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Living at risk: Exploring the psychological effects of childhood food allergy on mothers

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Abstract
Objectives: Food allergy (FA) is a growing public health concern, imposing significant psychosocial burdens on families and necessitating strict allergen avoidance. The unpredictability of severe reactions is associated with increased anxiety, dietary restrictions, and reduced quality of life.
Methods: We conducted a cross-sectional study including 77 mothers of children (0–12 years) with FA and 71 mothers of healthy children. Participants completed the Spielberger State-Trait Anxiety Inventory (STAI), Zarit Caregiver Burden Scale (ZCBS), and European Health Impact Scale (EUROHIS-QOL). Statistical analyses compared anxiety, caregiver burden, and quality of life between groups and explored sociodemographic factors.
Results: Mothers in the FA group had significantly higher state anxiety (STAI-S) ($P < 0.001$) and ZCBS scores ($P < 0.001$) compared to controls. However, trait anxiety (STAI-T) did not differ significantly between groups ($P = 0.508$). Additionally, mothers of children with FA reported lower EUROHIS-QOL scores ($P = 0.009$). Low maternal educational levels ($P = 0.005$) and middle-range income levels ($500–1000/month, $P = 0.027$) were significantly associated with higher anxiety and caregiver burden. Cow's milk protein allergy (CMPA) specifically increased trait anxiety ($P = 0.035$) and reduced mothers' quality of life ($P = 0.003$). No significant associations were found between anxiety or caregiver burden and anaphylaxis or other allergenic triggers.
Conclusion: Food allergy significantly elevates maternal anxiety and caregiving burden, and reduces quality of life, especially in CMPA cases. Sociodemographic factors exacerbate these effects, highlighting the need for comprehensive, multidimensional interventions. Psychological support and broader public awareness initiatives may help alleviate adverse outcomes and improve caregiver well-being.

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Introductıon

Food allergy (FA) is an important public health concern, with increasing prevalence reported in recent years.[1-3] FA affects approximately 10% of infants and 4–5% of older children.[4] Management primarily involves avoiding exposure to allergens and implementing a treatment plan in case of accidental exposure.[5] In some cases, exposure to food allergens can be life-threatening. While FA-related anaphylaxis is rare, the estimated incidence of fatal food anaphylaxis is 1.81 per million people per year.[6]

The unpredictability of severe allergic reactions significantly impacts families, resulting in heightened anxiety, dietary restrictions, and decreased quality of life.[7] The constant necessity to avoid allergenic foods can limit social activities, leading to social isolation.[8] Routine daily activities, such as meal preparation, school attendance, or dining out, can impose substantial psychosocial burdens.[9] Research has highlighted that families of children with FA experience a reduction in their quality of life.[8-10] Children with FA and their families have reported experiencing anxiety and depressive symptoms due to these changes.[11,12] Caregivers of children with a history of anaphylaxis also tend to adopt a more protective and cautious attitude.[13] These findings highlight that FAs impact not only physical health but also psychological well-being. Therefore, understanding the psychosocial burden this situation places on families is of great importance.

Social support has been identified as a protective factor against psychiatric symptoms and disorders among families of children with FA.[14] However, research on quality of life, caregiver burden, and psychological effects among these families, especially in our country, remains limited. This lack of data hampers the development of comprehensive support systems.

In this study, we aim to assess the quality of life, caregiver burden, and anxiety levels among mothers of children with FA, examine the influence of demographic factors, and compare these outcomes to those of mothers with healthy children.

Methods

Study design and participants

This cross-sectional study included mothers of children aged 0–12 years diagnosed with FA attending the Pediatric Allergy and Immunology Clinic at Kartal Dr. Lutfi Kirdar City Hospital from June 1, 2023, to September 1, 2023. The control group comprised mothers of children aged 0–12 years visiting the Pediatric Health and Disease Clinic for routine checkups without active complaints (e.g., vaccinations, monthly assessments, nutritional education, growth, and development monitoring). Exclusion criteria included metabolic diseases, immune deficiencies, chronic heart diseases, endocrine, renal, pulmonary, gastrointestinal, hepatic, central nervous system diseases, malignancies, or other chronic illnesses in children or family members. Mothers with active psychiatric conditions, those receiving psychiatric medications, or those unwilling to participate were also excluded. Written informed consent was obtained from all participants after detailed explanations. Participants completed a demographic questionnaire, Spielberger State-Trait Anxiety Inventory (STAI), Zarit Caregiver Burden Scale (ZCBS), and European Health Impact Scale (EUROHIS-QOL).

Ethical approval was granted by the Ethics Committee of Kartal Dr. Lutfi Kirdar City Hospital (Approval No: 2023/514/250/29, Date: May 29, 2023), and the study was conducted per the Declaration of Helsinki. A sample size of at least 140 participants (70 per group) was determined using G*Power 3.1, considering an alpha error of 0.05, power of 0.9, and effect size of 0.5.

Food allergy

Food Allergy diagnosis was made by pediatric allergy specialists based on clinical history, positive skin prick test results, and/or specific IgE testing. Food challenge tests were performed when clinically indicated.[15]

Spielberger State-Trait Anxiety Inventory

Developed by Spielberger et al.,[16] the Turkish validity of the scale was established by Öner.[17] The scale consists of two subscales, each containing 20 items that assess state and trait anxiety. The State Anxiety Inventory (STAI-S) measures how an individual feels at a particular moment under specific conditions, while the Trait Anxiety Inventory (STAI-T) reflects how an individual generally feels. Scores on the scale range from 20 to 80, with higher scores on each subscale indicating higher levels of anxiety.

Zarit Caregiver Burden Scale

Developed by Zarit et al. and validated in Turkish by Özlü et al., the Zarit Caregiver Burden Scale (ZCBS) consists of 19 items rated from 1 to 5, with scores ranging from 19 to 95.[18,19] Higher scores indicate increased distress and caregiver burden.

European Health Impact Scale-8 (EUROHIS-QOL)

EUROHIS-QOL is an 8-item scale adapted from the World Health Organization Quality of Life Scale. This scale covers various topics, including quality of life, health status, energy level, independence in daily activities, self-esteem, social relationships, economic situation, and living environment. The scale scores each item from 0 (not at all) to 5 (completely).[20] Eser et al. conducted the Turkish validity and reliability study of the scale in 2010. There are various methods to calculate the scale scoring, including taking the average of responses, summing the scores, or converting the total score to a scale of 100.[21] Higher scores represent a better quality of life.

Statistical analysis

The data were analyzed using IBM SPSS Statistics Standard Concurrent User V 29 (IBM Corp., Armonk, New York, USA).

Descriptive statistics were presented as the number of units (n), percentage (%), mean ± standard deviation, median, interquartile range, minimum, and maximum values. We assessed the normal distribution of numerical variables using the Shapiro–Wilk normality test. The homogeneity of variances among groups was analyzed using Levene's test. If the data had a normal distribution, we performed independent sample t-tests for comparisons between two groups of numerical variables; otherwise, we used the Mann–Whitney U test. We conducted one-way analysis of variance for comparisons among three groups of numerical variables, based on the normal distribution of the data. For comparisons of categorical variables among groups, Pearson's chi-square analysis was employed. If the results of the chi-square analysis were significant, we conducted subgroup analyses using the Bonferroni-corrected two-proportion Z test. Based on the normality of the data, we used Pearson or Spearman correlation coefficients to compare numerical variables with each other. P-value < 0.05 was considered statistically significant.

Results

This cross-sectional study included 77 mothers of children aged 0–12 years diagnosed with FA and 71 mothers of healthy children. As shown in Table 1, the average age of mothers did not significantly differ between the FA group and the control group (P = 0.213). Likewise, there was no significant difference in the median age of children, which was 18.0 months (IQR: 22.5) in the FA group and 24.0 months (IQR: 27.0) in the control group (P = 0.128). Gender distribution between groups also showed no significant difference, with 44.2% (n = 34) females in the FA group and 59.2% (n = 42) females in the control group (P = 0.068). The groups did not differ significantly in terms of maternal education levels (P = 0.124) or employment status (P = 0.074). The median duration of food allergy diagnosis was 12 months (IQR: 13.5), and 13.0% (n = 10) of mothers reported having another child with FA (Table 1).

The most frequently reported allergenic foods were eggs (72.7%, n = 56) and cow's milk (66.2%, n = 51), followed by hazelnuts (16.9%, n = 13) and peanuts (15.6%, n = 12). Other allergens, including sesame, wheat, fruit, and fish, were reported less frequently. The most commonly observed clinical symptoms among children with FA were redness (88.3%, n = 68), restlessness (84.4%, n = 65), and itching (81.8%, n = 63). Additional symptoms observed were rashes (49.4%, n = 38), diarrhea (27.3%, n = 21), stomach ache (18.2%, n = 14), vomiting (10.4%, n = 8), respiratory distress or wheezing indicative of anaphylaxis (6.5%, n = 5), and constipation (5.2%, n = 4) (Table 2).

As presented in Table 3, mothers in the FA group had significantly higher scores on the STAI-S (P < 0.001) and ZCBS (P < 0.001) compared to mothers of healthy children. There was no significant difference in STAI-T scores between groups (P = 0.508). Mothers in the FA group also reported significantly lower EUROHIS-QOL scores (P = 0.009). Analysis by sociodemographic characteristics revealed that mothers with primary or secondary education had significantly higher STAI-T scores compared to those with higher education levels (P = 0.005). Caregiver

Table 1 Comparison of sociodemographic characteristics between food allergy and control groups.

	Groups		
	Food allergy (n = 77)	Control (n = 71)	P
Mother's age (year)	31.8 ± 5.1	30.9 ± 4.3	0.213‡
Child's age (month)	18.0 (22.5)	24.0 (27.0)	0.128†
Gender, n (%)			
Girl	34 (44.2)	42 (59.2)	0.068¶
Boy	43 (55.8)	29 (40.8)	
Mother's education level, n (%)			
Primary and Secondary school	9 (11.7)	16 (22.5)	0.124¶
High school and above	68 (83.3)	55 (77.5)	
Employment status, n (%)			
Employed	15 (19.5)	24 (33.8)	0.074¶
Unemployed	62 (80.5)	47 (66.2)	
Family income, n (%)			**0.001**¶
<500 $	17 (22.1)[a]	24 (33.8)[a]	
500-1000 $	31 (40.3)[a]	9 (12.7)[b]	
> 1000 $	29 (37.6)[a]	38 (53.5)[a]	
Duration of food allergy (months)	12 (13.5)		
Food allergy in another child, n (%)	10 (13.0)		

n: Unit (patient); number %: Column per cent, numerical data are given as mean ± standard deviation, median (minimum–maximum) or median (interquartile range) values; ‡: Independent samples *t* test; †: Mann–Whitney U test, ¶: Pearson chi-square test. P < 0.05 is statistically significant.

[a,b]indicate differences between groups in each row. There is no statistical difference between groups with the same superscripts.

Table 2 Foods causing allergic reactions and observed symptoms.

Allergic foods	n	%
Egg	56	72.7
Cow's milk	51	66.2
Hazelnut	13	16.9
Peanut	12	15.6
Sesame	3	3.9
Wheat	1	1.3
Fruit	1	1.3
Fish	1	1.3
Others	8	10.4
Symptoms		
Redness	68	88.3
Restlessness	65	84.4
Itching	63	81.8
Rashes	38	49.4
Diarrhea	21	27.3
Stomach ache	14	18.2
Vomiting	8	10.4
Shortness of breath - Wheezing	5	6.5
Constipation	4	5.2

n: Unit (participant) number; %: Column per cent.

burden was significantly higher in mothers earning $500-1000 per month (46.4 ± 12.3) compared to those earning less than $500 (40.4 ± 9.0) or more than $1000 (42.7 ± 9.1) per month (P = 0.027). Furthermore, mothers with another child who had FA showed significantly higher ZCBS scores (P = 0.024). No other significant associations were found between anxiety, caregiver burden, or quality of life scores and maternal age, child age, child gender, number of siblings, employment status, or duration of food allergy diagnosis.

Evaluation based on specific allergenic triggers indicated that only cow's milk protein allergy (CMPA) was significantly associated with elevated STAI-T scores (P = 0.035) and decreased EUROHIS-QOL scores (P = 0.003). Egg allergy was not significantly associated with differences in any of the assessed scales (STAI-T, P = 0.472; STAI-S, P = 0.615; ZCBS, P = 0.991; EUROHIS-QOL, P = 0.671) (Figure 1) (Table 4).

As presented in Table 5, significant positive correlations were found between STAI-S and STAI-T scores (r = 0.572, P < 0.001). Similarly, ZCBS scores showed significant positive correlations with both STAI-S (r = 0.416, P < 0.001) and STAI-T (r = 0.574, P < 0.001) scores. Conversely, significant negative correlations were observed between EUROHIS-QOL scores and STAI-S (r = −0.306, P = 0.007), STAI-T (r = −0.518, P < 0.001), and ZCBS (r = −0.501, P < 0.001) scores, highlighting that increased anxiety and caregiver burden were associated with reduced quality of life.

Discussion

It is crucial to understand and address the potential psychosocial effects of FA on families to optimize FA management strategies and provide targeted support for parents. Numerous studies in the literature have separately evaluated caregiver burden, depression, and anxiety in families with food-allergic children.[8,22-24] Living with constant concerns about potential allergic reactions and the necessity for rigorous allergen avoidance significantly impacts the daily routines of both children with FA and their families.[25] In the present study, we evaluated the quality of life, caregiver burden, and anxiety levels among mothers of children diagnosed with FA and compared these outcomes with mothers of healthy children.

Previous studies have emphasized that the greatest psychological impact of FA in children is on mothers.[26] Accordingly, this study specifically targeted mothers to explore the psychosocial consequences of FA on families. Consistent with existing literature, we employed the STAI to assess parental anxiety related to their child's FA.[27,28] The STAI effectively distinguishes between state anxiety—reflecting transient feelings of anxiety experienced during specific situations—and trait anxiety, indicative of a person's enduring predisposition to perceive situations as stressful.[28] State anxiety, therefore, captures maternal anxiety at the moment of FA assessment, while trait anxiety reflects more generalized anxiety tendencies. Goodwin et al. previously reported no significant differences in anxiety or depression between families of children with FA and those without.[29] However, in alignment with the majority of published studies, our findings revealed significantly higher anxiety levels among mothers of children with FA compared to controls.[22,27,28] Kılıç et al. similarly reported increased anxiety, depression, and caregiver burden in mothers of FA-affected children.[8] Our results demonstrated significantly elevated state anxiety among mothers in the FA group; however, trait anxiety did not differ significantly from controls. This contrasts with Soller et al., who reported a correlation between elevated state anxiety and heightened FA-related anxiety among parents.[30] Possible explanations for this discrepancy may include differences in sample characteristics, such as the severity of allergic reactions experienced, parental educational levels, socioeconomic status, and availability of social support systems. Methodological differences, including variations in the timing of assessments or the specific instruments used to measure FA-related anxiety, may also have contributed to these contrasting results. Further research addressing these factors could help clarify the nuanced relationship between situational anxiety responses and general anxiety predisposition among parents managing food allergies. Similar to prior research, our data did not identify associations between maternal anxiety levels and child age, gender, number of children, or previous anaphylaxis history.[28] Nevertheless, mothers with only primary education exhibited significantly higher STAI-T scores compared to those with higher educational attainment. Charana et al.,[31] in a study conducted in Greece, also found higher STAI-T anxiety among parents with either low or high education levels compared to intermediate education levels. This suggests that individuals with lower educational attainment might face greater challenges in disease understanding and management, consequently experiencing increased anxiety.

Consistent with the previous literature, our findings indicate that mothers of children with FA experience a significantly greater caregiver burden compared to mothers

Table 3 Comparison of scale scores by groups and sociodemographic characteristics.

	STAI-S			STAI-T			ZCBS			EUROHIS-QOL		
	rho	Mean± SD	P	rho	Mean ± SD	P	rho	Mean ± SD	P	rho	Mean ± SD	P‡
Groups												
Food allergy		42.2 ± 10.7	**<0.001**‡		43.5 ± 8.7	0.508‡		46.1 ± 11.9	**<0.001**‡		27.0 ± 5.4	**0.009**‡
Control		34.9 ± 8.3			42.6 ± 8.3			39.8 ± 6.6			29.1 ± 4.3	
Mother's age	0.083¥		0.315	0.056¥		0.497	0,037¥		0.651	−0,003¥		0.968
Child's age	−0.154		0.062	−0.007		0.928	−0.035		0.674	−0.063		0.447
Child's age,(yr)												
≤3		39.6 ± 10.7	0.066‡		42.9 ± 8.7	0.710‡		39.2 ± 8.8	0.339‡		28.2 ± 5.0	0.389‡
>3		36.1 ± 8.5			43.5 ± 8.1			42.4 ± 10.2			27.4 ± 5.0	
Gender												
Girl		37.4 ± 10.4	0.104‡		42.4 ± 8.4	0.338‡		42.0 ± 10.2	0.203‡		28.1 ± 5.1	0.832‡
Boy		40.2 ± 10.0			43.8 ± 8.6			44.2 ± 10.2			27.9 ± 4.9	
Number of siblings	−0.019		0.823	0.106		0.200	−0.074		0.374	−0.057		0.493
Mother's education level												
Primary and secondary school		39.2 ± 10.5	0.825‡		47.4 ± 10.0	**0.005**‡		42.1 ± 8.6	0.607‡		27.2 ± 5.1	0.369‡
High school and above		38.7 ± 10.3			42.2 ± 7.9			43.3 ± 10.5			28.2 ± 5.0	
Employment status												
Employed		38.9 ± 9.9	0.899‡		43.2 ± 7.6	0.902‡		44.5 ± 9.1	0.341‡		27.9 ± 4.1	0.917‡
Unemployed		38.7 ± 10.4			43.0 ± 8.8			42.6 ± 10.6			28.0 ± 5.3	
Family income												
<$500		38.5 ± 10.6	0.302Φ		44.0 ± 8.8	0.271Φ		40.4 ± 9.0	**0.027**¤		27.1 ± 5.0	0.23Φ
$500-1000		40.8 ± 11.3			44.2 ± 9.1			46.4 ± 12.3			27.8 ± 5.5	
> $1000		37.7 ± 9.3			41.8 ± 7.9			42.7 ± 9.1			28.7 ± 4.6	
Duration of food allergy	−0.048		0.680	−0.111		0.339	0.014		0.903	−0.109		0.346
Food allergy in another child												
Yes		44.9 ± 9.9	0.403‡		48.1 ± 6.9	0.073‡		54.0 ± 11.2	**0.024**‡		26.8 ± 3.4	0.901‡
No		41.9 ± 10.8			42.8 ± 8.8			44.9 ± 11.6			27.0 ± 5.6	
Anaphylaxis												
Yes		36.8 ± 8.9	0.241		37.0 ± 6.8	0.083		41.8 ± 15.7	0.405		28.6 ± 6.2	0.495
No		42.6 ± 10.7			44.0 ± 8.7			46.4 ± 11.7			26.9 ± 5.3	

‡: Independent samples t test; rho: Spearman correlation coefficient; ¥: Pearson correlation coefficient; Φ: One-way analysis of variance. P < 0.05 is statistically significant.

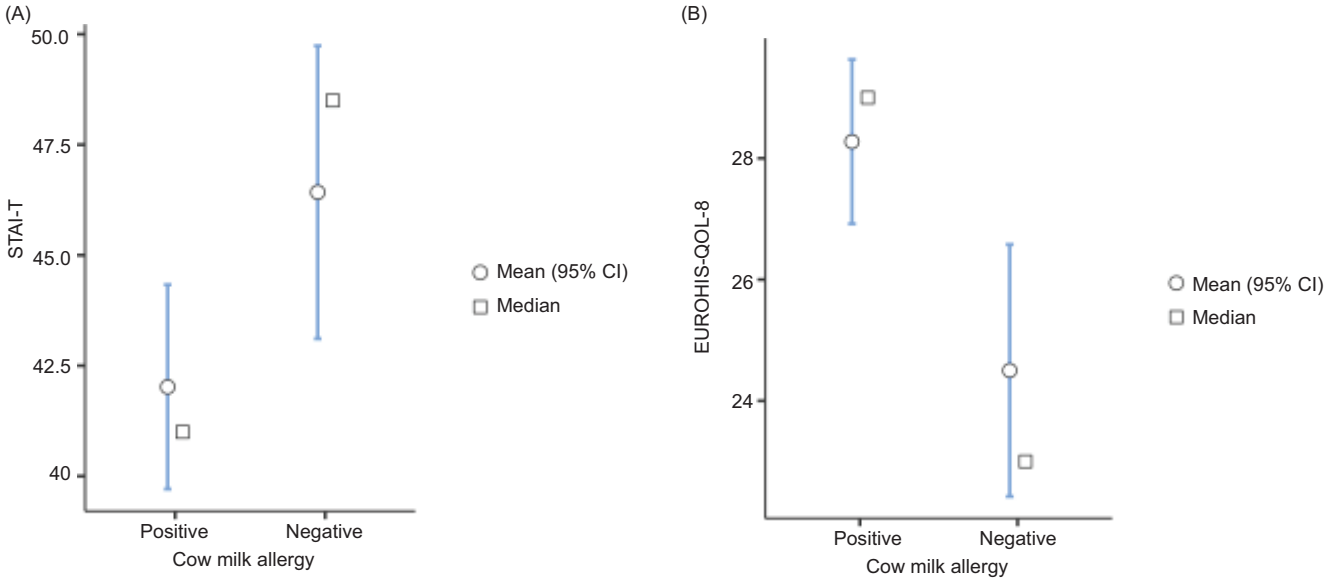

Figure 1 Comparison of STAI-T and EUROHIS-QOL scores in mothers of children with CMPA and other food allergies.

Table 4 Comparison of scales based on food allergy triggers.

		Group	N	Mean	P
Cow's milk protein allergy	STAI-T	Yes	51	42.0 ± 8.4	**0.035**
		No	26	46.4 ± 8.6	
	STAI-S	Yes	12	44.2 ± 8.6	0.502
		No	65	41.9 ± 11	
	ZCBS	Yes	51	45.5 ± 12.0	0.521
		No	26	47.3 ± 11.8	
	EUROHIS-QOL	Yes	51	28.3 ± 5.0	**0.003**
		No	26	24.5 ± 5.4	
Egg Allergy	STAI-T	Yes	56	43.9 ± 7.9	0.472
		No	21	42.3 ± 10.6	
	STAI-S	Yes	56	42.6 ± 10.4	0.615
		No	21	41.2 ± 11.7	
	ZCBS	Yes	56	46.1 ± 11.7	0.991
		No	21	46.1 ± 12.7	
	EUROHIS-QOL	Yes	56	27.2 ± 4.8	0.671
		No	21	26.6 ± 6.7	

P < 0.05 is statistically significant.

of healthy children.[5,8,12,32] Our results also align with studies demonstrating that this caregiver burden is closely associated with elevated anxiety levels among caregivers managing FA.[33,34] Howe et al. reported that multiple factors—including multiple food allergies, the age at initial allergic reaction, socioeconomic status, atopic dermatitis, and the risk of anaphylaxis—can markedly influence caregiver quality of life. Their findings particularly highlighted that allergies to milk or eggs notably increased the caregiving burden.[35] Parents described the experience as caring for a child "living at risk."[36] Similarly, our study found that low family income and having another child diagnosed with FA were significant factors contributing to increased caregiver burden. Unlike other studies, however, our findings did not demonstrate an increased caregiver burden associated with anaphylaxis, which we attribute to the relatively small number of anaphylactic cases in our sample. While previous studies frequently employed the Food Allergy Quality of Life–Parental Burden Questionnaire to evaluate parental quality of life and caregiver burden, we utilized the ZCBS in this study due to the absence of a validated Turkish version of the former instrument.[10,34]

Previous research has consistently highlighted that caregivers of children with chronic illnesses exhibit more psychiatric symptoms and experience a lower overall quality of life.[37-39] In line with these findings, our study also demonstrated reduced quality of life among families caring for children with FA.[40,41] Parents of children with FA

Table 5 Relationships between scale scores.

	STAI-S		STAI-T		ZCBS	
	r	P	r	P	r	P
STAI-T	0.572	<0.001				
ZCBS	0.416	<0.001	0.574	<0.001		
EUROHIS-QOL	−0.306	0.007	−0.518	<.001	−0.501	<0.001

r: Pearson correlation coefficient.

commonly reported experiencing constant vigilance and an overwhelming need to monitor their child's daily activities closely. These concerns were frequently attributed to inadequate awareness about FA in educational settings and insufficient support from healthcare providers.[42] The necessity to strictly avoid allergenic foods can significantly restrict social participation, dietary habits, and lead to social isolation for both the affected child and their family, further diminishing their quality of life.[8] Mandell et al. also emphasized that dietary restrictions due to FA have profound implications for the entire family, including siblings, who often also modify their behavior to prevent exposure to allergens.[43] Interventions such as ensuring widespread availability of epinephrine auto-injectors in schools, enhancing food labeling clarity to better support parental understanding, and establishing parent-to-parent support groups have the potential to significantly enhance the quality of life for families impacted by FA.[10] Additionally, it is essential for healthcare professionals to recognize the psychological burden that FA places on families and to refer patients and caregivers for appropriate psychological or psychiatric support when necessary.

In our patient group, CMPA and egg allergy were identified as the most common allergy triggers. Our findings demonstrated that CMPA significantly affected both trait anxiety and quality of life among caregivers. Abrams et al. similarly reported that avoiding cow's milk often results in substantial social restrictions, placing children with CMPA at a higher risk of psychosocial difficulties compared to those with other food allergies.[44] In our country, cow's milk and dairy products play a prominent role in traditional dietary patterns. Previous research highlights that the impact of food allergies can vary significantly between cultures, influenced by dietary practices, cultural norms, and the prevalence of specific allergenic foods.[34,45] For instance, Jung et al. studied 190 Korean families and observed reduced quality of life among parents of children allergic to soy or cow's milk, emphasizing the central role of soy in Asian diets.[34] Similarly, Warren et al. indicated that avoidance of commonly consumed foods such as cow's milk and eggs poses greater daily challenges for families in Western societies, further decreasing parental quality of life.[10]

Our study has several limitations, including its single-center design and relatively small sample size, which may limit the generalizability of the findings. Additionally, only mothers were included, based on previous research suggesting that mothers tend to experience greater psychosocial impacts.[26] Despite these limitations, the use of multiple validated scales adapted for the Turkish population enhances the robustness and reliability of our results.

Conclusion

In conclusion, our study demonstrates that mothers of children with food allergies experience significantly higher anxiety levels, greater caregiver burden, and diminished quality of life. Specifically, mothers of children with CMPA exhibited particularly elevated anxiety levels, further exacerbating their quality-of-life impairment. These findings highlight the importance of addressing the psychiatric support needs of mothers managing childhood food allergies, alongside enhancing societal awareness of the challenges associated with food allergies. Comprehensive interventions encompassing medical, social, and psychological support, as well as structured educational programs and supportive community-based activities, are recommended to substantially improve the overall quality of life for these caregivers.

Ethics Approval and Consent to Participate

The study was approved by the Dr. Lütfi Kırdar City Hospital Ethics Committee, Approval number 2023/514/250/29, dated May 29, 2023, and informed consent has been obtained from all participants.

Consent for Publication

Participants were enrolled with informed consent, and the study was conducted per the Declaration of Helsinki.

Availability of Data and Materials

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Competing Interests

The authors declare no competing interests.

Clinical Trial Number

Clinical trial number: not applicable.

Authors' Contributions

All authors contributed equally to this article.

Conflicts of Interest

The authors declare no potential conflicts of interest to research, authorship and/or publication of this article.

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