

## **Behavioral and Psychological Symptoms of Dementia in Nigerian Hospital Patients: Prevalence, Correlates and Caregiver Burden**

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### **Authors' contributions**

*This work was carried out in collaboration between all authors. Authors AOB and OB designed the study and wrote the protocol of the study. Author IIA performed the statistical analysis and managed the analyses of the study. Author AOB wrote the first draft of the manuscript and managed the literature searches. Authors OB and FOA corrected the manuscript of this study. All authors read and approved the final manuscript.*

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### **ABSTRACT**

**Aims:** This study was aimed at measuring the prevalence and impact of Behavioral and Psychological Symptoms of Dementia (BPSD) of elderly hospital attendees in Lagos Nigeria; and determining socio-cultural factors associated with the health of these elderly people with dementia.

**Study Design:** This was a cross-sectional descriptive study. Fifty patients with dementia attending out-patient facilities of three tertiary hospitals in Lagos were interviewed along with their caregivers.

**Place and Duration of Study:** The study was conducted over a 6 month period at the out-patient clinics of the Federal Neuro-Psychiatric Hospital, Yaba and the Neurology and Psychiatric Clinics of Lagos University Teaching Hospital, Idi-Araba Lagos.

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**Methodology:** Consecutively presenting patients who met the inclusion criteria for the study were recruited after obtaining consent from the participant and caregivers. The Mini Mental State Examination, Stick design and Indiana University Token test were administered to the patient, while Blessed Dementia Scale and Neuropsychiatry Inventory were administered to the caregivers.

**Results:** Mean age was 72.5( $\pm$ 6.4) years, 52% were females and 54% had primary school education or less. Ninety-two percent lived with family and 96% had at least one BPSD, the commonest being hallucinations (68%), agitation (68%) and night-time behaviour (62%). The most severe BPSD using the mean NPI score (Frequency X Severity) were night-time behaviour 3.84, (SD3.71), aberrant motor behaviour 3.74, (SD4.06) and agitation 3.53, (SD3.52). The more distressing symptoms experienced by caregivers were agitation 1.78, (SD1.56), night-time behaviour 1.78, (SD1.43), and aberrant motor behaviour 1.66, (SD1.59). On regression analysis, BPSD independently predicted caregiver distress.

**Conclusion:** These findings are similar to previous studies with high prevalence of BPSD in patients with dementia and distress in caregivers. Improving access to treatment of BPSD is vital in alleviating caregiver distress especially in low income countries where family care is about the only option for dementia care.

*Keywords: Elderly; dementia; behavioral symptoms; caregivers distress.*

## 1. INTRODUCTION

Dementia has been described as the commonest neuro-psychiatric disorder of old age, characterized by cognitive decline, functional impairment as well as behavioural symptoms [1]. It occurs in every region of the world, with an estimated prevalence of 24.3 million cases worldwide and an annual incidence of 4.6 million cases [2]. Studies in community dwellers in Nigeria have reported prevalence rates between 2.29% and 2.79% [3,4].

Behavioural and Psychological Symptoms of Dementia (BPSD) are often part of the presentation of dementia and in certain cases might start in the pre-dementia phase of mild cognitive impairment [5,6]. Generally, the severity of BPSD increases as dementia progresses until probably the end stage of life. BPSD refers to a heterogeneous range of psychological reactions, psychiatric symptoms, and behaviours occurring in people with dementia of any aetiology [7]. These symptoms include delusions, hallucinations, agitation, depression, anxiety, elation, apathy, disinhibition, irritability, aberrant motor behaviour, night time behaviour, and appetite change [8].

Though an important clinical dimension of dementia, BPSD has not received expected attention from the point of view of research and treatment. Yet unlike the impaired cognitive and functional abilities often seen in dementia, BPSD is amenable to treatment, with important implications to both the dementia patient and the caregivers.

In developed countries, the reported prevalence of BPSD ranged from about 50 to 100% [9,10]. Previous authors have found comparable rates of BPSD in developing countries, though the pattern of BPSD symptoms varied widely across studies [11,12]. BPSD worsens the overall morbidity profile in Dementia and negatively impacts the outcome of affected individuals and their caregivers [12,13]. Studies have shown that BPSD are a major cause of concern and burden to the caregivers, and are more difficult to cope with than the cognitive changes of dementia [14,15]. Allegri and others reported that BPSD, rather than cognitive impairment, were the best predictor of caregiver burden [16]. Untreated BPSD is predictive of informal caregiver distress [16], increased overall cost of dementia care [17,18] premature transition to structured living environment and institutionalization [19,20], significant caregiver stress to nursing staff in residential facilities [21,22] and lower quality of life for both the caregiver and the patient [23,24]. Studies have shown that remission or reduction of BPSD is associated with remarkable improvement in the functional abilities of the patient [7]. These findings underscore the importance of ascertaining and treating BPSD in all patients with dementia.

In the Nigerian context, care giving is usually borne by family and friends due to unavailability of structured care facilities for patients with dementia [11]. There is limited information on the prevalence and correlates of BPSD in patients with Dementia in Sub-Saharan Africa, especially in clinical settings. A handful of studies have been conducted on impact and burden of

dementia on the family [25,26], however, the majority of these studies did not focus on the impact of BPSD on caregiver distress. Two studies done on individuals with dementia [6,11] were in community dwellers; however Ojagbemi and others studied BPSD in hospital patients with Parkinson's disease [27].

The current study aimed to determine the relationship between Behavioural and Psychological Symptoms of Dementia and caregiver distress in patients attending out-patient facilities in Lagos, Nigeria.

## **2. MATERIALS AND METHODS**

This was a cross-sectional descriptive study conducted between October 2011 and April 2012 at the out-patient clinics of the Federal Neuro-Psychiatric Hospital, Yaba and the Neurology and Psychiatric Clinics of Lagos University Teaching Hospital, Idi-Araba Lagos. The Federal Neuro-Psychiatric Hospital, Yaba is a psychiatric facility mainly with service orientation, while the Lagos University Teaching Hospital is a university medical center with specialist facilities in internal medicine, neurology, psychiatry, surgery, obstetrics and gynecology. Both facilities are funded by the Federal Government of Nigeria and accessed by patients from all parts of the densely populated Lagos metropolis and other parts of Nigeria. Ethical approval for the study was obtained from the Ethical & Research Committees of the Federal Neuro-Psychiatric Hospital, Yaba and the Lagos University Teaching Hospital, Idi-Araba. The participants were elderly patients with dementia attending the out-patient clinics at the study locations in the company of their caregivers.

Inclusion criteria for the participants were meeting the ICD 10 diagnostic criteria for dementia and aged 65 years and above as at the time of recruitment. While the exclusion criteria were presence of pre-existing cognitive impairment from developmental disabilities such as Down's syndrome and cerebral palsy; presence of psychiatric conditions such as schizophrenia and elderly people with physical disabilities, such as hearing or visual impairment and also those with substance use disorder.

Consecutively presenting patients who met the inclusion criteria for the study were recruited from the out-patient clinics at the study locations on

their clinic days after obtaining consent from the participant and caregivers unless where the patient is too impaired to give consent, consent was obtained from caregiver usually a spouse or child.

The Mini Mental State Examination, Stick design and Indiana University Token test were administered to the patient, while Blessed Dementia Scale and Neuropsychiatry Inventory were administered to the caregivers.

The Yoruba versions of the instruments were available with satisfactory psychometric properties. They were used for non-English speaking subjects who understood the Yoruba language. This had been previously used in the Ibadan Dementia Research Project [3,28,29].

### **2.1 Measures**

#### **2.1.1 Socio-demographic questionnaire**

A Socio-demographic and Clinical Questionnaire was designed by the researchers to elicit the socio-demographic characteristics and appropriate clinical variables of the subjects. The items in the socio-demographic and clinical questionnaire were based on a review of the literature and clinical risk factors which included the age, gender, level of education, income, marital status, place of residence, family size and family history of psychiatric disorders. Demographic information on the primary caregiver was also collected.

#### **2.1.2 Mini mental state examination**

The Mini Mental State Examination (MMSE) developed by Folstein et al consists of 20 items assessing various aspects of cognition [30]. It is used as a screening tool for dementia as well as assessing its severity. Subjects are scored from 0 to 30, with higher scores interpreted as lower severity of dementia or no dementia. The MMSE was used as adapted from the Ibadan Dementia Research Project [28,29].

#### **2.1.3 The stick design test**

The Stick Design is a 4 item instrument used to assess visuo-constructional ability. It forms a part of the neuropsychological battery used in the Indianapolis Ibadan Dementia Project. The Stick Design is sensitive to dementia and has tested validity and reliability [4,29].

#### **2.1.4 Indiana university token test**

The Indiana University Token Test is a 12 item construct which was used to measure executive functioning, also shown to be very sensitive in dementia [31,32]. It was also used in the Indianapolis Ibadan dementia project [3,29].

#### **2.1.5 Blessed dementia scale**

Blessed Dementia Scale is a widely used questionnaire for assessing activities of daily living in subjects with dementia [33]. It is a 12 item questionnaire administered to an informant, usually a relative of the subject. It measures activities of daily living both instrumental and personal care aspects.

The Blessed Dementia Scale is easy to administer and has been used in previous studies in Nigeria [3,4,11]. The instrument generates scores ranging from 0 to 17, with higher scores indicating impairment.

#### **2.1.6 The neuropsychiatry inventory**

The Neuropsychiatric Inventory [8]: This was used to assess Behavioral and Psychological Symptoms of Dementia (BPSD). The instrument measures the frequency and severity of BPSD as well as the level of caregivers' distress. It has been used in many countries including Nigeria [11,27].

The NPI assesses 12 behavioral domains which include: irritability and/or lability, agitation and/or aggressiveness, anxiety, depression, elation, disinhibition, apathy, aberrant motor behavior, delusions, hallucinations, sleep, appetite and eating disorders. The NPI consists of three sections for each symptom: frequency, severity and caregiver distress. Caregivers were asked to recall behavioral symptoms that occurred in the preceding 4 weeks and rate the frequency, severity and distress caused by subject's display of the behavioral symptoms. Frequency was scored in the following manner: 0= not present, 1= occasionally, 2= often, 3= frequent and 4=very frequent. Severity was scored as 1= mild, 2 = moderate and 3= marked. Because it is possible for a symptom to be present many times but without being considered severe, or to occur occasionally but with high severity, the clinical presentation rather than the total severity score for each symptom is a product of frequency and severity. The distress experienced by the carer was measured as follows: 0= none, 1= minimal,

2=mild, 3= moderate, 4= severe and 5= very severe. The total severity (frequency x severity) score and total distress score were calculated as the sum of the appropriate scores for each symptom.

The NPI has previously been used in the Nigerian older adults with good reliability (Cronbach alpha ranged from 0.73-0.80, test-retest reliability ranged from 0.9-1.0). There were good correlations with cognitive and functional markers of dementia [11,27].

### **2.2 Statistical Analysis**

Analysis was done using the Statistical Package for Social Sciences (SPSS) version 15. Total severity scores of BPSD were calculated as the product of frequency and severity for each symptom. Inferential statistics were utilized to examine the relationships between BPSD and identified independent variables. Group comparisons were done using chi-squares for categorical variables, and the Student t-test for associations between two continuous variables. Pearson's correlation coefficients were calculated to test for the associations between continuous variables. Significant variables on bivariate analysis were entered into regression analysis. All tests were 2-tailed, and the level of significance was set at  $p < 0.05$ .

### **3. RESULTS AND DISCUSSION**

The study group consisted of 50 elderly patients with dementia. The socio-demographic characteristics of the patients are shown in Table 1. Their ages ranged from 65 to 90 years, with a mean age of  $72.46 \pm 6.49$  years. There were more females (52%) than males in the study population with 64% of them married. The majority had just primary school education or less (54%) while even less than this percentage (32%) receive pension and 92% lived with at least one family member. A multigenerational living arrangement was common. Of the caregivers, (88%) stated that care-giving was voluntary while 34% prefer for someone else to take the up that role.

Table 2 presents the socio-demographic characteristics of the caregivers. The majority of the caregivers were female (82%). There was a preponderance of married people (84%) among them. Daughters constituted the majority (46%), followed by spouses (34%).

**Table 1. Socio-demographic characteristics of the subjects (N = 50)**

Variables	Frequency (%)
<b>Age range (years)</b>	
65-74	32 (64%)
75-84	17 (34%)
>84	1 (2%)
<b>Gender</b>	
Male	23 (46%)
Female	27 (54%)
<b>Level of education</b>	
Primary or less	27 (54%)
Secondary	10 (20%)
Tertiary	13 (26%)
<b>Pension</b>	
Receiving	16 (32%)
Not receiving pension	34 (68%)
<b>Household composition</b>	
Lived with spouse	17 (34%)
Lived with daughter	23 (46%)
Lived with son	6 (12%)
Others	4 (8%)
<b>Residence</b>	
Urban	38 (76%)
Suburban	12 (24%)
<b>Voluntary care giving</b>	
Yes	44 (88%)
No	6 (12%)
<b>Care giving</b>	
Needs assistance with ADL	17 (34%)
Does not need assistance with ADL	33 (66%)

**Table 2. Socio-demographic characteristics of the caregivers (N = 50)**

Variables	Frequency n (%)
<b>Gender</b>	
Male	9 (18.0)
<b>Marital status</b>	
Married	42 (84.0)
Unmarried	8 (16.0)
<b>Relationship with subject</b>	
Spouse	17 (34.0)
Daughter	23 (46.0)
Son	6 (12.0)
Others	4 (8.0)
<b>Employment status</b>	
Employed	21(42.0)
Unemployed	8(16.0)
Self-employed	21(42.0)

Fig. 1 shows the mean distress scores for each symptom as measured by the Neuropsychiatric

Inventory. The mean total distress score for all the symptoms was 13.40 ±7.63. The most distressing symptoms to the caregivers were agitation and night time behavioral changes with mean distress score of (1.78±1.43) and (1.78±1.56) respectively. This was followed by aberrant motor behavior (1.66±1.59), delusion (1.46±1.21) and hallucinations (1.34±1.33) and lesser values in other domains.

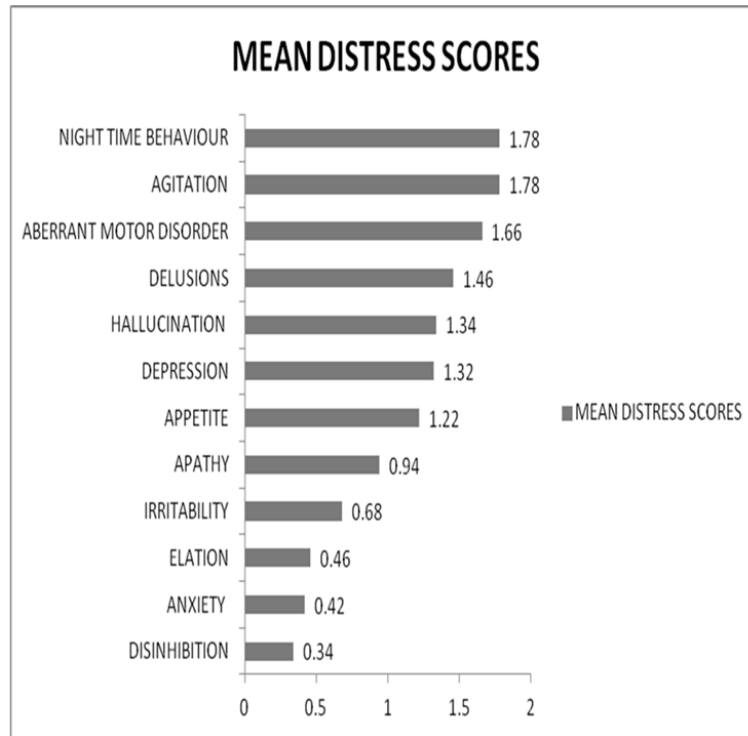
Table 3 gives the mean value (frequency x severity) and distress scores of behavioural and psychological symptoms of dementia in the study group.

**Table 3. Mean value (FXS) and distress scores of behavioural and psychological symptoms of dementia**

	Distress score	
Delusions	2.90	1.46
Hallucinations	2.88	1.34
Agitation	3.52	1.78
Depression	2.20	1.32
Anxiety	0.66	0.42
Elation	0.78	0.46
Apathy	2.14	0.94
Disinhibition	0.56	0.34
Irritability	1.44	0.68
Aberrant motor disorder	3.74	1.66
Night time behaviour	3.84	1.78
Appetite	2.54	1.22
<b>Total NPI score</b>	<b>27.20</b>	<b>13.40</b>

Table 4 shows the relationship between BPSD (mean frequency and severity scores) and the level of caregiver distress. All domains of BPSD had significant association with caregiver distress. Behavioral and Psychological Symptoms of Dementia has a positive correlation with caregiver distress with a statistically significance (r=0.941; p<0.001).

Table 5 shows a regression analysis of the variables associated with caregiver distress on bivariate-analysis. This positive association indicates that with increasing level of BPSD, there is also an increase in caregiver distress. On logistic regression analysis, Behavioral and Psychological Symptom of Dementia and Blessed Dementia Scale score remained the only independent determinant of caregiver distress. However, Total severity score on the BPSD was the single best predictor (p<0.001) of caregiver distress.



**Fig. 1. Bar chart showing increasing mean distress scores reported by caregivers using the neuropsychiatric inventory**

**Table 4. Relationship between behavioural and psychological symptoms of dementia and caregiver distress**

Symptoms	Correlation (r)	p-value
Delusions	0.888	<0.001
Hallucinations	0.922	<0.001
Agitation	0.904	<0.001
Depression	0.908	<0.001
Anxiety	0.892	<0.001
Elation	0.923	<0.001
Apathy	0.906	<0.001
Disinhibition	0.898	<0.001
Irritability	0.922	<0.001
Aberrant motor disorder	0.941	<0.001
Night time behaviour	0.942	<0.001
Appetite	0.857	<0.001
Total distress score	0.941	<0.001

### 3.1 Discussion

This study assessed the prevalence and pattern of BPSD among elderly patients with dementia in

three tertiary hospital clinics in Lagos, Nigeria. The preponderance of females in this study is comparable to previous studies on dementia in both developed and developing countries [4,11, 34,35,36].

The reason for the female preponderance in dementia is yet to be fully understood, but the simplest explanation proffered is that of the longer lifespan seen in women [37,38]. Boutstani in Indiana reported that men had the tendency to die earlier than women and attributed the lower prevalence of dementia in males to the difference in mortality between both genders [39].

The mean age of the subjects in this study was 72.4 ±6.49years; comparable to the mean age reported by other hospital based studies [12,37, 40], while a higher mean ages has been reported in community based studies [4,11]. The findings of higher ages in the community based studies may be due to the differences in the setting of the study or; due to the fact that, patients who present to the hospital may have more severe illness necessitating their presentation to the hospital at an earlier age or very old patients are too frail to attend hospital.

**Table 5. Coefficients<sup>a</sup>**

Model		Unstandardized coefficients		Standardized coefficients	T	Sig.
		B	Std. error	Beta		
1	(Constant)	.549	11.005		.050	.960
	GRP marit stat	.161	.814	.010	.198	.844
	GRP Educ Lev	1.257	.935	.141	1.344	.187
	Grouped age	-.335	1.852	-.023	-.181	.857
	Grouped age onset	.108	1.010	.010	.107	.916
	MMSE score grouped	.517	.714	.042	.724	.474
	BDS grouped	-2.148	.800	-.161	-2.686	.011
	Total freqsev	.448	.028	.986	15.815	.000
	Age	.084	.199	.071	.420	.677
	Year education	-.129	.127	-.114	-1.013	.317
	Carersex	-1.445	.976	-.073	-1.481	.147

<sup>a</sup>Dependent variable: Total distress score

The majority of the subjects were married (64%) and lived with their relations (94%). This finding is in keeping with previous findings of a higher rate of family cohesion and integration in developing countries unlike developed countries with a higher rate of institutionalization or living alone [4,11,12,36]. Furthermore, multigenerational living arrangements have been shown to be very common in most developing countries, with very few elderly people living alone [11,12]. Another important finding was the preference of the family members to care for their wards (66%), and the majority (88%) of caregivers stated that care giving was voluntary. However a third (34%) of them desired the opportunity of having their relations being cared for by proxy. This reflects that the choice of institutionalization such as nursing home arrangement or long stay hospital ward could be desired when the family caregivers are overwhelmed by the demands of caregiving. Such facilities are however not readily available in Nigeria.

In the current study; we found a high overall prevalence of Behavioral and Psychological Symptoms of Dementia (96%) in agreement with findings from previous studies. The high rate of BPSD found in our sample is consistent with report both in developed and developing countries. Baliero et al. reported a prevalence rate of 96% among 50 Dementia patients attending a tertiary out-patient clinic using the NPI [40]. In the USA Cache County Study of 198 patients with Dementia, 61% had BPSD [5]. Ikeda and others found that 88.3% of a sample of patients with Dementia in Japan had BPSD [41], while Pollero reported a prevalence of 87.5% in a similar sample in Argentina [42].

In a study conducted in a developing country setting in India, Shaji and colleagues reported that 97% of their sample of patients with Dementia had one or more BPSD [12]. In sub-Saharan Africa, Baiyewu et al reported that the prevalence of BPSD among 40 community dwelling elderly patients with Dementia was 80% [11]. The differences between this present study when compared with the earlier study by Baiyewu et.al in this environment a decade ago generate some interesting observations. Although the category of the subjects was the same being elderly patients 65 years and above, the instruments and methodology are also the same. However, the settings differ and thus the difference in terms of the clinical profile and the level of BPSD.

There is a higher level of BPSD among the hospital based clients (96%) as compared with the 80% reported among the community dwelling elderly people [11]. The most obvious reason for the higher prevalence of BPSD among hospital patients could be more severe behavioral and psychological symptoms necessitating their presentation to the hospital. This would also inform the burden of care and need to seek for help thereby reaching for available.

Interestingly in this current study, the commonest BPSD were hallucinations (68%), agitation (68%), night time behavior (62%) and delusions (60%). This result differs from the Baiyewu et al, study among community based elderly patients with dementia where the commonest BPSD were changes in appetite (42.5%), depression (32.5%), irritability (27.5%) and aggression (20%). This pattern showed milder symptoms which are deemed more tolerable with less

frequency and severity. The total distress score ( $13.40 \pm 7.63$ ) in the current study is higher than that reported in western populations. This may be attributed to the fact that caregivers in western settings may relinquish their care giving role by placing their wards in nursing homes or other long term care facility when they are overwhelmed by their care giving role. They also have available to them, a viable public support system and other independent agencies ready to help this vulnerable group and their caregivers. On the other hand caregivers in Nigeria do not have such options available to them; they enjoy little or no respite from caring for their elderly relatives with dementia. The mean distress score reported in this study is greater than ( $5.63 \pm 6.61$ ) reported by Baiyewu et al understandably from previous line of thought [11]. In the present study, the mean distress score for each of the symptoms reported by caregivers showed the most distressful symptoms to be agitation (mean  $1.78 \pm 1.56$ ) night time behavior (mean  $1.78 \pm 1.43$ ), aberrant motor behavior ( $1.66 \pm 1.59$ ) and delusions ( $1.46 \pm 1.26$ ). These findings converge with that of Baiyewu et al who found a high level of distress among the caregivers with the highest reported for the domains of night time behavior ( $2.86 \pm 1.21$ ), disinhibition ( $2.75 \pm 2.06$ ), anxiety ( $2.50 \pm 0.76$ ) and agitation ( $2.25 \pm 1.28$ ). The level of distress reported by the caregivers of elderly subjects with dementia in the community was high possibly due to no available intervention or lifestyle modification skills among those living with dementia in the community.

Similarly, Tan and colleagues found that the most distressing BPSD symptoms of patients with dementia reported by their caregivers were agitation and disinhibition which is consistent with our findings [43]. Family caregivers were reported to be significantly more distressed than professional caregivers especially over the delusion, agitation, depression and aberrant motor domains. Matsumoto and others also reported that the most distressing symptoms to caregivers of patients with dementia were agitation, delusion, apathy, irritability and aberrant motor behavior, comparable to the findings in this present study [44]. In the study by Baliero and colleagues caregiver distress reported correlation between BPSD and Caregiver Distress in patients with dementia [40]. Similar to this present study, the most distressing symptoms were delusions, depression, agitation, irritability, and aberrant motor disorder. In a cross-sectional hospital based study of caregiver burden among the Taiwanese, the most

distressing symptoms were found to be delusions, agitation, anxiety and irritability [45]. These variations in these pattern of symptoms noted to be the most distressing to caregivers across studies may be attributable to methodological differences such as the setting of the study (hospital versus community based), sample size and ascertainment procedures.

Another important finding of the current study is that on regression analysis, BPSD was the best predictor of caregiver distress. This agrees with reports from previous studies which showed the impact of Behavioral and Psychological Symptoms of Dementia to be increased caregiver distress [16,46]. The finding that BPSD rather than cognitive deficits independently predicted caregiver distress is of clinical importance. Unlike cognitive deficits, which are recalcitrant to treatment, effective interventions are available for BPSD. Therefore, improving access to comprehensive assessment and management of BPSD in patients with dementia is a fundamental step in addressing caregiver distress. With on-going social changes in Nigeria such as the whittling down of the extended family system and multigenerational living, it can no longer be taken for granted that family members will be able to cope with the enormous task of care giving. Alleviating caregiver distress will positively impact on the continuity of informal support for patients with dementia.

#### 4. CONCLUSION

In conclusion, we found a high prevalence of BPSD among elderly out-patients with dementia in Lagos, Nigeria. These findings are consistent with previous reports in the literature especially from hospital-based studies and the burden of BPSD is shown to be higher among hospital patients than those in community. These suggest that BPSD are common globally in patients with dementia, with only a little variation in their pattern from one setting to another. BPSD was also the single best predictor of caregiver distress among the studied sample. Considering the impact of BPSD on dementia, there is need to improve access of patients with dementia to early mental health assessment and interventions, especially in resource poor settings.

Our findings also suggest that improvement on treatment for BPSD among patients with dementia may greatly reduce the burden borne by caregivers. Consequently, interventions to



alleviate caregiver distress should include effective assessment and treatment of BPSD in patients with dementia.

This study was hospital based and may be limited in generalization of findings to the community. However, it provides very useful information in an under-studied population. The strength of the study lies in the rigorous ascertainment of caseness of dementia among the participants. The instruments used also had good psychometric property in our study setting.

### CONSENT

All authors declare that written informed consent was obtained from the patient and their caregivers for the publication of this article.

### ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

### COMPETING INTERESTS

Authors have declared that no competing interests exist.

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