BMJ Open Factors associated with parental burden among parents of children with food allergies in China: a crosssectional study

Zeen Li , ¹ Lang Tian, ² Haiyan Liu, ² Siyuan Tang , ¹ Qirong Chen

To cite: Li Z, Tian L, Liu H, et al. Factors associated with parental burden among parents of children with food allergies in China: a crosssectional study. BMJ Open 2022;12:e065772. doi:10.1136/ bmjopen-2022-065772

Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2022-065772).

Received 17 June 2022 Accepted 09 September 2022



@ Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹Xiangva School of Nursing. Central South University, Changsha, Hunan, China ²Third Xiangya Hospital, Central South University, Changsha, Hunan, China

Correspondence to

Dr Qirong Chen; qirong.chen@csu.edu.cn and Dr Siyuan Tang; tsycongcong@126.com

ABSTRACT

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

Design Cross-sectional study.

Setting The participants were recruited through the internet and one child health centre of a tertiary hospital in Chanosha, China,

Participants A total of 346 parents of children with FA were recruited using a convenience sampling method. After excluding the invalid questionnaires, 330 questionnaires were included for the analysis.

Outcome measures The data of general and diseasespecific information of children with FA 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 analyse the data.

Results Financial affordability regarding their children's FA and parents' social support were key protective factors against parental burden ($\beta=-0.224$, p<0.001 and $\beta=-0.226$, p<0.001, respectively). This study also found that parents' working conditions, the number of highly suspected food allergens, the number of children's FAaffected systems 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 highly suspected food allergens and more FA-affected systems because these parents often have a higher parental burden. Furthermore, it is important to improve financial support for children's FA and social support for parents of children with FA to decrease their parental burden.

BACKGROUND

Food allergy (FA) is a common allergic disease in childhood; it is a hypersensitive reaction of the immune system to proteins in food. It can affect the skin and gastrointestinal, respiratory and cardiovascular systems with varying degrees of severity. Children with FA often have multiple allergic comorbidities, such

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We simultaneously included parents' demographic characteristics, social support and coping style in this study to explore the factors influencing parental burden among parents of children with food aller-
- ⇒ The participants were recruited through a convenience sampling method in two ways: through the internet and from a child health centre in a tertiary hospital in Changsha, China.
- ⇒ The coping style measurement employed in the study consider only two coping styles (ie, active and passive), and more comprehensive tools should be considered to accurately identify additional types of coping styles for fuller understanding of parental burden.
- ⇒ A longitudinal study with a larger sample size is needed to explore the influencing factors of parental burden among parents of children with FA.

as asthma, eczema and hay fever.² FA affects approximately 5% of global children aged 0-5 years diagnosed by open oral food challenge (OFC) testing,³ and it has become one of the fastest-growing public health problems with epidemiological characteristics, especially in developed countries. 4-6 The prevalence of FA in children has also been increasing at an alarming rate recently in China. ⁷⁸ FA requires strict avoidance of food allergens. Accidental exposure to food allergens can endanger children's health if effective avoidance measures are not taken. Avoiding these allergens is not simple, as many products contain 'hidden ingredients' or traces of food allergens, such as nuts. 10

For younger children with FA, the disease burden not only falls on the child but also on the parents. 11-13 Parents of children with FA may be particularly concerned about their children's allergies and take on additional burdens in their daily lives, as they often play an important role in managing



their children's allergies. Specifically, studies have shown that families with children with FA spend more time and energy on grocery shopping because avoiding allergens requires caregivers to double-check food labels for allergens. Preparing food also increases extra work for families with children with FA, as parents need to prepare separate meals for allergic children and prevent crosscontamination. 13 Parents also report its negative effects on daily activities and socialisation. 11 12 14 There is growing evidence that families with children with FA have higher financing costs than those whose children are without FA. 15 In addition to practical and financial needs, research suggests that FA is also associated with negative psychological consequences for parents, including greater stress and worry. 11 FA does hurt parental health-related quality of life. 16 This may lead to a decrease in parental caring capacity and affect the development of children.

Evidence in the literature shows that the younger the child, the greater the burden of care on the parents.¹¹ Furthermore, the severity of FA, the presence of concomitant allergic diseases, the number of food allergens and children's allergy history also influence parental burden. 17-19 Regarding parent-related factors, the gender of the parents (father/mother) influenced the caregiving burden. Four studies compared the caregiving burden between parents and found that mothers had a higher caregiving burden than fathers in at least one area. 18-21 Nevertheless, existing studies on the factors influencing parental burden among parents of children with FA have been limited to factors related to children with FA, neglecting the influence of other factors, such as demographic characteristics (eg, age, gender and education degree) and other changeable variables (eg, social support and coping style) of parents. Social support and coping style are considered two changeable variables that may influence the parental burden on parents of children with FA. Social support acts as an available external resource against stress.²² Good social support from family, society and others can reduce an individual's stress and thus may lower caregivers' burden.²³ In addition, coping style refers to an individual's efforts to change cognition and behaviour to meet specific internal and external environmental requirements beyond their existing capacity and resources.²⁴ Caregivers with an active coping style could better cope with their problems and thus may reduce the burden of caring for children with FA.²⁵ However, there is a lack of research exploring the relationship between social support/coping style and parental burden among the parents of children with FA.

In addition, the literature on this topic in China is limited. Only one study focused on parental quality of life in families with children with FA in Hong Kong, a developed city in China. However, this article emphasised the validation and discriminative ability of the traditional Chinese version of the Food Allergy Quality of Life-Parental Burden (TC-FAQL-PB) questionnaire in Hong Kong. It only used univariate analysis to identify the influencing factors, so the results were yet to be

verified. Furthermore, because of the culture, society and economic differences between Hong Kong and mainland China, the results may not be representative, and the associated factors of parental burden in the context of mainland China need to be further explored. Recently, the authors of this study developed and validated the simplified Chinese version of the Food Allergy Quality of Life-Parental Burden (SC-FAQL-PB) questionnaire, which has a wider range of applications than TC-FAQL-PB in China. It has been proven to have good psychometric properties and can be used as an effective measure in further studies.

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

METHODS Study design

A cross-sectional study was conducted to explore the factors influencing parental burden among parents of children with FA in China. This study was reported following the Strengthening the Reporting of Observational Studies in Epidemiology checklist (online supplemental file S1).

Setting and participants

FA tends to commonly occur in early childhood, first occurring before the age of 5 years, ²⁶ and the parents of the children aged 0-5 are largely responsible for managing their child's FA and thus often experience a high parental burden. Therefore, we identified parents of a child aged 0-5 years with FA as our study population. A total of 346 parents of children aged 0-5 years diagnosed as having FA were recruited through convenience sampling of the internet and a child health centre in a tertiary hospital in Changsha, China. There was no significant difference between participants recruited via these two methods. Inclusion criteria were as follows: (1) a parent aged ≥18 years who (2) had at least one child aged ≤5 years who were clinically diagnosed as having FA by a clinician. OFC, skin prick test, spot patch test, serum IgE detection or dietary avoidance can be used in the diagnosis, (3) was the main caregiver of children and (4) could understand and communicate normally. Exclusion criteria were as follows: (1) a parent whose child was complicated with malignant diseases or other organic lesions and (2) a parent whose child had a mental illness or cognitive impairment.

The sample size was calculated using an independent variable-to-subject ratio reported by Kendall *et al.*²⁷ He recommended at least a 1:10 ratio for a cross-sectional investigation. Moreover, the 'rules of thumb' for determining the sample size for regression equations using six or more predictors stated that an absolute minimum of 10 participants per predictor variable was appropriate.²⁸ The independent variables in this study included general

information, social support and coping style. Considering the 28 independent variables and a 15% invalid rate, a minimum of 330 cases was required. Thus, a sample size of 346 in this study met this requirement.

Recruitment and data collection

Before completing the questionnaire, the participants were informed of the research-related information, including the research's objectives and investigation process, anonymity and voluntary participation. The questionnaires were completed on the Internet using Wenjuanxing, an online questionnaire collection platform in mainland China. Wenjuanxing ensured that respondents completed the entire questionnaire to avoid missing data. It also avoided the problems of manual data entry and improved the efficiency and accuracy of data collection and screening. Those who had difficulty filling out the electronic questionnaire could contact researchers to guide them to finish the e-questionnaire or ask for a paper questionnaire. The researchers' contact information was provided to the participants at the time of recruitment. Before the formal survey, we selected 10 subjects who met the study inclusion criteria for the presurvey. The presurvey ensured that the general information items and questionnaire instructions developed by our research team were logical and easy to understand. Data collection began in December 2021 and lasted for 3 months.

MEASURES

General information questionnaire

A general information questionnaire consisted of items to gather details about the children's and parents' demographic information and other disease-specific characteristics of children with FA. The children's information included months of age, gender, growth standards (using Z-scores), the number of identified food allergens, the number of highly suspected food allergens, the number of children's FA-affected systems, the number of FA-related symptoms, the time of the first diagnosis of FA, the frequency of adverse reactions, whether they were going to kindergarten, whether they were taking breast milk, whether they had an intake of special formula milk powder, whether they had an egg allergy, whether they had a milk allergy, whether they had experienced severe anaphylaxis, 29 30 whether they had a history of antiallergy drug use (referring only referred to antihistamine use) and whether they had visited the emergency room. Parents' information included gender, age, parental history of self-reported allergies, education level, working conditions, financial affordability regarding their children's FA, knowledge about FA (self-reported), whether they were obtaining learning knowledge about FA from health professionals and whether they had a medical knowledge background.

SC-FAQL-PB questionnaire

The FAQL-PB questionnaire was developed by Cohen et al. The original English version has been translated into

many languages and validated in the UK, Australia, Thailand, Iran, South Korea, Hong Kong and mainland China. The authors adapted and validated the Chinese version, SC-FAQL-PB. It uses a 7-point Likert scale ranging from 1 (not troubled) to 7 (extremely troubled). There are 17 items covering family and social activities, meal preparation, health issues and emotional issues, measuring two dimensions of limitations in life (three items) and emotional distress (14 items). Items for the measurements of parental burden were negatively worded (eg, 'How much would your choice of vacation be limited by your child's food allergy?'). A higher SC-FAQL-PB score indicates a higher parental burden. The confirmatory factor analysis results confirmed the two-factor model proposed by Leung et al as the most reasonable fit for explaining the factor construct of the SC-FAQL-PB.³⁰ The internal coefficient of consistency was 0.946, with a test-retest reliability of 0.926. The Cronbach's alpha of the scale in our sample was 0.958.

Social Support Rating Scale

The social support level was assessed with the Social Support Rating Scale (SSRS), which was developed by Xiao.³² It includes 10 items measuring three dimensions: subjective support (three items), objective support (four items) and support usage (three items). Objective support refers mainly to visible practical support, such as direct material assistance and social networks. Subjective support refers to an individual's emotional feelings and satisfaction with being supported, respected and understood in society. Support usage refers to the extent to which individuals utilise social support.³³ A higher total score indicated a higher social support level. This total support score was classified into three categories: low (\leq 22), moderate (23–44) and high (\geq 45) levels.³⁴ The SSRS has been widely used in Chinese domestic contexts. 35-37 The cumulative contribution rate of the three common factors was 54.26%. 38 The internal consistency of the SSRS in this study was acceptable. The Cronbach's alpha of the scale in our sample was 0.778.

Simplified Coping Style Questionnaire

Coping style was accessed with the Simplified Coping Style Questionnaire (SCSQ), which is a self-report survey that includes two subscales: active coping (12 items) and passive coping (eight items). 39 All items were rated using a 4-point Likert scoring method, ranging from 0 (never) to 3 (always). The scores of each subscale item were summed up to generate a subscale score. Dai proposed a formula for the coping style tendency—coping style tendency=active coping criterion score $(Z_a \text{ score})$ -passive coping criterion score (Z_n score)—to determine an individual's main coping style in stress situations. 40 $Z_a/Z_p = (actual)$ score for the subscale-mean of the score for the subscale among the national norm sample)/(SD of the score for the subscale among the national norm sample). If the value of the coping style tendency >0, it means the individual mainly adopts an active coping style. The Chinese

national norm for the active coping score is 1.78±0.52 and for the passive coping score, it is 1.59±0.66.³⁹ The SCSQ has been widely used to assess caregivers' coping styles in China, and the Cronbach's alpha coefficiency of the two subscales ranged from 0.75 to 0.90.^{41–45} The cumulative contribution rate of the two common factors was 48.5%.⁴⁶ In the present study, the Cronbach's alphas of the active and passive coping styles were 0.909 and 0.752, respectively.

DATA ANALYSIS

The collected data were analysed using the IBM SPSS V.26.0 programme. Descriptive statistics were used to investigate the demographic and disease-specific characteristics of children with FA and their parents, social support, coping style and parental burden among the parents of children with FA. The Kolmogorov-Smirnov test was performed to confirm the normality of the measurement data. Means with SDs (mean±SD) were calculated for normally distributed data, while median and IQRs were calculated for non-normally distributed measures. Frequencies and percentages were calculated for the count data. Between-group differences were tested using t-tests and analysis of variance for normally distributed data to investigate parental burden. Spearman's correlation analysis was used to analyse the correlations between parental burden, coping style and social support among the parents of children with FA. All reported p values were two-sided, with a significance level of 0.05.

Multivariate stepwise regression analysis was performed to identify the factors influencing parental burden among parents of children with FA, with the total FAQL-PB score as the dependent variable. The variables with a p<0.1 for univariate analysis were all introduced. Some non-normally distributed continuous variables were logtransformed (y=log10 (x+1)) to normalise their distribution before their introduction to multivariate stepwise regression analysis. The variables were screened stepwise based on the criteria of $\alpha \le 0.05$ in and $\alpha \ge 0.1$ out model. When the independent variables were unordered categorical variables, they were converted into dummy variables and then included in the regression analysis. The analysis used R² as the power of a linear model to represent the percentage of the current variation of y explained by the independent variables in the current model.

Patient and public involvement

None.

RESULTS

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 5 min (six questionnaires) and because the parents were not the primary caregivers of children in their daily

lives (10 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.

Analysis of factors influencing parental burden among parents of children with FA

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±17.57) than those whose children did not (62.15±21.28), and parents whose children had a history of antiallergy drug use (67.14±19.10) had a higher parental burden score than those whose children did not (62.75±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±17.97). Moreover, parents whose children had up to 10 times adverse reactions (70.18±19.80) had higher parental burden scores than parents whose children had 1-5 times (62.77±20.33, p<0.01) and 6-10 times adverse reactions (60.07 ± 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±17.12) had a higher parental burden than those who were at work (61.77±20.44). In addition, all of them reported significant statistical differences (p<0.05). However, no significant difference in parental burden existed between groups divided by children's and parents' genders, when children had visited the emergency room, when children had experienced severe anaphylaxis, when there was a parental history of self-reported allergies, etc. The bivariate correlation analysis results in table 3 show that parental burden was negatively correlated with the parents' social support (r=-0.291, p<0.001) and coping style (r=-0.240, p<0.001). Because the analysis above did not control other confounding factors, these statistically significant factors in this part need to be identified in multiple stepwise linear regression.



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

			Parental burden				
Characteristics		Mean	SD	t/F/r	P value		
Gender, n (%)				0.62	0.54		
Male	187 (56.7)	65.19	21.24				
Female	143 (43.3)	63.85	18.18				
Whether they were going to kindergarten, n (%)				-1.55	0.12		
Yes	10 (3.0)	55	19.16				
No	320 (97.0)	64.91	19.93				
Growth standards, n (%)				-1.02	0.31		
Without growth retardation	313 (94.8)	64.35	20.05				
With growth retardation	17 (5.2)	69.41	17.99				
Whether they were taking in breast milk, n (%)				0.31	0.76		
Yes	77 (23.3)	65.22	20.82				
No	253 (76.6)	64.42	19.72				
Whether they had an intake of special formula milk powder, n (%)	, ,			3.39	0.02*		
Moderately hydrolysed formula	64 (19.4)	60.69	18.97				
Deep hydrolysed formula	106 (32.1)	63.75	20.21				
Amino acid milk powder	75 (22.7)	70.67	17.97				
None ^a	85 (25.8)	63.29	21.15				
Whether they had an egg allergy				2.45	0.02*		
Yes	154 (46.7)	67.42	17.57				
No	176 (53.3)	62.15	21.28				
Whether they had a milk allergy	,			1.4	0.16		
Yes	249 (75.5)	65.91	20.08				
No	81 (24.5)	61.91	19.44				
The time of the first diagnosis of FA (month of age), n (%)	- (- /			0.76	0.45		
0–5 months	260 (78.8)	65.04	19.68				
>5 months	70 (21.2)	63	21.01				
The frequency of adverse reactions, n (%)	,			6.84	< 0.01*		
1–5 times	154 (46.7)	62.77	20.3				
6–10 times	69 (20.9)	60.07	17.63				
>10 times	107 (32.4)	70.18	19.8				
Whether they had experienced severe anaphylaxis, b n (%)	(,			0.24	0.81		
Yes	3 (0.91)	67.33	26.86				
No	327 (99.1)	64.58	19.94				
Whether they had a history of antiallergy drug use, c n (%)	(551.)			1.98	< 0.05*		
Yes	140 (42.4)	67.14	19.1				
No	190 (21.8)	62.75	20.41				
Whether they had visited the emergency room, n (%)	,			0.58	0.57		
Yes	72 (21.8)	65.83	20.35	0.00	0.01		
No	258 (78.2)	64.27	19.87				
Children' month of age, mean±SD	15.07±8.18	· /	. 5.57	-0.06	0.26		
The number of identified food allergens, median (IQR)			2 (2)	0.197	<0.001		
The number of highly suspected food allergens, median (IQR)			2 (2)	0.219	<0.001		
The number of children's FA-affected systems, d median (IQR)			2 (1)	0.213	<0.001		
			- (1)	0.210	10.001		

Continued

Table 1 Continued

	Parental burden			
Characteristics	Mean	SD	t/F/r	P value
The number of children's FA-related symptoms, median (IQR)		2 (3)	0.252	<0.001***

^{*} p<0.05; **p<0.01; ***p<0.001.

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

Some factors were introduced in a multiple stepwise linear regression to ensure a stable model. The childrenrelated factors included the number of identified food allergens, the number of highly suspected food allergens, the number of children's FA-affected systems, the number of children's FA-related symptoms, the frequency of adverse reactions, whether they had an intake of special formula milk powder, whether they had an egg allergy, whether they had experienced severe anaphylaxis and whether they had a history of antiallergy drug use. Parentrelated factors included education level, working conditions, financial affordability regarding their 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 highly suspected food allergens (β =0.162, p<0.01), the number of children's FA-affected systems (β =0.129, p<0.05), amino acid milk powder intake (β =0.154, p<0.01), working conditions (β =-0.169, p=0.000), financial affordability regarding their children's FA (β =-0.224, p=0.000) and social support (β =-0.226, p=0.000) 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=6.769) and explained 27.4% of the variance (adjusted R^2 was 26.0%).

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).⁴⁷

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. 17 30 47 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. 11 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. 48 There is a great need for comprehensive and systematic FA-based health education programmes. 49-51 On the one hand, it will help parents manage their children's food allergies (FA) correctly and find alternative nutrients to ensure normal growth and development. 52 53 On the other hand, it will change wrong cognitions related to FA to decrease the parental burden among parents of children with FA.⁵⁰ Additionally, amino acid milk powder is more expensive than ordinary powdered milk. Because FA-related economic aid is not provided in China, parents whose children consumed amino acid milk powder must spend more to provide it, which would increase their financial burden.

Among the parent-related characteristics, this study revealed that the parental burden of parents who were not at work was high, which coincides with the results in the previous literature. This situation can be interpreted in such a way that parents at work have higher economic power, a better social environment and better use of their social support systems. When parents do not work and devote themselves to the care of the FA child, they may lack social support and develop psychosocial symptoms, which may increase the burden. This study also showed that the lower the financial affordability regarding their children's FA, the heavier the parental burden. This

^aChildren did not take in special formula milk powder, only took in breast milk or formula milk.

^bSevere anaphylaxis refers to acute systemic allergic reactions that can be life-threatening, including anaphylactic shock, angio-oedema, bronchospasm and hypotension.

^cThe antiallergy drugs referred to here are antihistamines. In China, patients are not prescribed self-injectable epinephrine.

^dFA-affected systems involve the integumentary system, respiratory system and gastrointestinal system.

FA, food allergies.

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

		Parental burden				
Characteristics	Mean		SD	t/F/r	P value	
Gender, n (%)				-0.37	0.71	
Male	19 (5.8)	62.95	22.29			
Female	311 (94.2)	64.71	19.84			
Parental history of self-reported allergies, n (%)				-0.08	0.94	
Yes	211 (67.0)	64.55	19.29			
No	109 (33.0)	64.73	21.34			
Education level, n (%)				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			
Working conditions, n (%)				-4.03	<0.01**	
At work	231 (70.0)	61.77	20.44			
Not at work	99 (30.0)	71.22	17.12			
Financial affordability regarding their children's FA, n (%)				15.04	<0.01**	
Fully affordable	62 (18.8)	56.69	20.14			
Able to afford	195 (59.1)	62.56	19			
Harder to afford	67 (20.3)	76.1	17.22			
Unable to afford	6 (1.8)	84.5	12.11			
Knowledge about FA (self-reported), n (%)				-1.36	0.17	
Yes	113 (34.2)	62.54	18.31			
No	217 (65.8)	65.69	20.72			
Whether they were obtaining knowledge about FA from health professionals, n (%)				-1.85	0.07	
Yes	233 (70.6)	63.3	20.22			
No	97 (29.4)	67.75	19.04			
Whether they had a medical background, n (%)				-0.77	0.45	
Yes	56 (17.0)	62.75	20.14			
No	274 (83.0)	64.99	19.93			
Parents' age (years), mean±SD	30.41±3.68			-0.06	0.26	

was consistent with the results of a study focusing on the economic impact of childhood FA in the USA. 58 The high costs, such as direct medical costs, dietary costs and opportunity costs (such as restricted career choices), definitely increase the burden on parents and may not be affordable for some families. Couch et al suggested that earlier OFCs should be considered to identify food allergens and reduce families' additional financial expenses, especially for opportunity costs. This would effectively decrease the financial burden on parents.⁵⁹ Furthermore, there is an urgent need for providing a robust health insurance system for relieving their parental burden financially.⁶⁰

The present study found that the gender of parents was not an influencing factor associated with parental burden, which differs from the results of Springston et al. 18-20 This may be because the sample size of the fathers in this study was small, which may have led to the difference in parental burden between the mothers and fathers not being identified. The reason for the small sample size of fathers recruited in this study is also related to the societal context of China, where women often assume the role of childcare. 61 62

With the highest standardised beta in the regression equation, parents' social support was a key protective

Bivariate correlation between parental burden and social support and coping style (n=330)

colar cappert and copining crysta (in color)						
	Parental burden					
	Spearman correction coefficients (r)					
Social support	-0.291***					
Coping style ^a	-0.240***					
***n~0 001						

^{.100.0&}gt;a*

influencing factor against parental burden among parents of children with FA. Specifically, parental burden decreases as parents' social support increases. Previous studies have also suggested that when parents (children's caregivers) lack social support during the caregiving process, they may develop physical symptoms, such as weight loss and fatigue, and psychosocial symptoms, such as anxiety, social isolation and decreased quality of life, which all increase the burden of care. 63-65 Adequate social support may help reduce the parental burden. Social support has traditionally been provided by families and friends in China and less provided by the community service agency and the government. ^{37 66 67} In a qualitative study concerning caregivers caring for a family member, 62% of respondents identified a lack of social support as one of their caregiving challenges. Moreover, 83% of participants identified emotional support (ie, seeking out to friends and family or others) to be effective in dealing

with these challenges.⁶⁸ This individual level of social support will help parents establish and improve their social support system so that they can feel more supported while dealing with the problems and emotional reactions related to their children's FA. 64 69 Parents can also use social media platforms and websites to share information and learn more about FA. 70 71 In addition, community support services, such as health professional help, structured educational programmes and workshops related to the management of food allergens, should be available to parents of children with FA. 72 They will provide better community social support and richer knowledge about managing FA for parents and help them cope with caring for a child with FA, thus relieving the parental burden. ⁵⁰ 73 Additionally, health-related departments should improve medical policies and reimbursement rates to provide financial support for parents with children with FA.⁶⁰

However, parents' coping style did not exhibit a relationship with parental burden in the multiple stepwise regression of this study. The reason may be that although some parents adopted an active coping style (eg, positively learning knowledge about their children's FA and avoiding allergens as much as possible) to deal with their children's FA, their specific, positive measures cannot immediately cure or control their children's allergy reactions.⁷⁰ Furthermore, allergic reactions are unpredictable and, for many children, FA is sometimes accompanied with food intolerance for which the symptoms are similar to those of the FA and difficult to avoid. 74-77 In these conditions, an active coping style cannot always obtain positive feedback. This would cause anxiety and a heavy burden, especially an emotional burden, on

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

Coefficient								
	Unstandardised coefficient		Standard coefficient					
Model	В	SE	Beta	t	P value			
(Constant)	61.438	7.225		8.47	0.000***			
The number of highly suspected food allergens ^a	13.489	4.127	0.162	3.269	0.001**			
The number of children's FA-affected systems ^a	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 ^b	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	-0.58	0.127	-0.226	-4.582	0.000***			

R²=0.274; adjusted R²=0.260; ^F=7.769; *p<0.05; **p<0.01; ***p<0.001; dependent variable: parental burden among parents with an FA child. The variables with p<0.1 from univariate analysis were introduced.

^alt represents the coping style tendency (identified after Zconversion), which means the individual's main coping style in stress states.

FA, food allergies.

^aThe variables introduced in a multiple stepwise linear regression here were log-transformed (y=log,, (x+1)) to approximate a normal distribution.

blt was set as a reference variable for 'Intake of special formula milk' in the process of introducing dummy variables into regression analysis. FA, food allergies.



parents.¹⁴ ⁷⁰ In addition, the SCSQ used to measure coping style focused on only two types. However, coping styles are much more complex than merely positive and negative. The quantitative measurement instrument we used ignored the complexity of coping styles, which may have influenced the final results. Therefore, instruments that can identify the complexity of coping styles should be developed. Furthermore, qualitative studies should be considered to explore the relationship between coping style and parental burden.

LIMITATIONS

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

CONCLUSION

Parents whose children had more highly suspected food allergens and had more FA-affected systems had a higher parental burden. Moreover, the burden of parents whose children took in amino acid milk powder was higher than that of parents whose children did not. Parents' working conditions were also a significant influencing factor of parental burden. All these factors could greatly predict parental burden among parents with children with FA. Above all, parents with lower financial affordability regarding their children's FA and lower social support experienced higher parental burdens. Thus, the level of financial affordability regarding their children's FA and parents' state of social support can serve as key predictors of parental burden among parents of children with FA. These findings point to several measures that can help ease the parental burden. FA should be included within the scope of medical insurance reimbursement, which can partially alleviate financial pressure on parents. Additionally, high-quality FA-related health education programmes should be provided by community health service centres

to support parents in monitoring and flexibly responding to children's FA. Moreover, it can reduce the daily life and social burden of parents with children with FA, thereby promoting their physical and mental health. This study provided basic evidence to explore strategies for relieving the parental burden among parents of children with FA. In the future, more empirical studies (eg, longitudinal studies and intervention studies) are needed to verify and further the results of this study.

Acknowledgements The authors would like to express our sincere appreciation to the experts and the students, who participated in the study.

Contributors Methodology: ZL and QC. Formal analysis: ZL and LT. Investigation: ZL, HL. Writing – original draft preparation: ZL. Writing – review and editing: ZL, QC, LT. Supervision: ST and QC. Project administration: QC. Guarantor responsible for the overall content: QC.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Ethical Review Committee of Xiangya School of Nursing, Central South University on 15 July 2021 (IRB Approval Number: E202192). All participants filled out questionnaires voluntarily, from whom signed informed consent was obtained. It was emphasised that the participation was anonymous, and all data were kept strictly confidential and used for research purposes only.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs

Zeen Li http://orcid.org/0000-0002-2332-7028 Siyuan Tang http://orcid.org/0000-0001-9940-5072 Qirong Chen http://orcid.org/0000-0003-1908-290X

REFERENCES

- 1 Pyrhönen K, Hiltunen L, Kaila M, et al. Heredity of food allergies in an unselected child population: an epidemiological survey from Finland. Pediatric Allergy Immunology 2011;22:e124–32.
- 2 Gore C, Griffin R, Rothenberg T, et al. New patient-reported experience measure for children with allergic disease: development, validation and results from integrated care. Arch Dis Child 2016:101:935–43.
- 3 Motosue, Megan Set al. National trends in emergency department visits and hospitalizations for food-induced anaphylaxis in US US children. In: Pediatric allergy and immunology: official publication of the European Society of pediatric allergy and immunology, 2018.
- 4 Sicherer SH, Furlong TJ, Maes HH, et al. Genetics of peanut allergy: a twin study. *J Allergy Clin Immunol* 2000;106:53–6.



- 5 Mullins RJ. Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006. Med J Aust 2007;186:618–21.
- 6 Du Toit G, Foong R-X, Lack G. Prevention of food allergy Early dietary interventions. *Allergol Int* 2016;65:370–7.
- 7 Liu FL, Ning YB, DF M. A survey of self-reported allergy, food allergy and intolerance in infants aged 0-36 months in eight cities of China and analysis of influencing factors. *Chinese Journal of Pediatrics* 2013;51:6.
- 8 ZY M. Epidemiological study on infant food allergy in Chongqing and its changes in 20 years. *Chongqing Medical University. Chongqing Medical University* 2021.
- 9 Plaza-Martin AM. Food allergies in paediatrics: current concepts. Anales de Pediatría 2016;85:50.e1-50.e5:50.e1-50.e5.
- 10 Peniamina RL, Bremer P, Conner TS, et al. Understanding the needs of Food-Allergic adults. Qual Health Res 2014;24:933–45.
- 11 Golding MA, Gunnarsson NV, Middelveld R, et al. A scoping review of the caregiver burden of pediatric food allergy. Ann Allergy Asthma Immunol 2021;127:536–47.
- 12 Chooniedass R, Temple B, Martin D, et al. A qualitative study exploring parents' experiences with epinephrine use for their child's anaphylactic reaction. Clin Transl Allergy 2018;8:43.
- 13 Pitchforth E, Weaver S, Willars J, et al. A qualitative study of families of a child with a nut allergy. *Chronic Illn* 2011;7:255–66.
- 14 SBB A, Rn BJ, Lutz PhD R. FNAP, FAAN B, Christa Cook ABA. becoming the parent of a child with life-threatening food allergies. *Journal of Pediatric Nursing* 2015;30:532–42.
- 15 Golding MA, Simons E, Abrams EM, et al. The excess costs of childhood food allergy on Canadian families: a cross-sectional study. Allergy Asthma Clin Immunol 2021;17:28.
- 16 Stensgaard A, Bindslev-Jensen C, Nielsen D. Peanut allergy as a family project: social relations and transitions in adolescence. J Clin Nurs 2017;26:3371–81.
- 17 Allen CW, Bidarkar MS, vanNunen SA, et al. Factors impacting parental burden in food-allergic children. J Paediatr Child Health 2015;51:696–8
- 18 Springston EE, Smith B, Shulruff J, et al. Variations in quality of life among caregivers of food allergic children. Ann Allergy Asthma Immunol 2010:105:287–94.
- 19 Warren CM, Gupta RS, Sohn M-W, et al. Differences in empowerment and quality of life among parents of children with food allergy. Ann Allergy Asthma Immunol 2015;114:117–25.
- 20 Hoehn JL, Dahlquist LM, Hahn AL, et al. Parents of children with food allergy: gender differences in perceived impact and perceived food allergy severity. J Pediatr Psychol 2016;15:jsw059.
- 21 King RM, Knibb RC, Hourihane J O'B. Impact of peanut allergy on quality of life, stress and anxiety in the family. *Allergy* 2009;64:461–8.
- 22 Lee E. Do technology-based support groups reduce care burden among dementia caregivers? A review. J Evid Inf Soc Work 2015;12:474–87.
- 23 Lee K-C, Yiin J-J, Chao Y-F. Effect of integrated caregiver support on caregiver burden for people taking care of people with cancer at the end of life: a cohort and quasi-experimental clinical trial. *Int J Nurs* Stud 2016;56:17–26.
- 24 Guan Z, Wiley JA, Tang S, et al. Internalised stigma, social support, coping and care-giving burden among Chinese family caregivers of adults diagnosed with schizophrenia: a parallel mediation analysis. Health Soc Care Community 2022. doi:10.1111/hsc.13780. [Epub ahead of print: 30 Mar 2022].
- 25 Hu X, Huang W, Su Y, et al. Depressive symptoms in Chinese family caregivers of patients with heart failure: a cross-sectional study. Medicine 2017;96:e6480.
- 26 Cui AH. Analysis of influencing factors of food allergy and its impact on infant health and parental parenting stress. Shandong University, 2021.
- 27 Kendall SM, Stuart A, Ord JK. Kendall''s Advanced Theory of Statistics. Journal of the Royal Statistical Society Series D 1994;43.
- 28 Ding TYG, De Roza JG, Chan CY, et al. Factors associated with family caregiver burden among frail older persons with multimorbidity. BMC Geriatr 2022;22:160.
- 29 Sampson HA, Muñoz-Furlong A, Campbell RL, et al. Second symposium on the definition and management of anaphylaxis: summary report--Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network symposium. J Allergy Clin Immunol 2006;117:391–7.
- 30 Leung TF, Yung E, Wong YS, et al. Quality-Of-Life assessment in Chinese families with food-allergic children. Clin Exp Allergy 2009;39:890–6
- 31 Cohen BL, Noone S, Muñoz-Furlong A, et al. Development of a questionnaire to measure quality of life in families with a child with food allergy. J Allergy Clin Immunol 2004;114:1159–63.

- 32 SY X. The theoretical basis and applications of social support rating scale (SSRs). *J Clinical Psychiatry* 1994;4:98–100.
- 33 Liu Z, King M. The influencing factors and coping styles of mental health stress responses of stroke caregivers. Work 2021;69:499–513.
- 34 Chu H, Yang Y, Zhou J, et al. Social support and suicide risk among Chinese university students: a mental health perspective. Front Public Health 2021;9:566993.
- 35 Hou T, Zhang T, Cai W, et al. Social support and mental health among health care workers during coronavirus disease 2019 outbreak: a moderated mediation model. PLoS One 2020:15:e0233831.
- 36 Lei X, Kantor J. Social support and family functioning in Chinese families of children with autism spectrum disorder. *Int J Environ Res Public Health* 2021;18. doi:10.3390/ijerph18073504. [Epub ahead of print: 28 03 2021].
- 37 Wu F, Sheng Y, network Ssupport. Social support network, social support, self-efficacy, health-promoting behavior and healthy aging among older adults: a pathway analysis. Arch Gerontol Geriatr 2019:85:103934.
- 38 Caiyun Y, Li Q, Sudan H. Reliability and validity analysis of social support rating scale in miners. Science Tribune 2019;04:154–6.
- 39 Xie Y. Reliability and validity of simplified coping style questionnaire. Chinese Journal of Clinical Psychology 1998;6:114–5.
- 40 Jie L, Chuang T, Xlaoyang D. Correlation analysis between self-worth and coping style of rural left-behind children. *Chinese Journal of Clinical Psychology* 2012;20:96–8.
- 41 Liu Y, Guo H. Empowerment in Chinese primary caregivers of poststroke patients with disability: a cross-sectional study. *Medicine* 2021;100:e23774.
- 42 Yu W, Lu Q, Lu Y, et al. Anticipatory grief among Chinese family caregivers of patients with advanced cancer: a cross-sectional study. Asia Pac J Oncol Nurs 2021;8:369–76.
- 43 Wu C, Liu Y, Ma S, et al. The mediating roles of coping styles and resilience in the relationship between perceived social support and posttraumatic growth among primary caregivers of schizophrenic patients: a cross-sectional study. BMC Psychiatry 2021;21:58.
- 44 Yu W, Hu J, Li L. And mental health: a longitudinal study of primary caregivers of schizophrenia patients. *Chinese Journal of Clinical Psychology* 2019:27:1031–5.
- 45 Liu G. Study on training needs of elderly service personnel in Shihezi urban area. Shihezi University, 2020.
- 46 Yaning X. A preliminary study on the reliability and validity of the simplified coping style scale. Chinese Journal of Clinical Psychology 1998;02.
- 47 Knibb RC, Stalker C. Validation of the food allergy quality of Life-Parental burden questionnaire in the UK. Qual Life Res 2013;22:1841–9.
- 48 Maryniak NZ, Sancho Al, Hansen EB, et al. Alternatives to cow's milk-based infant formulas in the prevention and management of cow's milk allergy. Foods 2022;11. doi:10.3390/foods11070926. [Epub ahead of print: 23 03 2022].
- 49 Sicherer SH, Vargas PA, Groetch ME, et al. Development and validation of educational materials for food allergy. J Pediatr 2012:160:651–6.
- 50 Vargas PA, Sicherer SH, Christie L, et al. Developing a food allergy curriculum for parents. Pediatr Allergy Immunol 2011;22:575–82.
- 51 Rosen J, Albin S, Sicherer SH. Creation and validation of web-based food allergy audiovisual educational materials for caregivers. *Allergy Asthma Proc* 2014;35:178–84.
- 52 Contreras-Porta J, Ruiz-Baqués A, Gabarron Hortal E, et al. Evaluation of an educational programme with workshops for families of children with food allergies. Allergol Immunopathol 2016;44:113–9.
- 53 Ruiz-Baqués A, Contreras-Porta J, Marques-Mejías M, et al. Evaluation of an online educational program for parents and caregivers of children with food allergies. J Investig Allergol Clin Immunol 2018;28:37–41.
- 54 Pelit Aksu S, Şentürk Erenel A, Aksu SP. Caregiver burden and the level of perceived social support of caregivers helping with inpatient care of patients with gynecologic cancer. Florence Nightingale J Nurs 2021;29:113–23.
- 55 Stenberg U, Cvancarova M, Ekstedt M, et al. Family caregivers of cancer patients: perceived burden and symptoms during the early phases of cancer treatment. Soc Work Health Care 2014;53:289–309.
- 56 Habib A-RR, Manji J, Wilcox PG, et al. A systematic review of factors associated with health-related quality of life in adolescents and adults with cystic fibrosis. Ann Am Thorac Soc 2015;12:420–8.
- 57 Wojtaszczyk A, Glajchen M, Portenoy RK, et al. Trajectories of caregiver burden in families of adult cystic fibrosis patients. Pall Supp Care 2018;16:732–40.
- 58 Patel N, Herbert L, Green TD. The emotional, social, and financial burden of food allergies on children and their families. *Allergy Asthma Proc* 2017;38:88–91.



- 59 Couch C, Franxman TJ, Greenhawt M. The health and economic impact of delaying oral food challenges. *Annals of allergy, asthma & immunology: official publication of the American College of Allergy, Asthma, & Immunology* 2015;115:A7.
- 60 Mao W, Tang S, Zhu Y, et al. Financial burden of healthcare for cancer patients with social medical insurance: a multi-centered study in urban China. Int J Equity Health 2017;16:180.
- 61 Ai Y, Yaojiang S, Renfu L. China's Invisible Crisis: Cognitive Delays among Rural Toddlers and the Absence of Modern Parenting. *China J* 2017;78:50–78.
- 62 Yue A, Gao J, Yang M, et al. Caregiver depression and early child development: a mixed-methods study from rural China. Front Psychol 2018:9:2500.
- 63 Rost M, Wangmo T, Rakic M, et al. Burden of treatment in the face of childhood cancer: a quantitative study using medical records of deceased children. Eur J Cancer Care 2018;27:e12879..
- 64 Ozdemir Koyu H, Tas Arslan F, Koyu HO. The effect of physical and psychosocial symptoms on caregiver burden of parents of children with cancer. *Eur J Cancer Care* 2021;30:e13513.
- 65 Gill FJ, Hashem Z, Stegmann R, et al. The support needs of parent caregivers of children with a life-limiting illness and approaches used to meet their needs: a scoping review. Palliat Med 2021;35:76–96.
- 66 Zhu Z, Tang W, Liu G, et al. The Effect of Psychological Suzhi on Suicide Ideation in Chinese Adolescents: The Mediating Role of Family Support and Friend Support. Front Psychol 2020;11:632274.
- 67 Ma Z, Zhao J, Li Y, et al. Mental health problems and correlates among 746 217 college students during the coronavirus disease 2019 outbreak in China. *Epidemiol Psychiatr Sci* 2020;29:e181.

- 68 Oliver DP, Demiris G, Washington KT, et al. Challenges and strategies for hospice caregivers: a qualitative analysis. *Gerontologist* 2016;28:gnw054...
- 69 Chang P-Y, Chang T-H, Yu J-M. Perceived stress and social support needs among primary family caregivers of ICU patients in Taiwan. *Heart Lung* 2021;50:491–8.
- 70 Chooniedass R, Soller L, Hsu E, et al. Parents of children with food allergy: a qualitative study describing needs and identifying solutions. Ann Allergy Asthma Immunol 2020;125:674–9.
- 71 Ross J, Fishman J, Wang J. Internet and food allergy: what patients are seeking and what they do with the information. *J Allergy Clin Immunol Pract* 2017;5:494–5.
- 72 Ong HL, Vaingankar JA, Abdin E, et al. Resilience and burden in caregivers of older adults: moderating and mediating effects of perceived social support. BMC Psychiatry 2018;18:27.
- 73 Hao H. The development of online doctor reviews in China: an analysis of the largest online doctor review website in China. J Med Internet Res 2015;17:e134.
- 74 Bindslev-Jensen C, Skov PS, Madsen F, et al. Food allergy and food intolerance--what is the difference? Ann Allergy 1994;72:317–20.
- 75 Di Costanzo M, Berni Canani R. Lactose intolerance: common misunderstandings. *Ann Nutr Metab* 2018;73 Suppl 4:30–7.
- 76 Lin CH. Food allergy: what it is and what it is not? Curr Opin Gastroenterol 2019:35:114–8.
- 77 Gargano D, Appanna R, Santonicola A, et al. Food allergy and intolerance: a narrative review on nutritional concerns. *Nutrients* 2021;13. doi:10.3390/nu13051638. [Epub ahead of print: 13 May 2021].

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

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or	1-2
		the abstract	
		(b) Provide in the abstract an informative and balanced summary of	2
		what was done and what was found	
Introduction			
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
Methods		Say Farface Africa	1 -
Study design	4	Present key elements of study design early in the paper	6
Setting Setting	5	Describe the setting, locations, and relevant dates, including periods of	6-7
Setting	5	recruitment, exposure, follow-up, and data collection	0 /
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection	6-7
i articipants	O	of participants	0 /
Variables	7	Clearly define all outcomes, exposures, predictors, potential	8-10
, ш .шого	,	confounders, and effect modifiers. Give diagnostic criteria, if applicable	0.10
Data sources/	8*	For each variable of interest, give sources of data and details of	8-10
measurement	Ü	methods of assessment (measurement). Describe comparability of	0.10
		assessment methods if there is more than one group	
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	8-10
C		applicable, describe which groupings were chosen and why	Tables
		7	1-4
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	11
		confounding	
		(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	N/A
		sampling strategy	
		(e) Describe any sensitivity analyses	N/A
Results			•
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	12-14
		potentially eligible, examined for eligibility, confirmed eligible,	
		included in the study, completing follow-up, and analysed	
		(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,	12-14
		social) and information on exposures and potential confounders	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
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
Discussion			
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
Other information			
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.