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Current tools measuring anxiety in parents of food-allergic children are inadequate

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Abstract

Background: In the context of food allergy, excessive parental anxiety can be maladaptive and lead to unnecessary restriction of social activities. No validated tool exists to measure food allergy–associated anxiety (FAAA). This study sought to explore factors associated with parental FAAA, determine sensitivity and specificity of using generic state anxiety measure—State-Trait Anxiety Inventory (STAI) versus FAAA, and determine whether validated tools for generalized anxiety or food allergy–specific quality of life (QoL) could be used as surrogates for FAAA.

Methods: Canadian parents of food-allergic children completed an online survey. Without a validated tool for FAAA, a visual analogue scale was used to assess parent-reported FAAA. Multivariable linear regression was performed with FAAA as the outcome. Sensitivity and specificity analysis of state anxiety vs. FAAA, and factor analysis of state anxiety and QOL, was performed to determine whether these could be used as surrogates for FAAA.

Results: A total of 548 of 1244 parents (44.1%) completed the survey. Factors positively associated with FAAA included parental burden, risk perception, state anxiety, intolerance of uncertainty and perceived severity of child's food allergy; personal/family history of mental health was negatively associated. Sensitivity and specificity of state anxiety were 68.6% and 70.0%. Factor analysis revealed that state anxiety and QOL were correlated ($r = 0.54$, $P < .001$) but distinct constructs.

Conclusion: Our study identified factors associated with FAAA, and determined that generic anxiety and QOL tools do not accurately categorize parents with self-reported high FAAA. Future research will develop a validated screening tool to help allergists identify anxious parents and provide psychosocial resources.

KEYWORDS
anxiety, food allergy, mental health, parental anxiety, quality of life, screening tool, state anxiety

1 | BACKGROUND

Parents of children with food allergy often experience anxiety due to the real possibility of accidental exposures, the need for constant vigilance to prevent these exposures and the limitations that food allergy has on daily life.[1] An appropriate level of anxiety is beneficial and required for food allergy, since parents must remain vigilant to ensure a safe environment for their child.[2] However, excessive parental anxiety can be maladaptive and can lead to unnecessary restriction of age-appropriate social activities.[1,3] The difference between adaptive and maladaptive can be difficult to determine, and data on the association between food allergy and anxiety remain vague. There is a need to better understand parental anxiety in the context of food allergy so that healthcare providers, including allergists, can identify parents who can benefit from psychosocial support and resources.[4]

Generic anxiety questionnaires such as the State-Trait Anxiety Inventory (STAI)[5] and food allergy–specific questionnaires measuring related concepts such as quality of life (QoL) (eg Food Allergy Quality of Life-Parental Burden, FAQL-PB)[6] have been used to measure concepts related to anxiety (parental worry, distress and fear) in parents of children with food allergy. These questionnaires have been used to measure the effect of various interventions to reduce parental anxiety, including cognitive behavioural therapy,[7] treatment of food allergy using oral immunotherapy[8] and use of adrenaline autoinjectors to treat allergic reactions,[9] among others. Although generic measures can be useful for comparing across diseases, they do not incorporate issues directly related to the disease in question, and may not adequately measure the concept nor detect changes as a result of interventions.[10]

To inform the creation of a tool to adequately measure food allergy–associated anxiety (FAAA), this study sought to explore demographic and psychosocial factors associated with parental anxiety in the context of food allergy, determine the sensitivity and specificity of the STAI in identifying parents with self-reported FAAA, and determine whether parental state anxiety as measured by STAI and QoL as measured by FAQL-PB are similar or distinct concepts using factor analysis.

2 | METHODS

2.1 | Participants and recruitment

Parents were recruited through Food Allergy Canada, a patient advocacy and education organization, to complete an online survey in November/December 2017. The survey included clinical information about the allergic child, parental demographics and parent psychosocial measures.

2.2 | Variables and measures

Allergic child characteristics included age (in years), sex (male/female), multiple food allergies (yes/no), anaphylaxis history (yes/no) and emergency room visit history (yes/no).

> **Key Message**
>
> This is the first Canadian study to explore parental anxiety in the context of food allergy. Not only did this study identify that a subset of Canadian parents who completed the survey appear to be highly anxious about their child's food allergy, it also highlights that the current available tools to measure anxiety may not be accurately identifying individuals who need support the most, and emphasizes that a validated tool is needed.

Parent demographic characteristics included age (in years), sex (male/female), post-secondary degree (yes/no), health professional (yes/no), married or living with a partner (yes/no) and income greater than $100 000 per year (yes/no).

The parent psychosocial variables measured in this survey are described below and include the following: Food Allergy Quality of Life-Parental Burden (FAQL-PB), Food Allergy Independent Measure (FAIM) (chance of having a severe reaction, and chance of dying, if the child were to ingest their allergen), state anxiety, trait anxiety, intolerance of uncertainty, perceived severity of child's food allergy (mild, moderate, severe), personal/family history of mental illness (yes/no) and personal/family history of anxiety/anxiety disorder (yes/no).

The FAQL-PB is a validated questionnaire with 17 items and two expectation of outcome questions.[6] For the 17 items, parents rank each question on a scale of 0 = not troubled to 6 = extremely troubled. Questions pertain to issues that parents who have a child with food allergy live with on a daily basis, and the goal of this questionnaire is to assess the level of burden that food allergy places on the parent, and hence provide a measure of quality of life. The total scale and two factors (limitations on life and emotional distress) have high internal reliability ($\alpha > 0.85$). For the expectation of outcome questions, parents rank each question regarding the likelihood of future reactions or death should their child ingest food(s) to which he/she is allergic, on a scale of 0 = no chance to 6 = always.

The State-Trait Anxiety Inventory (STAI) is a 40-item self-report measure for adults, with two sections of 20 questions each measuring state (STAI-S, how you feel right now) and trait (STAI-T, how you feel generally) anxiety.[5] Items are rated on a 4-point scale ('almost never' to 'almost always'), with higher scores indicating higher anxiety. Internal consistency is 0.92 for STAI-S and 0.90 for STAI-T.

The Intolerance of Uncertainty Scale, Short Form (IUS-12) is a 12-item questionnaire measuring individuals' feelings about uncertainty, ambiguous situations and the future.[11] Parents rate on a 5-point Likert scale ranging from 1 = not at all characteristic of me to 5 = entirely characteristic of me. The internal consistency is 0.91.

The visual analogue scale (VAS) is a single item developed for this study to measure food allergy–associated anxiety (FAAA), and is hence non-validated. It asks parents 'How anxious are you about your child's food allergy/allergies?' Parents move the bar along a scale, with the extreme left side labelled 'not anxious at all' and the extreme right side labelled 'extremely anxious', to the position that corresponds to their anxiety level. A higher score indicates higher anxiety. Scores range from 0 to 100.

Ethics approval was obtained through the University of British Columbia Children's and Women's Research Ethics Board. Parents acknowledged consent via the online survey.

2.3 | Data analysis

Descriptive statistics were compiled for all variables.

To explore factors associated with parental anxiety in the context of food allergy, multivariable linear regression was performed with FAAA as the outcome and included the following sets of predictor variables: allergic child characteristics, parent demographic characteristics and parent psychosocial characteristics. Unstandardized and standardized beta values were calculated. The collinearity between predictor variables was assessed using a correlation matrix, and variables were removed from the regression if their correlation coefficient was >0.60. A post hoc power calculation was performed for the multivariate logistic regression using $\alpha = 0.05$ with sample size = 440 (participants with complete data were included in the regression). We tested the hypothesis of no correlation (r-squared = 0) versus some correlation (r-squared ≠ 0), between each of the 19 variables and the outcome of FAAA. The power was determined to be 99.7%.

We compared the sensitivity and specificity of a generalized anxiety measure (STAI-S) and a food allergy–specific anxiety measure (VAS). 'High' state anxiety was defined as a score of ≥47 from the STAI manual,[5] and 'high' FAAA was defined as ≥92.7, one standard deviation above the mean for VAS in this study. STAI-T was not considered as it does not accurately measure current anxiety status.

To evaluate whether food allergy QoL (parental burden) and state anxiety were similar or different constructs, factor analyses were performed on items from each questionnaire separately (20 items from STAI-S, then 17 items from FAQL-PB), and then on all items simultaneously (ie 37 items total). If the two measures share a similar concept, the combined factor analysis would enable to group the items that are part of a similar concept together.

Data were analysed using Stata 15.

3 | RESULTS

Of 1,244 parents who clicked on the survey, 548 completed it (response rate = 44.1%). Most parents were females (94.5%) with a post-secondary degree (93.6%) (Table 1).

The mean FAQL-PB score was 53.7 (95%CI, 51.7, 55.6). The mean STAI-S score was 42.0 (95%CI: 40.9, 43.1). The mean score for FAAA was 71.2 (95%CI, 69.5, 73.0).

3.1 | Multivariable linear regression

The collinearity matrix yielded two variables, which were highly correlated with $r = 0.76$: STAI-S and STAI-T; since STAI-S is more representative of current anxiety, STAI-T was removed from the regression. In the multivariable linear regression using standardized beta values, parents had higher FAAA if they (listed in order of strongest to weakest predictor): had greater parental burden (lower QoL), had higher perception of risk that their child would have a severe reaction upon ingesting their allergen, had higher intolerance of uncertainty, had higher state anxiety, had higher perception of risk that their child would die upon ingesting their allergen or perceived their child's food allergy as more severe. Those reporting personal/family history of mental health issues had lower FAAA (Table 2). The regression model explained 52% of the variability in the outcome (adjusted R-squared = 0.52).

3.2 | Sensitivity and specificity

37.0% of parents were in the 'high' STAI-S group defined as ≥47, and 18.0% of parents were in the 'high' FAAA group defined as ≥92.7. The sensitivity of the STAI-S in correctly identifying patients with high FAAA was 68.6%, indicating that 31.4% of patients with high FAAA would be misclassified as not anxious if STAI-S was used. The specificity of STAI-S in correctly identifying patients with low FAAA was 70%, indicating that 30.0% of patients with low FAAA would be misclassified as anxious if STAI-S was used (see Figure 1).

3.3 | Factor analysis

Factor analysis of the FAQL-PB yielded two factors (physical limitations on life (5 items, $\alpha = 0.85$) vs emotional distress (12 items, $\alpha = 0.95$)). Factor analysis loadings can be found in Table S1. Similarly, factor analysis of the STAI-S yielded two factors (presence of anxiety (10 items, $\alpha = 0.95$) versus absence of anxiety (10 items, $\alpha = 0.92$)). Scores on STAI-S and FAQL-PB were significantly correlated ($r = 0.54$, $P < .001$). However, the combined (STAI-S and FAQL-PB) factor analysis resulted in four factors, maintaining each of the original factors and demonstrating that parental anxiety and QoL are two distinct concepts (see Figure 2).

4 | DISCUSSION

This is the first Canadian study to explore parental anxiety in the context of food allergy. Not only did this study identify that a subset

TABLE 1 Demographic and psychosocial characteristics of survey participants

Allergic child characteristics	
Age, median (IQR)	8 (4, 12)
Sex, n (%)	386 (60.5%) male
Food allergies, n (%) (Note: Multiple answers allowed)	Peanut: 465 (72.9%); tree nut: 364 (57.1%); fish: 69 (10.8%); shellfish: 63 (9.87%); sesame: 78 (12.2%); milk: 186 (29.2%); egg: 191 (29.9%); wheat: 35 (5.49%); soy: 45 (7.05%); other: 151 (23.7%)
Multiple food allergies, n (%)	451 (70.7%)
Ever had anaphylaxis, n (%)	440 (69.0%)
Ever had an emergency department visit, n (%)	442 (69.3%)
Parent demographic characteristics	
Age, median (IQR)	40 (36, 45)
Sex, n (%)	519 (94.5%) female
Post-secondary degree, n (%)	514 (93.6%)
Health professional, n (%)	107 (19.5%)
Married/living with partner, n (%)	510 (92.9%)
Income>$100,000 per year, n (%)	332 (61.0%)
Parent psychosocial characteristics	
Food allergy–associated anxiety, mean (95%CI)	71.2 (69.5, 73.0) out of 100
'High' FAAA (ie ≥92.7), n (%)	102 (18.0%)
Parental burden due to food allergy (QoL), mean (95%CI)	53.7 (51.7, 55.6) out of 102
How great do you think your child's chance is of having a serious reaction upon ingesting the food(s) to which she/he is allergic? n (%)	No chance: 0 (0.0%) Very small chance: 11 (1.9%) Small chance: 26 (4.6%) Moderate chance: 52 (9.2%) Large chance: 66. (11.6%) Very large chance: 171 (30.1%) Always: 242 (42.6%)
How great do you think your child's chance is of dying if your child should ingest food(s) to which she/he is allergic? n (%)	No chance: 9 (1.6%) Very small chance: 44. (7.8%) Small chance: 84 (14.8%) Moderate chance: 132 (23.2%) Large chance: 117 (20.6%) Very large chance: 132 (23.2%) Always: 50 (8.8%)
State anxiety, mean (95%CI)	42.0 (40.9, 43.1) out of 80
'High' state anxiety (ie ≥47), n (%)	210 (37.0%)
Intolerance of uncertainty, mean (95%CI)	31.3 (30.5, 32.1) out of 60
Perceived severity of child's food allergy, n (%)	6 (0.91%) mild; 66 (10.1%) moderate; 539 (82.7%) severe; 41 (6.29%) don't know/missing
Personal/family history of mental illness, n (%)	164 (29.9%)
Personal/family history of anxiety/anxiety disorder, n (%)	228 (41.5%)

of Canadian parents who completed the survey appear to be highly anxious about their child's food allergy, it also highlights that the current available tools to measure anxiety may not accurately identify individuals who need support the most, and emphasizes that a validated tool is needed.

The regression analysis indicates that parents with a higher parental burden (worse QoL) report higher FAAA. This is in line with a qualitative study of eight mothers participating in semi-structured interviews about how food allergy impacts their lives, which found a similar relationship.[2]

In the same qualitative study, it was noted that higher parental anxiety is correlated with higher perceived risk of their child dying from food allergy in the future,[2] which was also found in this study. Perceived risk of having a severe reaction or dying was also captured in another study to determine the effect of a brief psychologic intervention on reducing stress, anxiety and risk perception of parents

TABLE 2 Multivariable linear regression analysis of predictors of FAAA

	Unstandardized beta[a] (95% CI[b])	Standardized beta[c]
Allergic child characteristics		
Age	−0.03 (−0.47, 0.41)	−0.0064
Male	1.21 (−1.74, 4.16)	0.0273
Multiple food allergies	−0.71 (−3.98, 2.56)	−0.0148
Ever had anaphylaxis	−1.70 (−5.45, 2.05)	−0.0353
Ever had an emergency department visit	−0.70 (−4.38, 2.97)	−0.0143
Parent demographic characteristics		
Age	−0.18 (−0.53, 0.18)	−0.0508
Male	−0.89 (−7.31, 5.52)	−0.0094
Post-secondary degree	1.23 (−5.09, 7.56)	0.0134
Health professional	−0.33 (−3.92, 3.26)	−0.0061
Married/living with partner	−0.13 (−2.39, 2.13)	−0.0039
Income>$100,000 per year	0.47 (−2.90, 3.83)	0.0097
Parent psychosocial characteristics		
Parental burden due to food allergy (QoL)	0.42 (0.34, 0.51)	0.4561
How great do you think your child's chance is of having a serious reaction upon ingesting the food(s) to which she/he is allergic?	2.23 (0.86, 3.60)	0.1302
How great do you think your child's chance is of dying if your child should ingest food(s) to which she/he is allergic?	1.46 (0.24, 2.69)	0.0999
State anxiety	0.19 (0.05, 0.33)	0.116
Intolerance of uncertainty	0.28 (0.10, 0.47)	0.1243
Perceived severity of child's food allergy	5.51 (1.10, 9.92)	0.0954
Personal/family history of mental illness	−4.55 (−8.14, −0.96)	-0.0989
Personal/family history of anxiety/anxiety disorder	1.33 (−2.13, 4.80)	0.0306

[a]A positive value for beta indicates that the outcome (in this case, food allergy–associated anxiety) is increasing, as the predictor variable (eg perceived severity of child's allergy) increases. On the other hand, a negative value for beta indicates that the outcome is decreasing as the predictor variable increases. For example, the interpretation for the relationship between FAAA and perceived severity is that the parent's FAAA score is increasing by 5.51 points (ie the parent is more anxious) as the perception of severity of their child's food allergy increases from mild, to moderate, to severe. It is important to note that the units of the variables are all different, and therefore, one cannot compare the relative magnitude of one beta value with another.

[b]A 95% confidence interval for a beta value where neither the lower nor upper limits cross zero indicates that the relationship between the outcome and the predictor variable is statistically significant. If the CI crosses zero, then the relationship is considered non-significant. Cells shaded in grey are statistically significant.

[c]Beta values have been standardized so that the relative magnitude of predictors can be compared. A larger beta value indicates a stronger relationship between the predictor and the outcome.

with food-allergic children.[7] Their study reported reduced state anxiety at six weeks post-intervention, and persistent reduction in perceived risk of having a severe reaction/dying up to one year after the intervention.[7]

Parents with higher state anxiety reported higher FAAA. It was expected that state anxiety would be a better predictor of FAAA than trait anxiety, since state anxiety captures how individuals feel 'now'. Previous literature has used STAI to measure anxiety in parents of children with food allergy and changes in anxiety after interventions,[7,12] but it has never been used in conjunction with a visual analogue scale for FAAA like the one created for this study.

Parents with a higher degree of intolerance towards uncertainty reported higher FAAA. One prior study measuring intolerance of uncertainty in the food-allergic population found that mothers who

followed through with a food challenge referral reported a lower intolerance of uncertainty, although this was not significant.[13] It has been noted that individuals who are highly intolerant of uncertainty are more likely to experience health anxiety and seek additional information to alleviate their anxiety.[13]

Similar to Saleh-Langenberg's research, this study found that higher perceived severity of food allergy was associated with higher anxiety.[14] It is not surprising that parents who think their child's allergy is more severe are more worried about accidental exposure and are at heightened vigilance, regardless of whether the allergy is clinically more severe.

It was interesting that personal or family history of mental illness was negatively associated with FAAA. One of the hypotheses is that parents who have an underlying history of mental illness may

		Food allergy–associated anxiety			
		Yes	**No**	
	High anxiety	True Positive (TP)=70	False Positive (FP)=139	**Positive predictive value:** =TP/(TP+FP) =70/(70+139) =33.5%
State Anxiety	**Low anxiety**	False Negative (FN)=32	True Negative (TN)=325	**Negative predictive value:** =TN/(FN+TN) =325/(32+325) =91.0%
		Sensitivity: =TP/(TP+FN) =70/(70+32) =68.6%	**Specificity:** =TN/(FP+TN) =325/(139+325) =70.0%	

FIGURE 1 Sensitivity = proportion of patients who have a high FAAA score who also have a high STAI score. Specificity = proportion of patients who have a low FAAA score who also have a low STAI score. Positive predictive value = per cent chance that a patient with a high STAI score actually has FAAA. Negative predictive value = per cent chance that a patient with a low STAI score actually does not have FAAA. *Note: 'High' state anxiety was defined as a score of ≥ 47 from the STAI manual, and 'high' FAAA was defined as ≥ 92.7, one standard deviation above the mean for the visual analogue scale

FIGURE 2 Note: r = correlation coefficient; α = Cronbach's alpha, internal consistency among items within each factor
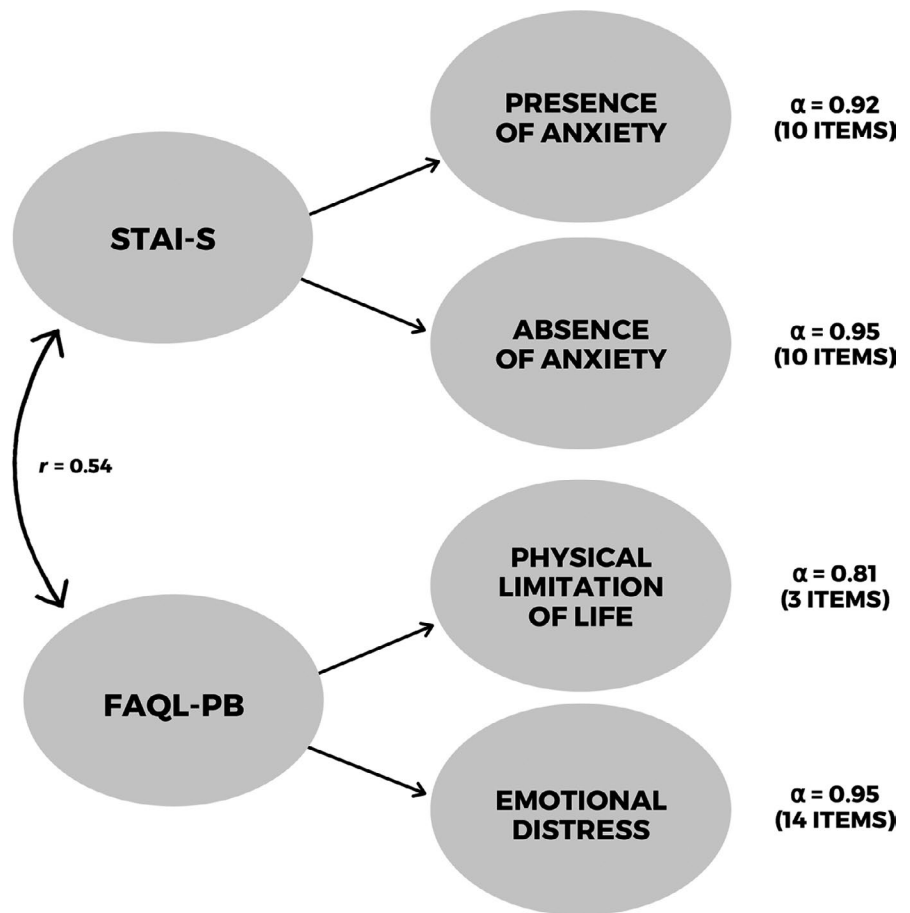
have received medical or psychologic support, and may be better equipped with coping strategies and resources that they can apply to living with their child's food allergy diagnosis.[15]

18.0% of parents in this study reported high FAAA. Although there was no control group in this study, others have found higher anxiety in parents of food-allergic children compared with controls.[16] Compared with mean STAI-S scores from studies of mothers of patients enrolled from paediatric allergy clinics, the mean STAI-S score for parents in this study (42.0) was higher than that reported in three studies in the United Kingdom (34.6, 36.2, 38.0),[7,17,18] and similar to a Turkish study (41.5).[19] Normative STAI-S data available from the United Kingdom indicate a score of 33.3,[17] lower than all published studies of parents of food-allergic children. There are no published Canadian data available on

STAI-S for the general population nor for parents of food-allergic children.

This study found that a subset of parents of food-allergic children are highly anxious according to both the STAI-S and the VAS, but the STAI-S was not sensitive enough to correctly identify all of these parents; over 30% of the parents who reported feeling highly anxious about their child's food allergies were not captured by the STAI-S measure. This poor sensitivity therefore does not allow the STAI-S to be considered as a screening tool for FAAA, and the STAI-S would additionally be time-consuming for clinicians to use in their practices.

Additionally, this study's findings confirmed that the FAQL-PB and the STAI-S are distinct concepts. It was interesting that a previous study also conducted a factor analysis on the FAQL-PB and identified two similar latent variables.[20] These results suggest that utilizing a tool that assesses QOL and assuming the results are measuring anxiety as it pertains to food allergy are inappropriate. Hence, FAQL-PB also cannot be used as a screening tool for FAAA.

While we wait for a screening tool for FAAA to be developed, we recommend using validated measures (ie FAQL-PB) alongside the VAS, and other (non-validated) measures that assess parental distress and coping (ie Food Allergy Parent Questionnaire (FAPQ)).[21] Although imperfect, these measures assessing multiple dimensions of parental experience can help us interpret parental distress and coping in the context of food allergy.

4.1 | Limitations

This study is limited in that a validated tool for FAAA to compare with STAI-S was not available. Although we developed a VAS as a possible surrogate of FAAA, the VAS approach is non-validated and insufficient for widespread clinical use. Unfortunately, this will continue to be a limitation of all food allergy research on anxiety until a validated disease-specific tool is created.

In addition, this survey was unable to confirm physician diagnosis of food allergy since it was administered online; therefore, our sample may include a proportion of children with misdiagnosed food allergy. However, research has shown that the lived experience of those with self-reported food allergy is similar to those with a physician-diagnosed food allergy.[22]

Finally, the sample of parents who participated in this survey, primarily highly educated mothers with relatively high income who are part of a national advocacy group, is not representative of all families with food allergy.

5 | CONCLUSIONS

In summary, this study identified a variety of psychosocial characteristics, which predicted higher FAAA (and one characteristic that predicted lower FAAA). In addition, sensitivity and specificity analysis, and factor analysis, from this study points to a common theme that

current available measures (eg STAI, FAQL-PB), while frequently used in food allergy research, do not adequately identify parents who are highly anxious about their child's food allergy. Given that excessive anxiety in parents of children with chronic disease can have negative consequences on the parent and the child,[16] it is important to develop a validated FAAA screening tool for use outside of research that can be completed quickly by parents and interpreted easily by allergists. Building upon these results, future research by the authors of this study will include development of a validated FAAA screening tool for the clinical setting, to identify parents with high FAAA so that psychosocial supports and resources (which are limited in many settings) can be targeted towards those who most need them.

CONFLICT OF INTEREST

LS participates in research sponsored by DBV Technologies. ESC has received research support from DBV Technologies, has been a member of advisory boards for Pfizer, Pediapharm, Leo Pharma and Kaleo, is a member of the healthcare advisory board for Food Allergy Canada, was an expert panel and coordinating committee member of the National Institute of Allergy and Infectious Diseases (NIAID)–sponsored Guidelines for Peanut Allergy Prevention, and is co-lead of the CSACI oral immunotherapy guidelines. The other co-authors have no conflicts to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.