



Knowledge and Attitudes of Caregivers' of People with Schizophrenia towards the Illness: A Cross-Sectional Study from a Regional Psychiatric Hospital in Nigeria

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Authors' contributions

This work was carried out in collaboration among all authors. Authors EAUB, OOS and OOJ designed the study, wrote the protocol and wrote the first draft of the manuscript. Authors EAUB and OJB performed and managed the statistical analysis of the study. Authors OOJ and OOS managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To ascertain the attitudes of caregivers of patients with schizophrenia comprising their knowledge of the illness and social distance towards people with the illness.

Study Design: A cross sectional study design.

Place and Duration of Study: Federal Neuropsychiatric Hospital, Edo State, Nigeria, between April and July 2015.

Methodology: A systematic random sample of caregiver/patient dyads (n=281) were recruited. Caregivers were administered a socio-demographic questionnaire and, a brief interview on their knowledge of the aetiological factors, treatment for schizophrenia and level of social distance towards people with schizophrenia. Patients were administered a socio-demographic questionnaire and the PANSS.

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Results: Three hundred and forty-one caregivers were approached but 281 gave consent and participated in the study (response rate was 82%, level of significance value was set at $p < 0.05$ and 95% confidence interval was used). Among the 281 caregivers surveyed, 22.7% mostly ascribed psychosocial cause for schizophrenia, their level of knowledge of schizophrenia was generally average (49.5%). More than two-thirds of the caregivers reported high social distancing. Better attitudes to schizophrenia among caregivers was significantly associated with caregivers who were unemployed ($p < 0.03$) and caregivers whose patients' had at least 12 years of formal education ($p < 0.01$).

Conclusion: Average knowledge of disease aetiology among caregivers was associated with high social distancing. Qualitative studies are required to explore the interactions of these identified factors.

Keywords: Caregivers; schizophrenia; knowledge; attitudes.

1. INTRODUCTION

Schizophrenia is a chronic and relapsing disorder which affects approximately 1% of the population [1]. When people develop schizophrenia and other forms of mental illness, they are usually cared for by their relatives [2]. Family members carry out this role with little or no information about the illness [3]. Sometimes, relatives become overwhelmed with the care of the patient which may result to negative attitudes toward the illness.

In developing countries in particular, the attitudes of caregivers is very important because government resources and support are scarce, and caregivers determine the form of care the patient receives [4–6]. Negative attitudes to the illness among caregivers could manifest as their unwillingness to reveal a relationship with the patient, or accept that their relative is mentally ill or needs treatment [5]. This will eventually hinder treatment and social integration for the patient [7]. However, when relatives hold positive attitudes to mental illness, they tend to support the patient all the way to recovery [8].

A community study of attitudes toward people with mental illness in Nigeria revealed a preponderance of negative attitudes [9]. Also, studies in developing countries assessing beliefs on the cause of mental illness reveal a preponderance of a spiritual causation for mental illness [9–11]. The implication of causal attribution is that it is a determinant of health seeking behavior, treatment adherence, duration of untreated illness and stigma [12].

While some studies on family attitudes have been conducted in developed and developing countries, [4–6,13] very few have been

conducted in Nigeria. It is against this backdrop that, the attitudes of caregivers of patients with schizophrenia comprising their knowledge of the illness and social distance towards people with the illness were assessed.

2. MATERIALS AND METHODS

2.1 Study Design

It was a cross sectional study of caregivers who accompanied patients with schizophrenia to the outpatient clinic of a stand-alone psychiatric hospital in the southern part of Nigeria.

2.2 Study Setting

This study was conducted at the Out-Patient Department of the Federal Neuropsychiatric Hospital, Uselu, Benin City, Nigeria. The hospital is located in Benin City and is a 230-bed facility. The hospital provides inpatient and outpatient services, as well as emergency services to walk-in and referred cases across Edo and its neighbouring states; a catchment population of 8 million persons. Out-patient clinics run 5 days (Mondays to Fridays) a week.

2.3 Study Participants

Two hundred and eighty-one caregivers were surveyed. Caregivers of patients with an ICD-10 case note diagnosis of schizophrenia, who had been living in the same household with the patient for at least a year and, were not paid for their care role were included in the study. Caregivers excluded were those who could not comprehend the questions asked in the various questionnaires (in terms of English language and perceived technicality of the questionnaire

items), were too ill to participate or refused to give consent for the study. Caregivers below 18 years of age were excluded from the study because the researchers chose to limit the study to an adult population.

2.4 Sample Size Calculation

The formula for sample size calculation utilising a known mean and standard deviation was used for this study [14].

$$N = (u + v)^2 \sigma^2 / (\mu - \mu_0)^2$$

Where N = required sample size

u= one-sided percentage point of the normal distribution corresponding to 100%, using a study power of 80%, u=0.84.

v= Percentage point of the normal distribution corresponding to the (two-sided) significance level with a significance level=5% at 95% confidence interval then, v=1.96.

σ = standard deviation

μ = mean

μ_0 = hypothesis value (mean)

According to the study by Adewuya and colleagues [15] a mean value of 6.71 was obtained on the DAI-10, with a standard deviation of 1.94. A hypothetic mean of 7.05 (being mean non-adherence rate from a systematic review [16]) was used.

$$N = (0.84 + 1.96)^2 \times 1.94^2 / (6.71 - 7.05)^2$$

$$N = 29.47 / 0.116$$

$$N = 254.93$$

$$N = 255$$

Allowing for an attrition of 10%

$$255 + 25.5 = 280.5$$

Thus a total of 281 patients and 281 caregivers were enrolled for this study.

2.5 Study Questionnaires

A semi-structured socio-demographic questionnaire (caregivers & patients) was designed by the researchers to elicit; caregivers' socio-demographic variables such as age, gender, ethnicity, level of education, marital status, occupation, religion and number of years

spent living with the patient. Patients' socio-demographic variables such as age, gender, and ethnicity, level of education, marital status, occupation and religion were collected. Clinical variables include number of years patient has been assessing care from the hospital, number of years since the diagnosis has been made and psychiatric diagnosis.

A modified version of the knowledge and attitudes (social distance) towards people with schizophrenia survey questionnaire was administered to caregivers. The original version of this tool was designed by Stuart and Arboleda-Flórez in [14] to measure attitudes toward schizophrenia. It was developed for the "World Psychiatric Association Programme to Reduce Stigma and Discrimination because of Schizophrenia" [15] because existing questionnaires measured attitudes to mental illness in general. It is a 16-item questionnaire which evaluates knowledge and attitudes (social distance) towards people with schizophrenia. An adaptation of this questionnaire was used for this study. In applying this instrument to a community sample, the authors generated scores for knowledge and attitude (social distance) to schizophrenia [14]. The knowledge score for each participant was created by summing correct responses to the 10 knowledge questions depicted in question '5'. Correct responses were allocated a score of '1' and incorrect responses were allocated a score of '0'. The attitude scores were generated by summing desirable responses to the six social distance questions depicted in question '7' [14].

Positive and Negative Syndrome Scale for Schizophrenia questionnaire was administered to the patients. It consists of three subscales: (a) positive (b) negative and (c) general psychopathology. Research evidence shows that these syndromes have a bearing on attitudes to the illness and adherence to antipsychotic medications [16–20]. The positive and the negative subscales, which are used for assessing the patients' symptoms, have seven items each, which can be rated on a scale of 1–7, giving a possible range of scores between 7 and 49 for each subscale. The general psychopathology subscale has 16 items giving a range of scores between 16 and 112. Previous studies have found the PANSS to be a valid instrument with good psychometric properties in the assessment of symptoms of schizophrenia [21]. The positive, negative, and general psychopathology subscales were found by

coefficient alpha, split-half method, and test-retest reliability testing to be internally consistent and highly reliable [19]. The PANSS has been used previously in this environment [22].

2.6 Study Procedure

In the process of recruitment, the patients' case notes were first checked to confirm a diagnosis of schizophrenia. Caregivers and patients were approached in the clinic and were informed about the nature and purpose of the study. A systematic random sampling was employed for this study. An initial list comprising the patient's name, allocated serial numbers and case note diagnosis of schizophrenia was drawn each clinic day. This list formed the sample frame for each clinic day. An initial simple random sampling of the first 10 patients who presented to the clinic with an ICD 10 diagnosis of schizophrenia was done to get the first participant. Subsequently, every 7th patient was recruited. An average of four (4) patients were recruited per clinic day. Patients who did not come with a relative were skipped. One of the researchers (UBEA) administered the questionnaires to the study participants who provided written informed consents. The study period lasted fourteen weeks to recruit 281 patients with their caregivers.

Data was collected from 281 patients and their caregivers visiting the Outpatient Department of the Federal Neuropsychiatric Hospital, Benin City.

2.7 Data Analysis

Analysis of the data was done using the Statistical Package for the Social Sciences (SPSS), version 16. Results are presented in frequencies, percentages and tables as appropriate.

For the purpose of analysis, some socio-demographic and clinical variables of the caregivers were dichotomised. The caregivers' age class was dichotomised using the median score of 46 into "18-45" and "46-80", family size was split into 2-6 and 7-20 using a median score of 6. Educational status was dichotomised into greater than 12 years of formal education and less than or equal to 12 years of formal education and; marital status was

dichotomised into those with a live-in partner (married / cohabiting) and those without a live-in partner (single/ divorced/ separated/ widowed).

For the knowledge and attitude (social distance) towards people with schizophrenia, a computed knowledge score was derived and categorised into three groups "above average", "average" and "below-average" knowledge. Average knowledge was a score within the mean ± 1 SD of the group. Above average knowledge was score greater than the mean +1SD, while below average was less than the mean by 1SD. The total attitude or social distance score was also categorised into three groups. The groups were the low social distance (if all items were answered desirably, a score of 6), moderate social distance (only 1 item was answered undesirably, a score of 5) and high social distance (if two or more items were answered undesirably, scores 0 - 4). Also, attitude to schizophrenia scores were further dichotomised into 'good' and 'poor' attitude. 'Good attitude' represents a social distance score of 5-6 which is equivalent to 'low or moderate social distance' while, 'Poor attitude' represents a score of 0-4 which is equivalent to 'high social distance'.

The chi-square test was used to identify the relationship between categorical socio-demographic variables and attitude to schizophrenia. Significant variables were entered into a binary logistic regression analysis to ascertain predictors of caregivers' attitudes to schizophrenia.

3. RESULTS

The majority of caregivers were within the ages of 18 to 45 years (n=141; 50.2%). They were mostly female (n=151; 53.7%) with less than twelve years of formal education (n=169; 60.1%) and first degree relatives. Three-quarters of the caregivers were employed and had a live-in partner (63.7%). Similarly, the patients were mostly within the ages of 35 to 69 years (n=150; 53.4%), largely female (n=144; 51.2%) with less than twelve years of formal education (n=198; 70.4%), however three-quarters of the patients did not have a live-in partner (n=251; 75.4%). The commonest ICD-10 case note diagnosis was paranoid schizophrenia (n=188; 66.9%). See Table 1.

Table 1. Socio-demographic characteristics of caregivers and patients (N=281)

Variable	Caregivers		Patients	
	n	%	n	%
Age class				
18-30	48	17.1	88	31.3
31-40	54	19.2	115	40.9
41-50	65	23.1	44	15.7
51-60	65	23.1	23	8.2
≥ 61	49	17.5	11	3.9
Gender				
Male	130	46.3	137	48.8
Female	151	53.7	144	51.2
Marital status				
Single	61	21.7	176	62.6
Divorced/separated	11	3.9	30	10.7
Widowed	30	10.7	9	3.2
Married	179	63.7	65	23.1
Cohabiting	-	-	1	0.4
Educational status				
No formal education	17	6.0	7	2.5
Primary	51	18.3	42	14.9
Secondary	101	35.9	149	53.0
Tertiary	95	33.8	74	26.3
Postgraduate	17	6.0	9	3.3
Ethnic group				
Bini	108	38.4	108	38.4
Esan	54	19.2	57	20.3
Ibo	42	14.9	41	14.6
Others	77	27.5	75	26.7
Religion				
Christian	272	96.8	272	96.8
Muslim	8	2.8	8	2.8
African traditional religion	1	0.4	1	0.4
Employment status				
Unemployed	69	24.6	189	67.3
Employed	212	75.4	92	32.7
Occupation classification (ISCO-08)* (n=212)				
Managers	1	0.5	1	1.1
Professionals	24	11.3	5	5.4
Technicians and associate professionals	15	7.1	6	6.5
Clerical support workers	9	4.2	8	8.8
Services and sales workers	127	59.9	50	54.3
Skilled agriculture, forestry and fishery workers	11	5.2	7	7.6
Craft and related trade workers	10	4.7	6	6.5
Plant and machine operators and assemblers	11	5.2	9	9.8
Elementary occupations	4	1.9	-	-
Relationship to patient				
Parent	112	39.9	-	-
Sibling	102	36.3	-	-
Child	28	10.0	-	-
Spouse	27	9.6	-	-
*others	12	4.2	-	-
Number of years living with the patient				
1-10	80	28.5	-	-
11-20	35	12.5	-	-

21-30	84	29.9	-	-
31-40	70	24.9	-	-
41-50	10	3.6	-	-
51-60	2	0.7	-	-
ICD 10 diagnosis				
Paranoid schizophrenia	-	-	188	66.9
Hebephrenic schizophrenia	-	-	21	7.5
Undifferentiated schizophrenia	-	-	68	24.1
Catatonic schizophrenia	-	-	3	1.1
Schizophrenia residual type	-	-	1	0.4
Age at onset of illness class (in years)				
5-27	-	-	142	50.5
28-65	-	-	139	49.5
Duration of treatment class(months)				
6-36	-	-	150	53.4
37-360	-	-	131	46.6

*ISCO-08 International Standard Classification of Occupations, 2008; *Others- uncle (1), aunt (6), cousin (3) and grandmother (2)

Although, the majority could not report a cause for schizophrenia, however, among those who ascribed a cause for the illness, psychosocial causes were the most attributed (n=64; 22.7%). These psychosocial causes include poor upbringing by parents, physical abuse, stress (such as losing a job, social stress), traumatic event or shock (e.g. assault, death and accident), poverty and general breakdown in social values. Only one participant was aware of the estimated prevalence of schizophrenia.

Participants with an average knowledge of schizophrenia accounted for 49.5%, above average knowledge of schizophrenia were 26.78% and below average knowledge of schizophrenia were 23.80%. Two-thirds of the caregivers were in favour of having a group home for 6 to 8 people with schizophrenia in their neighbourhood (196: 69.8%). Generally, most of the caregivers had high social distance towards people with schizophrenia (82.6%). See Tables 2 & 3.

Table 2. Caregivers' knowledge of schizophrenia (N=281)

Variable	n	%
To the best of your knowledge, what causes schizophrenia?		
Don't know or exact cause is unknown	103	36.7
Biological	25	8.9
Psychosocial	64	22.7
Drugs	44	15.7
Spiritual	45	16.0
Can be successfully treated outside the hospital in the community		
Frequently	62	22.1
Often	72	25.6
Rarely	32	11.4
Never	115	40.9
Tend to be mentally retarded or of lower intelligence		
Frequently	79	28.1
Often	109	38.8
Rarely	75	26.7
Never	18	6.4
Hear voices telling them what to do		
Frequently	169	60.1
Often	73	26.0
Rarely	26	9.3
Never	13	4.6

Need prescription drugs to control their symptoms		
Frequently	253	90.0
Often	26	9.3
Rarely	2	0.7
Can be successfully treated without drugs using psychotherapy or social interventions		
Frequently	63	22.4
Often	72	25.6
Rarely	41	14.6
Never	105	37.4
Are a public nuisance due to begging, poor hygiene or odd behaviour		
Frequently	66	23.5
Often	84	29.9
Rarely	105	37.4
Never	26	9.2
Suffer from split or multiple personalities		
Frequently	69	24.6
Often	148	52.7
Rarely	43	15.3
Never	21	7.4
Can be seen talking to themselves or shouting in the streets		
Frequently	109	38.8
Often	96	34.2
Rarely	52	18.5
Never	24	8.5
Can work in regular jobs		
Frequently	127	45.2
Often	65	23.1
Rarely	62	22.1
Never	27	9.6
Are dangerous to the public because of violent behavior		
Frequently	37	13.2
Often	55	19.6
Rarely	70	24.9
Never	119	42.3
To be best of your knowledge, what percentage of the population suffers from schizophrenia? Round off percentage		
Don't know	96	34.1
1%	1	0.4
≥2%	184	65.5

**Categories for causes of schizophrenia: Biological causes- Physical abnormalities in the brain, chemical imbalance in the brain, brain disease, virus during pregnancy, genetic inheritance and other biological factors. Psychosocial causes- Poor upbringing by parents, Physical abuse, Stress (such as losing a job, social stress), Traumatic event or shock (e.g. assault, death, accident), poverty and general breakdown in social values Drugs - Drug or alcohol abuse Spiritual- Possession by an evil spirit and God's punishment*

Caregivers with more than twelve years of formal education ($P < .04$) and were unemployed ($P < .01$) were significantly more likely to have better attitudes to schizophrenia. No significant differences were observed when relatives' age class ($P = .85$), gender ($P = .40$), marital status ($P = .47$) and family size ($P = .33$)

were compared with their attitudes to schizophrenia.

The mean PANSS scores for the patients were; on the positive subscale 12.33 ± 5.25 ; on the negative scale 11.68 ± 5.04 ; on the general scale 23.78 ± 7.50 and the total score was 47.77 ± 14.92 .

There was no statistically significant difference in mean scores of caregivers' attitude to schizophrenia and the severity of psychopathology in the patients in all domains of PANSS subscales assessed. Patients with more than twelve years of formal education were significantly more likely to be related to caregivers with better attitudes to schizophrenia ($P<.001$). See Table 5.

Significant correlates on bivariate analysis were entered into a binary regression model, which showed that better attitudes to schizophrenia was significantly predicted by caregivers who were unemployed ($P<.03$) and patients who had more than 12 years of formal education ($P<.01$). See Table 5.

4. DISCUSSION

Family caregivers are a very important group because they have prolonged contact with the patients, and are involved in various aspects of care tasks [2] with little assistance from limited public services in Nigeria [23,24]. Hence, a care plan which improves caregivers attitudes will eventually result in improved health outcomes of the patients [12].

The mean age of caregivers in this study was 46.39 years which is similar to findings from other studies among caregivers wherein relatives that accompany patients to the hospital were usually middle-aged [4,23]. In developing countries, when individuals develop a mental illness, they are most likely to be cared for and live with their family of birth [2]. This could explain the finding in this study that most relatives were first degree relatives, especially the patients' parents. Furthermore, this study found a preponderance of female caregivers similar to findings from previous studies conducted in this environment [2,23] but at variance with a study conducted in India, another developing country [25]. This has been ascribed to mothers being traditionally more involved in the caring role and usually brought their wards to the hospital [2,24].

Psychosocial causes for schizophrenia was the most endorsed among caregivers in this study. This is at variance with findings from an earlier community-based study done in Nigeria where the most endorsed cause for mental illness was psychoactive substance use [9] as well as a more recent study conducted among caregivers in South-South region of Nigeria where

supernatural causes were mostly endorsed [10]. The difference in specific samples surveys and methodology could have accounted for this variance. This study used an instrument which listed all the possible causes of mental illness and was not limited to various forms of supernatural causes like the latter study cited [10]. However, for developed countries, biological causes of schizophrenia are mostly endorsed [14]. This is a crucial aspect in the care of patients with schizophrenia as causal beliefs translates to health-seeking behavior and attitudes to the illness and its treatment. Individuals who endorsed a non-biomedical disease model reported increased stigma, delayed presentation for treatment and poor medication adherence [26,27].

High social distance was prevalent in this study implying that the participants mostly had a predominant negative attitude towards people with schizophrenia. This is similar to findings from a previous community-based study in this setting [9]. High social distance among relatives of patients with schizophrenia in the present study was worrisome and not consistent with the assertion that increased exposure results in low social distance [28]. It is however possible that, irrespective of the exposure to patients with schizophrenia, caregivers may still hold the prevalent beliefs expressed in the community.

Caregivers of patients with higher educational attainment significantly reported better attitudes towards people with schizophrenia in this study. A previous study in Asia with similar findings [5] alluded that caregivers who were more educated had better attitudes to people with mental illness because they were more exposed to the social media hence becoming more aware of the myths surrounding mental illness. In addition, higher educational attainment made it more likely for individuals to understand and accept a biological basis for mental illness which ultimately results in better attitudes [29]. Furthermore, a higher educational attainment among patients with schizophrenia was predictive of better attitudes to schizophrenia among caregivers. This finding was contrary to the findings from an earlier study conducted in Germany; where better educated people maintained greater social distance with mentally ill patients fostering discrimination [30].

Unemployed caregivers reported better attitudes towards persons with schizophrenia, and this has not been reported in previous studies. It possibly reflects the concept of increased exposure being

linked to lower social distance, [28] as caregivers who are unemployed spend more time attending to the needs of the patients thereby benefitting from the positive aspects of the caring role which entails feelings of achievement and personal growth resulting in low social distance [28,31]. They are also able to observe more positive

characteristics in the patients even in the acute phase of the illness [32,33]. However, our findings may reflect the fact that those who were unemployed depended on another family member for financial support for themselves and the patient, thus mitigating the stress of the caregiving role.

Table 3. Caregivers attitude (social distance) towards persons with schizophrenia (N=281)

Variable (N= 281)	n	%
Please tell me how you would feel in each of the following situations.....		
Would you feel afraid to have a conversation with someone who has schizophrenia?		
Definitely	25	8.9
Probably	27	9.6
Probably not	22	7.8
Definitely not	207	73.7
Would you be upset or disturbed about working on the same job with someone who has schizophrenia?		
Definitely	33	11.7
Probably	30	10.7
Probably not	35	12.5
Definitely not	183	65.1
Would you be able to maintain a friendship with someone who has schizophrenia?		
Definitely	138	49.1
Probably	79	28.1
Probably not	33	11.7
Definitely not	31	11.1
Would you feel upset or disturbed about rooming with someone who has schizophrenia?		
Definitely	31	11.1
Probably	37	13.2
Probably not	38	13.5
Definitely not	175	62.2
Would you feel ashamed if people knew someone in your family has been diagnosed with schizophrenia?		
Definitely	83	29.5
Probably	49	17.4
Probably not	19	6.8
Definitely not	130	46.3
Would you marry someone with schizophrenia?		
Definitely	54	19.2
Probably	58	20.6
Probably not	34	12.1
Definitely not	135	48.1
How would you feel about having a group home for six to eight people with schizophrenia in your neighbourhood?		
Would you be...		
In favour	196	69.8
Opposed	67	23.8
indifferent	18	6.4

Table 4. Comparison of caregivers’ socio-demographic characteristics and their attitudes to schizophrenia

Variable	Good attitude to Schizophrenia (N=49) n (%)	Poor attitude to Schizophrenia (N=232) n (%)	Statistics
Age class			
18-45	24 (17.7)	117 (82.9)	$X^2=.03$
46-80	25 (17.9)	115 (82.1)	$P=.85$
Years of formal education			
<12 years	23 (13.6)	146 (86.4)	$X^2=4.32$
>12 years	26 (23.2)	86 (76.8)	$P<.04$
Gender			
Male	20 (15.4)	110 (84.6)	$X^2=.71$
Female	29 (19.2)	122 (80.8)	$P=.40$
Employment Status			
Unemployed	19 (27.5)	50 (72.5)	$X^2=6.48$
Employed	30 (14.2)	182 (85.8)	$P<.01$
Marital status			
Single/ divorced/separated/ Widowed	20 (19.6)	82 (80.4)	$X^2=.52$
Married/ cohabiting	29 (16.2)	150 (83.8)	$P=.47$
Family size			
2-6	27 (15.7)	145 (84.3)	$X^2=.93$
7-20	22 (20.2)	87 (79.8)	$P=.33$

Table 5. Predictors of caregivers’ attitudes to schizophrenia

Variable	B	SE	Wald	OR	95% CI	p
Relative’s employment status	0.73	0.35	4.50	2.08	1.06-4.09	.03
Relative’s educational status	-0.25	0.35	0.53	0.78	0.39-1.53	.47
Patient’s educational status	-0.91	0.35	6.87	0.40	0.21-0.80	.01

5. CONCLUSION

The majority of caregivers in this study reported negative attitudes towards people with schizophrenia. Caregivers who were unemployed and having patients with greater than 12 years of formal education were predictors of good attitude toward people with schizophrenia. Qualitative studies are required to explore the dynamic interaction of these factors in mitigating poorer attitudes.

CONSENT AND ETHICAL APPROVAL

Ethical approval for the study was obtained from the Research and Ethics Committee of the hospital. Participants were informed about the nature and purpose of the study and a written consent was obtained. All data were treated with confidentiality and anonymity. Caregivers were also assured that they could opt out of the study at any stage without fear of any form of repercussion for their patients.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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