

ORIGINAL ARTICLE

The Food hypersensitivity famiLy ImPact (FLIP) questionnaire - development and first results

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Abstract

Background: Elimination of the offending food(s) is the usual treatment when a child suffers from food hypersensitivity. This treatment can impair everyday life in families with affected children. Instruments to assess these impairments generated from families attending primary care and in comparison to families with children without food hypersensitivity are scarce. The aim of this study is to develop and test a method to assess food hypersensitivity's impact on everyday life on affected families.

Methods: The Food hypersensitivity famiLy ImPact (FLIP) questionnaire was developed and validated on parents of children (0.5–7 years) with cow's milk protein hypersensitivity, exclusively or in combination with other food hypersensitivity, together with the Swedish Parental Stress Questionnaire (SPSQ) and in comparison to parents with children without food hypersensitivity.

Results: The validation of FLIP on 94 families indicated excellent internal consistency (Cronbach α 0.9) and good reproducibility (ICC 0.71). The FLIP showed moderate correlation with the SPSQ ($r = 0.48$) and proved capable of discriminating families by disease burden. Affected families experienced higher stress on their daily lives ($p = 0.02$) and higher impact on nutrition concerns ($p < 0.0001$) compared to families with children without food hypersensitivity.

Conclusions: The FLIP is a reliable, valid and sensitive instrument and could be valuable both clinically and in research. The results confirm recommendations of the need for continuous and updated dietary treatment and support for the families with young children with food hypersensitivity.

Cow's milk (CM) protein is the most usual food hypersensitivity (FH), affecting 2–3% of infants born every year worldwide and is often accompanied by other FHs. Symptoms of cow's milk protein hypersensitivity (CMPH) range from mild reactions to life-threatening anaphylaxis, and the usual treatment is avoidance of CM and items containing CM (1). However, being a basic ingredient in infants' diet, CM is more difficult to avoid than, for example peanuts as CM is included in many products, from charcuteries to hygiene products (2). Special diets may lead to nutritional risks, including hypoproteinaemia, anaemia, caries, impaired weight and height development, and delayed development of eating behaviour (3–7). Constant vigilance and diet limitations are often burdensome to affected families (8).

Normal stress during parenthood, defined as the conflict between parental resources and demands connected to the parental role, may increase in affected families, who often report significant emotional impact, limitation on family activities and social life and impact of FH on the child's general health (9, 10). Families depend on others in their environment in preventing and managing adverse reactions which may be an additional source of stress in these families. There is a need for standardized questionnaires focusing on common FHs and their effects on families with younger children, which can be easily used in Primary Care (11). The results can yield information valuable in increasing access to appropriate, high quality care, and preventing adverse consequences affecting the child's health, nutritional status

and promoting their optimal physical and emotional development.

We sought to (1) develop a reliable, valid and sensitive multidimensional measure to assess perceived impairment in families of children (0.5–7 years) with CMPH, exclusively or in combination with other FHs; (2) to test the hypothesis that impact on affected families correlates with age, birth order, additional FHs and number of symptom organs as reported by parents from the clinical examination; and (3) to compare the impairment on these parents to that on parents with children without FH. The name of this instrument is referred to as the FLIP (Food hypersensitivity famiLy ImPact) questionnaire.

Methods

Participants engaged in the development of the instrument are detailed in Fig. 1. Families with children with CMPH, exclusively or in combination with other FHs, attending the Pediatric Clinics of Primary Care in Gothenburg, individually or in parental groups were asked to describe, orally or in writing, problems resulting from their child's nutritional treatment (Sample I, $n = 83$) (12). The answers, transformed into statements, were submitted to new parents (Sample II, $n = 50$) for determination of item importance through telephone interviews using the clinical impact method (13). Parents were asked to rank the items' importance in a five-category Likert scale (0 = irrelevant/not endorsed - 4 = very important/always endorsed). This served to calculate mean importance (MI) (frequency/mean rating score) and overall importance (OI) (frequency * MI). Items scoring OI one or lower were dropped at this stage, excepting items of special interest.

Reliability and validity

A preliminary questionnaire was inspected by 12 parents with affected children, two of the authors (MPB and AM), two paediatricians and two dietitians experienced in the field (face and content validity. Sample III, $n = 18$). In order to test the FLIP's validity, correlations were calculated to the total score of the Swedish Parenthood Stress questionnaire (SPSQ) (14). It was hypothesized that the total score of the FLIP and its respective subscales should show concordance to the SPSQ total scores (construct validity). The SPSQ was considered appropriate because of its focus on parents' experienced stress. It has been used in food-related diseases and targets children of 0–7 years of age, as the present study (15, 16). New parents with children having the diagnosis for 3 months or longer (Sample IV, $n = 94$) received the questionnaire package including an information letter, a background questionnaire, the FLIP and the SPSQ. A subset of these parents was asked to fill in the forms and questionnaires a month later for reliability purposes (Sample IV_R, $n = 26$). Diet prescription was unchanged in this interval. Non-responders received up to two reminders, 2–4 wk apart. Non-responders in the test–retest subset received one reminder after 2 wk. Families with children without FH (Sample V) were recruited as controls from Child Health Centers from the same area and received a questionnaire package including an adapted information letter, the FLIP's Nutrition-related questions, that is, the non-disease-specific questions, and the SPSQ. No reminders were sent to this group for technical reasons.

Approval for this study was obtained from the Ethics Committee of the Sahlgrenska Academy at the University of Gothenburg and signed consent from participants.

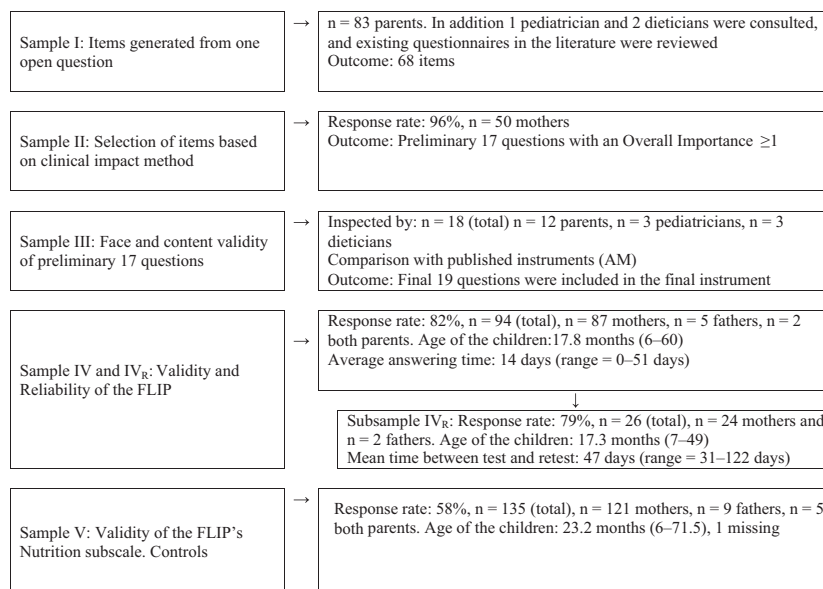


Figure 1 Groups included in the development of the FLIP.

Statistical analyses

Factor analysis was performed by principal component analysis with Varimax rotation on the FLIP to reveal underlying structure and aid the construction of subscales (Sample IV), after checking the suitability of the data; sample size (Kaiser-Meyer-Olkin Measure of Sampling Adequacy ≥ 0.6 and statistically significant Bartlett's test of sphericity); and the strength of the relationship among the items (i.e. high proportion of items loading ≥ 0.3 in the correlation matrix) (17). The total scores of the FLIP and SPSQ displayed normal distributions, but not the respective subscales, therefore non-parametric tests were chosen. The FLIP's reliability was assessed by calculating Cronbach α . Reproducibility was assessed by calculation of the intra class correlation coefficient (ICC) between test and retest occasions a month apart. The same tests were performed on the SPSQ. Several types of validity were studied for the FLIP: (1) The proportion of participants scoring lowest, that is, no effect, or highest, that is, always affected (floor-ceiling effects) (18); (2) the FLIP's sensitivity to differentiate within affected families according to age, birth order, number of FHs; and number of affected symptom organs as reported by parents from the clinical examination (discriminative validity; Mann-Whitney *U*-test when two variables and Kruskal-Wallis test when ≥ 3). Boys and girls in cases and controls were pooled for the analysis after having checked that there were no statistically significant differences in scores on the FLIP, the SPSQ and their respective subscales (results not shown); (3) the degree to which the FLIP and the SPSQ were measuring similar constructs was assessed (Spearman rho correlation coefficient) between total scores from the FLIP and subscales against total scores of the SPSQ in cases (Sample IV) and on the FLIP's Nutrition subscale's scores and SPSQ's total scores between cases (Sample IV) and controls (Sample V) (Construct validity, Mann-Whitney *U*-test).

Analyses were performed with SPSS for Windows 19.0 (SPSS, Inc., Chicago).

Results

Cases' characteristics are detailed in Table 1. Most responders were mothers. Demographic data were not collected for samples I, II and III. Most children in the control group (Sample V) ate a normal diet. Some avoided occasional fruits, vegetables, nuts and/or eggs due to fear of reactions despite absence of diagnosis ($n = 11$). A few avoided meats following personal choice ($n = 2$) or religion ($n = 4$).

Item generation and selection

In combination with review of the literature, 83 parents, one paediatrician and two dieticians provided 68 statements related to the care of affected children (Sample I). Two parents declined participation in the determination of frequency of item importance, declaring voluntarily lack of time (Sample II). Items scoring 0 or lower were dropped at this stage ($n = 52$) excepting two items of special interest regarding upbringing and others' comments.

Table 1 Symptoms and diagnostic characteristics of cases (Sample IV)

	Cases Sample IV $n = 94$ (%)
Symptoms	
Skin	68 (73)
Gastrointestinal	60 (65)
Airways	9 (10)
Other	4 (4)
One symptom	53 (57)
Two symptoms	32 (34)
Three or more symptoms	8 (9)
Diagnosis	
Skin prick test (SPT)	38 (41)
Radioallergosorbent test (RAST)	9 (10)
SPT and RAST	37 (40)
Elimination/challenge and allergy test(s)	5 (5)
Mean duration of cow's milk free diet in months	7.25 (3–54) 2*

*Missing data.

Construction of the questionnaire

The FLIP's final version includes 19 questions answered in a 7-point Likert scale and a 'non-applicable' alternative. Total score is the mean score for all answers (minimum = 1, maximum = 7). Negatively formulated questions ($n = 18$) are to be inverted before calculation. High scores indicate high impact (See Appendix 1). The data proved suitable for factor analysis (58% of the items loaded above 0.3 in the interitem correlation matrix, Kaiser-Meyer-Olkin = 0.84 and Bartlett's test of sphericity $p = 0.0001$). Varimax rotation was performed on 3, 4 and 5 factors explaining 55%, 62% and 67% of the variance, respectively. The three-factor solution was considered to make the best sense and guided the grouping into the subscales: Nutrition, Health and Emotions and Everyday Life. Additionally, the three-factor solution corresponded to the non-disease-specific questions administered to controls.

Reliability

A total of 94 (82% response rate) complete questionnaires were returned (Sample IV). Dropouts in the test-retest subset ($n = 36$) at the first ($n = 4$) and second ($n = 6$) administrations left a total of 26 analysable questionnaires (Sample IV_R). The FLIP showed good reproducibility for the whole scale (ICC = 0.71), the Health and Emotions and Everyday Life subscales (ICC = 0.73 and 0.83 respectively) and lower for the Nutrition subscale (ICC = 0.40). A total of 135 (response rate 58%) complete questionnaires were returned from controls (Sample V). The FLIP showed high internal consistency totally (Cronbach $\alpha = 0.9$) and for all subscales (Nutrition, Cronbach $\alpha = 0.7$; Health & Emotions, Cronbach $\alpha = 0.9$ and Everyday Life, Cronbach $\alpha = 0.8$).

Validity

Parents, clinicians and dieticians (sample III) considered the questions included in the FLIP to be relevant (face validity) and to cover all areas of concern (content validity). These findings were confirmed by comparison to existing instruments (10, 11, 19, 20). No participants scored highest possible effect and few scored no effect on the total FLIP score (1%), or the subscales Health and Emotions (2%), Everyday Life (2%) and Nutrition (4%). This shows little risk of missing the targeted population or failing to measure change when re-administering the questionnaire (floor and ceiling effects) (18).

Comparison within cases

Families with older children experienced higher impact on their daily lives than families with younger children compared across three age groups (≤ 11 , 12–17 and ≥ 18 months of age) according to the total scores on the FLIP ($p = 0.01$), the FLIP's Everyday Life subscale ($p = 0.002$) and the SPSQ ($p = 0.04$) (Table 2). Most families had a single child ($n = 59$, 63%). Families with children born second or later in the sibling group ($n = 30$, 32%) showed greater impact compared to affected families with one child on the total scores of the FLIP ($p = 0.02$) and the SPSQ ($p = 0.002$) and the FLIP's subscales Health and Emotions ($p = 0.04$) and Everyday Life ($p = 0.002$). Families with children avoiding two or more foods experienced more impact compared to families of children avoiding only CM ($p = 0.002$). Number of affected symptom organs as reported by parents from the clinical examination, ongoing or following unintentional ingestion, showed no statistically significant difference to the impact on affected families (data not shown). The FLIP's total scores and subscales' scores revealed statistically significant moderate correlations to the SPSQ's total scores (Spearman's $\rho = 0.48$, $p = 0.01$ and $0.4–0.5$, $p = 0.01$, respectively) showing that both questionnaires concur in measuring similar phenomena (construct validity). However, all correlations are moderate demonstrating that the questionnaires measure a construct dissimilar enough to justify the use of our disease-specific questionnaire.

Comparison to controls

There were no statistically significant differences between cases and controls concerning the child's birth order, parental country of origin, that is, Swedish vs. non-Swedish parents and parental education (Table 3). Cases showed statistically significant higher impact than controls in the FLIP's Nutrition subscale ($p = 0.0001$). Cases showed higher stress as measured by the SPSQ's total score compared to controls ($p = 0.02$), (Table 3). As described earlier, it was only possible for controls to complete the non-disease specific part of FLIP (Nutrition).

Discussion

The FLIP proved reliable, valid and sensitive in measuring impact caused by FH on affected families. The impact

Table 3 Comparison of cases and controls with respect to background variables.

	Cases Sample IV $n = 94$ (%)	Controls Sample V $n = 135$ (%)	p-values
Place in the sibling group	5* (5)		
Single/first child	59 (63)	100 (74)	0.3†
Middle/youngest child	30 (32)	35 (26)	
Country of origin			
Swedish mother	79 (84)	121 (90)	0.3†
Swedish father	83 (88)	113 (84)	0.4†
Mother's education	1*	1*	
Up to secondary level	20 (22)	26 (19)	0.8†
Tertiary level	73 (79)	108 (81)	
Father's education	1*	1*	
Up to secondary level	31 (33)	39 (29)	0.6†
Tertiary level	62 (67)	95 (71)	
Scores on FLIP-Nutrition and SPSQ			
FLIP-Nutrition median scores	3.00 (2*)	2.40	0.0001‡
SPSQ median scores	2.38 (3*)	2.24 (2*)	0.02‡

*Missing data.

†Chi-square test for difference between cases and controls.

‡Mann-Whitney U-Test.

Table 2 Comparison within cases according to age, birth order and number of foods cases and controls avoided

	Age				Birth order (1*, 4†)			Food items avoided		
	≤ 11 months ($n = 35$)	12–17 months ($n = 32$)	≥ 18 months ($n = 27$)	p-value	1st or only child ($n = 59$)	2nd or later ($n = 30$)	p-value	Cow's Milk ($n = 54$)	Cow's Milk + ≥ 1 foods ($n = 40$)	p-value
Median score										
FLIP total score	2.53 (2*)	2.47 (1*)	3.58	0.01	2.53 (2*)	3.00 (1*)	0.02	2.37 (3*)	3.16	0.002
Nutrition	3.00 (1*)	2.80 (1*)	3.60	NS	3.00 (2*)	3.30 (1*)	NS	3.00 (2*)	3.10	NS (0.06)
Health & Emotions	2.57	2.36	3.00	NS	2.43	3.00	0.04	2.29	3.00	0.002
Everyday Life	2.29 (1*)	2.36	4.00	0.002	2.29	3.57 (1*)	0.002	2.29	3.29	0.004
SPSQ total score	2.26 (2*)	2.26 (1*)	2.71	0.04	2.26 (2*)	2.79 (1*)	0.002	2.38 (1*)	2.40 (2*)	NS

*Missing values.

†Twin pairs excluded from this analysis.

increased with age, birth order and additional FHs, but not with number of affected symptom organs as reported by parents from the clinical examination.

The FLIP showed excellent internal reliability (Cronbach $\alpha = 0.9$). Despite test–retest period of 47 days on average, the reproducibility of the FLIP's subscales Health and Emotions and Everyday Life was excellent (ICC = 0.73 and 0.83, respectively). The FLIP's Nutrition subscale showed lower reproducibility (ICC = 0.40) suggesting greater changes occur at this age even during limited periods of time and despite unchanged diet prescription. This would confirm the importance of continuous nutritional counselling and support to prevent strain on these families and complications to the child's health and development.

As in other studies, response rate was lower in controls (58%) compared to cases (82%), indicating affected families' need to communicate their concerns for their children's health (21). Despite free access to group treatment (12), affected families experienced a high degree of impairment, suggesting updated nutritional counselling should be complemented with emotional support and individually tailored follow-ups. Many affected children develop other atopic diseases (22), adding further stress on parents and jeopardizing the child's optimal growth and development. Number of affected symptom organs appeared to be of little consequence to the impact on affected families in discordance with earlier studies (11, 13). However, this may be a consequence of the wider range of symptoms and diagnoses in children attending paediatric clinics in primary care compared to children attending paediatric allergy clinics. Future studies should include families with affected children from primary, secondary and tertiary care levels in terms of FH to further test the FLIP's ability to measure disease burden in terms of severity.

This study adds to the literature a comparison of affected families to population-based controls. The moderate correlations between the FLIP and SPSQ indicate the FLIP's usefulness in adding improved information from the affected families' perspective. The SPSQ measures parenting stress, whereas the FLIP measures identifiable and tangible sources of stress resulting from the child's FH enhancing health care's possibilities to offer adequate support to affected families. Previous studies include additional measures to assess expect-

tation of outcome (10, 11, 19, 20), for example, 'What chance do you think your child has of dying from his/her food allergy following ingestion in the future?' (23). This was not considered ethically justified in our study and in relation to the managing of FH in Sweden, that is, no routine prescription of emergency medication, which might have a dramatic impact on anxiety (7, 10, 11, 19). Regardless of this, normal parental stress increases with FH in affected families. Growth and development of eating behaviour of affected children might be jeopardized by FH with consequences later in life (7). A limitation of our study is the relatively small number of participants. Larger studies using this method can elucidate the burden of FH according to the characteristics of the family, the child and the FH.

Clinicians and health allies, preoccupied in making diagnoses and alleviating symptoms, do not always have the chance to appreciate the impact of FH on families and children. A recent review by Santos and Lack supports further education for families and care professionals alike (24). We suggest the FLIP to be administered to gain insight from the family's perspective, to help identify problems, guide decisions and allocate resources in clinical practice. Therefore, we have made the English version of the FLIP available through this publication. The FLIP might also be useful in clinical research to assess impact on families resulting from diagnosis, management and novel treatments, such as allergen-specific immunotherapy.

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Appendix 1 The Food hypersensitivity family ImPact (FLIP) questionnaire*

Identity Code: _____

Please answer **every question** by drawing a cross in the right circle. Choose only one answer for each question.

1. If you and your family were planning a holiday/vacation, how much would your choice be limited by your child's food hypersensitivity?

Extremely limited	Very limited	Quite a bit limited	Moderately limited	Somewhat limited	Hardly limited at all	Not limited	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

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?

Extremely limited	Very limited	Quite a bit limited	Moderately limited	Somewhat limited	Hardly limited at all	Not limited	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

3. If you and your family were planning to participate in social activities with others involving food (e.g. parties, holiday, etc) how limited would your ability to participate be because of your child's food hypersensitivity?

Extremely limited	Very limited	Quite a bit limited	Moderately limited	Somewhat limited	Hardly limited at all	Not limited	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

4. Have you ever experienced any difficulties in teaching your child to eat?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

Appendix 1. (Continued).

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?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

6. In the past month, how often have you been worried that your child will have a reaction due to the food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

7. In the past month, how worried have you been that your child may not out grow the food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

8. In the past month, how troubled have you been about leaving your child in the care of others because of the food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

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?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

10. In the past month, how often have you felt unsafe when leaving your child at the kindergarten/babysitter because of the food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

11. In the past month, how often have you felt sad because of your child's food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

12. In the past month, how often have you felt worried that your child will not have a normal upbringing because of the food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

Appendix 1. (Continued).**13.** In the past month, how often have you felt worried about your child's health because of the food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

14. In the past month, how often have you experienced lack of variation in your child's diet?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

15. In the past month, how troubled have you been about planning what to cook or serve to your child?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

16. In the past month, how often have you felt concerned about the nutritional content in your child's diet?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

17. In the past month, how troubled have you been about increased food costs because of your child's food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

18. In the past month, how troubled have you been by comments from others concerning your child's food hypersensitivity?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

19. In the past month, how often have you experienced that your child is happy and satisfied?

All the time	Almost all the time	Often	Sometimes	A little	Almost never	Never	Not relevant
☐	☐	☐	☐	☐	☐	☐	☐

*This questionnaire was originally developed in Swedish, translated to English and back-translated to Swedish according to the guidelines of the World Health Organization.