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BMJ Open Extent and pattern of burden of care and its associated factors among

Eritrean families of persons living with schizophrenia: a cross-sectional study

Tesfaldet Habtemariam Hidru,¹ Mohammed Hamid Osman,² Sainyugu Lolokote,¹ Xiaofeng Li¹

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¹Department of Epidemiology and Biostatistics, Dalian Medical University, Dalian, Liaoning, PR China ²School of Nursing, Asmara College of Health Sciences, Asmara, Eritrea

Correspondence to

Professor Xiaofeng Li; lxf_chen@163.com

ABSTRACT

Purpose: To assess the caregiving burden and its associated factors among Eritrean families of persons living with schizophrenia.

Methods: A cross-sectional study was conducted for 146 caregivers with their respective known patients with schizophrenia of Saint Mary's Neuropsychiatric National Referral Hospital (SMNNRH). Data were collected using Pai and Kapur's Family Burden Interview Schedule (FBIS), the Positive and Negative Syndrome Scale (PANSS) and self-prepared sociodemographic sheet. Data were analysed using SPSS V.21. Descriptive statistics, independent t-tests, one-way analysis of variance (ANOVA) and multiple regression analysis was employed to analyse the data.

Results: In this study, 84 (57.5%) were males and 62 (42.5%) were females. The mean age was 33.96+10.37 (median=31) for the patients and 46.76+13.96 (median=48) for the caregivers. Total mean objective score was 29.47+6.67. Family caregivers who were single (F=3.224, p<0.005, effect size (ES)=0.064), had educational level at elementary (F=5.647 p=0.001, ES=0.11), had low monthly income (t=7.727, p<0.001, ES=0.01) and were dissatisfied with family support (t=2.889, p<0.01, ES=0.01) experienced greater burden relative to the counterparts. Caregiver's age (β=0.156; p<0.05), duration of caregiving (β =0.131; p<0.05), monthly household family income (β=-0.298; p<0.001), history of self-injury (β =0.151; p=0.05), positive scale (β=0.344; p<0.001), negative scale (β=0.278; p<0.001) and general psychopathological scale (β=0.146; p<0.01) emerged as significant predictors of objective burden.

Conclusions: Family caregivers of a person living with schizophrenia experience a significant burden of care. Our findings highlight that there is a need of strengthening social and psychological support to reduce the caregiving burden.

INTRODUCTION

Schizophrenia poses a major burden on family caregivers in developed and

Strengths and limitations of this study

- This is the first study to investigate the extent and pattern of the burden of care and its associated factors among Eritrean family caregivers of a person living with schizophrenia.
- This study used a standard, reliable and valid data collection tools and considered multiple covariates in order to minimise the confounding effect and to reflect an accurate image of the caregiving burden in Eritrea.
- This study evaluated the impact of symptom severity but not disease severity of patient function or violent tendencies during the trajectory progress of schizophrenia.
- Results generated from the perspectives of the family caregivers who accompanied the patient during the follow-up visit in the outpatient department (OPD) clinic might not reflect the levels of caregiver burden within the family unit.
- So far Family Burden Interview Schedule (FBIS) is not validated based on the Eritrean culture, though it is widely used regimen.

developing countries.1 It has been several decades since the emergence of the concept of burden and several studies have mainly focused on the area of caregiving burden due to mental illnesses including schizophrenia.² Responsibilities of caregiving burden greatly influence the major life aspects of the caregivers particularly physical, social, emotional and financial areas.³ The impact of caregiving burden in these areas is of considerable influence in the daily life activities of the caregivers. Generally, the effect of the burden on the caregivers in the aforementioned areas can be measured using objective and subjective burden analytics to assess the quantifiable challenges and perceived burden of care, respectively.⁴

Efforts to improve global mental health have been focused on improving care for individuals living with psychological disorders. WHO strongly recommends adherence and an extension of comprehensive assessment beyond the definition of mental health to recognise the impact of public health implications of psychological disorders. High-income countries have already gained sufficient experience to reduce the cost of care and increase the healthcare accessibility through decreasing the length of hospital stay. However, the development of community-based mental healthcare that guarantees comprehensive assessment in developing countries, such as Eritrea, is at its initial level.

Caregivers of a person living with schizophrenia have always been a subject to massive input of physical, social, psychological and financial burden. Studies on the factors associated with caregiver burden among families or close caregivers of a person living with schizophrenia in Africa are very few and sparse. The majority of the already published reports evaluated the determinants of the various domains of caregiving burden on the families or caretakers.⁷ In Eritrea, to the best of our knowledge, there is no published study on this particular area. Considerable work is needed to elucidate the specific factors that determine the extent of caregiving burden and to rigorously identify the influential factors and recommend appropriate measures. Therefore, the purpose of the present study is to understand the level of the objective burden of the family caregivers and to identify the factors that affect the caregiver burden. This study puts more emphasis on the basic sociodemographic and clinical variables that affect caregiving burden among the caregivers. Therefore, the mental health professionals can take into account or consider the common predictors of caregiving burden among the family/primary caregivers of the people living with schizophrenia.

METHODS Study design

A cross-sectional study was conducted in Saint Mary's Neuropsychiatric National Referral Hospital (SMNNRH) between October 2015 and February 2016. It is sought to describe the levels of the family burden among the caregivers and identify the determinant factors that influence the caregiving burden. The study involved caregivers of people with schizophrenia, attendees at the follow-up clinic, who meet the selection criteria for this study. Family Burden Interview Schedule (FBIS) was used to assess family burden while Positive and Negative Syndrome Scale (PANSS) was used to measure symptom severity among the patients. Caregivers were interviewed separately from their respective patients to promote comfort and response. Data on sociodemographic and the caregiving burden gathered by qualified health professionals. Data collectors spoke out the questions to the caregivers and checked off the caregivers' responses on the forms, whereas, the sociodemographic and clinical characteristics of the patients were recorded by the

psychiatric nurses. The patients went through an interview with a psychiatric nurse using the PANSS.

The psychiatric nurses were trained on the use of PANSS instrument prior to data collection. All participants were informed of the purpose of the study prior to the interview. Participation was voluntary and written informed consent was obtained from each of the participants prior to the interview.

Setting and participants

Caregivers of patients with schizophrenia who visited SMNNRH were asked to take part in this study. Patients with schizophrenia were screened based on their capacity to understand the relevant information and capacity to give informed consent. Exclusion criteria were any comorbid disorders (any known physical/mental/ neurological disorders as per the patients chart), the age of <18 years old and duration of caregiving for <1 year. Also, caregivers who were not staying with patient currently and who had any known (informed by any health professional) physical and psychological disabilities were excluded from this study. A total of 146 primary caregivers of their respective patients were selected using convenience sampling technique. Prior to the recruitment of caregivers, selection of the patients without any additional comorbidity was made by the psychiatric nurses. All patients recruited for this study met the principal diagnosis of schizophrenia according to the Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) criteria.

The caregiver was defined as a nonprofessional person who was most involved with the everyday care of the patient and would be very likely to respond to all the difficulties, challenges and special assistance at any time without any economic benefit.⁸

Measures

Demographic characteristics

Demographic information included (1) patient's age, gender, duration of illness, side effects of medication and history of self-injuring behaviour and (2) caregivers' age, kinship, educational level, marital status, employment, religious activities and monthly family income. Income was measured at the household level and classified into two groups: low income (<2500 nakfa) and high income (>2500 nakfa). The patients were also requested to respond if they received any family, friends and medical staff support (yes=1, no=0). History of selfinjury was determined from the caregivers' response (yes or no) to a question, if the patients had any previous history of suicidal attempt or history of deliberate alteration of body tissue without conscious suicidal intent such as cutting, burning, punching, falling from heights and drinking harmful chemicals.

Pai and Kapur's FBIS: measure of caregivers' burden

Objective and subjective burden among the caregivers was assessed using Pai and Kapur's FBIS. It is a

standardised instrument¹⁰ for assessing family burden among hospital attendees and people residing in the community. 11 This instrument has been used in different studies among caregivers of patients with schizophrenia. 12 The scale assesses the subjective and objective burden. The objective burden is determined using 24 items grouped into 6 categories: financial burden, disruption of routine family activities, disruption of family leisure, disruption of family interaction, the effect on the physical health of others and effect on mental health of others. The subjective burden was assessed by asking a question ('How much would you say you have suffered owing to the patient's illness?') and scoring the answer (0=not at all, 1=a little, 2=severely). FBIS is scored on 3-point scales (no burden=0, moderate burden=1 and severe burden=2) to measure the burden experienced by the caregivers. Higher scores indicate the severity of the magnitude of the burden. It is a reliable instrument¹² and the authors of the schedule reported that its internal reliability is >0.78.¹³ In this study, Cronbach's as for the FBIS was 0.84.

PANSS: measure of symptom severity

The PANSS is a 30-item scale and was used to measure symptom severity in a person living with schizophrenia. 14 15 This regimen proved high internal reliability, 16 17 ity, ¹⁶ ¹⁷ good construct validity ¹⁶ and excellent sensitivity. ¹⁸ ¹⁹ The scale is composed of three subscales; positive symptoms subscale, negative symptoms subscale and general psychopathology subscale. This instrument was administered by trained clinicians in order to evaluate the clinical status of patients over the prior month. The symptom severity level is scored on a 1-point to 7-point Likert scale (increasing levels of psychopathology ranging from absent to extreme). Higher scores indicate the severity of the magnitude of the symptoms. The scores for the three subscales were attained by summation of ratings for the component items. The extended potential ranges for the positive and negative subscales are 7-49 (as each subscale has 7 components) and 16-112 for the general psychopathology subscale (as the subscale has 16 components) of the PANSS. In this study, Cronbach's as for the overall score was 0.89.

Statistical analysis

IBM-SPSS software, V.21, was used for the statistical analysis. Descriptive statistics was employed to describe the sociodemographic and clinical characteristics of participants and to assess the extent and pattern of caregiving burden among the families of persons' living with schizophrenia. The differences in caregiver burden among the nominal variables of demographic and clinical characteristics were tested using independent t-tests and one-way analysis of variance (ANOVA). Effect sizes (ESs) for independent t-tests and one-way ANOVA were calculated by Eta squared and Cohen's d (0.1: small effect; 0.6: medium effect; 0.14: large) to assess the magnitude of the significant group differences.²⁰ We run

stepwise multiple regression analysis to assess the predictors of caregiving burden. Preliminary analyses were conducted to ensure no violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity. Independence of residuals (casewise diagnostics) was assessed as part of the regression analysis. A single participant was found falling outside the range of the standardised residual and the undue effect of this single participant in the results of the model was checked by cook's distance. Fortunately, the maximum value of the cook's distance was 0.02, suggesting that there were no major problems. A p value of 0.05 was considered statistically significant.

RESULTS

Patients' and family caregivers' characteristics

Table 1 presents sociodemographic characteristics of the participants. Out of the total 146 caregivers, 84 (57.5%) were males and 62 (42.5%) were females. The mean age was 33.96 ± 10.37 (median=31) for the patients and 46.76 ± 13.96 (median=48) for the caregivers. Most primary family caregivers were parents of the affected individuals (n=73, 50%). The majority, 97(66.4%) of the caregivers were reported as employed.

Table 2 presents clinical characteristics of the patients. The mean score of the severity of the symptoms from the symptom rating scale was 25.31±9.77 for positive PANSS scale score, 15.45±8.54 for negative PANSS scale score, 32.41±+14.87 for general PANSS scale score and 73.18±22.56 for total PANSS score.

Extent and pattern of caregiving burden

The level of objective caregiving burden is presented in table 3. The extent of the caregiving burden varied in all domains. The mean burden score was 6.86±2.44 for financial burden, 6.73±2.27 for disruption of routine family activities, 4.88±1.64 for the disruption of family leisure, 6.07±2.45 for disruption of family interactions, 1.63±1.37 for the effect on physical health of others, 3.29±0.87 for the effect on mental health of others and 29.47±6.67 for the total mean objective score.

Reported level of subjective burden of caregivers

Out of the total participants, 52% reported severe level of caregiving burden, 32% reported a little burden and only 16% of the participants reported no caregiving burden. Figure 1 displays the magnitude of the reported subjective caregiving burden.

Caregiving differences

Table 4 shows caregiving differences among the participants. Family caregivers of patients with positive history of self-injury behaviour had significantly higher objective caregiving burden relative to their counterparts (p<0.01). Furthermore, family caregivers who were single (F=3.224, p<0.005, ES=0.064), had educational level at elementary (F=5.647 p=0.001, ES=0.11), had a

Table 1 Sociodemographic characteristics of participants (N=146)

(N=146)			
Variables	n	Per cent	Mean±SD
Characteristics of patients			
Age			33.96±0.86
Gender			
Male _	84	57.5	
Female	62	42.5	
Marital status	70	40.00	
Married Single	72 46	49.32 31.51	
Divorced	21	14.38	
Widowed	7	4.79	
Education	•	0	
Illiterate	8	5.47	
Elementary	46	31.51	
Junior	46	31.51	
Secondary and above	46	31.51	
Employment			
Yes	47	32.19	
No .	99	67.81	
Family support		00.7	
Dissatisfied	58	39.7	
Satisfied Support from friends	88	60.3	
Dissatisfied	70	47.9	
Satisfied	76	52.1	
Medical staff support	, 0	02.1	
Dissatisfied	29	19.9	
Satisfied	117	80.1	
Religious activities			
None or not frequent	90	61.6	
Regular	56	38.4	
Characteristics of Caregiver	rs		
Age			46.76±1.16
Gender		=0.4	
Male	76	52.1	
Female	70	47.9	
Duration of caregiving Mean=6.90			
Marital status			
Married	106	72.6	
Single	25	17.1	
Divorced	7	4.8	
Widowed	8	5.5	
Education			
Illiterate	27	18.5	
Elementary	22	15.1	
Junior	55	37.7	
Secondary and above	42	28.8	
Employment	0-	00.4	
Yes	97	66.4	
No Kinghin with the nations	49	33.6	
Kinship with the patient Parents	73	50.0	
Spouse	73 29	19.9	
Sibling	17	11.6	
Other*	27	18.5	
Monthly household income		10.0	
Low income	97	66.4	
High income	49	33.6	
	10	00.0	

low monthly income (t=7.727, p<0.001, ES=0.01) and were dissatisfied with family support (t=2.889, p<0.01, ES=0.01), experienced greater burden relative to the counterparts.

Predictors of caregiving burden

Table 5 depicts that caregivers' age, caregiving duration, household income, history of self-injury, positive scale PANSS, negative scale PANSS and general psychopathological scale explained a significant 63.8% of the total variance in caregiver burden.

Caregivers' age (b=0.156; p<0.05), duration of caregiving (β =0.131; p<0.05), monthly household family income (β =-0.298; p<0.001), history of self-injury (β =0.151; p=0.05), positive scale (β =0.344; p<0.001), negative scale (β =0.278; p<0.001), general psychopathological scale (β =0.146; p<0.01) emerged as significant predictors of objective burden.

DISCUSSION

This study, as the first study of its kind to be conducted in Eritrea, shows that the caregivers of persons living with schizophrenia experience a significant level of burden (see figure 1 and table 3). In general, this can be explained due to the chronic aspect of the disease that poses a lifetime lost productivity and long-term psychosocial and economic dependence on the caregiver.⁴ A perceived stigma from society and persistent worry of danger for the patient may also be additional contributors of the burden to the primary caregivers. Lack of social networks that can support the caregivers and limited welfare services for patients with schizophrenia have put the responsibility of living allowances and accommodation, and day care services for the patient to rest completely on available family members. The comprehensive burden on the family caregivers can be reduced through the strengthening of the relationship between caregivers and the mental health services, which is aimed at breaking the long-term psychosocial and economic dependence of the patient on their families. This can be accomplished by initiating a social network and by strengthening adherence and access to effective pharmacological treatment. The high burden reported from this study is consistent with other findings that stated high objective and subjective burden in Nigeria.⁹

Kinship does not show any significant differences in the degree of caregiving burden. These findings are inconsistent with the previously published report.²¹ However, the relationship of the caregiver was significantly correlated with the caregiving burden.

In this study, caregiving duration emerged as a predictor of caregiving burden. The Eritrean culture favours the middle to large family size. Sharing of tasks at the family base and providing care for the ailing family member is the sociocultural obligation rather than delegation to someone else for care. Therefore, the association of caregiving duration and caregiving burden

Table 2 Clinical characteristics of the patients			
Characteristics of patients	N (%)	Mean±SD	Median
History of self-injuring behaviour	No=27 (18.5)		
	Yes=119 (81.5)		
Side effects of medication	No=60 (41.1)		
	Yes=86 (58.9)		
Positive PANSS scale score		25.31±9.77	
Negative PANSS scale score		15.45±8.54	
General PANSS scale score		32.41±14.87	
Total PANSS score		73.18±22.56	
Length of illness*			6
Number of the previous hospitalisation			3
*Length of illness was measured in terms of year. PANSS, Positive and Negative Syndrome Scale.			

FBIS	Mean±SD	Skewness	Kurtosis
Financial burden	6.86±2.44	-0.20	-0.521
Disruption of routine family activity	6.73±2.27	0.43	-1.07
Disruption of family leisure	4.88±1.64	-0.26	-0.72
Disruption of family interaction	6.07±2.45	0.16	-0.74
Effect on physical health of others	1.63±1.37	0.32	-1.16
Effect on mental health of others	3.29±0.87	-0.72	-0.65
Total objective burden	29.47±6.67	0.49	-0.59

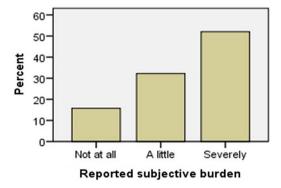


Figure 1 The magnitude of the reported subjective caregiving burden.

could be explained due to differences in the availability of other dependent family members and family size. The bigger the family size, it likely lessens the caregiving burden due to the sharing of the task of care.

There was no significant correlation between the caregiver's burden and the patient's gender, caregiver's gender, educational status and employment in this study. The findings are in conformity with the findings reported from India. In contrast to reports indicating that a higher burden was associated with hospitalisation, there was no significant association in this present study. This could be due to free healthcare delivery; treatment, hospitalisation and psychoeducation in Eritrea.

Monthly income was negatively associated with caregiving burden scores in this study. Despite free healthcare, several caregivers had reported a substantial level of burden of care. In contrast to a report explaining that caregivers of people with schizophrenia still suffered from out-of-pocket expenses in the many countries with a poor national health profile, there is no out-of-pocket expense for the care of patients in Eritrea. However, this could potentially be explained by the inequality of healthcare accessibility, uncertain healthcare quality and inconsistent psychoeducation delivery, transportation expenses to attend follow-ups or seek emergency care during the episodes of the clinical manifestations and dependence of the patients on their families. This finding is consistent with a study conducted in Nigeria.

Caregivers' age was positively correlated with caregiving burden. This finding is in accordance with a study that suggested older caregivers experience higher levels of caregiving burden than younger caregivers. Also, the younger generation of Eritrea tends to have a better educational background. This educational attainment may contribute to a better socioeconomic advantage or a better understanding and acceptability of the condition that mitigates the negative impact of the caregiving burden compared with the older generation.

High levels of symptomology have a substantial impact on caregiver burden. ²¹ Positive scale, negative scale and general psychopathological scale emerged as significant predictors of objective burden. The significant association between caregiver burden and the scores of psychopathology are consistent with previous

Table 4	Caregiving differences among the participants	
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		Objective burder	1		
Variables	n (%)	Mean±SD	t/F	p Value	ES
Characteristics of the patient					
Gender					
Male	84	29.43±6.71	-0.078	0.938	
Female	62	29.52±6.65			
Marital status					
Married	72	29.63±7.05	0.505	0.680	
Single	46	29.59±5.98			
Divorced	21	28.05±6.93			
Widowed	7	31.29±6.73			
Education					
Illiterate	8	31.50±4.81	1.107	0.349	
Elementary	46	28.41±6.22			
Junior	46	30.57±7.21			
Secondary and above	46	29.07±6.74			
Employment					
Yes	47	28.51±6.88	1.195	0.234	
No	99	29.92±6.54			
History of self-injury					
No	119	28.57±6.13	-3.574	0.000	0.0
Yes	27	33.44±7.55			
Side effects of medication					
No	86	29.17±5.16	-0.631	0.529	
Yes	60	29.88±8.39			
Family support					
Dissatisfied	58	27.55±5.30	2.889	0.004	0.16
Satisfied	88	30.73±7.18			
Support from friends					
Dissatisfied	70	28.71±6.77	-1.311	0.192	
Satisfied	76	30.16±6.53			
Medical staff support					
Dissatisfied	29	30.24±6.97	0.699	0.486	
Satisfied	117	29.27±6.60			
Religious activities					
None or not frequent	90	29.69±6.86	0.512	0.610	
Regular	56	29.10±6.38	0.012	5.0.0	
Characteristics of caregivers		_3.10_0.00			
Gender					
Male	76	28.90±6.64	-1.080	0.282	
Female	70	30.09±6.68	1.000	J.LUL	
Marital status	10	00.00±0.00			
Married	106	28.51±6.52	3.224	0.025	0.0
Single	25	32.64±6.75	0.224	0.020	0.00
Divorced	25 7	32.43±1.72			
Widowed	8	29.63±8.03			
Education	3	29.00±0.03			
	07	20 67 6 00	E 647	0.001	0.4
Illiterate	27 55	28.67±6.00	5.647	0.001	0.1
Elementary	55	34.59±6.65			
Junior	22	28.73±5.89			
Secondary and above	42	28.26±7.01			
Employment	07	00.57.0.70	0.050	0.707	
Yes	97	29.57±6.76	0.258	0.797	
No	49	29.27±6.54			
Kinship with the patient		00.07.7	4.000	0.44=	
Parents	73	28.67±7.16	1.999	0.117	
Spouse	29	30.66±5.65			
Sibling	17	27.59±6.15			
Other*	27	31.52±6.18			
Monthly household income					
Low income	97	32.02±6.23	7.727	0.000	1.15
	49	24.40±4.16			

	Unstandardised coefficients B	SE	Standardised coefficients β	t	p Value	R²	F change
(Constant)	25.803	3.315		7.784	0.000	0.638	26.517
Caregivers' age	0.074	0.035	0.156	2.128	0.035		
Duration of caregiving	0.149	0.061	0.131	2.445	0.016		
Income	-4.194	0.775	-0.298	-5.411	0.000		
History of self-injury	2.579	0.899	0.151	2.868	0.005		
Positive scale PANSS	0.234	0.038	0.344	6.218	0.000		
Negative scale PANSS	0.217	0.044	0.278	4.972	0.000		
General psychopathological scale	0.065	0.023	0.146	2.795	0.006		

studies.²⁶ Patients who experience high levels of symptoms may have greater impairment in their functioning levels, thereby, depend heavily on their caregivers. The correlation between the total score of the subscales of symptom severity and caregiver burden underscores the pharmacological and psychosocial interventions in Eritrea. Emphasis has to be given to improving the access and quality of healthcare to minimise (if possible to control) the symptoms of schizophrenia, which in turn address the reduction of caregiver burden.

The negative symptoms lead to social withdrawal or dysfunction of persons suffering from psychotic disorders, ²⁸ which can interfere in continuing of employment and the independent functioning level of the patient with schizophrenia in the community. ²⁹ Though the pharmacotherapy intervention and psychosocial support will help in reducing the schizophrenic symptoms, ³⁰ the emphasis of family support contributes better in the recovery of the patient. ³¹

In this study, the caregiving burden among the family caregivers due to the high levels of symptomology and the length of caregiving duration can benefit from effective psychoeducation. Although the use of psychoeducation for the effectiveness of the therapy is proven, to date psychoeducation is barely a part of standard care in the outpatient sector,³² a phenomenal scenario in developing countries, including in Eritrea. It, therefore, seems to be essential to provide systematic and structured psychoeducation for more patients who are living with schizophrenia and their families than is the case today. As such, linking and integrating the patients, families and health professionals in an integrated care initiative that centres psychoeducation can make an essential contribution to improving patient outcome and to reduce the caregiving burden of the caregivers.

This study has several limitations. First, this study was a cross-sectional design. In this study, the associated factors and caregiving burden were measured simultaneously. This makes it difficult to determine whether the caregiving burden followed the independent influential factors or the exposure of some confounding factors such as expressed emotions, exacerbate the severity of

the symptoms which in turn resulted in increasing caregiving burden. Therefore, this study doesn't fully prevent the effect of confounding factors and there is a risk of biased responses from the participants. Second, the situation may provide differing results if another timeframe was used or different family member had been chosen. Therefore, the results generated from the perspectives of the family caregivers who accompanied the patient during the follow-up visit in the outpatient department (OPD) clinic might not reflect the levels of caregiver burden within the family unit. Third, the social support was assessed subjectively. Fourth, all relevant influential factors or contributors to the burden of care were not taken into account in this study, such as the caregiving stay of caregivers in terms of hours, disease severity of patient function or violent tendencies during the trajectory progress of schizophrenia.

CONCLUSION

Families of persons living with schizophrenia experience a significant burden of care. Caregiving burden of families of persons living with schizophrenia is predicted by caregivers' age, duration of caregiving, monthly household family income, history of self-injury and severity of the symptoms. We recommend the strengthening of psychological and social support to reduce caregiving burden of the caregivers.

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Contributors THH contributed to conception and design, data analysis and interpretation, drafting the manuscript, revising and organising the manuscript. MHO was involved in data collection, data analysis and interpretation, and revising the manuscript critically. SL participated in data analysis and interpretation, and revised the manuscript critically. XL conceived of the study, participated in its design and coordination, helped to draft the manuscript, and revised the manuscript critically. All authors agree to be accountable for all aspects of the work and have read and approved the final manuscript.

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Competing interests None declared.

Patient consent Obtained.



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Data sharing statement No additional data are available.

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