



Development of the scale of psychosocial factors in food allergy (SPS-FA)

Aaron Cortes, Angela Castillo & Alicia Sciaraffia

Section of Immunology, HIV and Allergy, Hospital Clínico Universidad de Chile, Santiago, Chile

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Correspondence

Aaron Cortes, Santos Dumont 999, 5to piso Sector E, Sección de Inmunología, VIH y Alergias, Hospital Clínico Universidad de Chile, Independencia, Santiago, Chile.
Tel.: +56 9 7891 6421
Fax: +56 2 2732 2798
E-mail: aacortes@hcuch.cl

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Abstract

Background: Food allergy (FA) is a growing condition among children and its psychological impact over the patients and their caregivers is well known, establishing a vicious circle that perpetuates stress levels. However, psychosocial factors are not commonly included in allergy treatments. Based on the lack of evidence of records about a scale that indicates the level of interaction between biopsychosocial factors in the patient–caregivers dyad for FA, the present research aims to develop a scale with these characteristics as a helpful tool to achieve a more comprehensive system of health care. **Methods:** A preliminary 28-item scale was generated (sample N = 99). The scale was adjusted in contents and language after expert opinion and application on patients. A factor analysis was carried out selecting the items from the final scale.

Results: The final 9-item scale included three areas: impact on quality of life, social impact and conflicts. The scale had a good internal consistency (Cronbach's $\alpha = 0.870$) and correlated significantly with anxiety and depression measurements. Moreover, it was able to discriminate between study groups (members and non-members of peer support groups) and proved construct validity.

Conclusions: The SPS-FA is the first scale for the assessment of the interaction of biopsychosocial factors on FA that includes the patient–caregiver dyad. Its application might be relevant for future research, and it can provide the clinician and the researcher with a solid tool to define which type of psychosocial support is required to provide a more comprehensive care in FA.

Food allergy (FA) affects 6–8% of children (1, 2), and this phenomena may be in a global growing wave (3) and developing countries may follow this trend (4). Different genetic as well as environmental and psychological factors is implicated in its genesis, and their influence leads to the loss of tolerance to usually innocuous substances, that upon being inhaled, contacted or ingested (5), trigger the various clinical manifestations of such pathology.

It has been sustained that 90% of parents of atopic children perceive that their parenthood implies higher levels of troubles when compared with healthy children and that these troubles have a clinical impact (6). Specifically, FA accounts for a large number of these clinical presentations, having a great impact on the quality of life of the affected individuals (7, 8): the daily activities of patients and their families become limited, and both experience anxiety about eating, behavioural changes, social restrictions, a poorer perception of healthiness and even post-traumatic stress if they have experienced serious complications of their disease such as anaphylactic shock (1, 9, 10).

On the other hand, both acute and chronic stress are able to affect the immune system. Acute stress increases general

immune response, triggering asthma and atopic dermatitis symptoms (11–13). Chronic stress, promote a Th2-type immune response, that has been defined as the allergic profile (14–16). Additionally, an association between a history of trauma in childhood, such as violence or parent loss and psychiatric pathologies (17), has been described with food-related physical symptoms.

Several studies suggest that stress control (in case of atopic eczema), control of depression/anxiety (in asthma) and social interaction improve control of the underlying allergic pathology, thus preventing exacerbations (18–21). These studies clarify the vicious circle between allergy and stress, showing how psychosocial and immunological factors interact in allergy states. However, no records of scales related to the interaction of carer's psychosocial variables and children's allergic symptoms have been found in the literature.

Recently developed scales have evaluated health-related quality of life (HRQL) in children–adolescents and/or carers of allergic children (22, 23). These scales evaluate the impact of allergic symptoms over children's or carers' quality of life. However, no scales have been based on the assumption of the

interaction of these variables; how stress, anxiety, depression and social support levels interact with the number and/or intensity of allergic symptoms.

Therefore, a brief and easy-to-apply scale to evaluate the impact of caring children with FA that consider the biopsychosocial interaction between allergy symptoms and psychological variables has been developed. This scale aims to: provide a timely diagnosis; know the prevalence of psychosocial alterations in carers of children with FA; and propose an integrative management that might contribute to improve the outcome of allergic condition.

Methods

The following stages were followed to develop the Scale:

Stage 1 – Procurement of data (N = 23): It was carried out through (i) literature analysis to identify the psychosocial factors most commonly described in allergy; (ii) semistructured recorded interviews to patients (N = 20; mothers of children with FA) and physicians (N = 3; allergy specialists); and (iii) thematic analysis of data.

Stage 2 – Pre-testing of the preliminary scale (N = 13): items were discussed with experts (N = 7; validity of contents) and were presented to a sample of participants (N = 6) to identify language comprehension difficulties or other problematic items.

Stage 3 – Item reduction (N = 63): the scale was applied together with validated psychological tests. Tests were applied to correlative patients attending the Allergy Centre of the Hospital Clínico of the Universidad de Chile (N = 29) and to members of a peer-to-peer support group (PSG) for parents of children with FA (N = 34).

This project was approved by the Ethics Committee of the Hospital Clínico of the Universidad de Chile (Minute N°44 of 27 July 2011).

Sample

The N was calculated to estimate the prevalence of the studied variables on the assigned population. Studies have shown that in general population, the prevalence of depression is 9% and 9.7% for anxiety (24). Therefore, this latter percentage (to obtain the bigger sample) was used for the calculation computed by the 'Sample Size and Power Calculation 7.12' (<http://www.imim.es/ofertadeserveis/software-public/granmo>). Accepting an alpha risk of 0.05 for a precision of ± 0.05 units for an estimated proportion of 0.097 and considering 20% of sampling withdrawal, 73 subjects randomly selected are required. The total N attained was 99 participants (Stage 1: N = 23; Stage 2: N = 13; Stage 3: N = 63). In order to take part on the research protocol, patients from the Allergy Centre and from the PSG needed a medical diagnosis of FA made by a specialist in allergy, had laboratory tests (prick, parch or IgE), and to answer to an interview to corroborate the diagnosis. The allergies included were the four most commonly found in our population: milk, egg (yolk and/or white), nuts and soya. Participants were given information and the opportunity to ask questions regarding the research and their participation in it.

Participants were invited to take part in the study, and in the event of accepting, they signed the informed consent specifying the stage/s where they would take part and their physician or patient nature.

Additionally applied instruments

Based on the literature review, anxiety and depression assessments were included through the Hospital Anxiety and Depression Scale (HADS) (25).

Approach to item reduction

The first version of the scale had 28 items. A pilot application was performed to test the scale. Item reduction focused on: (i) item performance: ceiling effect, language problems; (ii) factor analysis to establish interaction between items; and (iii) internal consistency of the scale and of the resulting factors.

Reliability and validity of the scale

Internal consistency

Cronbach's α analysis was used for the full scales and subscales. It is accepted crossways that $\alpha > 0.7$ is acceptable, >0.8 is good and >0.9 is excellent (26).

Construct validity

Usually to assess the validity of the construct of a developing scale, the latter is compared with the results of validated scales evaluating the same (or similar) construct (convergent validity) or to subscales relating to different constructs (divergent validity). However, in the absence of similar scales, the construct was compared with psychological variables that have been described in association with allergies (anxiety and depression) using the Pearson correlation coefficient. On the other hand, the t-test was used to assess the ability of the scale to detect intergroup expected differences (known-groups validity) of members and non-members of PSG for parents of children with FA.

Data screening

Participants were asked to provide demographic data and to evaluate, in a 5-point-Likert scale, different items relating to organic, social-environmental and psychological aspects.

Results

Pilot application, rate and sample characteristics

The study included a total of 99 participants, and the survey was applied on 63 individuals. Table 1 shows the demographic characteristics of the sample. Seven items showed a ceiling effect (80% or higher), and four items experienced more than 5% data loss. Therefore, such items and/or subitems were removed from the analysis.

Table 1 Sample characteristics (N: 63)

Gender: n (%)	
Male:Female	38(58.7):26(41.3)
Age [months]: mode/median [Range]	1.17/11[1–146]*
Mother's qualifications: n(%)	
Primary school	1(1.6)
High school	12(19)
Technician	17(27)
University	29(46)
Missing	4(6.3)
Perception of the income: n(%)	
Very insufficient	3(4.8)
Insufficient	12(19)
Sufficient	18(28.6)
More than sufficient	26(41.3)
Much more than sufficient	4(6.3)
FA diagnosis issued by a physician: n(%)	
Yes	63(100)

*Intergroup significant difference $p = 0.01$.

Development of the scale

After data exploration, 21 items were included in the factor analysis. Factors had an oblique rotation (Promax), and only factors reaching more than 0.40 were considered for the analysis.

Seven components were extracted using the principal component analysis (PCA). However, due to item distribution, the analysis was forced to four factors, with one item remaining under the cut-off criterion [0.40], reason for which it was removed from the scale. The scale internal consistency was evaluated with the Cronbach's α , as a result; four items from the same factor were removed from the scale, leaving such factor with one single item (item 19b). After the removal of item 19b, item 20 did not contribute to the internal consistency of the scale and therefore was also removed. To summarize, seven items were removed, with a resulting internal consistency of $\alpha = 0.870$.

The final version of the SPS-FA consists of nine items distributed into three factors: *quality of life*, *crisis* and *social impact*. A higher score indicates a higher impact of psychosocial factors on FA in the patient-caregiver dyad. Appendix 1 shows the full scale. The final scale score (range: 0–56) becomes a factor indicating the likelihood of influence or crossed disorder between biological, psychosocial and social variables. That is to say, a 0 score indicates a 0.0 (0%) factor for likelihood of disorders, a 45 score indicates a 0.803 (80.3%) factor for the likelihood of crossed disorder between psychosocial factors. Moreover, the scale subvariables indicate which areas are the most (or the least) affected by such crossed interaction and therefore provide guidance on strategies to follow.

A version that issues the score and final factor automatically (Excel format) for the scale, and each subvariable was created to facilitate the tabulation process.

Evaluating the reliability and validity of the scale

The scale showed a good internal consistency (Cronbach's $\alpha = 0.870$). Likewise, subscales showed at least an acceptable internal consistency (Table 2). As for convergent validity, SPS-FA showed an intermediate correlation with anxiety ($r = 0.521$; $p < 0.001$) and depression ($r = 0.523$; $p < 0.001$). That is to say that the higher the score in the SPS-FA scale, the higher depression and anxiety indices were observed (Table 3).

As for divergent validity (known-groups analysis), SPS-FA risk factor was able to detect differences between PSG members and non-members ($t = -2.066$; $df = 58$; $p = 0.05$) pointing to a higher level of psychosocial impact among members of the group. The *quality of life* factor showed the highest intergroup difference ($t = -0.720$; $df = 58$; $p = 0.014$).

The correlation seen between SPS-FA and the studied variables is in accordance with the literature. Thus, in our sample of allergic patients and their families, depression (15.9%) and anxiety (44%) levels described are higher than in general population (9% approximately).

A series of symptoms commonly described in allergies (cutaneous, digestive and respiratory) were included as an extra indicator of validity. The recurrence of such symptoms correlated significantly with psychosocial factors included in our scale, especially digestive symptoms (Table 4). The latter accounts for the ability of the SPS-FA to discriminate focused on FA patients. The emotional impact on the family of such patients and a greater limitation of their daily life were also reflected by the results of the scale, in accordance with the literature (4). For instance, 35% of patients mentioned having a non-resolved crisis and that such crisis was directly related to a greater digestive symptoms ($r = 0.576$; $p < 0.001$).

Table 2 Reliability statistics

	Cronbach's alpha	No of items
Total scale	0.87	14
Quality of life factor	0.816	7
Crisis factor	0.805	5
Social factor	0.787	3

Table 3 Interscales and interdemographic correlations

Variable	SPS-FA factor	F1 quality of life	F2 social	F3 crisis
HADS anxiety				
<i>r</i>	0.520 [†]	0.619 [†]	0.152	0.402 [†]
<i>p</i>	0.000	0.000	0.246	0.001
<i>N</i>	60	60	60	60
HADS depression				
<i>r</i>	0.524 [†]	0.536 [†]	0.298*	0.385 [†]
<i>p</i>	0.000	0.000	0.021	0.002
<i>N</i>	60	60	60	60

*Correlation is significant at the 0.05 level (two-tailed).

[†]Correlation is significant at the 0.01 level (two-tailed).

Table 4 Correlations between allergic symptoms and SPS-FA (N: 60)

	SPS-FA factor	Factor 1 quality of life	Factor 2 social	Factor 3 crisis
No of cutaneous symptoms				
R	0.252	0.207	0.161	0.233
Sig.	0.052	0.112	0.220	0.073
No of digestive symptoms				
R	0.558 [†]	0.373 [†]	0.392 [†]	0.576 [†]
Sig.	0.000	0.003	0.002	0.000
No of respiratory symptoms				
R	0.302*	0.300*	0.184	0.228
Sig.	0.019	0.020	0.160	0.080

*Correlation is significant at the 0.05 level (two-tailed).

[†]Correlation is significant at the 0.01 level (two-tailed).

Discussion

A novel approach that included data from the interaction of biological, psychological and social factors in FA, was used for the design of the SPS-FA scale. Additionally, it is the first scale that focuses on the dyad carer–child. This scale showed good internal consistency, construct validity and convergent and divergent validity. Interaction between biopsychosocial factors has been largely documented in different health statuses. However, the difficulty in applying research discoveries and transforming them into easy-to-use, replicable and cost-effective products (27) has complicated their inclusion in clinical practice. The SPS-FA is a self-applied psychosocial impact scale in FA, and it is a brief and low-cost way of offering the possibility to assemble data that may guide the clinician to decide which factors should be included in a multidisciplinary approach to their patients.

One of the key factors of the items included on the SPS-FA is their correlation with allergic symptoms, especially gastric; with this strategy, the scale reflects the bidirectional impact of biopsychological factor on FA. Therefore, the SPS-FA is proposed as a tool capable of providing the clinician and the researcher with key information to estimate the interaction between psychosocial factors and the progress of FA in the patient–caregiver dyad. Hence, it will be possible to establish strategies more relevant to the issue in order to face the observed situations and thus integrate in a practical tactic, a systemic hands-on approach in health care.

Strengths and limitations

The SPS-FA includes a systemic perspective (biopsychosocial) in the study of FA in children. It includes the psychosocial interaction of the patient–caregiver dyad during the allergic

and psychological symptomatology onset. Additionally, a systemic perspective was considered for its construction: the resulting items were a product of the study of available research, interviews to both experts and caregivers of children with FA.

However, as shown in Table 1, the age of patients from the PSG was significantly higher than in the non-member group. Therefore, regarding the validity of the study, older children from PSG-member-parents and younger children from non-member-parents might be under-represented and data generalization might be reduced for such groups. Consequently, the scale validation process requires a larger and ideally a transcultural sample. On the other hand, the studies sustain that FA affects mainly younger children (28–30) an observation that is reflected in our sample (92% < 1 year old).

Conclusion

The aim of the SPS-FA scale is to be a reliable and easy-to-implement tool acting as a guide for the addition of psychosocial factors in the care provided to children suffering from FA. It enables the fast creation of a family operation scheme, while aiming at being a concrete tool for the clinician, to allow the early referral and optimized health care of the patient. Additionally, it aims for the inclusion of a biopsychosocial perspective on the study of FA.

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Conflict of interest

The authors have no conflict of interest to declare.

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Appendix 1
Psycho Social Factors in Food Allergy Scale (PSF-FA)

Cortés, A., Castillo, A. Sciaraffia, A.

A: Name Age
 Occupation Date Gender (M/F)

1 Do you think that your child's allergy symptoms affect your mood?
 very much quite a bit mildly a little not at all

--	--	--	--	--

2 Do you think that your mood affects your child's allergy symptoms?
 very much quite a bit mildly a little not at all

--	--	--	--	--

3 Due to your child's condition, you have developed:
 always often sometimes uncommonly never
 a) sleep disorders

--	--	--	--	--

 b) greater irritability

--	--	--	--	--

4 Do you feel that your child's allergic symptoms have affected you psychologically?
 very much quite a bit mildly a little not at all

--	--	--	--	--

5 Do you feel that the symptoms have affected the development of physical activity in your child?
 very much quite a bit mildly a little not at all

--	--	--	--	--

6 Over the last year, has there been any crisis that might have provoked (on you and/or your family) high stress or anxiety levels?
 yes no

--	--

a) If your answer was "Yes", on which area did that crisis occur?
 Area 1 (health, couple or family) Area 2 (work, financial, studies) both

--	--	--

b) Such situation is currently... in process of
 solved almost solved resolution looking for solutions unsolved

--	--	--	--	--

c) Do you believe this crisis has worsened your child's allergy symptoms?
 very much quite a bit mildly a little not at all

--	--	--	--	--

7 Have you felt discriminated because of your child's condition?
 very much quite a bit mildly a little not at all

--	--	--	--	--

8 Do you feel that the disease has affected your family budget?
 very much quite a bit mildly a little not at all

--	--	--	--	--

9 Do you feel that your child's symptoms have affected your social interactions?
 very much quite a bit mildly a little not at all I don't have
 a) with your friends

--	--	--	--	--	--

 b) with your family

--	--	--	--	--	--

 c) with your couple

--	--	--	--	--	--

MANY THANKS FOR YOUR ANSWERS