

1 **TITLE PAGE**

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3 **Validation of the Food Allergy Quality of Life - Parental Burden Questionnaire in the**

4 **U.K.**

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11 **Running title:** Validation of the FAQL-PB in the UK

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26 ABSTRACT

27 *Purpose:* Food allergy can have a profound effect on quality of life (QoL) of the family. The
28 Food Allergy Quality of Life – Parental Burden Questionnaire (FAQL-PB) was developed on a
29 U.S. sample to assess QoL of parents with food allergic children. The aim of this study was
30 to examine the reliability and validity of the FAQL-PB in a U.K. sample and to assess the
31 affect of asking about parental burden in the last week compared to parental burden in
32 general, with no time limit for recall given.

33 *Methods:* 1200 parents who had at least one child with food allergy were sent the FAQL-PB
34 and the Child Health Questionnaire (CHQ-PF50); 63% responded.

35 *Results:* Factor analysis of the FAQL-PB revealed two factors: limitations on life and
36 emotional distress. The total scale and the two sub-scales had high internal reliability (all
37 $\alpha > 0.85$). There were small to moderate but significant correlations between total FAQL-PB
38 scores and health and parental impact measures on the CHQ-PF50 ($p < 0.01$). Significantly
39 greater parental burden was reported for the non-time limited compared to the time limited
40 version ($p < 0.01$).

41 *Conclusions:* The FAQL-PB is a reliable and valid measure for use in the U.K. The scale
42 could be used in clinic to assess physical and emotional quality of life in addition to the impact
43 on total quality of life.

44

45 Key words

46 food allergy; parental burden; quality of life, validity; reliability

47

48 Abbreviations used

49 FAQL-PB: Food Allergy Quality of Life - Parental Burden Scale

50 QoL: Quality of Life

51 CHQ-PF50: Child Health Questionnaire – Parent Form

52

53 INTRODUCTION

54 Food Allergy is an immunologically-mediated adverse reaction to food, with the majority of
55 reactions from milk, eggs, peanuts, tree nuts and shellfish [1]. There is no cure for food
56 allergies and the only way to prevent an allergic reaction is constant vigilance and strict
57 avoidance of the particular food. Symptoms can range from mild itching or a rash, treated
58 with anti-histamine, to anaphylactic shock which includes swelling of airways, difficulty
59 breathing, loss of consciousness and death if not promptly treated with adrenaline [1]. The
60 prevalence of food allergies appears to be increasing and is currently thought to affect
61 between 2% and 10% of the population in the U.K. [1-3].

62

63 Research has identified that those suffering from food allergy as well as those caring for food
64 allergic children have a poorer quality of life (QoL) than either healthy controls or those
65 suffering from other chronic conditions [4-10]. Sicherer et al [4] reported parents of children
66 with nut allergy reported lower scores than a healthy norm group for general health
67 perception, had greater distress and worry for their child's condition and felt there were
68 greater limitations and interruptions to family life. Marklund et al [6] compared parents of food
69 hypersensitive school children with parents of children with no allergic disease and found that
70 the former reported a significantly greater impact on parental emotions, parental time and
71 family activities. A study in the U.K. [7] demonstrated that having a child with peanut allergy
72 particularly affected the mothers, who had poorer quality of life and higher stress and anxiety
73 levels than fathers. More recently a study also found that mothers of food allergic children
74 reported poorer overall quality of life and had a poorer social relationships than mothers of
75 healthy children [10].

76

77 The majority of these studies used generic QoL measures and recently validated food allergy
78 specific quality of life measures have been published [11-14]. Gerth van Wijk [15] has
79 suggested that this is an area that would benefit from the development and validation of more
80 specific measurements, particularly for the affect of a child's food allergy. In order to address
81 this, Cohen et al [16] developed the food allergy quality of life parent burden questionnaire
82 (FAQL-PB), which was validated on a sample of 352 parent participants from the USA. This

83 process highlighted that further development was needed to overcome methodological issues
84 and validation was also needed on other populations. The aim of the present study was to
85 validate the FAQL-PB on a sample of parent participants from the U.K. As the scale was
86 developed in the U.S. there may be environmental or cultural differences or differences in
87 health care regarding food allergy which means that the items developed are not valid in other
88 countries [17]. By establishing if the FAQL-PB is a valid measure in the UK it will ensure it
89 can be utilised in further studies and interventions which aim to improve QoL in parents of
90 children with food allergies.

91

92 In addition Cohen et al [16] noted that it may be useful to look at whether the time span
93 participants are given to report the burden of food allergy has an effect on the results.

94 Therefore in this study a proportion of participants were asked to respond to how their child's
95 food allergy had affected their life in general (with no time span given) and other participants
96 were asked to record impact they had experienced over the previous week (as stated in the
97 original version of the scale).

98

99 **METHODS**

100 **Design**

101 This was a questionnaire based cross-sectional design and involved the administration of a
102 questionnaire pack consisting of questions designed to ascertain demographic information,
103 the Food Allergy Quality of Life- Parental Burden questionnaire (FAQL-PB) to identify levels of
104 parental burden and the Child Health Questionnaire – Parent Form (CHQ-PF50) to measure
105 child's health.

106

107 **Materials**

108 ***The Food Allergy Quality of Life – Parental Burden scale (FAQL-PB)*** [16]

109 The Food Allergy Quality of Life – Parental Burden (FAQL-PB) scale is a 17-item instrument.

110 It utilises a 7-point Likert scale ranging from 1 (not troubled) to 7 (extremely troubled).

111 Questions include issues concerning going on vacation, social activities and worries and

112 anxieties over the previous week. The number circled for each question is summed to

113 provide a total continuous score with a higher score indicating greater burden on the family.
114 Scores can range from 17 to 119 or can be divided by 17 to obtain a mean total score from 1
115 to 7. Internal validity has been reported as strong (Cronbach α , 0.95) [17].

116

117 In the present study the FAQL-PB scale was modified, for a sample of participants, to look at
118 how the child's food allergy affects parents when no time limit for recall is given. For
119 example, a question with a time limit stated 'In the past week, how troubled have you been
120 that your child may not overcome their allergy?' For the modified version the words 'In the
121 past week...' were removed and parents were asked to rate each item based on how they felt
122 each item affected them in general. This allowed participants to answer without being
123 restricted to just recalling what had happened in the past week. This is in line with issues
124 identified by Cohen et al. [16] who noted that participants mentioned that sometimes their
125 results were affected by what they had been doing in the previous week and if that wasn't
126 typical of their normal routine then that may not accurately reflect the parental burden. In all
127 versions the word 'holiday' was used instead of the word 'vacation' as the former is a term
128 more generally used in the U.K.

129

130 ***The Children's Health Questionnaire – PF50*** (CHQ-PF50) [18]

131 The Child Health Questionnaire-Parent Form - 50 is a frequently used basic generic health
132 measurement tool, which is used to examine physical and psychosocial functioning in
133 children; it has been validated for parents of children aged 5 – 18 years and was used by
134 Cohen et al [13] in their validation study. It consists of 15 subscales (with 1 to 6 items in each
135 sub-scale) which measure functioning on a range of physical and psychosocial dimensions.
136 Items are rated on 4 to 6 point Likert scales with responses typically ranging from limited a lot
137 to not limited at all. Scores are summed and then divided by the number of items within the
138 scale to obtain a mean score for each sub-scale; a lower score indicates poorer child health.
139 It has been validated on both clinical and non-clinical samples and has excellent reliability
140 with Cronbach's α >0.85 for child and parent normal sub-sample groups and >0.84 for an
141 asthma clinic population [18]. Internal consistency for this sample of U.K. parents was good

142 with alphas ranging from .76 to .92, apart from two sub-scales measuring parental impact-
143 emotional ($\alpha=.67$) and general health perceptions ($\alpha=.63$).

144

145 ***Demographic and food allergy questionnaire***

146 A demographic questionnaire consisted of a series of closed response questions to gather
147 details about the foods, symptoms and severity of food allergy suffered by each child and
148 demographic information about the child and parent completing the scales. This questionnaire
149 was designed by the researcher, based on questionnaires used in previous published
150 research [19].

151

152 Parents also answered two expectation of outcome questions, following what had been used
153 by Cohen et al [16]. These were “How great do you think your child’s chance is of having a
154 serious reaction upon ingesting the food(s) to which s/he is allergic?” and “How great do you
155 think your child’s chance is of dying if your child should ingest food(s) to which s/he is
156 allergic?” These were answered on a 7-point Likert scale (no chance, very small chance,
157 small chance, moderate chance, large chance, very large chance, always).

158

159 **Participants**

160 Participants were all parents of children with food allergy, identified through the Anaphylaxis
161 Campaign, U.K. This is a charity that offers support predominantly to parents of children with
162 food allergy. In order to comply with data protection, ethical and confidentiality guidelines the
163 charity were provided with the questionnaire packs to distribute; this ensured that the
164 researchers had no access to identifiable personal information about the sample. The charity
165 were responsible for selecting 1200 of their members from their database to whom they sent
166 packs out, 754 were returned (a response rate of 63%).

167

168 **Procedure**

169 Questionnaire packs were sent to 6 members of The Anaphylaxis Campaign for pilot testing
170 and all participants stated the instructions and questions were clear. The Anaphylaxis
171 Campaign U.K. was then asked to post questionnaire packs out to a random sample of 1200

172 members, which equates to approximately 20% of their members. Questionnaire packs were
173 delivered to The Anaphylaxis Campaign with the two versions of the questionnaire placed in
174 the packs in a random order and the Campaign was asked to send these to a random
175 selection of 1200 parents from their database of parents who had children with food allergy.
176 The packs included a cover letter explaining how to take part in the study, ethical
177 considerations and how to return the questionnaires. Participants were asked to complete the
178 questionnaires and place them in a postage paid envelope addressed to the lead researcher.
179 As the study was anonymous no follow-up of non-responders was conducted.

180

181 **Ethical considerations**

182 The study was conducted in accordance with the British Psychological Society's Code of
183 Ethics and Conduct [20] and was approved by the Department's Psychology Research Ethics
184 Committee and the Medical Advisory Board of the Anaphylaxis Campaign. All participants
185 gave their informed consent to take part in the study.

186

187 **Data Analysis**

188 Data was analysed using SPSS version 18.0. There were no floor or ceiling effects for any of
189 the items in the FAQL-PB. Kolmogorov-Smirnov tests were run to assess normality, which
190 revealed most scale scores were not normally distributed, although the FAQL-PB total score
191 was within accepted levels for skewness. Non-parametric tests were therefore conducted.
192 χ^2 squares and Mann Whitney U tests were conducted to assess differences between
193 demographic information in the two groups of participants. Principle Components Factor
194 analysis with an orthogonal varimax rotation was conducted on the FAQL-PB. This
195 exploratory method was chosen as factor analysis had not previously been applied to this
196 scale and so there were no hypotheses regarding presence of sub-scales. The determinant
197 for the correlation matrix was 0.2 showing that there was no multicollinearity in the data. The
198 Kaiser-Meyer-Olkin measure of sampling adequacy was 0.955 and the Bartlett's test was
199 significant (χ^2 (136) = 9520.48, $p < 0.001$), indicating that patterns of correlations are relatively
200 compact and factor analysis should produce distinct, reliable and meaningful factors [21].

201

202 Reliability analysis was conducted on the FAQL-PB in order to ascertain Cronbach's α
203 coefficient for each version of the scale. In order to assess convergent validity Spearman's
204 bivariate correlations were conducted between the FAQL-PB questionnaire mean total score
205 and the CHQ-P50 mean sub-scale scores and with the expectation of outcome mean scores.
206 A priori hypotheses were set regarding reliability and validity of the scale, following criteria set
207 out by Pesudovs et al. [22] and the results reported by Cohen et al. [16]. We expected
208 Cronbach's alpha of >0.7 and <0.9 and moderate convergent validity correlations of >0.3 with
209 sub-scales measuring similar aspects to the scale, including affects on parent's time,
210 emotions, activities and general health. We expected low correlations <0.3 with the other
211 sub-scales. Mann Whitney U tests were conducted to see if there were different total burden
212 scores for the FAQL-PB and the modified FAQL-PB. Due to the number of comparisons run
213 Bonferonni corrections were applied to reduce Type I errors which reduced the accepted
214 alpha level to 0.01.

215

216 **RESULTS**

217 **Characteristics of respondents**

218 A total of 444 parents returned the time limited questionnaire (63.4% response rate) and 310
219 with no time limit (62%) were returned. The majority (92.5%) were completed by the mothers
220 of children with food allergy. Demographics and food allergy characteristics of the time
221 limited and no-time limited group were not significantly different apart from children with
222 allergy being slightly younger in the no time limit group and number of children in the family
223 being slightly higher in the time limit group (Table 1). Almost all respondents stated that their
224 child's food allergy had been clinically diagnosed by skin prick, blood test or food challenge
225 (98.7%). The remainder stated their child's allergy had been diagnosed by clinical history
226 only (Table 1). Children suffered mainly from an allergy to peanut and tree nuts (37%),
227 peanut only (14.8%), tree nut only (1.9%), dairy (9.4%), egg (15.6%), fish (4.2%), fruit (6.8%)
228 and sesame (0.4%). Symptoms included facial swelling (25.5%), hives (14.9%), itching or a
229 rash (20.9%), breathing difficulties (15.8%) and 22.9% had suffered anaphylactic symptoms.

230

231 **Factor Structure of the FAQL-PB**

232 Principal Components Factor Analysis with varimax rotation was conducted to look at the
233 factor structure of the FAQL-PB with and without a time limit and on the overall group. All
234 analyses provided the same solution; therefore results of the whole group are reported here.
235 The analysis revealed two factors with eigenvalues over one. The component transformation
236 matrix was symmetrical showing that the two factors were not correlated. An oblique rotation
237 was run and produced factor loadings that were virtually identical. As the transformation
238 matrix was symmetrical the varimax rotated solution was retained.

239

240 Table 2 shows both factors with factor loadings, eigenvalues and the variance explained. All
241 items had factor loadings of >0.4 apart from item 15: "How troubled have you been about
242 concerns for your child's nutrition because of their food allergy?" This item also had the
243 lowest corrected item-total correlation (0.50) and inter-item correlation (0.28). However, the
244 loading for this was adequate at 0.39. Two items had cross loadings (loadings in brackets in
245 Table 2) and were assigned to the factor with the highest loading. The first factor consists of
246 11 items and relates to emotional distress with questions such as "How troubled have you
247 been by sadness regarding the burden your child carries because of their food allergy?" The
248 second factor consists of 6 items and refers to limitations on life such as "If you and your
249 family were planning a holiday/vacation, how much would your choice of holiday/vacation be
250 limited by your child's food allergy?"

251

252 **Internal reliability of the questionnaire**

253 Cronbach's alphas were excellent for the overall scale for the whole group and for the time
254 limited and no-time limited groups (all $\alpha >0.94$), although the very high alpha indicates some
255 possible redundancy within the scale. Internal consistency was also good for the two
256 domains revealed in the factor analysis (Table 3). Alphas in all versions dropped if any items
257 were deleted (apart from item 15, although this only increased alpha by 0.03), demonstrating
258 all items were important to the scale. Inter-item correlations were above 0.30 for all items
259 (apart from item 15 which was 0.28). Corrected item-total correlations were above 0.50 for all
260 items. Guttman split-half coefficients were >0.90 for both versions of the scale and for the
261 whole group.

262

263 Convergent validity of the scale

264 The total mean score for the FAQL-PB was significantly negatively correlated with all sub-
265 scales of the CHQ-PF50, apart from changes in health and family cohesion (Table 4). As
266 expected, correlations were small to moderate. The same pattern was found for the time
267 limited and no-time limited versions of the scale, except in addition the time limited version did
268 not correlate with self-esteem and the no-time limited version did not correlate with global
269 behaviour. Total FAQL-PB mean score also correlated significantly with both expectation of
270 outcome questions and the mean of the expectation of outcome questions, demonstrating
271 food allergy specific construct validity (Table 4).

272

273 Discriminative validity of the scale**274 *The whole group***

275 There was a significant difference between mean FAQL-PB scores depending on whether
276 you were married/co-habiting or single/divorced/widowed, with the latter having a significantly
277 higher burden score ($p < 0.001$) (Table 5). Employed parents had significantly lower scores
278 than unemployed parents ($p = 0.003$) and parents of children with only one food allergy scored
279 lower than parents of children with more than one food allergy, ($p = 0.006$). Parents of children
280 who suffered from anaphylaxis also scored higher than parents of children who did not,
281 ($p = 0.002$) (Table 5).

282

283 *Time and no-time limited version of the scale*

284 The time limited version of the scale discriminated along marital status with married parents
285 scoring significantly lower than those not married, divorced or widowed, ($p = 0.01$). Parents
286 who worked scored significantly lower than parents who did not work, ($p = 0.01$) (Table 5).

287 There were no other significant differences at the $p < 0.01$ level for this version of the scale.

288 The no-time limited version only discriminated along marital status ($p = 0.002$) (Table 5).

289 Neither version of the scale differentiated between gender of child, number of children with
290 food allergy, number of allergies and presence or not of atopy and anaphylaxis. Comparisons
291 for carrying medication could not be made due to low numbers of those who did not.

292

293 ***Parental burden with and without a time limit***

294 The mean FAQL-PB score for the whole group was 69.99 (S.D.=23.17). It has been
295 suggested [23] that a score difference of 0.5 in a questionnaire with a 7-point Likert scale is
296 the smallest difference in score which patients would perceive as beneficial and would
297 mandate a change in the patient's management [24]. Mean item scores ranged from 1.12 to
298 7, indicating that all parents in this sample were over the threshold for minimal important
299 difference, although caution should be exercised as this measure is more often used in
300 longitudinal studies to measure change after an intervention [25]. Mann Whitney U Test
301 showed that participants in the no-time limited group reported significantly poorer quality of
302 life (total mean score=79.9; S.D.=20.0) than those in the time limited group (mean=63.3;
303 S.D.=22.9), ($p<0.001$). Total mean scores in the no-time limited group were significantly
304 higher than the time limited group along a number of demographic and food allergy
305 parameters (Table 5) (all $p<0.001$).

306

307 DISCUSSION

308 The FAQL-PB has previously been shown to be a reliable and valid tool to use in a U.S.
309 sample of parents. The aim of the present study was to investigate the generalisability of the
310 scale to a U.K. sample, using support group parents of children with food allergy. The study
311 also aimed to investigate whether the length of time a parent is asked about the burden of
312 food allergy has an impact on the level of burden they report. The results demonstrated the
313 scale to have excellent internal consistency with high alpha levels in both the time limited and
314 non-time limited versions and across the whole group. The high Cronbach's alpha for the
315 scale does suggest there may be some redundancy in the scale and a shorter one, more
316 ideal for clinical use, could be developed while retaining the overall reliability and validity of
317 the scale. Factor analysis demonstrated that the scale may be measuring two types of
318 parental burden: limitations on life and emotional distress. Both of these domains had
319 excellent internal reliability in both versions of the scale. It may therefore be possible to adapt
320 the scale to incorporate 2 sub-scale scores as well as an overall score in order to provide
321 more information on the type of parental burden that is most salient, particularly as factor
322 analysis revealed that these two latent variables were not correlated and so measured
323 different aspects of the parent burden construct. Similar results have been found in a study
324 assessing QoL in Chinese families [26]. Leung et al's factor analysis of the FAQL-PB also
325 resulted in two factors with broadly the same items loading onto each factor. They found a
326 smaller number of items loading onto factor two but identified that one factor concerned social
327 limitations and the other concerned emotional impact and food anxiety, similar to the present
328 study. Confirmatory factor analysis will need to be conducted on the scale before the factor
329 structure of the scale can be confirmed.

330

331 The scale demonstrated good cross-sectional convergent validity with significant correlations
332 with most of the sub-scales of the CHQ-PF50. In most cases the strength of the correlations
333 was weak to moderate; this was expected and suggests the scale is not merely measuring
334 parental burden associated with general health. The strongest correlations were with general
335 health perceptions, parental impact –time and parental impact-emotional and family activities,
336 areas found to significantly correlate with the original U.S. sample [16]. Interestingly, no

337 version of the FAQL-PB scale correlated with changes in health or family cohesion, which is
338 different to findings of other studies. Marklund et al [6] found that food hypersensitive children
339 with food-induced breathing difficulties reported improved family cohesion. Similarly, Sicherer
340 et al [4] found family cohesion to be stronger in families with a peanut allergic child compared
341 to healthy norm population scores. This may be because changes in health and family
342 cohesion are measured using only one item in the CHQ-PF50 which can reduce reliability or
343 because the present study was not restricted to children with peanut allergy or breathing
344 difficulties. Changes in general health may also not be sensitive to differences in burden
345 associated with food allergy. More recent studies have also failed to find an association
346 between quality of life and family cohesion [13] and so further research is needed to
347 understand its relationship with families with food allergy.

348

349 The scale demonstrated good convergent disease specific validity with significant correlations
350 with the expectation of outcome questions. The strength of the correlations were similar to
351 that found previously by Cohen et al [16] although were slightly less strong than correlations
352 found in the development of other health related quality of life scales using these expectation
353 of outcome questions [27]. The scale was able to discriminate between some demographic
354 characteristics, however, despite previous research highlighting the importance of gender in
355 food allergy [4], there were no differences in scores depending on gender of food allergic child
356 or gender of parent. This is probably due to the very low number of fathers completing the
357 scale and due to the FAQL-PB measuring burden on the whole on the family, rather than the
358 QoL of the child (which is where gender differences have been found in previous studies).
359 This may mean that burden on family is not influenced by the gender of the child.

360

361 Removing the time limit had a significant impact on the level of burden reported. This version
362 of scale may therefore be useful to gauge how the child's food allergy affects all areas of
363 family life as it is not restricted to just looking at what has occurred over the previous week
364 and would be relevant for a first time use in clinic or for research purposes. This idea was
365 supported in that some parents that returned the time-limited version of the questionnaire
366 stated that they felt restricted reporting how they had felt over the past week and that this did

367 not give an accurate representation of their levels of parental burden. Having a time limit of
368 one week could affect results gained from the scale in two ways. Parents may have an
369 untypical week and be planning a holiday or a social outing in the week preceding completion
370 of the scale, possibly increasing burden scores, or may not be doing something they usually
371 do thus reducing their burden scores. Completing the scale over school holidays may also
372 affect the scores. So looking at burden in the previous week may be a useful clinical tool to
373 assess burden felt at that moment in time but may not accurately reflect the benefits of any
374 interventions that may be put in place. Interventions may focus on better coping and food
375 allergy management skills across a range of areas and so a scale that asks about the burden
376 parents feel in general may better reflect changes in their perceived ability to cope and the
377 burden they feel. Having two versions gives more choice for clinicians and researchers to
378 choose the most appropriate depending on their aims for administering the scale.

379

380 There are a number of limitations of this study. Although parents represented a range of
381 demographics, they were also predominantly white and mothers of food allergic children.
382 This is very typical of members of the Anaphylaxis Campaign and foods reported were fairly
383 representative of the pattern of food allergy reported in the UK [1,3], however there may be a
384 response bias, as we were not able to ascertain characteristics of members of the Campaign
385 who were not selected or did not return their questionnaires. These parents may represent
386 parents of highly allergic children who therefore report a greater burden of food allergy. Or
387 they may feel they suffer less burden, as they have the help and support of the Anaphylaxis
388 Campaign, who run a website, a helpline and a small number of parent workshops each year.
389 It would therefore be useful to validate this scale on clinic populations and parents who do not
390 belong to a support group.

391

392 **Conclusions**

393 This study has demonstrated that the FAQL-PB (with a time limit or without) is reliable and
394 valid for a U.K. population. Factor analysis revealed two distinct domains: emotional distress
395 and limitations on life. Gaining information on which type of parental burden is more salient
396 may be useful in order to appropriately direct support for parents. Having versions of the

397 scale with and without time limits increases the choice for clinical and research use and can
398 be utilised to measure short and longer-term changes over time or effects of an intervention.
399 Validation using a range of different time frames and on clinic and non-support group
400 populations is now needed.

401

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405

406

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502 Dubois, A. E. (2002). Development and validation of a health-related quality-of-life
503 questionnaire in patients with yellow jacket allergy. *Journal of Allergy and Clinical*
504 *Immunology*, 109, 162-70.

505 Table 1. Characteristics of respondents in the time limited and no-time limited group and the
 506 whole group

		Whole group	Time limited group	No-time limited group	P values
Gender of respondent		699 (92.5)	412 (92.8)	286 (92.3)	0.79
Mother					
Married/Co-habiting		645 (85.3)	377 (84.9)	268 (86.5)	0.56
Single/divorced/widowed		85 (11.3)	53 (11.9)	31 (10.0)	0.41
Work status	Working full-time or part- time	533 (70.5)	320 (72.0)	213 (68.8)	0.32
	Homemaker/Unemployed/Retired	195 (25.7)	108 (24.3)	86 (27.7)	0.30
Children in family (mean N)		2.1	2.2	2.0	0.01
Children in family with food allergy (mean N)		1.1	1.1	1.1	0.98
Food allergic children's age (mean years)		8.9	9.5	8.2	<0.001
Gender of child with food allergy		500 (60.9)	303 (62.6)	196 (58.5)	0.24
Male					
	Female	321 (39.1)	181 (37.4)	139 (41.5)	0.24
Number of food allergies reported	1	402 (49.1)	246 (51.0)	155 (46.3)	0.20
allergy	>1 allergy	417 (50.9)	236 (49.0)	180 (53.7)	0.16
Allergy diagnosed clinically		810 (98.7)	483 (99.8)	327 (97.6)	0.12
Suffers from anaphylaxis		474 (57.7)	275 (56.8)	197 (58.9)	0.57
Has medication		790 (96.2)	465 (96.1)	323 (96.4)	0.80
Carries EpiPen/AnaPen		749 (91.2)	442 (91.3)	306 (91.3)	0.95
Has eczema/asthma/hayfever		580 (76.7)	340 (76.6)	239 (77.1)	0.59

507 Values given as number (%)

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513 Table 2. Factor analysis loadings, eigenvalues and % variance explained for FAQL-PB

Item (abbreviated wording)	Factor One Emotional Distress	Factor Two Limitations on Life
Frightened by thought child will have a reaction	.828	
Worry won't be able to help child if they have allergic reaction	.812	
Worry that child may not overcome their food allergy	.808	
Sadness regarding burden child carries because of food allergy	.796	
Troubled by concerns over child's health	.785	
Troubled by child attending school, camp or daycare	.769	
Anxiety related to child's food allergy	.756	
Troubled by leaving child in care of others	.751	
Concern over child being near others while eating	.710	
Frustration over others lack of appreciation of seriousness of allergy	.695	
Worry child will not have normal upbringing	.683	
Choices limited when planning a holiday		.837
Choices limited when going to a restaurant		.835
Limited when participating in social activities		.800
Have to spend extra time preparing meals	(.426)	.625
Take special precautions before leaving the house	(.497)	.585
Concern over child's nutrition		.392
Eigenvalue	7.21	3.99
% variance explained	42.39	23.48

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516 Table 3. Cronbach's alpha for FAQL-PB scale and the two sub-scales

	Factor One	Factor Two	Overall scale
	Limitations on life	Emotional distress	
Whole group	0.952	0.860	0.952
Time limited group	0.950	0.860	0.952
No-time limited group	0.930	0.857	0.941

517

518 Table 4. Correlations between the FAQL-PB mean total score with the CHQ-PF50 mean sub-
 519 scale scores and expectation of outcome questions

CHQ-PF50	Whole group	Time limited group	No-time limited group
Global Health (GGH)	-.260**	-.243**	-.360**
Physical Functioning (PF)	-.205**	-.223**	-.208**
Role/Social Limitations – Emotional- Behavioural (REB)	-.238**	-.270**	-.231**
Role/Social Limitations-Physical (RP)	-.256**	-.216**	-.341**
Bodily Pain (BP)	-.169**	-.139**	-.235**
General Behaviour (BE)	-.155**	-.172**	-.150*
Global Behaviour (GBE)	-.102*	-.148**	-.085
Mental health (MH)	-.251**	-.267**	-.240**
Self-Esteem (SE)	-.109**	-.059	-.193**
General Health Perceptions (GH)	-.408**	-.373**	-.540**
Changes in Health (CH)	.070	.095	.040
Parental Impact – Emotional (PE)	-.314**	-.351**	-.348**
Parental Impact – Time (PT)	-.419**	-.466**	-.450**
Family Activities (FA)	-.390**	-.446**	-.411**
Family Cohesion (FC)	-.031	-.009	-.054
Expectation of Outcome			
Serious reaction on ingestion of food	.218**	.189**	.255**
Dying on ingestion of food	.361**	.317**	.455**
Expectation of outcome mean score	.344**	.301**	.418**

520 *p<0.05 **p<0.01

521 Table 5. Mean (standard deviation) FAQL-PB total scale scores for the time limited group, no-time limited group and the whole group, split by respondent
 522 characteristics

		Whole group	Time limited group	No time-limited group	p-values^a
Parent gender	male	66.69 (17.74)	61.83 (17.02)	72.93 (17.23)	0.18
	female	69.88 (23.62)	63.10 (23.38)	79.71 (20.33)	<0.001
Marital status	married	69.00 (23.27) ^b	62.42 (22.85) ^c	78.29 (20.58) ^d	<0.001
	single/divorced/widowed	75.56 (21.87) ^b	68.30 (22.98) ^c	86.46 (14.39) ^d	<0.001
Work status	working	68.19 (23.55) ^b	61.50 (23.09) ^c	78.31 (20.47)	<0.001
	not working	73.96 (22.33) ^b	67.57 (22.70) ^c	82.00 (19.27)	<0.001
Gender of child with allergy					
	male	69.94 (23.23)	64.09 (23.32)	78.73 (20.08)	<0.001
	female	70.07 (23.12)	62.02 (22.28)	80.43 (19.97)	<0.001
N of children with food allergy					
	1 child	69.30 (23.30)	62.33 (22.93)	79.27 (20.02)	<0.001
	>1 child	75.24 (24.05)	71.11 (24.88)	80.74 (22.15)	0.53
N of allergies					
	1 allergy	67.47 (22.58) ^b	61.36 (22.86)	76.68 (18.51)	<0.001
	>1 allergy	72.37 (23.51) ^b	65.33 (22.91)	81.70 (21.02)	<0.001

Table 5 continued

Child atopic

yes	70.82 (23.36)	64.10 (23.21)	80.33 (20.11)	<0.001
no	67.28 (22.41)	60.88 (21.99)	76.37 (19.53)	<0.001

Child suffers from anaphylaxis

yes	72.23 (23.37) ^b	64.30 (23.35)	83.04 (18.59) ^d	<0.001
no	66.55 (22.73) ^b	62.10 (22.56)	73.37 (21.33) ^d	<0.001

523 Values given as mean (SD); ^a p-values for comparisons between time-limited and no-time limited group; ^b p<0.01 for comparisons between the participant
 524 characteristic for the whole group; ^c p<0.01 for comparisons between the participant characteristic for the time limited group; ^d p<0.01 for comparisons between the
 525 participant characteristic for the no-time limited group.