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## Factors associated with parental burden among parents of children with food allergies in China: A cross-sectional study.

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**Title:** Factors associated with parental burden among parents of children with food allergies in China: A cross-sectional study.

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**Keywords:** Food allergy; food hypersensitivity; caregiver burden; social support; child

**Word count:** 4448

**Abstract**

**Objective:** This study aimed to investigate the factors associated with parental burden among parents of children with food allergies (FAs) in China.

**Design:** Cross-sectional study.

**Setting:** The participants were recruited through the Internet and one child health center of a tertiary hospital in Changsha, China.

**Participants:** A total of 346 parents of children with FA were recruited using a convenient sampling method. After excluding the invalid questionnaires, 330

questionnaires were included for the analysis.

**Outcome measures:** The data of general and disease-specific information of children with FAs and their parents, as well as parental burden, social support, and coping style of parents, were collected using a self-developed questionnaire and standard measurement tools with good psychometric properties. Univariate analysis and multivariate stepwise regression analysis were used to analyze the data.

**Results:** The valid questionnaire rate was 95.38% (330/346). Parents' financial affordability for their children's FAs and their social support were key protective factors for parental burden. This study also found that parents' working conditions, the number of identified and highly suspected food allergens, the number of children's FA-related symptoms, and whether children took amino acid milk powder were the factors associated with parental burden.

**Conclusions:** Health professionals should pay more attention to parents who are not at work and whose children have more food allergens and more FA-related symptoms because these parents often have a higher parental burden. Furthermore, it is important to improve financial support for children's FAs and social support for parents of children with FA to decrease their parental burden.

#### **Strengths and limitations of this study**

- To our knowledge, this study was the first time to select social support as well as coping styles as the independent variable to investigate the factors associated with parental burden among parents of children with food allergies.
- A longitudinal study with larger sample size is needed to explore the linkage

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4 between caregiver burden and influencing factors.  
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## 6 7 **1. Background**

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9 Food allergy (FA) is a common allergic disease in childhood; it is a hypersensitive  
10 reaction of the immune system to proteins in food. It can affect the skin and  
11 gastrointestinal, respiratory, and cardiovascular systems with varying degrees of  
12 severity<sup>1</sup>. Children with FA often have multiple allergic comorbidities, such as asthma,  
13 eczema, and hay fever<sup>2</sup>. FA affects approximately 5% of global children aged 0–5 years  
14 diagnosed by open oral food challenge (OFC) testing<sup>3</sup>, and it has become one of the  
15 fastest-growing public health problems with epidemiological characteristics, especially  
16 in developed countries<sup>4-6</sup>. The prevalence of FA in children has also been increasing at  
17 an alarming rate recently in China<sup>7-8</sup>. FA requires strict avoidance of food allergens.  
18 Accidental exposure to food allergens can endanger children's health if effective  
19 avoidance measures are not taken<sup>9</sup>. Avoiding these allergens is not simple, as many  
20 products contain "hidden ingredients" or traces of food allergens, such as nuts<sup>10</sup>.  
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40 For younger children with FA, the disease burden not only falls on the child but  
41 also on the parents<sup>11-13</sup>. Parents of children with FA may be particularly concerned  
42 about their children's allergies and take on additional burdens in their daily lives, as  
43 they often play an important role in managing their children's allergies. Specifically,  
44 studies have shown that families with children with FA spend more time and energy on  
45 grocery shopping because avoiding allergens requires caregivers to double-check food  
46 labels for allergens. Preparing food also increases extra work for families with children  
47 with FA, as parents need to prepare separate meals for allergic children and prevent  
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4 cross-contamination<sup>13</sup>. Parents also report its negative effects on daily activities and  
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6 socialization<sup>11 12 14</sup>. There is growing evidence that families with children with FA have  
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8 higher financing costs than those whose children are without FA<sup>15</sup>. In addition to  
9  
10 practical and financial needs, research suggests that FA is also associated with negative  
11  
12 psychological consequences for parents, including greater stress and worry<sup>11</sup>. FA does  
13  
14 hurt parental health-related quality of life<sup>16</sup>. This may lead to a decrease in parental  
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16 caring capacity and affect the development of children.  
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22 Evidence in the literature shows that the younger the child, the greater the burden  
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24 of care on the parents [16]. Furthermore, the severity of FA, the presence of  
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26 concomitant allergic diseases, the number of food allergens, and children's allergy  
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28 history also influence parental burden<sup>17-19</sup>. Regarding parent-related factors, the gender  
29  
30 of the parents (father/mother) influenced the caregiving burden. Four studies<sup>18-21</sup>  
31  
32 compared the caregiving burden between parents and found that mothers had a higher  
33  
34 caregiving burden than fathers in at least one area. Nevertheless, existing studies on the  
35  
36 factors influencing parental burden among parents of children with FA have been  
37  
38 limited to factors related to children with FA, neglecting the influence of other factors,  
39  
40 such as demographic characteristics (e.g., age, gender, and education degree) and other  
41  
42 changeable variables (e.g., social support and coping style) of parents. Social support  
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44 and coping style are considered two changeable variables that may influence the  
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46 parental burden on parents of children with FA. Social support acts as an available  
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48 external resource against stress<sup>22</sup>. Good social support from family, society, and others  
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50 can reduce an individual's stress and thus may lower caregivers' burden<sup>23</sup>. In addition,  
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4 coping style refers to an individual's efforts to change cognition and behavior to meet  
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6 specific internal and external environmental requirements beyond their existing  
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8 capacity and resources <sup>24</sup>. Caregivers with an active coping style could better cope with  
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10 their problems and thus may reduce the burden of caring for children with FA <sup>25</sup>.  
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12 However, there is a lack of research exploring the relationship between social  
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14 support/coping style and parental burden among the parents of children with FA.  
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20 In addition, the literature on this topic in China is limited. Only one study focused  
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22 on parental quality of life in families with children with FA in Hong Kong, a developed  
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24 city in China. However, this article emphasized the validation and discriminative ability  
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26 of the traditional Chinese version of the Food Allergy Quality of Life-Parental Burden  
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28 (TC-FAQL-PB) questionnaire in Hong Kong. It only used univariate analysis to  
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30 identify the influencing factors, so the results were yet to be verified. Furthermore,  
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32 because of the culture, society, and economic differences between Hong Kong and  
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34 mainland China, the results may not be representative, and the associated factors of  
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36 parental burden in the context of mainland China need to be further explored. Recently,  
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38 the authors of this study developed and validated the simplified Chinese version of the  
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40 Food Allergy Quality of Life-Parental Burden (SC-FAQL-PB) questionnaire, which  
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42 has a wider range of applications than TC-FAQL-PB in China. It has been proven to  
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44 have good psychometric properties and can be used as an effective measure in further  
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46 studies.  
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56 Therefore, this study aims to explore the factors associated with parental burden  
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58 among parents of children with FA in China, considering general information about  
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4 children and parents and the social support and coping styles of parents.  
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## 6 **2. Methods**

### 7 **2.1 Study design**

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11 A cross-sectional study was conducted to explore the factors influencing parental  
12 burden among parents of children with FA in China. This study was reported following  
13 the STROBE checklist (see Supplementary File S1).  
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### 19 **2.2 Setting and participants**

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22 A total of 346 parents of children aged 0–5 years diagnosed with FA were recruited  
23 by a convenient sampling method through the Internet and one child health center of a  
24 tertiary hospital in Changsha, China. Inclusion criteria were as follows: (a) a parent  
25 aged  $\geq 18$  years, (b) had at least a child aged  $\leq 5$  years who was clinically diagnosed  
26 with FA by a clinician, (c) was the main caregiver of children, and (d) could understand  
27 and communicate normally. Exclusion criteria were as follows: (a) a parent whose child  
28 was complicated with malignant diseases or other organic lesions and (b) a parent  
29 whose child had a mental illness or cognitive impairment.  
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43 The sample size was calculated using an independent variable-to-subject ratio  
44 reported by Kendall <sup>26</sup>. He recommended at least a 1:10 ratio for a cross-sectional  
45 investigation. Moreover, the “rules of thumb” for determining the sample size for  
46 regression equations using six or more predictors stated that an absolute minimum of  
47 10 participants per predictor variable was appropriate <sup>27</sup>. The independent variables in  
48 this study included general information, social support, and coping style. Considering  
49 the 27 independent variables and a 15% invalid rate, a minimum of 318 cases was  
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4 required. Thus, a sample size of 346 in this study met this requirement.  
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### 6 7 **2.3 Recruitment and data collection** 8

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10 Before completing the questionnaire, the participants were informed of the  
11 research-related information, including the research's objectives and investigation  
12 process, anonymity, and voluntary participation. The questionnaires were completed on  
13 the Internet using Wenjuanxing, an online questionnaire collection platform in  
14 mainland China. Wenjuanxing ensured that respondents completed the entire  
15 questionnaire to avoid missing data. It also avoided the problems of manual data entry  
16 and improved the efficiency and accuracy of data collection and screening. Those who  
17 had difficulty filling out the electronic questionnaire could contact researchers to guide  
18 them to finish the e-questionnaire or ask for a paper questionnaire. The researchers'  
19 contact information was provided to the participants at the time of recruitment. Before  
20 the formal survey, we selected 10 subjects who met the study inclusion criteria for the  
21 pre-survey. The pre-survey ensured that the general information items and  
22 questionnaire instructions developed by our research team were logical and easy to  
23 understand. Data collection began in December 2021 and lasted for three months.  
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### 45 46 **2.4 Measures** 47

#### 48 *General information questionnaire* 49

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51 A general information questionnaire consisted of items to gather details about the  
52 children's and parents' demographic information and other disease-specific  
53 characteristics of children with FA. The children's information included months of age,  
54 gender, growth standards (using Z-point), the number of identified and highly suspected  
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4 food allergens, the number of FA-affected systems, the number of FA-related  
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6 symptoms, the time of the first diagnosis of FA, the frequency of adverse reactions,  
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8 whether they were going to kindergarten, whether they were taking breast milk, whether  
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10 they had an intake of special formula milk powder, whether they had an egg allergy,  
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12 whether they had a milk allergy, whether they had experienced severe anaphylaxis,  
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14 whether they had a history of anti-allergy drug use, and whether they had visited the  
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16 emergency room. Parents' information included gender, age, parental history of self-  
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18 reported allergies, education level, working conditions, financial affordability for  
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20 children's FAs, knowledge about FA (self-reported), whether they were obtaining  
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22 learning knowledge about FA from health professionals, and whether they had a  
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24 medical knowledge background.  
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32 *The Simplified Chinese version of the Food Allergy Quality of Life-Parental Burden*  
33 *(SC-FAQL-PB) questionnaire*  
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37 The FAQL-PB questionnaire was developed by Cohens *et al.*<sup>28</sup>. The original  
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39 English version has been translated into many languages and validated in the United  
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41 Kingdom, Australia, Thailand, Iran, South Korea, Hong Kong, and China. The authors  
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43 adapted and validated the Chinese version, SC-FAQL-PB. It utilizes a 7-point Likert  
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45 scale ranging from 1 (not troubled) to 7 (extremely troubled). There are 17 items  
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47 covering family and social activities, meal preparation, health issues, and emotional  
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49 issues, measuring two dimensions of limitations in life (3 items) and emotional distress  
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51 (14 items). Items for the measurements of parental burden were negatively worded (e.g.,  
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53 “How much would your choice of vacation be limited by your child's food allergy?”).  
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4 A higher SC-FAQL-PB score indicates a higher parental burden. The confirmatory  
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6 factor analysis results confirmed the two-factor model proposed by Leung as the most  
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8 reasonable fit for explaining the factor construct of the SC-FAQL-PB <sup>29</sup>. The internal  
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10 coefficient of consistency was 0.946, with a test-retest reliability of 0.926. The  
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12 Cronbach's alpha of the scale in our sample was 0.958.  
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### 16 17 *Social Support Rating Scale (SSRS)*

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19 The social support level was assessed with the Social Support Rating Scale (SSRS),  
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21 which was developed by Dr. Xiao <sup>30</sup>. It includes 10 items measuring three dimensions:  
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23 subjective support (3 items), objective support (4 items), and support utilization (3  
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25 items). Objective support refers mainly to visible practical support, such as direct  
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27 material assistance and social networks. Subjective support refers to an individual's  
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29 emotional feelings and satisfaction with being supported, respected, and understood in  
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31 society. Support utilization refers to the extent to which individuals utilize social  
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33 support <sup>31</sup>. A higher total score indicated a higher social support level. This total support  
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35 score was classified into three categories: low ( $\leq 22$ ), moderate (23–44), and high ( $\geq$   
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37 45) levels <sup>32</sup>. The SSRS has been widely used in Chinese domestic contexts <sup>33–35</sup>. The  
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39 cumulative contribution rate of the three common factors was 54.26% <sup>36</sup>. The internal  
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41 consistency of the SSRS in this study was acceptable. The Cronbach's alpha of the scale  
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43 in our sample was 0.778.  
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### 52 53 *Simplified Coping Style Questionnaire (SCSQ)*

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55 Coping style was accessed with the Simplified Coping Style Questionnaire, which  
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57 is a self-report survey that includes two subscales: active coping (12 items) and passive  
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4 coping (eight items) <sup>37</sup>. All items were rated using a 4-point Likert scoring method,  
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6 ranging from zero (never) to three (always). The scores of each subscale item were  
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8 summed up to generate a subscale score. Dai proposed a formula for the coping style  
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10 tendency—coping style tendency = active coping criterion score ( $Z_a$  score) - passive  
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12 coping criterion score ( $Z_p$  score)—to determine an individual's main coping style in  
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14 stress situations <sup>38</sup>.  $Z_a/Z_p = (\text{actual score for the subscale} - \text{mean of the score for the}$   
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16  $\text{subscale among the national norm sample}) / (\text{standard deviation of the score for the}$   
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18  $\text{subscale among the national norm sample})$ . If the value of the coping style tendency >  
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20 0, it means the individual mainly adopts an active coping style. The Chinese national  
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22 norm for the active coping score is  $1.78 \pm 0.52$ , and for the passive coping score, it is  
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24  $1.59 \pm 0.66$  <sup>37</sup>. The SCSQ has been widely used to assess caregivers' coping styles in  
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26 China, and the Cronbach's alpha coefficient of the two subscales ranged from 0.75 to  
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28 0.90 <sup>39-43</sup>. The cumulative contribution rate of the two common factors was 48.5% <sup>44</sup>.  
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30 In the present study, the Cronbach's alphas of the active and passive coping styles were  
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32 0.909 and 0.752, respectively.  
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## 43 **2.5 Data analysis**

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45 The collected data were analyzed using the IBM SPSS 26.0 program. Descriptive  
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47 statistics were used to investigate the demographic and disease-specific characteristics  
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49 of children with FA and their parents, social support, coping style, and parental burden  
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51 among the parents of children with FA. The Kolmogorov–Smirnov test was performed  
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53 to confirm the normality of the measurement data. Means with standard deviations  
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55 (Mean  $\pm$  SD) were calculated for normally distributed data, while median and  
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4 interquartile ranges were calculated for non-normally distributed measures.  
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7 Frequencies and percentages were calculated for the count data. Between-group  
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9 differences were tested using T-tests and ANOVA for normally distributed data to  
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11 investigate parental burden. Spearman's correlation analysis was used to analyze the  
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13 correlations between parental burden, coping style, and social support among the  
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15 parents of children with FA. All reported *P* values were two-sided, with a significance  
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17 level of 0.05.  
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23 Multivariate stepwise regression analysis was performed to identify the factors  
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25 influencing parental burden among parents of children with FA, with the total FAQL-  
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27 PB score as the dependent variable. The variables with a *P* < 0.1 for univariate analysis  
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29 were all introduced. In the stepwise regression analysis, the variables were screened  
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31 stepwise based on the criteria of  $\alpha \leq 0.05$  in and  $\alpha \geq 0.1$  out model. When the  
32  
33 independent variables were unordered categorical variables, they were converted into  
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35 dummy variables and then included in the regression analysis. The analysis used  $R^2$  as  
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37 the power of a linear model to represent the percentage of the current variation of *y*  
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39 explained by the independent variables in the current model.  
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## 45 **2.6 Ethical consideration**

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48 This research was approved by the Ethical Review Committee of Xiangya School  
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50 of Nursing, Central South University, on July 15, 2021 (approval number: E202192).  
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52 All participants filled out questionnaires voluntarily, from whom signed informed  
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54 consent was obtained. It was emphasized that the participation was anonymous, and all  
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56 data were kept strictly confidential and used for research purposes only.  
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## 2.7 Patient and public involvement

The study was designed to investigate the factors associated with parental burden among parents of children with food allergies (FAs) in China. However, participants were not involved in the survey instrument, recruitment, or study conduct. Participants are anonymous in this study, and therefore the study team will be unable to disseminate the results to study participants.

## 3. Results

### 3.1 General characteristics of children with FA and their parents

A total of 346 parents of children with FA were enrolled in this study, with a response rate of 100%. Sixteen questionnaires were removed because the filling time was less than five minutes (six questionnaires) and because the parents were not the primary caregivers of children in their daily lives (ten questionnaires). The valid questionnaire rate was 95.38% (330/346). Table 1 shows the characteristics of the children with FA and the relationships between the characteristics and parental burden among parents. Most children (75.5%, 249/330) had milk allergies, and 46.7% (154/330) of the children were allergic to eggs. Only three children had experienced severe anaphylaxis, and 21.8% (72/330) had visited the emergency room. As presented in Table 2, the male-to-female ratio of parents was 1:16.4, their mean age was 30.41 years, and most completed college or had a higher degree (87.9%, 290/330). More than half of the parents (70.0%, 231/330) were at work, and most parents (77.9%) reported that the financial costs caused by FA were affordable. More details can be found in tables 1 and 2.

**Table 1. General characteristics of children with food allergies and the relationship between the characteristics and parental burden (n=330).**

Characteristics	Parental burden			
	Mean	SD	t/F/r	P
<b>Gender, n (%)</b>			0.62	0.54
Male	187 (56.7)	65.19	21.24	
Female	143 (43.3)	63.85	18.18	
<b>Whether they were going to kindergarten, n (%)</b>			-1.55	0.12
Yes	10 (3.0)	55.00	19.16	
No	320 (97.0)	64.91	19.93	
<b>Growth standards, n (%)</b>			-1.02	0.31
Without growth retardation	313 (94.8)	64.35	20.05	
With growth retardation	17 (5.2)	69.41	17.99	
<b>Whether they were taking in breast milk, n (%)</b>			0.31	0.76
Yes	77 (23.3)	65.22	20.82	
No	253 (76.6)	64.42	19.72	0.02*
<b>Whether they had an intake of special formula milk powder, n (%)</b>				
Moderately hydrolyzed formula	64 (19.4)	60.69	18.97	
Deep hydrolyzed formula	106 (32.1)	63.75	20.21	
amino acid milk powder	75 (22.7)	70.67	17.97	
None <sup>a</sup>	85 (25.8)	63.29	21.15	
<b>Whether they had an egg allergy</b>			2.45	0.02*
Yes	154 (46.7)	67.42	17.57	
No	176 (53.3)	62.15	21.28	
<b>Whether they had a milk allergy</b>			1.40	0.16
Yes	249 (75.5)	65.91	20.08	
No	81 (24.5)	61.91	19.44	
<b>The number of identified and highly suspected food allergens, n (%)</b>			-3.33	<0.01**
5 or fewer	225 (68.2)	62.21	20.13	
More than 5	105 (31.8)	69.74	18.65	
<b>The number of FA-affected systems<sup>b</sup>, n (%)</b>			-3.38	<0.01**
1 or 2	270 (81.8)	62.88	19.76	
More than 2	60 (18.2)	72.42	19.27	
<b>The number of the FA-related symptoms, n (%)</b>			-3.81	<0.01**
3 or fewer	231 (70.0)	61.93	19.75	
More than 3	99 (30.0)	70.87	19.11	
<b>The time of the first diagnosis of FA (month of age), n (%)</b>			0.76	0.45
0-5 months	260 (78.8)	65.04	19.68	
>5 months	70 (21.2)	63.00	21.01	
<b>The Frequency of adverse reactions, n (%)</b>			6.84	<0.01**
1-5 times	154 (46.7)	62.77	20.30	
6-10 times	69 (20.9)	60.07	17.63	
>10 times	107 (32.4)	70.18	19.80	
<b>Whether they had experienced severe anaphylaxis, n (%)</b>			0.24	0.81
Yes	3 (0.91)	67.33	26.86	
No	327 (99.1)	64.58	19.94	
<b>Whether they had a history of anti-allergy drug use, n (%)</b>			1.98	<0.05*
Yes	140 (42.4)	67.14	19.10	
No	190 (21.8)	62.75	20.41	
<b>Whether they had visited the emergency room, n (%)</b>			0.58	0.57
Yes	72 (21.8)	65.83	20.35	
No	258 (78.2)	64.27	19.87	
<b>Children' month of age, Mean±SD</b>		15.07±8.18		0.26

\*P&lt;0.05. \*\*P&lt;0.01.

<sup>a</sup> Children didn't take in special formula milk powder, only took in breast milk or formula milk.<sup>b</sup> FA-affected systems involve the integumentary system, respiratory system and gastrointestinal system.



**Table 2. General characteristics of parents having children with food allergies and the relationships between the characteristics and parental burden (n=330).**

Characteristics	Parental burden			
	Mean	SD	t/F/r	P
<b>Gender, n (%)</b>				
Male	19 (5.8)	62.95	22.29	-0.37
Female	311 (94.2)	64.71	19.84	0.71
<b>Parental history of self-reported allergies, n (%)</b>				
Yes	211 (67.0)	64.55	19.29	-0.08
No	109 (33.0)	64.73	21.34	0.94
<b>Education level, n (%)</b>				
Junior high school or below	12 (3.6)	82.75	16.48	5.79
Senior high school	28 (8.5)	72.68	18.15	<0.01**
College	95 (28.8)	67.02	20.44	
Undergraduate	158 (47.9)	61.44	19.73	
Graduate or above	37 (11.2)	59.95	16.68	
<b>Working conditions, n (%)</b>				
at work	231 (70.0)	61.77	20.44	-4.03
Not at work	99 (30.0)	71.22	17.12	<0.01**
<b>Financial affordability for children's FAs, n (%)</b>				
Fully affordable	62 (18.8)	56.69	20.14	15.04
Able to afford	195 (59.1)	62.56	19.00	<0.01**
Harder to afford	67 (20.3)	76.10	17.22	
Unable to afford	6 (1.8)	84.50	12.11	
<b>Knowledge about FA (self-reported), n (%)</b>				
Yes	113 (34.2)	62.54	18.31	-1.36
No	217 (65.8)	65.69	20.72	0.17
<b>Whether they were obtaining knowledge about FA from health professionals, n (%)</b>				
Yes	233 (70.6)	63.30	20.22	-1.85
No	97 (29.4)	67.75	19.04	0.07
<b>Whether they had a medical background, n (%)</b>				
Yes	56 (17.0)	62.75	20.14	-0.77
No	274 (83.0)	64.99	19.93	0.45
<b>Parents' age (years), Mean±SD</b>	30.41±3.68			-0.06

\* $P < 0.05$ . \*\* $P < 0.01$ .

### 3.2 Factors influencing parental burden among parents of children with FA

The results in Table 1 show that parents whose children were allergic to eggs ( $67.42 \pm 17.57$ ) had a higher parental burden score than those whose children did not ( $62.15 \pm 21.28$ ), and parents whose children had a history of antiallergy drug use ( $67.14 \pm 19.10$ ) had a higher parental burden score than those whose children did not ( $62.75 \pm 20.41$ ). In addition, the parental burden increased with the number of children's identified and highly suspected food allergens, the number of children's FA-affected systems, and the number of children's FA-related symptoms. The intake of children's special formula milk affected the parental burden score, and parents whose children took in amino acid

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4 milk powder had the highest parental burden ( $70.67 \pm 17.97$ ). Moreover, parents whose  
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6 children had up to 10 times adverse reactions ( $70.18 \pm 19.80$ ) had higher parental  
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8 burden scores than parents whose children had 1–5 times ( $62.77 \pm 20.33$ ,  $P < 0.01$ ) and  
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10 6–10 times adverse reactions ( $60.07 \pm 17.63$ ,  $P < 0.01$ ). As Table 2 shows, the parental  
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12 burden scores among the parents of children with FA decreased with educational level  
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14 and financial affordability for children's FA. Moreover, parents who were not at work  
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16 ( $71.22 \pm 17.12$ ) had a higher parental burden than those who were at work ( $61.77 \pm$   
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18  $20.44$ ). In addition, all of them reported significant statistical differences ( $P < 0.05$ ).  
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20 However, no significant difference in parental burden existed between groups divided  
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22 by children's and parents' genders when children had visited the emergency room,  
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24 when children had experienced severe anaphylaxis, when there was a parental history  
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26 of self-reported allergies, etc. The correlation analysis results in Table 3 show that  
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28 parental burden was negatively correlated with the parents' social support ( $r = -0.291$ ,  
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30  $P < 0.001$ ) and coping style ( $r = -0.225$ ,  $P < 0.001$ ).  
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40 **Table 3. Correlation between parental burden and social support and coping style (n=330).**

	Parental Burden
	<i>Spearman correction coefficients (r)</i>
Social support	-0.291***
Coping style <sup>a</sup>	-0.240***

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43 \*\*\*  $P < 0.001$ .

44 <sup>a</sup> It represents the coping style tendency (identified after Z-conversion), which means the  
45 individual's main coping style in stress states.

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47 Some factors were introduced in a multiple stepwise linear regression to ensure a  
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49 stable model. The children-related factors included the number of identified and highly  
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51 suspected food allergens, the number of FA-affected systems, the number of FA-related  
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53 symptoms, the frequency of adverse reactions, whether they had an intake of special  
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55 formula milk powder, whether they had an egg allergy, whether they had experienced  
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57 severe anaphylaxis, and whether they had a history of antiallergy drug use. Parent-  
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related factors included education level, working conditions, financial affordability for children's FA, knowledge of FA (self-reported), medical knowledge background, social support, coping style, and whether they were obtaining learning knowledge from health professionals. "Intake of special formula milk powder-None" was set as a reference variable for 'Intake of special formula milk' in introducing dummy variables into regression analysis. In Table 4, the results show that the number of identified and highly suspected food allergens ( $\beta = 0.128$ ,  $P < 0.01$ ), the number of the FA-related systems ( $\beta = 0.108$ ,  $P < 0.05$ ), amino acid milk powder intake ( $\beta = 0.152$ ,  $P < 0.01$ ), working conditions ( $\beta = -0.171$ ,  $P = 0.000$ ), financial affordability for children's FA ( $\beta = 0.223$ ,  $P = 0.000$ ), and social support ( $\beta = -0.238$ ,  $P < 0.01$ ) are independently associated with the parental burden on parents of children with FA. Coping style was not entered into the regression equation in this study. The multiple linear regression equation models were statistically significant ( $P < 0.001$ ,  $F = 18.240$ ) and explained 25.3% of the variance (Adjusted  $R^2$  was 23.9%).

**Table 4. A multivariate linear stepwise regression analysis of the factors influencing the parental burden of parents having children with food allergies (n=330).**

Model	Coefficient			<i>t</i>	<i>P</i>
	Unstandardized coefficient		Standard coefficient		
	<i>B</i>	<i>SE</i>	<i>Beta</i>		
(Constant)	63.968	7.357		8.695	0.000 ***
The number of identified and highly suspected food allergens	5.462	2.093	0.128	2.610	0.009 **
The number of the FA-related symptoms	4.699	2.157	0.108	2.179	0.030 *
Intake of special formula milk powder - Amino acid milk powder intake	7.239	2.332	0.152	3.105	0.002 **
Whether they had an intake of special formula milk powder - None <sup>a</sup>	0				
Working conditions	- 7.450	2.111	- 0.171	-3.529	0.000 ***
Financial affordability for children's FAs	6.539	1.480	0.223	4.419	0.000 ***
Social support	-0.612	0.128	-0.238	-4.773	0.004 **

Note:  $R^2=0.253$ ; adjusted  $R^2=0.239$ ;  $\Delta F=4.748$ ; \*  $P<0.05$ , \*\* $P<0.01$ , \*\*\* $P<0.001$ ; Dependent variable: parental burden among parents with a FA child. The variables with  $P < 0.1$  from univariate analysis were introduced.

<sup>a</sup> It was set as a reference variable for 'Intake of special formula milk' in the process of introducing dummy variables into regression analysis.

#### 4. Discussion

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4 Providing quality care for children with FA will undoubtedly place a burden on  
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6 their parents. The purpose of the study was to explore the associated factors of parental  
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8 burden among the parents of children with FA. In our sample, the score for parental  
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10 burden was 64.61 (SD = 19.96). Among children-related characteristics, it was  
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12 determined that the number of identified and highly suspected food allergens and the  
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14 number of FA-related systems positively influenced the parental burden among parents  
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16 of children with FA. These results are consistent with previous studies<sup>17 29 45</sup>. When  
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18 children have more food allergens, their parents need to spend more effort to take a  
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20 wide range of avoidance measures, which increases the parental burden. In addition,  
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22 when FA affects many systems involving the skin and the gastrointestinal, respiratory,  
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24 and cardiovascular systems, parents feel more worried about their children's health<sup>11</sup>.  
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26 In one of the noteworthy findings of this study, the parental burden of parents whose  
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28 children took in amino acid milk powder was high. This may be related to the fact that  
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30 parents were worried about the lack of pure nutrient intake when amino acid milk  
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32 powder was an alternative to breast milk and cow's milk<sup>46</sup>. There is a great need for  
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34 comprehensive and systematic FA-based health education programs<sup>47-49</sup>. On the one  
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36 hand, it will help parents manage their children's food allergies correctly and find  
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38 alternative nutrients to ensure normal growth and development<sup>50 51</sup>. On the other hand,  
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40 it will change wrong cognitions related to food allergies to decrease the parental burden  
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42 among parents of children with FA<sup>48</sup>.  
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56 Among the parent-related characteristics, this study revealed that the parental  
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58 burden of parents who were not at work was high, which coincides with the results in  
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4 the previous literature<sup>52-53</sup>. This situation can be interpreted in such a way that parents  
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6 at work have higher economic power, a better social environment, and better use of  
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8 their social support systems<sup>54-56</sup>. When parents do not work and devote themselves to  
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10 the care of the FA child, they may lack social support and develop psychosocial  
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12 symptoms, which may increase the burden<sup>11-13</sup>. This study also showed that the lower  
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14 the financial affordability for children's FA, the heavier the parental burden. This was  
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16 consistent with the results of a study focusing on the economic impact of childhood FA  
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18 in the United State<sup>56</sup>. The high costs, such as direct medical costs, dietary costs, and  
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20 opportunity costs (such as restricted career choices), definitely increase the burden on  
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22 parents and may not be affordable for some families. Couch *et al.* suggested that earlier  
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24 OFCs should be considered to identify food allergens and reduce families' additional  
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26 financial expenses, especially for opportunity costs. This would effectively decrease  
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28 the financial burden on parents<sup>57</sup>. Furthermore, there is an urgent need for providing a  
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30 robust health insurance system for relieving their parental burden financially<sup>58</sup>. The  
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32 present study found that the gender of parents was not an influencing factor associated  
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34 with parental burden, which differs from the results of Springston *et al.*<sup>18-20</sup>. This may  
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36 be because the sample size of the fathers in this study was small, which may have led  
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38 to the difference in parental burden between the mothers and fathers not being identified.  
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40 The reason for the small sample size of fathers recruited in this study is also related to  
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42 the societal context of China, where women often assume the role of child care<sup>59-60</sup>.

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56 The research study concluded that parents' social support was an influencing factor  
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58 negatively associated with parental burden among parents of children with FA.  
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4 Specifically, the more social support parents receive, the lower their parental burden.  
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6 Previous studies have also suggested that when parents (children's caregivers) lack  
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8 social support during the caregiving process, they may develop physical symptoms,  
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10 such as weight loss and fatigue, and psychosocial symptoms, such as anxiety, social  
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12 isolation, and decreased quality of life, which all increase the burden of care <sup>61-63</sup>.  
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14 Adequate social support may help reduce the parental burden. Social support has  
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16 traditionally been provided by families and friends in China and less provided by the  
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18 community service agency and the government<sup>35 64 65</sup>. In a qualitative study concerning  
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20 caregivers caring for a family member, 62% of respondents identified a lack of social  
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22 support as one of their caregiving challenges. Moreover, 83% of participants identified  
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24 emotional support (i.e., seeking out to friends and family or others) to be effective in  
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26 dealing with these challenges <sup>66</sup>. This individual level of social support will help parents  
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28 establish and improve their social support system so that they can feel more supported  
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30 while dealing with the problems and emotional reactions related to their children's FA  
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32 <sup>62 67</sup>. Parents can also use social media platforms and websites to share information and  
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34 learn more about FAs <sup>68 69</sup>. In addition, community support services, such as health  
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36 professional help, structured educational programs, and workshops related to the  
37  
38 management of food allergens, should be available to parents of children with FA <sup>70</sup>.  
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40 They will provide better community social support and richer knowledge about  
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42 managing FA for parents and help them cope with caring for a child with FA, thus  
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44 relieving the parental burden <sup>48 71</sup>. Additionally, health-related departments should  
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46 improve medical policies and reimbursement rates to provide financial support for  
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4 parents with children with FA <sup>58</sup>.

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7 However, coping style was not associated with parental burden among the parents  
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9 of children with FA. It indicated that although some parents chose an active coping  
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11 style (e.g., positively learning knowledge about their children's FA and avoiding  
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13 allergens as much as possible) to deal with children's FA <sup>68</sup>, the unpredictability of  
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15 allergic reactions and parents' invalid specific measures they sometimes take still  
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17 caused a heavy burden on parents <sup>14 68</sup>.

### 21 22 **Limitations**

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25 Several limitations of this study are acknowledged. Parents with a child with FA  
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27 aged 0–5 years were selected for this study because FA tends to commonly occur in  
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29 early childhood, first occurring before the age of 5 years <sup>72</sup>. Therefore, the  
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31 generalization of the results requires caution for other populations. Since the mother is  
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33 primarily responsible for the care of the sick child in China, as in this study, the sample  
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35 size of fathers is limited. Further studies should recruit more fathers in the study sample.

### 39 40 **5. Conclusion**

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43 Parents whose children had more than five identified and highly suspected food  
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45 allergens and had more than two FA-related systems had a higher parental burden.  
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47 Moreover, the burden of parents whose children took in amino acid milk powder was  
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49 higher than that of parents whose children did not. Parents' working conditions were  
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51 also a significant influencing factor of parental burden. All these factors could greatly  
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53 predict parental burden among parents with children with FA. Above all, parents with  
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55 lower financial affordability for their children's FA and lower social support  
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4 experienced higher parental burdens. Thus, the level of financial affordability for  
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6 children's FA and parents' state of social support can serve as key predictors of parental  
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8 burden among parents of children with FA. These findings point to several measures  
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10 that can help ease the parental burden. FA should be included within the scope of  
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12 medical insurance reimbursement, which can partially alleviate financial pressure on  
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14 parents. Additionally, high-quality FA-related health education programs should be  
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16 provided by community health service centers to support parents in monitoring and  
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18 flexibly responding to children's FA. Moreover, it can reduce the daily life and social  
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20 burden of parents with children with FA, thereby promoting their physical and mental  
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22 health. This study provided basic evidence to explore strategies for relieving the  
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24 parental burden among parents of children with FA. In the future, more empirical  
25  
26 studies (e.g., longitudinal studies and intervention studies) are needed to verify and  
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28 further the results of this study.  
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40  
41  
42

#### 43 **Author contributions**

44  
45 *Methodology:* Z.L. and Q.C.;

46  
47  
48 *Formal Analysis:* Z.L. and L.T.;

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50  
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52  
53  
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56  
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59  
60 *Supervision:* S.T. and Q.C.;



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5

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12

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14

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16  
17 Xiangya School of Nursing, Central South University (IRB Approval Number:  
18  
19 E202192).  
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24 **Data sharing statement** No additional data available.  
25

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Table S1. STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	2
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	2-3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5 Tables 1-4
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5-8 Tables 1-2
		(b) Indicate number of participants with missing data for each variable of interest	N/A



Outcome data	15*	Report numbers of outcome events or summary measures	Tables 3-4
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	18-20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	21
Generalisability	21	Discuss the generalisability (external validity) of the study results	21
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22

\*Give information separately for exposed and unexposed groups.

# BMJ Open

## Factors associated with parental burden among parents of children with food allergies in China: A cross-sectional study.

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1 **Title:** Factors associated with parental burden among parents of children with food  
2 allergies in China: A cross-sectional study.

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13 **Keywords:** Food allergy; food hypersensitivity; caregiver burden; social support; child

14 **Word count:** 5802

15 **Abstract**

16 **Objective:** This study aimed to investigate the factors associated with parental burden  
17 among parents of children with food allergies (FA) in China.

18 **Design:** Cross-sectional study.

19 **Setting:** The participants were recruited through the Internet and one child health center  
20 of a tertiary hospital in Changsha, China.

21 **Participants:** A total of 346 parents of children with FA were recruited using a  
22 convenience sampling method. After excluding the invalid questionnaires, 330

1 questionnaires were included for the analysis.

2 **Outcome measures:** The data of general and disease-specific information of children  
3 with FA and their parents, as well as parental burden, social support, and coping style  
4 of parents, were collected using a self-developed questionnaire and standard  
5 measurement tools with good psychometric properties. Univariate analysis and  
6 multivariate stepwise regression analysis were used to analyze the data.

7 **Results:** Financial affordability regarding their children's FA and parents' social  
8 support were key protective factors against parental burden ( $\beta=-0.224$ ,  $P<0.001$  and  $\beta=-$   
9  $0.226$ ,  $P<0.001$ , respectively). This study also found that parents' working conditions,  
10 the number of highly suspected food allergens, the number of children's FA-affected  
11 systems, and whether children took amino acid milk powder were the factors associated  
12 with parental burden.

13 **Conclusions:** Health professionals should pay more attention to parents who are not at  
14 work and whose children have more highly suspected food allergens and more FA-  
15 affected systems because these parents often have a higher parental burden.  
16 Furthermore, it is important to improve financial support for children's FA and social  
17 support for parents of children with FA to decrease their parental burden.

#### 18 **Strengths and limitations of this study**

- 19 ➤ We simultaneously included parents' demographic characteristics, social support,  
20 and coping style in this study to explore the factors influencing parental burden  
21 among parents of children with food allergies.

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- 4 1 ➤ The participants were recruited through a convenience sampling method in two
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- 6 2 ways: through the Internet and from a child health center in a tertiary hospital in
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- 8 Changsha, China.
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- 11 4 ➤ The coping style measurement employed in the study consider only two coping
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- 13 styles (i.e., active and passive), and more comprehensive tools should be
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- 15 considered to accurately identify additional types of coping styles for fuller
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- 17 6 understanding of parental burden.
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- 19 7
- 20 8 ➤ A longitudinal study with a larger sample size is needed to explore the
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- 22 influencing factors of parental burden among parents of children with food
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- 24 allergies.
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## 11 1. Background

12 Food allergy (FA) is a common allergic disease in childhood; it is a hypersensitive

13 reaction of the immune system to proteins in food. It can affect the skin and

14 gastrointestinal, respiratory, and cardiovascular systems with varying degrees of

15 severity<sup>1</sup>. Children with FA often have multiple allergic comorbidities, such as asthma,

16 eczema, and hay fever<sup>2</sup>. FA affects approximately 5% of global children aged 0–5 years

17 diagnosed by open oral food challenge (OFC) testing<sup>3</sup>, and it has become one of the

18 fastest-growing public health problems with epidemiological characteristics, especially

19 in developed countries<sup>4,6</sup>. The prevalence of FA in children has also been increasing at

20 an alarming rate recently in China<sup>7,8</sup>. FA requires strict avoidance of food allergens.

21 Accidental exposure to food allergens can endanger children's health if effective

22 avoidance measures are not taken<sup>9</sup>. Avoiding these allergens is not simple, as many

23 products contain “hidden ingredients” or traces of food allergens, such as nuts<sup>10</sup>.

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4 1 For younger children with FA, the disease burden not only falls on the child but  
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6 2 also on the parents <sup>11-13</sup>. Parents of children with FA may be particularly concerned  
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9 3 about their children's allergies and take on additional burdens in their daily lives, as  
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11 4 they often play an important role in managing their children's allergies. Specifically,  
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14 5 studies have shown that families with children with FA spend more time and energy on  
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16 6 grocery shopping because avoiding allergens requires caregivers to double-check food  
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19 7 labels for allergens. Preparing food also increases extra work for families with children  
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22 8 with FA, as parents need to prepare separate meals for allergic children and prevent  
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25 9 cross-contamination <sup>13</sup>. Parents also report its negative effects on daily activities and  
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28 10 socialization <sup>11 12 14</sup>. There is growing evidence that families with children with FA have  
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31 11 higher financing costs than those whose children are without FA <sup>15</sup>. In addition to  
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34 12 practical and financial needs, research suggests that FA is also associated with negative  
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37 13 psychological consequences for parents, including greater stress and worry <sup>11</sup>. FA does  
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40 14 hurt parental health-related quality of life <sup>16</sup>. This may lead to a decrease in parental  
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43 15 caring capacity and affect the development of children.

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46 16 Evidence in the literature shows that the younger the child, the greater the burden  
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49 17 of care on the parents <sup>11</sup>. Furthermore, the severity of FA, the presence of concomitant  
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52 18 allergic diseases, the number of food allergens, and children's allergy history also  
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55 19 influence parental burden <sup>17-19</sup>. Regarding parent-related factors, the gender of the  
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58 20 parents (father/mother) influenced the caregiving burden. Four studies compared the  
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61 21 caregiving burden between parents and found that mothers had a higher caregiving  
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64 22 burden than fathers in at least one area <sup>18-21</sup>. Nevertheless, existing studies on the factors

1 influencing parental burden among parents of children with FA have been limited to  
2 factors related to children with FA, neglecting the influence of other factors, such as  
3 demographic characteristics (e.g., age, gender, and education degree) and other  
4 changeable variables (e.g., social support and coping style) of parents. Social support  
5 and coping style are considered two changeable variables that may influence the  
6 parental burden on parents of children with FA. Social support acts as an available  
7 external resource against stress<sup>22</sup>. Good social support from family, society, and others  
8 can reduce an individual's stress and thus may lower caregivers' burden<sup>23</sup>. In addition,  
9 coping style refers to an individual's efforts to change cognition and behavior to meet  
10 specific internal and external environmental requirements beyond their existing  
11 capacity and resources<sup>24</sup>. Caregivers with an active coping style could better cope with  
12 their problems and thus may reduce the burden of caring for children with FA<sup>25</sup>.  
13 However, there is a lack of research exploring the relationship between social  
14 support/coping style and parental burden among the parents of children with FA.

15 In addition, the literature on this topic in China is limited. Only one study focused  
16 on parental quality of life in families with children with FA in Hong Kong, a developed  
17 city in China. However, this article emphasized the validation and discriminative ability  
18 of the traditional Chinese version of the Food Allergy Quality of Life-Parental Burden  
19 (TC-FAQL-PB) questionnaire in Hong Kong. It only used univariate analysis to  
20 identify the influencing factors, so the results were yet to be verified. Furthermore,  
21 because of the culture, society, and economic differences between Hong Kong and  
22 mainland China, the results may not be representative, and the associated factors of



1 parental burden in the context of mainland China need to be further explored. Recently,  
2 the authors of this study developed and validated the simplified Chinese version of the  
3 Food Allergy Quality of Life-Parental Burden (SC-FAQL-PB) questionnaire, which  
4 has a wider range of applications than TC-FAQL-PB in China. It has been proven to  
5 have good psychometric properties and can be used as an effective measure in further  
6 studies.

7 Therefore, this study aims to explore the factors associated with parental burden  
8 among parents of children with FA in China, considering general information about  
9 children and parents and the social support and coping styles of parents.

## 10 **2. Methods**

### 11 **2.1 Study design**

12 A cross-sectional study was conducted to explore the factors influencing parental  
13 burden among parents of children with FA in China. This study was reported following  
14 the STROBE checklist (see Supplementary File S1).

### 15 **2.2 Setting and participants**

16 FA tends to commonly occur in early childhood, first occurring before the age of  
17 5 years<sup>26</sup>, and the parents of the children aged 0-5 are largely responsible for managing  
18 their child's FA and thus often experience a high parental burden. Therefore, we  
19 identified parents of a child aged 0-5 years with FA as our study population. A total of  
20 346 parents of children aged 0-5 years diagnosed as having FA were recruited through  
21 convenience sampling of the Internet and a child health center in a tertiary hospital in  
22 Changsha, China. There was no significant difference between participants recruited

1 via these two methods. Inclusion criteria were as follows: (a) a parent aged  $\geq 18$  years  
2 who (b) had at least one child aged  $\leq 5$  years who was clinically diagnosed as having  
3 FA by a clinician. OFC, skin prick test, spot patch test, serum IgE detection, or dietary  
4 avoidance can be used in the diagnosis, (c) was the main caregiver of children, and (d)  
5 could understand and communicate normally. Exclusion criteria were as follows: (a) a  
6 parent whose child was complicated with malignant diseases or other organic lesions  
7 and (b) a parent whose child had a mental illness or cognitive impairment.

8 The sample size was calculated using an independent variable-to-subject ratio  
9 reported by Kendall <sup>27</sup>. He recommended at least a 1:10 ratio for a cross-sectional  
10 investigation. Moreover, the “rules of thumb” for determining the sample size for  
11 regression equations using six or more predictors stated that an absolute minimum of  
12 10 participants per predictor variable was appropriate <sup>28</sup>. The independent variables in  
13 this study included general information, social support, and coping style. Considering  
14 the 28 independent variables and a 15% invalid rate, a minimum of 330 cases was  
15 required. Thus, a sample size of 346 in this study met this requirement.

### 16 **2.3 Recruitment and data collection**

17 Before completing the questionnaire, the participants were informed of the  
18 research-related information, including the research’s objectives and investigation  
19 process, anonymity, and voluntary participation. The questionnaires were completed on  
20 the Internet using Wenjuanxing, an online questionnaire collection platform in  
21 mainland China. Wenjuanxing ensured that respondents completed the entire  
22 questionnaire to avoid missing data. It also avoided the problems of manual data entry

1 and improved the efficiency and accuracy of data collection and screening. Those who  
2 had difficulty filling out the electronic questionnaire could contact researchers to guide  
3 them to finish the e-questionnaire or ask for a paper questionnaire. The researchers'  
4 contact information was provided to the participants at the time of recruitment. Before  
5 the formal survey, we selected 10 subjects who met the study inclusion criteria for the  
6 pre-survey. The pre-survey ensured that the general information items and  
7 questionnaire instructions developed by our research team were logical and easy to  
8 understand. Data collection began in December 2021 and lasted for three months.

## 9 **2.4 Measures**

### 10 *General information questionnaire*

11 A general information questionnaire consisted of items to gather details about the  
12 children's and parents' demographic information and other disease-specific  
13 characteristics of children with FA. The children's information included months of age,  
14 gender, growth standards (using Z-scores), the number of identified food allergens, the  
15 number of highly suspected food allergens, the number of children's FA-affected  
16 systems, the number of FA-related symptoms, the time of the first diagnosis of FA, the  
17 frequency of adverse reactions, whether they were going to kindergarten, whether they  
18 were taking breast milk, whether they had an intake of special formula milk powder,  
19 whether they had an egg allergy, whether they had a milk allergy, whether they had  
20 experienced severe anaphylaxis<sup>29 30</sup>, whether they had a history of anti-allergy drug use  
21 (referring only referred to antihistamine use), and whether they had visited the  
22 emergency room. Parents' information included gender, age, parental history of self-

1 reported allergies, education level, working conditions, financial affordability  
2 regarding their children's FA, knowledge about FA (self-reported), whether they were  
3 obtaining learning knowledge about FA from health professionals, and whether they  
4 had a medical knowledge background.

5 *The Simplified Chinese version of the Food Allergy Quality of Life-Parental Burden*  
6 *(SC-FAQL-PB) questionnaire*

7 The FAQL-PB questionnaire was developed by Cohens *et al.*<sup>31</sup>. The original  
8 English version has been translated into many languages and validated in the United  
9 Kingdom, Australia, Thailand, Iran, South Korea, Hong Kong, and mainland China.  
10 The authors adapted and validated the Chinese version, SC-FAQL-PB. It utilizes a 7-  
11 point Likert scale ranging from 1 (not troubled) to 7 (extremely troubled). There are 17  
12 items covering family and social activities, meal preparation, health issues, and  
13 emotional issues, measuring two dimensions of limitations in life (3 items) and  
14 emotional distress (14 items). Items for the measurements of parental burden were  
15 negatively worded (e.g., "How much would your choice of vacation be limited by your  
16 child's food allergy?"). A higher SC-FAQL-PB score indicates a higher parental burden.  
17 The confirmatory factor analysis results confirmed the two-factor model proposed by  
18 Leung as the most reasonable fit for explaining the factor construct of the SC-FAQL-  
19 PB<sup>30</sup>. The internal coefficient of consistency was 0.946, with a test-retest reliability of  
20 0.926. The Cronbach's alpha of the scale in our sample was 0.958.

21 *Social Support Rating Scale (SSRS)*

22 The social support level was assessed with the Social Support Rating Scale (SSRS),

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4 1 which was developed by Dr. Xiao <sup>32</sup>. It includes 10 items measuring three dimensions:  
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6 2 subjective support (3 items), objective support (4 items), and support utilization (3  
7  
8 3 items). Objective support refers mainly to visible practical support, such as direct  
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10 4 material assistance and social networks. Subjective support refers to an individual's  
11  
12 5 emotional feelings and satisfaction with being supported, respected, and understood in  
13  
14 6 society. Support utilization refers to the extent to which individuals utilize social  
15  
16 7 support <sup>33</sup>. A higher total score indicated a higher social support level. This total support  
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18 8 score was classified into three categories: low ( $\leq 22$ ), moderate (23–44), and high ( $\geq$   
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20 9 45) levels <sup>34</sup>. The SSRS has been widely used in Chinese domestic contexts <sup>35-37</sup>. The  
21  
22 10 cumulative contribution rate of the three common factors was 54.26% <sup>38</sup>. The internal  
23  
24 11 consistency of the SSRS in this study was acceptable. The Cronbach's alpha of the scale  
25  
26 12 in our sample was 0.778.

### 13 *Simplified Coping Style Questionnaire (SCSQ)*

14 Coping style was accessed with the Simplified Coping Style Questionnaire, which  
15 is a self-report survey that includes two subscales: active coping (12 items) and passive  
16 coping (eight items) <sup>39</sup>. All items were rated using a 4-point Likert scoring method,  
17 ranging from zero (never) to three (always). The scores of each subscale item were  
18 summed up to generate a subscale score. Dai proposed a formula for the coping style  
19 tendency—coping style tendency = active coping criterion score ( $Z_a$  score) - passive  
20 coping criterion score ( $Z_p$  score)—to determine an individual's main coping style in  
21 stress situations <sup>40</sup>.  $Z_a/Z_p = (\text{actual score for the subscale} - \text{mean of the score for the}$   
22  $\text{subscale among the national norm sample}) / (\text{standard deviation of the score for the}$

1 subscale among the national norm sample). If the value of the coping style tendency >  
2 0, it means the individual mainly adopts an active coping style. The Chinese national  
3 norm for the active coping score is  $1.78 \pm 0.52$ , and for the passive coping score, it is  
4  $1.59 \pm 0.66$ <sup>39</sup>. The SCSQ has been widely used to assess caregivers' coping styles in  
5 China, and the Cronbach's alpha coefficient of the two subscales ranged from 0.75 to  
6 0.90<sup>41-45</sup>. The cumulative contribution rate of the two common factors was 48.5%<sup>46</sup>.  
7 In the present study, the Cronbach's alphas of the active and passive coping styles were  
8 0.909 and 0.752, respectively.

## 9 **2.5 Data analysis**

10 The collected data were analyzed using the IBM SPSS 26.0 program. Descriptive  
11 statistics were used to investigate the demographic and disease-specific characteristics  
12 of children with FA and their parents, social support, coping style, and parental burden  
13 among the parents of children with FA. The Kolmogorov–Smirnov test was performed  
14 to confirm the normality of the measurement data. Means with standard deviations  
15 (Mean  $\pm$  SD) were calculated for normally distributed data, while median and  
16 interquartile ranges were calculated for non-normally distributed measures.  
17 Frequencies and percentages were calculated for the count data. Between-group  
18 differences were tested using T-tests and ANOVA for normally distributed data to  
19 investigate parental burden. Spearman's correlation analysis was used to analyze the  
20 correlations between parental burden, coping style, and social support among the  
21 parents of children with FA. All reported *P* values were two-sided, with a significance  
22 level of 0.05.

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4 1 Multivariate stepwise regression analysis was performed to identify the factors  
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6 2 influencing parental burden among parents of children with FA, with the total FAQL-  
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9 3 PB score as the dependent variable. The variables with a  $P < 0.1$  for univariate analysis  
10  
11 4 were all introduced. Some non-normally distributed continuous variables were log-  
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13 5 transformed ( $y = \log_{10}(x + 1)$ ) to normalize their distribution before their introduction  
14  
15 6 to multivariate stepwise regression analysis. The variables were screened stepwise  
16  
17 7 based on the criteria of  $\alpha \leq 0.05$  in and  $\alpha \geq 0.1$  out model. When the independent  
18  
19 8 variables were unordered categorical variables, they were converted into dummy  
20  
21 9 variables and then included in the regression analysis. The analysis used  $R^2$  as the power  
22  
23 10 of a linear model to represent the percentage of the current variation of  $y$  explained by  
24  
25 11 the independent variables in the current model.  
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## 32 **2.6 Ethical consideration**

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35 13 This research was approved by the Ethical Review Committee of Xiangya School  
36  
37 14 of Nursing, Central South University, on July 15, 2021 (approval number: E202192).  
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39 15 All participants filled out questionnaires voluntarily, from whom signed informed  
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41 16 consent was obtained. It was emphasized that the participation was anonymous, and all  
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43 17 data were kept strictly confidential and used for research purposes only.  
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## 48 **2.7 Patient and public involvement**

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51 19 None.  
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## 53 **3. Results**

### 54 **3.1 General characteristics of children with FA and their parents**

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58 22 A total of 346 parents of children with FA were enrolled in this study, with a  
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1 response rate of 100%. Sixteen questionnaires were removed because the filling time  
 2 was less than five minutes (six questionnaires) and because the parents were not the  
 3 primary caregivers of children in their daily lives (ten questionnaires). The valid  
 4 questionnaire rate was 95.38% (330/346). Table 1 shows the characteristics of the  
 5 children with FA and the relationships between the characteristics and parental burden  
 6 among parents. Most children (75.5%, 249/330) had milk allergies, and 46.7% (154/330)  
 7 of the children were allergic to eggs. Only three children had experienced severe  
 8 anaphylaxis, and 21.8% (72/330) had visited the emergency room. As presented in  
 9 Table 2, the male-to-female ratio of parents was 1:16.4, their mean age was 30.41 years,  
 10 and most completed college or had a higher degree (87.9%, 290/330). More than half  
 11 of the parents (70.0%, 231/330) were at work, and most parents (77.9%) reported that  
 12 the financial costs caused by FA were affordable. More details can be found in Tables  
 13 1 and 2.

14 **Table 1. General characteristics of children with food allergies and the relationship between**  
 15 **the characteristics and parental burden (n=330)**

Characteristics	Parental burden			
	Mean	SD	t/F/r	P
<b>Gender, n (%)</b>			0.62	0.54
Male	187 (56.7)	65.19	21.24	
Female	143 (43.3)	63.85	18.18	
<b>Whether they were going to kindergarten, n (%)</b>			-1.55	0.12
Yes	10 (3.0)	55.00	19.16	
No	320 (97.0)	64.91	19.93	
<b>Growth standards, n (%)</b>			-1.02	0.31
Without growth retardation	313 (94.8)	64.35	20.05	
With growth retardation	17 (5.2)	69.41	17.99	
<b>Whether they were taking in breast milk, n (%)</b>			0.31	0.76
Yes	77 (23.3)	65.22	20.82	
No	253 (76.6)	64.42	19.72	3.39
<b>Whether they had an intake of special formula milk powder, n (%)</b>				0.02*
Moderately hydrolyzed formula	64 (19.4)	60.69	18.97	
Deep hydrolyzed formula	106 (32.1)	63.75	20.21	
amino acid milk powder	75 (22.7)	70.67	17.97	
None <sup>a</sup>	85 (25.8)	63.29	21.15	
<b>Whether they had an egg allergy</b>			2.45	0.02*
Yes	154 (46.7)	67.42	17.57	
No	176 (53.3)	62.15	21.28	
<b>Whether they had a milk allergy</b>			1.40	0.16
Yes	249 (75.5)	65.91	20.08	



No	81 (24.5)	61.91	19.44		
<b>The time of the first diagnosis of FA (month of age), n (%)</b>				0.76	0.45
0-5 months	260 (78.8)	65.04	19.68		
> 5 months	70 (21.2)	63.00	21.01		
<b>The Frequency of adverse reactions, n (%)</b>				6.84	<0.01**
1-5 times	154 (46.7)	62.77	20.30		
6-10 times	69 (20.9)	60.07	17.63		
> 10 times	107 (32.4)	70.18	19.80		
<b>Whether they had experienced severe anaphylaxis<sup>b</sup>, n (%)</b>				0.24	0.81
Yes	3 (0.91)	67.33	26.86		
No	327 (99.1)	64.58	19.94		
<b>Whether they had a history of anti-allergy drug use<sup>c</sup>, n (%)</b>				1.98	<0.05*
Yes	140 (42.4)	67.14	19.10		
No	190 (21.8)	62.75	20.41		
<b>Whether they had visited the emergency room, n (%)</b>				0.58	0.57
Yes	72 (21.8)	65.83	20.35		
No	258 (78.2)	64.27	19.87		
<b>Children' month of age, Mean±SD</b>		15.07±8.18		-0.06	0.26
<b>The number of identified food allergens, Median (IQR)</b>			2(2)	0.197	<0.001**
<b>The number of highly suspected food allergens, Median (IQR)</b>			2(2)	0.219	<0.001**
<b>The number of children's FA-affected systems<sup>d</sup>, Median (IQR)</b>			2(1)	0.213	<0.001**
<b>The number of children's FA-related symptoms, Median (IQR)</b>			2(3)	0.252	<0.001**

\* $P < 0.05$ ; \*\* $P < 0.01$ ; \*\*\* $P < 0.001$ .

<sup>a</sup> Children didn't take in special formula milk powder, only took in breast milk or formula milk.

<sup>b</sup> Severe anaphylaxis refers to acute systemic allergic reactions that can be life-threatening, including anaphylactic shock, angioedema, bronchospasm, and hypotension.

<sup>c</sup> The anti-allergy drugs referred to here are antihistamines. In China, patients are not prescribed self-injectable adrenaline.

<sup>d</sup> FA-affected systems involve the integumentary system, respiratory system and gastrointestinal system.

**Table 2. General characteristics of parents having children with food allergies and the relationships between the characteristics and parental burden (n=330).**

Characteristics	Parental burden				
	Mean	SD	t/F/r	P	
<b>Gender, n (%)</b>					
Male	19 (5.8)	62.95	22.29	-0.37	0.71
Female	311 (94.2)	64.71	19.84		
<b>Parental history of self-reported allergies, n (%)</b>				-0.08	0.94
Yes	211 (67.0)	64.55	19.29		
No	109 (33.0)	64.73	21.34		
<b>Education level, n (%)</b>				5.79	<0.01**
Junior high school or below	12 (3.6)	82.75	16.48		
Senior high school	28 (8.5)	72.68	18.15		
College	95 (28.8)	67.02	20.44		
Undergraduate	158 (47.9)	61.44	19.73		
Graduate or above	37 (11.2)	59.95	16.68		
<b>Working conditions, n (%)</b>				-4.03	<0.01**
at work	231 (70.0)	61.77	20.44		
Not at work	99 (30.0)	71.22	17.12		
<b>Financial affordability regarding their children's FA, n (%)</b>				15.04	<0.01**
Fully affordable	62 (18.8)	56.69	20.14		
Able to afford	195 (59.1)	62.56	19.00		
Harder to afford	67 (20.3)	76.10	17.22		
Unable to afford	6 (1.8)	84.50	12.11		
<b>Knowledge about FA (self-reported), n (%)</b>				-1.36	0.17
Yes	113 (34.2)	62.54	18.31		
No	217 (65.8)	65.69	20.72		
<b>Whether they were obtaining knowledge about FA from health professionals, n (%)</b>				-1.85	0.07
Yes	233 (70.6)	63.30	20.22		

No	97 (29.4)	67.75	19.04	-0.77	0.45
<b>Whether they had a medical background, n (%)</b>					
Yes	56 (17.0)	62.75	20.14		
No	274 (83.0)	64.99	19.93		
<b>Parents' age (years), Mean±SD</b>	30.41±3.68			-0.06	0.26

\* $P < 0.05$ . \*\* $P < 0.01$ .

## 3.2 Analysis of Factors influencing parental burden among parents of children with FA

### 3.2.1 Univariate analysis on factors related to parental burden among parents of children with FA

The results in Table 1 show that parents whose children were allergic to eggs had a higher parental burden score ( $67.42 \pm 17.57$ ) than those whose children did not ( $62.15 \pm 21.28$ ), and parents whose children had a history of antiallergy drug use ( $67.14 \pm 19.10$ ) had a higher parental burden score than those whose children did not ( $62.75 \pm 20.41$ ). In addition, the parental burden increased with the number of children's identified food allergens, the number of highly suspected food allergens, the number of children's FA-affected systems, and the number of children's FA-related symptoms. The intake of children's special formula milk affected the parental burden score, and parents whose children took in amino acid milk powder had the highest parental burden ( $70.67 \pm 17.97$ ). Moreover, parents whose children had up to 10 times adverse reactions ( $70.18 \pm 19.80$ ) had higher parental burden scores than parents whose children had 1–5 times ( $62.77 \pm 20.33$ ,  $P < 0.01$ ) and 6–10 times adverse reactions ( $60.07 \pm 17.63$ ,  $P < 0.01$ ). As Table 2 shows, the parental burden scores among the parents of children with FA decreased with educational level and financial affordability regarding their children's FA. Moreover, parents who were not at work ( $71.22 \pm 17.12$ ) had a higher parental burden than those who were at work ( $61.77 \pm 20.44$ ). In addition, all of them

1 reported significant statistical differences ( $P < 0.05$ ). However, no significant  
 2 difference in parental burden existed between groups divided by children's and parents'  
 3 genders, when children had visited the emergency room, when children had  
 4 experienced severe anaphylaxis, when there was a parental history of self-reported  
 5 allergies, etc. The bivariate correlation analysis results in Table 3 show that parental  
 6 burden was negatively correlated with the parents' social support ( $r = -0.291$ ,  $P < 0.001$ )  
 7 and coping style ( $r = -0.240$ ,  $P < 0.001$ ). Because the analysis above did not control  
 8 other confounding factors, these statistically significant factors in this part need to be  
 9 identified in multiple stepwise linear regression.

10 **Table 3. Bivariate correlation between parental burden and social support and coping style**  
 11 **(n=330).**

	Parental Burden
	<i>Spearman correction coefficients (r)</i>
Social support	-0.291***
Coping style <sup>a</sup>	-0.240***

12 \*\*\*  $P < 0.001$ .

13 <sup>a</sup> It represents the coping style tendency (identified after Z-conversion), which means the  
 14 individual's main coping style in stress states.

15 3.2.2 Multiple linear regression analysis on factors related to parental burden among  
 16 parents of children with FA

17 Some factors were introduced in a multiple stepwise linear regression to ensure a  
 18 stable model. The children-related factors included the number of identified food  
 19 allergens, the number of highly suspected food allergens, the number of children's FA-  
 20 affected systems, the number of children's FA-related symptoms, the frequency of  
 21 adverse reactions, whether they had an intake of special formula milk powder, whether  
 22 they had an egg allergy, whether they had experienced severe anaphylaxis, and whether  
 23 they had a history of antiallergy drug use. Parent-related factors included education  
 24 level, working conditions, financial affordability regarding their children's FA,

1 knowledge of FA (self-reported), medical knowledge background, social support,  
 2 coping style, and whether they were obtaining learning knowledge from health  
 3 professionals. “Intake of special formula milk powder-None” was set as a reference  
 4 variable for ‘Intake of special formula milk’ in introducing dummy variables into  
 5 regression analysis. In Table 4, the results show that the number of highly suspected  
 6 food allergens ( $\beta = 0.162, P < 0.01$ ), the number of children’s FA-affected systems ( $\beta$   
 7 = 0.129,  $P < 0.05$ ), amino acid milk powder intake ( $\beta = 0.154, P < 0.01$ ), working  
 8 conditions ( $\beta = -0.169, P = 0.000$ ), financial affordability regarding their children’s FA  
 9 ( $\beta = -0.224, P = 0.000$ ), and social support ( $\beta = -0.226, P = 0.000$ ) are independently  
 10 associated with the parental burden on parents of children with FA. Coping style was  
 11 not entered into the regression equation in this study. The multiple linear regression  
 12 equation models were statistically significant ( $P < 0.001, \Delta F = 6.769$ ) and explained  
 13 27.4% of the variance (Adjusted  $R^2$  was 26.0%).

14 **Table 4. A multivariate linear stepwise regression analysis of the factors influencing the**  
 15 **parental burden of parents having children with food allergies (n=330).**

Model	Coefficient		Standard coefficient	<i>t</i>	<i>P</i>
	Unstandardized coefficient				
	<i>B</i>	<i>SE</i>	<i>Beta</i>		
(Constant)	61.438	7.225		8.470	0.000 ***
The number of highly suspected food allergens <sup>a</sup>	13.489	4.127	0.162	3.269	0.001 **
The number of children’s FA-affected systems <sup>a</sup>	20.118	7.733	0.129	2.602	0.010 *
Intake of special formula milk powder - Amino acid milk powder intake	7.328	2.292	0.154	3.198	0.002 **
Whether they had an intake of special formula milk powder – None <sup>b</sup>	0				
Working conditions	-7.346	2.082	-0.169	-3.529	0.000 ***
Financial affordability regarding their children’s FA	-6.568	1.454	-0.224	-4.517	0.000 ***
Social support	-0.580	0.127	-0.226	-4.582	0.000 ***

16 Note:  $R^2=0.274$ ; adjusted  $R^2=0.260$ ;  $\Delta F=7.769$ ; \* $P<0.05$ ; \*\* $P<0.01$ ; \*\*\* $P<0.001$ ; Dependent variable:  
 17 parental burden among parents with a FA child. The variables with  $P < 0.1$  from univariate analysis  
 18 were introduced.

19 <sup>a</sup> The variables introduced in a multiple stepwise linear regression here were log-transformed  
 20 ( $y=\log_{10}(x + 1)$ ) to approximate a normal distribution.

<sup>b</sup> It was set as a reference variable for 'Intake of special formula milk' in the process of introducing dummy variables into regression analysis.

#### 4. Discussion

Providing quality care for children with FA will undoubtedly place a burden on their parents. The purpose of the study was to explore the associated factors of parental burden among the parents of children with FA. In our sample, the score for parental burden was 64.61 (SD = 19.96), which was lower than the reported in the UK (69.99 (SD=23.17) <sup>47</sup>.

Among children-related characteristics, it was determined that the number of highly suspected food allergens and the number of FA-affected systems positively influenced the parental burden among parents of children with FA. These results are consistent with previous studies <sup>17 30 47</sup>. When children have more highly suspected food allergens, their parents need to spend more effort to take a wide range of avoidance measures and often feel worried, which increases the parental burden. In addition, when FA affects many systems involving the skin and the gastrointestinal, respiratory, and cardiovascular systems, parents feel more worried about their children's health <sup>11</sup>. In one of the noteworthy findings of this study, the parental burden of parents whose children took in amino acid milk powder was high. This may be related to the fact that parents were worried about the lack of pure nutrient intake when amino acid milk powder was an alternative to breast milk and cow's milk <sup>48</sup>. There is a great need for comprehensive and systematic FA-based health education programs <sup>49-51</sup>. On the one hand, it will help parents manage their children's food allergies correctly and find alternative nutrients to ensure normal growth and development <sup>52 53</sup>. On the other hand, it will change wrong cognitions related to food allergies to decrease the parental burden

1 among parents of children with FA <sup>50</sup>. Additionally, amino acid milk powder is more  
2 expensive than ordinary powdered milk. Because FA-related economic aid is not  
3 provided in China, parents whose children consumed amino acid milk powder must  
4 spend more to provide it, which would increase their financial burden.

5       Among the parent-related characteristics, this study revealed that the parental  
6 burden of parents who were not at work was high, which coincides with the results in  
7 the previous literature <sup>54-55</sup>. This situation can be interpreted in such a way that parents  
8 at work have higher economic power, a better social environment, and better use of  
9 their social support systems <sup>56-58</sup>. When parents do not work and devote themselves to  
10 the care of the FA child, they may lack social support and develop psychosocial  
11 symptoms, which may increase the burden <sup>11-13</sup>. This study also showed that the lower  
12 the financial affordability regarding their children's FA, the heavier the parental burden.  
13 This was consistent with the results of a study focusing on the economic impact of  
14 childhood FA in the United State <sup>58</sup>. The high costs, such as direct medical costs, dietary  
15 costs, and opportunity costs (such as restricted career choices), definitely increase the  
16 burden on parents and may not be affordable for some families. Couch *et al.* suggested  
17 that earlier OFCs should be considered to identify food allergens and reduce families'  
18 additional financial expenses, especially for opportunity costs. This would effectively  
19 decrease the financial burden on parents <sup>59</sup>. Furthermore, there is an urgent need for  
20 providing a robust health insurance system for relieving their parental burden  
21 financially <sup>60</sup>. The present study found that the gender of parents was not an influencing  
22 factor associated with parental burden, which differs from the results of Springston *et*

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4 1 *al.* <sup>18-20</sup>. This may be because the sample size of the fathers in this study was small,  
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6 2 which may have led to the difference in parental burden between the mothers and  
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8 3 fathers not being identified. The reason for the small sample size of fathers recruited in  
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10 4 this study is also related to the societal context of China, where women often assume  
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12 5 the role of childcare <sup>61 62</sup>.

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17 6 With the highest standardized beta in the regression equation, parents' social  
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19 7 support was a key protective influencing factor against parental burden among parents  
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21 8 of children with FA. Specifically, parental burden decreases as parents' social support  
22  
23 9 increases. Previous studies have also suggested that when parents (children's caregivers)  
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25 10 lack social support during the caregiving process, they may develop physical symptoms,  
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27 11 such as weight loss and fatigue, and psychosocial symptoms, such as anxiety, social  
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29 12 isolation, and decreased quality of life, which all increase the burden of care <sup>63-65</sup>.  
30  
31 13 Adequate social support may help reduce the parental burden. Social support has  
32  
33 14 traditionally been provided by families and friends in China and less provided by the  
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35 15 community service agency and the government<sup>37 66 67</sup>. In a qualitative study concerning  
36  
37 16 caregivers caring for a family member, 62% of respondents identified a lack of social  
38  
39 17 support as one of their caregiving challenges. Moreover, 83% of participants identified  
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41 18 emotional support (i.e., seeking out to friends and family or others) to be effective in  
42  
43 19 dealing with these challenges <sup>68</sup>. This individual level of social support will help parents  
44  
45 20 establish and improve their social support system so that they can feel more supported  
46  
47 21 while dealing with the problems and emotional reactions related to their children's FA  
48  
49 22 <sup>64 69</sup>. Parents can also use social media platforms and websites to share information and  
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1 learn more about FA <sup>70 71</sup>. In addition, community support services, such as health  
2 professional help, structured educational programs, and workshops related to the  
3 management of food allergens, should be available to parents of children with FA <sup>72</sup>.  
4 They will provide better community social support and richer knowledge about  
5 managing FA for parents and help them cope with caring for a child with FA, thus  
6 relieving the parental burden <sup>50 73</sup>. Additionally, health-related departments should  
7 improve medical policies and reimbursement rates to provide financial support for  
8 parents with children with FA <sup>60</sup>.

9 However, parents' coping style did not exhibit a relationship with parental burden  
10 in the multiple stepwise regression of this study. The reason may be that although some  
11 parents adopted an active coping style (e.g., positively learning knowledge about their  
12 children's FA and avoiding allergens as much as possible) to deal with their children's  
13 FA, their specific, positive measures cannot immediately cure or control their children's  
14 allergy reactions <sup>70</sup>. Furthermore, allergic reactions are unpredictable and, for many  
15 children, FA is always accompanied with food intolerance for which the symptoms are  
16 similar to those of the FA and difficult to avoid <sup>74-77</sup>. In these conditions, an active  
17 coping style cannot always obtain positive feedback. This would cause anxiety and a  
18 heavy burden, especially an emotional burden, on parents <sup>14 70</sup>. In addition, the SCSQ  
19 used to measure coping style focused on only two types. However, coping styles are  
20 much more complex than merely positive and negative. The quantitative measurement  
21 instrument we used ignored the complexity of coping styles, which may have  
22 influenced the final results. Therefore, instruments that can identify the complexity of



1 coping styles should be developed. Furthermore, qualitative studies should be  
2 considered to explore the relationship between coping style and parental burden.

### 3 **Limitations**

4 Several limitations of this study are acknowledged. Considering we only recruited  
5 the parents with a child aged 0-5 years with FA, the generalization of the results in this  
6 study requires caution for other populations. Second, convenience sampling cannot  
7 guarantee sample diversity. For example, the sample size of fathers is limited in this  
8 study. However, it is also consistent with the fact that the mother is primarily  
9 responsible for the care of the sick child in China. To better explore the fathers' parental  
10 burden, further studies need recruit more fathers in the study sample. Third, it was  
11 certainly a limitation that FA diagnosis was made using diverse methods and not always  
12 based on the gold standard of OFC. In middle- and low-income countries such as China,  
13 FA diagnosis is likely to be based on the skin prick test, serum IgE detection, or clinical  
14 history, while OFC is rarely used for diagnosis. Sometimes misdiagnosis may occur.  
15 Finally, the quantitative measurement instrument of coping style employed in this study  
16 ignores the complexity of coping styles, which may have influenced the results.  
17 Instruments that can identify the complexity of coping styles should be developed and  
18 used in future studies.

### 19 **5. Conclusion**

20 Parents whose children had more highly suspected food allergens and had more  
21 FA-affected systems had a higher parental burden. Moreover, the burden of parents  
22 whose children took in amino acid milk powder was higher than that of parents whose

1 children did not. Parents' working conditions were also a significant influencing factor  
2 of parental burden. All these factors could greatly predict parental burden among  
3 parents with children with FA. Above all, parents with lower financial affordability  
4 regarding their children's FA and lower social support experienced higher parental  
5 burdens. Thus, the level of financial affordability regarding their children's FA and  
6 parents' state of social support can serve as key predictors of parental burden among  
7 parents of children with FA. These findings point to several measures that can help ease  
8 the parental burden. FA should be included within the scope of medical insurance  
9 reimbursement, which can partially alleviate financial pressure on parents. Additionally,  
10 high-quality FA-related health education programs should be provided by community  
11 health service centers to support parents in monitoring and flexibly responding to  
12 children's FA. Moreover, it can reduce the daily life and social burden of parents with  
13 children with FA, thereby promoting their physical and mental health. This study  
14 provided basic evidence to explore strategies for relieving the parental burden among  
15 parents of children with FA. In the future, more empirical studies (e.g., longitudinal  
16 studies and intervention studies) are needed to verify and further the results of this study.

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19 **Author contributions**

20 *Methodology:* Z.L. and Q.C.;

21 *Formal Analysis:* Z.L. and L.T.;

22 *Investigation:* Z.L., H.L.;

1 *Writing – Original Draft Preparation: Z.L.;*

2 *Writing – Review & Editing: Z.L., Q.C., L.T.;*

3 *Supervision: S.T. and Q.C.;*

4 *Project Administration: Q.C.*

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For peer review only

Table S1. STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-10 Tables 1-4
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	11
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12-14
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-14 Tables 1-2
		(b) Indicate number of participants with missing data for each variable of interest	N/A

Outcome data	15*	Report numbers of outcome events or summary measures	Tables 3-4
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	17-20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21-22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	21
Generalisability	21	Discuss the generalisability (external validity) of the study results	21
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23

\*Give information separately for exposed and unexposed groups.

# BMJ Open

## Factors associated with parental burden among parents of children with food allergies in China: A cross-sectional study.

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1 **Title:** Factors associated with parental burden among parents of children with food  
2 allergies in China: A cross-sectional study.

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13 **Keywords:** Food allergy; food hypersensitivity; caregiver burden; social support; child

14 **Word count: 5802**

15 **Abstract**

16 **Objective:** This study aimed to investigate the factors associated with parental burden  
17 among parents of children with food allergies (FA) in China.

18 **Design:** Cross-sectional study.

19 **Setting:** The participants were recruited through the Internet and one child health center  
20 of a tertiary hospital in Changsha, China.

21 **Participants:** A total of 346 parents of children with FA were recruited using a  
22 convenience sampling method. After excluding the invalid questionnaires, 330

1 questionnaires were included for the analysis.

2 **Outcome measures:** The data of general and disease-specific information of children  
3 with FA and their parents, as well as parental burden, social support, and coping style  
4 of parents, were collected using a self-developed questionnaire and standard  
5 measurement tools with good psychometric properties. Univariate analysis and  
6 multivariate stepwise regression analysis were used to analyze the data.

7 **Results:** Financial affordability regarding their children's FA and parents' social  
8 support were key protective factors against parental burden ( $\beta=-0.224$ ,  $P<0.001$  and  $\beta=-$   
9  $0.226$ ,  $P<0.001$ , respectively). This study also found that parents' working conditions,  
10 the number of highly suspected food allergens, the number of children's FA-affected  
11 systems, and whether children took amino acid milk powder were the factors associated  
12 with parental burden.

13 **Conclusions:** Health professionals should pay more attention to parents who are not at  
14 work and whose children have more highly suspected food allergens and more FA-  
15 affected systems because these parents often have a higher parental burden.  
16 Furthermore, it is important to improve financial support for children's FA and social  
17 support for parents of children with FA to decrease their parental burden.

#### 18 **Strengths and limitations of this study**

- 19 ➤ We simultaneously included parents' demographic characteristics, social support,  
20 and coping style in this study to explore the factors influencing parental burden  
21 among parents of children with food allergies.



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- 4 1 ➤ The participants were recruited through a convenience sampling method in two
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- 6 2 ways: through the Internet and from a child health center in a tertiary hospital in
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- 8 Changsha, China.
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- 11 4 ➤ The coping style measurement employed in the study consider only two coping
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- 13 styles (i.e., active and passive), and more comprehensive tools should be
- 14
- 15 considered to accurately identify additional types of coping styles for fuller
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- 17 6 understanding of parental burden.
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- 19 7
- 20 8 ➤ A longitudinal study with a larger sample size is needed to explore the
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- 22 9 influencing factors of parental burden among parents of children with food
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- 24 10 allergies.
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## 29 11 **1. Background**

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31 12 Food allergy (FA) is a common allergic disease in childhood; it is a hypersensitive

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33 reaction of the immune system to proteins in food. It can affect the skin and

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35 gastrointestinal, respiratory, and cardiovascular systems with varying degrees of

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37 14 severity<sup>1</sup>. Children with FA often have multiple allergic comorbidities, such as asthma,

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39 15 eczema, and hay fever<sup>2</sup>. FA affects approximately 5% of global children aged 0–5 years

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41 16 diagnosed by open oral food challenge (OFC) testing<sup>3</sup>, and it has become one of the

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43 17 fastest-growing public health problems with epidemiological characteristics, especially

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45 18 in developed countries<sup>4,6</sup>. The prevalence of FA in children has also been increasing at

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47 19 an alarming rate recently in China<sup>7,8</sup>. FA requires strict avoidance of food allergens.

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49 20 Accidental exposure to food allergens can endanger children's health if effective

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51 21 avoidance measures are not taken<sup>9</sup>. Avoiding these allergens is not simple, as many

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53 22 products contain “hidden ingredients” or traces of food allergens, such as nuts<sup>10</sup>.

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4 1 For younger children with FA, the disease burden not only falls on the child but  
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6 2 also on the parents <sup>11-13</sup>. Parents of children with FA may be particularly concerned  
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9 3 about their children's allergies and take on additional burdens in their daily lives, as  
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11 4 they often play an important role in managing their children's allergies. Specifically,  
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14 5 studies have shown that families with children with FA spend more time and energy on  
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16 6 grocery shopping because avoiding allergens requires caregivers to double-check food  
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19 7 labels for allergens. Preparing food also increases extra work for families with children  
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22 8 with FA, as parents need to prepare separate meals for allergic children and prevent  
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25 9 cross-contamination <sup>13</sup>. Parents also report its negative effects on daily activities and  
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28 10 socialization <sup>11 12 14</sup>. There is growing evidence that families with children with FA have  
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31 11 higher financing costs than those whose children are without FA <sup>15</sup>. In addition to  
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34 12 practical and financial needs, research suggests that FA is also associated with negative  
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37 13 psychological consequences for parents, including greater stress and worry <sup>11</sup>. FA does  
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40 14 hurt parental health-related quality of life <sup>16</sup>. This may lead to a decrease in parental  
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43 15 caring capacity and affect the development of children.

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46 16 Evidence in the literature shows that the younger the child, the greater the burden  
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49 17 of care on the parents <sup>11</sup>. Furthermore, the severity of FA, the presence of concomitant  
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52 18 allergic diseases, the number of food allergens, and children's allergy history also  
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55 19 influence parental burden <sup>17-19</sup>. Regarding parent-related factors, the gender of the  
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58 20 parents (father/mother) influenced the caregiving burden. Four studies compared the  
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61 21 caregiving burden between parents and found that mothers had a higher caregiving  
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64 22 burden than fathers in at least one area <sup>18-21</sup>. Nevertheless, existing studies on the factors

1 influencing parental burden among parents of children with FA have been limited to  
2 factors related to children with FA, neglecting the influence of other factors, such as  
3 demographic characteristics (e.g., age, gender, and education degree) and other  
4 changeable variables (e.g., social support and coping style) of parents. Social support  
5 and coping style are considered two changeable variables that may influence the  
6 parental burden on parents of children with FA. Social support acts as an available  
7 external resource against stress<sup>22</sup>. Good social support from family, society, and others  
8 can reduce an individual's stress and thus may lower caregivers' burden<sup>23</sup>. In addition,  
9 coping style refers to an individual's efforts to change cognition and behavior to meet  
10 specific internal and external environmental requirements beyond their existing  
11 capacity and resources<sup>24</sup>. Caregivers with an active coping style could better cope with  
12 their problems and thus may reduce the burden of caring for children with FA<sup>25</sup>.  
13 However, there is a lack of research exploring the relationship between social  
14 support/coping style and parental burden among the parents of children with FA.

15 In addition, the literature on this topic in China is limited. Only one study focused  
16 on parental quality of life in families with children with FA in Hong Kong, a developed  
17 city in China. However, this article emphasized the validation and discriminative ability  
18 of the traditional Chinese version of the Food Allergy Quality of Life-Parental Burden  
19 (TC-FAQL-PB) questionnaire in Hong Kong. It only used univariate analysis to  
20 identify the influencing factors, so the results were yet to be verified. Furthermore,  
21 because of the culture, society, and economic differences between Hong Kong and  
22 mainland China, the results may not be representative, and the associated factors of

1 parental burden in the context of mainland China need to be further explored. Recently,  
2 the authors of this study developed and validated the simplified Chinese version of the  
3 Food Allergy Quality of Life-Parental Burden (SC-FAQL-PB) questionnaire, which  
4 has a wider range of applications than TC-FAQL-PB in China. It has been proven to  
5 have good psychometric properties and can be used as an effective measure in further  
6 studies.

7 Therefore, this study aims to explore the factors associated with parental burden  
8 among parents of children with FA in China, considering general information about  
9 children and parents and the social support and coping styles of parents.

## 10 **2. Methods**

### 11 **2.1 Study design**

12 A cross-sectional study was conducted to explore the factors influencing parental  
13 burden among parents of children with FA in China. This study was reported following  
14 the STROBE checklist (see Supplementary File S1).

### 15 **2.2 Setting and participants**

16 FA tends to commonly occur in early childhood, first occurring before the age of  
17 5 years<sup>26</sup>, and the parents of the children aged 0-5 are largely responsible for managing  
18 their child's FA and thus often experience a high parental burden. Therefore, we  
19 identified parents of a child aged 0-5 years with FA as our study population. A total of  
20 346 parents of children aged 0-5 years diagnosed as having FA were recruited through  
21 convenience sampling of the Internet and a child health center in a tertiary hospital in  
22 Changsha, China. There was no significant difference between participants recruited

1 via these two methods. Inclusion criteria were as follows: (a) a parent aged  $\geq 18$  years  
2 who (b) had at least one child aged  $\leq 5$  years who was clinically diagnosed as having  
3 FA by a clinician. OFC, skin prick test, spot patch test, serum IgE detection, or dietary  
4 avoidance can be used in the diagnosis, (c) was the main caregiver of children, and (d)  
5 could understand and communicate normally. Exclusion criteria were as follows: (a) a  
6 parent whose child was complicated with malignant diseases or other organic lesions  
7 and (b) a parent whose child had a mental illness or cognitive impairment.

8 The sample size was calculated using an independent variable-to-subject ratio  
9 reported by Kendall <sup>27</sup>. He recommended at least a 1:10 ratio for a cross-sectional  
10 investigation. Moreover, the “rules of thumb” for determining the sample size for  
11 regression equations using six or more predictors stated that an absolute minimum of  
12 10 participants per predictor variable was appropriate <sup>28</sup>. The independent variables in  
13 this study included general information, social support, and coping style. Considering  
14 the 28 independent variables and a 15% invalid rate, a minimum of 330 cases was  
15 required. Thus, a sample size of 346 in this study met this requirement.

### 16 **2.3 Recruitment and data collection**

17 Before completing the questionnaire, the participants were informed of the  
18 research-related information, including the research’s objectives and investigation  
19 process, anonymity, and voluntary participation. The questionnaires were completed on  
20 the Internet using Wenjuanxing, an online questionnaire collection platform in  
21 mainland China. Wenjuanxing ensured that respondents completed the entire  
22 questionnaire to avoid missing data. It also avoided the problems of manual data entry

1 and improved the efficiency and accuracy of data collection and screening. Those who  
2 had difficulty filling out the electronic questionnaire could contact researchers to guide  
3 them to finish the e-questionnaire or ask for a paper questionnaire. The researchers'  
4 contact information was provided to the participants at the time of recruitment. Before  
5 the formal survey, we selected 10 subjects who met the study inclusion criteria for the  
6 pre-survey. The pre-survey ensured that the general information items and  
7 questionnaire instructions developed by our research team were logical and easy to  
8 understand. Data collection began in December 2021 and lasted for three months.

## 9 **2.4 Measures**

### 10 *General information questionnaire*

11 A general information questionnaire consisted of items to gather details about the  
12 children's and parents' demographic information and other disease-specific  
13 characteristics of children with FA. The children's information included months of age,  
14 gender, growth standards (using Z-scores), the number of identified food allergens, the  
15 number of highly suspected food allergens, the number of children's FA-affected  
16 systems, the number of FA-related symptoms, the time of the first diagnosis of FA, the  
17 frequency of adverse reactions, whether they were going to kindergarten, whether they  
18 were taking breast milk, whether they had an intake of special formula milk powder,  
19 whether they had an egg allergy, whether they had a milk allergy, whether they had  
20 experienced severe anaphylaxis<sup>29 30</sup>, whether they had a history of anti-allergy drug use  
21 (referring only referred to antihistamine use), and whether they had visited the  
22 emergency room. Parents' information included gender, age, parental history of self-

1 reported allergies, education level, working conditions, financial affordability  
2 regarding their children's FA, knowledge about FA (self-reported), whether they were  
3 obtaining learning knowledge about FA from health professionals, and whether they  
4 had a medical knowledge background.

5 *The Simplified Chinese version of the Food Allergy Quality of Life-Parental Burden*  
6 *(SC-FAQL-PB) questionnaire*

7 The FAQL-PB questionnaire was developed by Cohens *et al.*<sup>31</sup>. The original  
8 English version has been translated into many languages and validated in the United  
9 Kingdom, Australia, Thailand, Iran, South Korea, Hong Kong, and mainland China.  
10 The authors adapted and validated the Chinese version, SC-FAQL-PB. It utilizes a 7-  
11 point Likert scale ranging from 1 (not troubled) to 7 (extremely troubled). There are 17  
12 items covering family and social activities, meal preparation, health issues, and  
13 emotional issues, measuring two dimensions of limitations in life (3 items) and  
14 emotional distress (14 items). Items for the measurements of parental burden were  
15 negatively worded (e.g., "How much would your choice of vacation be limited by your  
16 child's food allergy?"). A higher SC-FAQL-PB score indicates a higher parental burden.  
17 The confirmatory factor analysis results confirmed the two-factor model proposed by  
18 Leung as the most reasonable fit for explaining the factor construct of the SC-FAQL-  
19 PB<sup>30</sup>. The internal coefficient of consistency was 0.946, with a test-retest reliability of  
20 0.926. The Cronbach's alpha of the scale in our sample was 0.958.

21 *Social Support Rating Scale (SSRS)*

22 The social support level was assessed with the Social Support Rating Scale (SSRS),

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4 1 which was developed by Dr. Xiao <sup>32</sup>. It includes 10 items measuring three dimensions:  
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6 2 subjective support (3 items), objective support (4 items), and support utilization (3  
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8 3 items). Objective support refers mainly to visible practical support, such as direct  
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10 4 material assistance and social networks. Subjective support refers to an individual's  
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12 5 emotional feelings and satisfaction with being supported, respected, and understood in  
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14 6 society. Support utilization refers to the extent to which individuals utilize social  
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16 7 support <sup>33</sup>. A higher total score indicated a higher social support level. This total support  
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18 8 score was classified into three categories: low ( $\leq 22$ ), moderate (23–44), and high ( $\geq$   
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20 9 45) levels <sup>34</sup>. The SSRS has been widely used in Chinese domestic contexts <sup>35-37</sup>. The  
21  
22 10 cumulative contribution rate of the three common factors was 54.26% <sup>38</sup>. The internal  
23  
24 11 consistency of the SSRS in this study was acceptable. The Cronbach's alpha of the scale  
25  
26 12 in our sample was 0.778.

### 13 *Simplified Coping Style Questionnaire (SCSQ)*

14 Coping style was accessed with the Simplified Coping Style Questionnaire, which  
15 is a self-report survey that includes two subscales: active coping (12 items) and passive  
16 coping (eight items) <sup>39</sup>. All items were rated using a 4-point Likert scoring method,  
17 ranging from zero (never) to three (always). The scores of each subscale item were  
18 summed up to generate a subscale score. Dai proposed a formula for the coping style  
19 tendency—coping style tendency = active coping criterion score ( $Z_a$  score) - passive  
20 coping criterion score ( $Z_p$  score)—to determine an individual's main coping style in  
21 stress situations <sup>40</sup>.  $Z_a/Z_p = (\text{actual score for the subscale} - \text{mean of the score for the}$   
22  $\text{subscale among the national norm sample}) / (\text{standard deviation of the score for the}$



1 subscale among the national norm sample). If the value of the coping style tendency >  
2 0, it means the individual mainly adopts an active coping style. The Chinese national  
3 norm for the active coping score is  $1.78 \pm 0.52$ , and for the passive coping score, it is  
4  $1.59 \pm 0.66$  <sup>39</sup>. The SCSQ has been widely used to assess caregivers' coping styles in  
5 China, and the Cronbach's alpha coefficient of the two subscales ranged from 0.75 to  
6 0.90 <sup>41-45</sup>. The cumulative contribution rate of the two common factors was 48.5% <sup>46</sup>.  
7 In the present study, the Cronbach's alphas of the active and passive coping styles were  
8 0.909 and 0.752, respectively.

## 9 **2.5 Data analysis**

10 The collected data were analyzed using the IBM SPSS 26.0 program. Descriptive  
11 statistics were used to investigate the demographic and disease-specific characteristics  
12 of children with FA and their parents, social support, coping style, and parental burden  
13 among the parents of children with FA. The Kolmogorov–Smirnov test was performed  
14 to confirm the normality of the measurement data. Means with standard deviations  
15 (Mean  $\pm$  SD) were calculated for normally distributed data, while median and  
16 interquartile ranges were calculated for non-normally distributed measures.  
17 Frequencies and percentages were calculated for the count data. Between-group  
18 differences were tested using T-tests and ANOVA for normally distributed data to  
19 investigate parental burden. Spearman's correlation analysis was used to analyze the  
20 correlations between parental burden, coping style, and social support among the  
21 parents of children with FA. All reported *P* values were two-sided, with a significance  
22 level of 0.05.

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4 1 Multivariate stepwise regression analysis was performed to identify the factors  
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6 2 influencing parental burden among parents of children with FA, with the total FAQL-  
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9 3 PB score as the dependent variable. The variables with a  $P < 0.1$  for univariate analysis  
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11 4 were all introduced. Some non-normally distributed continuous variables were log-  
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13 5 transformed ( $y = \log_{10}(x + 1)$ ) to normalize their distribution before their introduction  
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15 6 to multivariate stepwise regression analysis. The variables were screened stepwise  
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17 7 based on the criteria of  $\alpha \leq 0.05$  in and  $\alpha \geq 0.1$  out model. When the independent  
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19 8 variables were unordered categorical variables, they were converted into dummy  
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21 9 variables and then included in the regression analysis. The analysis used  $R^2$  as the power  
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23 10 of a linear model to represent the percentage of the current variation of  $y$  explained by  
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25 11 the independent variables in the current model.  
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## 32 **2.6 Ethical consideration**

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35 13 This research was approved by the Ethical Review Committee of Xiangya School  
36  
37 14 of Nursing, Central South University, on July 15, 2021 (approval number: E202192).  
38  
39 15 All participants filled out questionnaires voluntarily, from whom signed informed  
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41 16 consent was obtained. It was emphasized that the participation was anonymous, and all  
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43 17 data were kept strictly confidential and used for research purposes only.  
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## 48 **2.7 Patient and public involvement**

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51 19 None.  
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## 53 **3. Results**

### 54 **3.1 General characteristics of children with FA and their parents**

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58 22 A total of 346 parents of children with FA were enrolled in this study, with a  
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1 response rate of 100%. Sixteen questionnaires were removed because the filling time  
 2 was less than five minutes (six questionnaires) and because the parents were not the  
 3 primary caregivers of children in their daily lives (ten questionnaires). The valid  
 4 questionnaire rate was 95.38% (330/346). Table 1 shows the characteristics of the  
 5 children with FA and the relationships between the characteristics and parental burden  
 6 among parents. Most children (75.5%, 249/330) had milk allergies, and 46.7% (154/330)  
 7 of the children were allergic to eggs. Only three children had experienced severe  
 8 anaphylaxis, and 21.8% (72/330) had visited the emergency room. As presented in  
 9 Table 2, the male-to-female ratio of parents was 1:16.4, their mean age was 30.41 years,  
 10 and most completed college or had a higher degree (87.9%, 290/330). More than half  
 11 of the parents (70.0%, 231/330) were at work, and most parents (77.9%) reported that  
 12 the financial costs caused by FA were affordable. More details can be found in Tables  
 13 1 and 2.

14 **Table 1. General characteristics of children with food allergies and the relationship between**  
 15 **the characteristics and parental burden (n=330)**

Characteristics	Parental burden			
	Mean	SD	t/F/r	P
<b>Gender, n (%)</b>			0.62	0.54
Male	187 (56.7)	65.19	21.24	
Female	143 (43.3)	63.85	18.18	
<b>Whether they were going to kindergarten, n (%)</b>			-1.55	0.12
Yes	10 (3.0)	55.00	19.16	
No	320 (97.0)	64.91	19.93	
<b>Growth standards, n (%)</b>			-1.02	0.31
Without growth retardation	313 (94.8)	64.35	20.05	
With growth retardation	17 (5.2)	69.41	17.99	
<b>Whether they were taking in breast milk, n (%)</b>			0.31	0.76
Yes	77 (23.3)	65.22	20.82	
No	253 (76.6)	64.42	19.72	3.39
<b>Whether they had an intake of special formula milk powder, n (%)</b>				0.02*
Moderately hydrolyzed formula	64 (19.4)	60.69	18.97	
Deep hydrolyzed formula	106 (32.1)	63.75	20.21	
amino acid milk powder	75 (22.7)	70.67	17.97	
None <sup>a</sup>	85 (25.8)	63.29	21.15	
<b>Whether they had an egg allergy</b>			2.45	0.02*
Yes	154 (46.7)	67.42	17.57	
No	176 (53.3)	62.15	21.28	
<b>Whether they had a milk allergy</b>			1.40	0.16
Yes	249 (75.5)	65.91	20.08	

No	81 (24.5)	61.91	19.44		
<b>The time of the first diagnosis of FA (month of age), n (%)</b>				0.76	0.45
0-5 months	260 (78.8)	65.04	19.68		
> 5 months	70 (21.2)	63.00	21.01		
<b>The Frequency of adverse reactions, n (%)</b>				6.84	<0.01**
1-5 times	154 (46.7)	62.77	20.30		
6-10 times	69 (20.9)	60.07	17.63		
> 10 times	107 (32.4)	70.18	19.80		
<b>Whether they had experienced severe anaphylaxis<sup>b</sup>, n (%)</b>				0.24	0.81
Yes	3 (0.91)	67.33	26.86		
No	327 (99.1)	64.58	19.94		
<b>Whether they had a history of anti-allergy drug use<sup>c</sup>, n (%)</b>				1.98	<0.05*
Yes	140 (42.4)	67.14	19.10		
No	190 (21.8)	62.75	20.41		
<b>Whether they had visited the emergency room, n (%)</b>				0.58	0.57
Yes	72 (21.8)	65.83	20.35		
No	258 (78.2)	64.27	19.87		
<b>Children' month of age, Mean±SD</b>		15.07±8.18		-0.06	0.26
<b>The number of identified food allergens, Median (IQR)</b>			2(2)	0.197	<0.001**
<b>The number of highly suspected food allergens, Median (IQR)</b>			2(2)	0.219	<0.001**
<b>The number of children's FA-affected systems<sup>d</sup>, Median (IQR)</b>			2(1)	0.213	<0.001**
<b>The number of children's FA-related symptoms, Median (IQR)</b>			2(3)	0.252	<0.001**

\* $P<0.05$ ; \*\* $P<0.01$ ; \*\*\* $P<0.001$ .

<sup>a</sup> Children didn't take in special formula milk powder, only took in breast milk or formula milk.

<sup>b</sup> Severe anaphylaxis refers to acute systemic allergic reactions that can be life-threatening, including anaphylactic shock, angioedema, bronchospasm, and hypotension.

<sup>c</sup> The anti-allergy drugs referred to here are antihistamines. In China, patients are not prescribed self-injectable adrenaline.

<sup>d</sup> FA-affected systems involve the integumentary system, respiratory system and gastrointestinal system.

**Table 2. General characteristics of parents having children with food allergies and the relationships between the characteristics and parental burden (n=330).**

Characteristics	Parental burden			
	Mean	SD	t/F/r	P
<b>Gender, n (%)</b>				
Male	19 (5.8)	62.95	22.29	
Female	311 (94.2)	64.71	19.84	
<b>Parental history of self-reported allergies, n (%)</b>				-0.08 0.94
Yes	211 (67.0)	64.55	19.29	
No	109 (33.0)	64.73	21.34	
<b>Education level, n (%)</b>				5.79 <0.01**
Junior high school or below	12 (3.6)	82.75	16.48	
Senior high school	28 (8.5)	72.68	18.15	
College	95 (28.8)	67.02	20.44	
Undergraduate	158 (47.9)	61.44	19.73	
Graduate or above	37 (11.2)	59.95	16.68	
<b>Working conditions, n (%)</b>				-4.03 <0.01**
at work	231 (70.0)	61.77	20.44	
Not at work	99 (30.0)	71.22	17.12	
<b>Financial affordability regarding their children's FA, n (%)</b>				15.04 <0.01**
Fully affordable	62 (18.8)	56.69	20.14	
Able to afford	195 (59.1)	62.56	19.00	
Harder to afford	67 (20.3)	76.10	17.22	
Unable to afford	6 (1.8)	84.50	12.11	
<b>Knowledge about FA (self-reported), n (%)</b>				-1.36 0.17
Yes	113 (34.2)	62.54	18.31	
No	217 (65.8)	65.69	20.72	
<b>Whether they were obtaining knowledge about FA from health professionals, n (%)</b>				-1.85 0.07
Yes	233 (70.6)	63.30	20.22	

No	97 (29.4)	67.75	19.04	-0.77	0.45
<b>Whether they had a medical background, n (%)</b>					
Yes	56 (17.0)	62.75	20.14		
No	274 (83.0)	64.99	19.93		
<b>Parents' age (years), Mean±SD</b>	30.41±3.68			-0.06	0.26

\* $P < 0.05$ . \*\* $P < 0.01$ .

## 3.2 Analysis of Factors influencing parental burden among parents of children with FA

### 3.2.1 Univariate analysis on factors related to parental burden among parents of children with FA

The results in Table 1 show that parents whose children were allergic to eggs had a higher parental burden score ( $67.42 \pm 17.57$ ) than those whose children did not ( $62.15 \pm 21.28$ ), and parents whose children had a history of antiallergy drug use ( $67.14 \pm 19.10$ ) had a higher parental burden score than those whose children did not ( $62.75 \pm 20.41$ ). In addition, the parental burden increased with the number of children's identified food allergens, the number of highly suspected food allergens, the number of children's FA-affected systems, and the number of children's FA-related symptoms. The intake of children's special formula milk affected the parental burden score, and parents whose children took in amino acid milk powder had the highest parental burden ( $70.67 \pm 17.97$ ). Moreover, parents whose children had up to 10 times adverse reactions ( $70.18 \pm 19.80$ ) had higher parental burden scores than parents whose children had 1–5 times ( $62.77 \pm 20.33$ ,  $P < 0.01$ ) and 6–10 times adverse reactions ( $60.07 \pm 17.63$ ,  $P < 0.01$ ). As Table 2 shows, the parental burden scores among the parents of children with FA decreased with educational level and financial affordability regarding their children's FA. Moreover, parents who were not at work ( $71.22 \pm 17.12$ ) had a higher parental burden than those who were at work ( $61.77 \pm 20.44$ ). In addition, all of them

1 reported significant statistical differences ( $P < 0.05$ ). However, no significant  
 2 difference in parental burden existed between groups divided by children's and parents'  
 3 genders, when children had visited the emergency room, when children had  
 4 experienced severe anaphylaxis, when there was a parental history of self-reported  
 5 allergies, etc. The bivariate correlation analysis results in Table 3 show that parental  
 6 burden was negatively correlated with the parents' social support ( $r = -0.291$ ,  $P < 0.001$ )  
 7 and coping style ( $r = -0.240$ ,  $P < 0.001$ ). Because the analysis above did not control  
 8 other confounding factors, these statistically significant factors in this part need to be  
 9 identified in multiple stepwise linear regression.

10 **Table 3. Bivariate correlation between parental burden and social support and coping style**  
 11 **(n=330).**

	Parental Burden
	<i>Spearman correction coefficients (r)</i>
Social support	-0.291***
Coping style <sup>a</sup>	-0.240***

12 \*\*\*  $P < 0.001$ .

13 <sup>a</sup> It represents the coping style tendency (identified after Z-conversion), which means the  
 14 individual's main coping style in stress states.

15 3.2.2 Multiple linear regression analysis on factors related to parental burden among  
 16 parents of children with FA

17 Some factors were introduced in a multiple stepwise linear regression to ensure a  
 18 stable model. The children-related factors included the number of identified food  
 19 allergens, the number of highly suspected food allergens, the number of children's FA-  
 20 affected systems, the number of children's FA-related symptoms, the frequency of  
 21 adverse reactions, whether they had an intake of special formula milk powder, whether  
 22 they had an egg allergy, whether they had experienced severe anaphylaxis, and whether  
 23 they had a history of antiallergy drug use. Parent-related factors included education  
 24 level, working conditions, financial affordability regarding their children's FA,

1 knowledge of FA (self-reported), medical knowledge background, social support,  
 2 coping style, and whether they were obtaining learning knowledge from health  
 3 professionals. “Intake of special formula milk powder-None” was set as a reference  
 4 variable for ‘Intake of special formula milk’ in introducing dummy variables into  
 5 regression analysis. In Table 4, the results show that the number of highly suspected  
 6 food allergens ( $\beta = 0.162, P < 0.01$ ), the number of children’s FA-affected systems ( $\beta$   
 7 = 0.129,  $P < 0.05$ ), amino acid milk powder intake ( $\beta = 0.154, P < 0.01$ ), working  
 8 conditions ( $\beta = -0.169, P = 0.000$ ), financial affordability regarding their children’s FA  
 9 ( $\beta = -0.224, P = 0.000$ ), and social support ( $\beta = -0.226, P = 0.000$ ) are independently  
 10 associated with the parental burden on parents of children with FA. Coping style was  
 11 not entered into the regression equation in this study. The multiple linear regression  
 12 equation models were statistically significant ( $P < 0.001, \Delta F = 6.769$ ) and explained  
 13 27.4% of the variance (Adjusted  $R^2$  was 26.0%).

14 **Table 4. A multivariate linear stepwise regression analysis of the factors influencing the**  
 15 **parental burden of parents having children with food allergies (n=330).**

Model	Coefficient		Standard coefficient	<i>t</i>	<i>P</i>
	Unstandardized coefficient				
	<i>B</i>	<i>SE</i>	<i>Beta</i>		
(Constant)	61.438	7.225		8.470	0.000 ***
The number of highly suspected food allergens <sup>a</sup>	13.489	4.127	0.162	3.269	0.001 **
The number of children’s FA-affected systems <sup>a</sup>	20.118	7.733	0.129	2.602	0.010 *
Intake of special formula milk powder - Amino acid milk powder intake	7.328	2.292	0.154	3.198	0.002 **
Whether they had an intake of special formula milk powder – None <sup>b</sup>	0				
Working conditions	-7.346	2.082	-0.169	-3.529	0.000 ***
Financial affordability regarding their children’s FA	-6.568	1.454	-0.224	-4.517	0.000 ***
Social support	-0.580	0.127	-0.226	-4.582	0.000 ***

16 Note:  $R^2=0.274$ ; adjusted  $R^2=0.260$ ;  $\Delta F=7.769$ ; \* $P<0.05$ ; \*\* $P<0.01$ ; \*\*\* $P<0.001$ ; Dependent variable:  
 17 parental burden among parents with a FA child. The variables with  $P < 0.1$  from univariate analysis  
 18 were introduced.

19 <sup>a</sup> The variables introduced in a multiple stepwise linear regression here were log-transformed  
 20 ( $y=\log_{10}(x + 1)$ ) to approximate a normal distribution.



<sup>b</sup> It was set as a reference variable for 'Intake of special formula milk' in the process of introducing dummy variables into regression analysis.

#### 4. Discussion

Providing quality care for children with FA will undoubtedly place a burden on their parents. The purpose of the study was to explore the associated factors of parental burden among the parents of children with FA. In our sample, the score for parental burden was 64.61 (SD = 19.96), which was lower than the reported in the UK (69.99 (SD=23.17)<sup>47</sup>.

Among children-related characteristics, it was determined that the number of highly suspected food allergens and the number of FA-affected systems positively influenced the parental burden among parents of children with FA. These results are consistent with previous studies<sup>17 30 47</sup>. When children have more highly suspected food allergens, their parents need to spend more effort to take a wide range of avoidance measures and often feel worried, which increases the parental burden. In addition, when FA affects many systems involving the skin and the gastrointestinal, respiratory, and cardiovascular systems, parents feel more worried about their children's health<sup>11</sup>. In one of the noteworthy findings of this study, the parental burden of parents whose children took in amino acid milk powder was high. This may be related to the fact that parents were worried about the lack of pure nutrient intake when amino acid milk powder was an alternative to breast milk and cow's milk<sup>48</sup>. There is a great need for comprehensive and systematic FA-based health education programs<sup>49-51</sup>. On the one hand, it will help parents manage their children's food allergies correctly and find alternative nutrients to ensure normal growth and development<sup>52 53</sup>. On the other hand, it will change wrong cognitions related to food allergies to decrease the parental burden



1 among parents of children with FA <sup>50</sup>. Additionally, amino acid milk powder is more  
2 expensive than ordinary powdered milk. Because FA-related economic aid is not  
3 provided in China, parents whose children consumed amino acid milk powder must  
4 spend more to provide it, which would increase their financial burden.

5       Among the parent-related characteristics, this study revealed that the parental  
6 burden of parents who were not at work was high, which coincides with the results in  
7 the previous literature <sup>54 55</sup>. This situation can be interpreted in such a way that parents  
8 at work have higher economic power, a better social environment, and better use of  
9 their social support systems <sup>56-58</sup>. When parents do not work and devote themselves to  
10 the care of the FA child, they may lack social support and develop psychosocial  
11 symptoms, which may increase the burden <sup>11 13</sup>. This study also showed that the lower  
12 the financial affordability regarding their children's FA, the heavier the parental burden.  
13 This was consistent with the results of a study focusing on the economic impact of  
14 childhood FA in the United State <sup>58</sup>. The high costs, such as direct medical costs, dietary  
15 costs, and opportunity costs (such as restricted career choices), definitely increase the  
16 burden on parents and may not be affordable for some families. Couch *et al.* suggested  
17 that earlier OFCs should be considered to identify food allergens and reduce families'  
18 additional financial expenses, especially for opportunity costs. This would effectively  
19 decrease the financial burden on parents <sup>59</sup>. Furthermore, there is an urgent need for  
20 providing a robust health insurance system for relieving their parental burden  
21 financially <sup>60</sup>. The present study found that the gender of parents was not an influencing  
22 factor associated with parental burden, which differs from the results of Springston *et*

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3  
4 1 *al.* <sup>18-20</sup>. This may be because the sample size of the fathers in this study was small,  
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6  
7 2 which may have led to the difference in parental burden between the mothers and  
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10 3 fathers not being identified. The reason for the small sample size of fathers recruited in  
11  
12 4 this study is also related to the societal context of China, where women often assume  
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14 5 the role of childcare <sup>61 62</sup>.

16  
17 6 With the highest standardized beta in the regression equation, parents' social  
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19 7 support was a key protective influencing factor against parental burden among parents  
20  
21 8 of children with FA. Specifically, parental burden decreases as parents' social support  
22  
23 9 increases. Previous studies have also suggested that when parents (children's caregivers)  
24  
25 10 lack social support during the caregiving process, they may develop physical symptoms,  
26  
27 11 such as weight loss and fatigue, and psychosocial symptoms, such as anxiety, social  
28  
29 12 isolation, and decreased quality of life, which all increase the burden of care <sup>63-65</sup>.  
30  
31 13 Adequate social support may help reduce the parental burden. Social support has  
32  
33 14 traditionally been provided by families and friends in China and less provided by the  
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35 15 community service agency and the government<sup>37 66 67</sup>. In a qualitative study concerning  
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37 16 caregivers caring for a family member, 62% of respondents identified a lack of social  
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39 17 support as one of their caregiving challenges. Moreover, 83% of participants identified  
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41 18 emotional support (i.e., seeking out to friends and family or others) to be effective in  
42  
43 19 dealing with these challenges <sup>68</sup>. This individual level of social support will help parents  
44  
45 20 establish and improve their social support system so that they can feel more supported  
46  
47 21 while dealing with the problems and emotional reactions related to their children's FA  
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49 22 <sup>64 69</sup>. Parents can also use social media platforms and websites to share information and  
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1 learn more about FA <sup>70 71</sup>. In addition, community support services, such as health  
2 professional help, structured educational programs, and workshops related to the  
3 management of food allergens, should be available to parents of children with FA <sup>72</sup>.  
4 They will provide better community social support and richer knowledge about  
5 managing FA for parents and help them cope with caring for a child with FA, thus  
6 relieving the parental burden <sup>50 73</sup>. Additionally, health-related departments should  
7 improve medical policies and reimbursement rates to provide financial support for  
8 parents with children with FA <sup>60</sup>.

9 However, parents' coping style did not exhibit a relationship with parental burden  
10 in the multiple stepwise regression of this study. The reason may be that although some  
11 parents adopted an active coping style (e.g., positively learning knowledge about their  
12 children's FA and avoiding allergens as much as possible) to deal with their children's  
13 FA, their specific, positive measures cannot immediately cure or control their children's  
14 allergy reactions <sup>70</sup>. Furthermore, allergic reactions are unpredictable and, for many  
15 children, FA is sometimes accompanied with food intolerance for which the symptoms  
16 are similar to those of the FA and difficult to avoid <sup>74-77</sup>. In these conditions, an active  
17 coping style cannot always obtain positive feedback. This would cause anxiety and a  
18 heavy burden, especially an emotional burden, on parents <sup>14 70</sup>. In addition, the SCSQ  
19 used to measure coping style focused on only two types. However, coping styles are  
20 much more complex than merely positive and negative. The quantitative measurement  
21 instrument we used ignored the complexity of coping styles, which may have  
22 influenced the final results. Therefore, instruments that can identify the complexity of

1 coping styles should be developed. Furthermore, qualitative studies should be  
2 considered to explore the relationship between coping style and parental burden.

### 3 **Limitations**

4 Several limitations of this study are acknowledged. Considering we only recruited  
5 the parents with a child aged 0-5 years with FA, the generalization of the results in this  
6 study requires caution for other populations. Second, convenience sampling cannot  
7 guarantee sample diversity. For example, the sample size of fathers is limited in this  
8 study. However, it is also consistent with the fact that the mother is primarily  
9 responsible for the care of the sick child in China. To better explore the fathers' parental  
10 burden, further studies need recruit more fathers in the study sample. Third, it was  
11 certainly a limitation that FA diagnosis was made using diverse methods and not always  
12 based on the gold standard of OFC. In middle- and low-income countries such as China,  
13 FA diagnosis is likely to be based on the skin prick test, serum IgE detection, or clinical  
14 history, while OFC is rarely used for diagnosis. Sometimes misdiagnosis may occur.  
15 Finally, the quantitative measurement instrument of coping style employed in this study  
16 ignores the complexity of coping styles, which may have influenced the results.  
17 Instruments that can identify the complexity of coping styles should be developed and  
18 used in future studies.

### 19 **5. Conclusion**

20 Parents whose children had more highly suspected food allergens and had more  
21 FA-affected systems had a higher parental burden. Moreover, the burden of parents  
22 whose children took in amino acid milk powder was higher than that of parents whose

1 children did not. Parents' working conditions were also a significant influencing factor  
2 of parental burden. All these factors could greatly predict parental burden among  
3 parents with children with FA. Above all, parents with lower financial affordability  
4 regarding their children's FA and lower social support experienced higher parental  
5 burdens. Thus, the level of financial affordability regarding their children's FA and  
6 parents' state of social support can serve as key predictors of parental burden among  
7 parents of children with FA. These findings point to several measures that can help ease  
8 the parental burden. FA should be included within the scope of medical insurance  
9 reimbursement, which can partially alleviate financial pressure on parents. Additionally,  
10 high-quality FA-related health education programs should be provided by community  
11 health service centers to support parents in monitoring and flexibly responding to  
12 children's FA. Moreover, it can reduce the daily life and social burden of parents with  
13 children with FA, thereby promoting their physical and mental health. This study  
14 provided basic evidence to explore strategies for relieving the parental burden among  
15 parents of children with FA. In the future, more empirical studies (e.g., longitudinal  
16 studies and intervention studies) are needed to verify and further the results of this study.

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19 **Author contributions**

20 *Methodology:* Z.L. and Q.C.;

21 *Formal Analysis:* Z.L. and L.T.;

22 *Investigation:* Z.L., H.L.;

1 *Writing – Original Draft Preparation: Z.L.;*

2 *Writing – Review & Editing: Z.L., Q.C., L.T.;*

3 *Supervision: S.T. and Q.C.;*

4 *Project Administration: Q.C.*

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8 **Patient consent for publication** Not required.

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11 E202192).

12 **Data sharing statement** No data are available.

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For peer review only

Table S1. STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-10 Tables 1-4
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	11
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12-14
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-14 Tables 1-2
		(b) Indicate number of participants with missing data for each variable of interest	N/A

Outcome data	15*	Report numbers of outcome events or summary measures	Tables 3-4
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	17-20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21-22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	21
Generalisability	21	Discuss the generalisability (external validity) of the study results	21
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23

\*Give information separately for exposed and unexposed groups.