anxiety

The reliability of Food Anxiety questions of Finnish FAQLQ-PF was observed to be good. Cronbach's alpha for all variables among ages 7–12 years was 0.899. Cronbach's alpha for all variables among ages 4–6 years was 0.927 and 0.911 among children ages 0–3 years.

3.5 | Social and dietary limitations

The reliability of Social and Dietary Limitations questions of Finnish FAQLQ-PF was approved to be good. Cronbach's alpha for all variables among ages 7–12 years was 0.915. Cronbach's alpha for all variables among children ages 4–6 years was 0.915 and 0.767 among children ages 0–3 years.

4 | DISCUSSION

This study demonstrates that the Finnish FAQLQ-PF had good construct validity and excellent internal consistency for measuring the impact of food allergy on quality of life in children under age 13 years. The Finnish FAQLQ-PF is the first HRQoL questionnaire validated for Finnish children including back-translation, cultural and linguistic adaptation according to WHO guidelines.^{20,24} Domain Structure and Internal Consistency was good in all children under age 13 years. Moreover, the FAQLQ-PF and the domains had good or excellent internal consistency.

Previous studies have shown that food allergy poses a substantial burden in many countries. Some food allergies are mild, and strict limitations are not needed. Nonetheless, the prevalence of food allergies and food-induced anaphylaxis is increasing.^{1–3,25} There is a growing interest in health assessment tools produced and validated throughout the world and able to quantify these subjective outcomes. Nevertheless, food allergy mostly affects children who are not able to report HRQoL impact, and parents are usually the intermediates.¹⁴

Families managing from food allergies widely report low HRQoL, compared to other chronic diseases included diabetes mellitus type 1, rheumatoid arthritis, irritable bowel syndrome and asthma.^{8–10} Assessing the impact of food allergy on HRQoL in adults and children in previous studies. This is not possible unless HRQoL questionnaires are first validated to language for target nationality.^{11–14} Herein, our Finnish version of the FAQLQ-PF begins to address this gap.

The FAQLQ-PF can assist clinicians in optimising management strategies for children with food allergies and their caregivers. Previous validation processes of FAQLQ-PF have shown that validation processes performed according to WHO guidelines has produced reliable instruments for measuring the HRQoL of food-allergic children in different countries speaking different languages.^{12,13}

Our study is novel, as the validation has been performed accurately according to the WHO guidelines. Major strengths of this study include back-translation performed by an independent native English-speaking translator and the back-translation approved by the original author of the FAQLQ-PF.

Our study had some limitations. First, the study population was composed of patients who had suspected severe food allergy. Thus, this study was conducted at a university hospital and did not include patients with mild allergy symptoms. Second, even the validity of the English-language version of the questionnaire has been proven and the questionnaire is a suitable instrument for the assessment of quality of life in food allergy, cultural differences may influence the ability of the questionnaire to identify essential items for Finnish-speaking patients with food allergy. However, this risk has been limited to as low as possible by pre-testing and cognitive interviewing to pre-test the instrument according to WHO guidelines. During the study period, there were some restrictions in Finland due to COVID-19, which may have had effects on the quality of life. However, between June 2021 and March 2023, there were no more major restrictions, such as no school closures, for children under age 16 years.

5 | CONCLUSION

We have reported on the validation of the first Finnish HRQoL questionnaire for children with food allergy. The Finnish FAQLQ-PF has good construct validity and excellent internal consistency for measuring the food allergy on quality of life in children under the age of 13. Domain Structure and Internal Consistency was good in all children under the age 13 years and the FAQLQ-PF and the domains had good or excellent internal consistency. The Finnish FAQLQ-PF is therefore suitable for the assessment of the quality of life of Finnish-speaking children with food allergy, under age 13 years and perform international collaborative studies.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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