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Research Paper

Impact of pharmacist intervention on antidepressant medication adherence and disease severity in patients with major depressive disorder in fragile north-east Nigeria

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Abstract

Objectives Medication adherence is emerging as a major public health challenge particularly in patients with depression. The aim of this study was to explore the usefulness of a pharmacist intervention to improve antidepressant medication adherence and disease severity in patients with major depressive disorder.

Methods This prospective interventional study was conducted between April 2019 and March 2020 among 101 patients at the Federal Neuro-Psychiatric Hospital, Maiduguri, Nigeria. Consenting patients were randomised into usual care or intervention groups using a computer-generated list. Data were collected at baseline, 3 months and 6 months. Medication adherence and depression severity were assessed using the Medication Adherence Rating Scale and Beck Depression Inventory respectively.

Key findings At baseline, both the usual care and intervention groups had low mean scores for medication adherence [5.22 (SD = 1.51) versus 5.46 (SD = 1.46)] and high mean scores for depression severity [24.16 (SD = 13.50) versus 27.07 (SD = 16.12)]. At 6 months, there was a significant difference ($P < 0.001$) between the mean medication adherence scores of 5.22 (SD = 1.90) and 9.15 (SD = 1.62), in the usual care and intervention groups respectively. A significant difference ($P = 0.033$) was also observed at 6 months between the mean depression severity scores of the usual care and intervention groups [21.40 (SD = 11.52) and 17.34 (SD = 6.96)]. Medication adherence ($P < 0.001$, Partial eta squared = 0.279) and depression severity ($P < 0.001$, Partial eta squared = 0.170) positively changed with time in the presence of the intervention.

Conclusions The intervention significantly improved antidepressant medication adherence and disease severity in patients with major depressive disorder.

Keywords: medication adherence; depression severity; pharmacist's intervention; major depressive disorder; Nigeria

Introduction

Major depressive disorder is one of the most prevalent mental disorders, with an estimate of over 300 million people affected globally.[1] It is associated with functional impairment, decreased quality of life and increased mortality.[2] Ranked as the single largest cause of global disability and suicide deaths, it is now regarded as a major public health concern.[2]

Medication adherence is the extent to which a person's behaviour with regards to his medication corresponds with medical or health advice provided by a health care provider.[3] Medication non-adherence is currently a major global public health challenge, and an estimated 40–50% of patients with chronic medical conditions do not adhere to their medication.[4] In the USA, it is estimated that between 33% and 69% of all medication-related admissions are due to poor adherence, with a resultant cost of approximately 100 billion US dollars per year.[5]

Despite the proven efficacy of antidepressant medication, many depressed patients do not adhere to their treatment regimen. Consequently, observational studies have reported antidepressant discontinuation rates of 28% at 1 month, and between 44% and 52% at 3 months.[6] Non-adherence to antidepressant medication may result in serious consequences such as treatment failure, relapse, complications, physical and mental agony, economic burden and increased pressure on the healthcare system.[6] Inadequate antidepressant adherence is also believed to be an underlying cause in some cases of chronic depression.[7]

Pharmacists have a broad range of useful pharmaceutical care skills that can be utilized during the provision of mental health services to ensure optimal service quality. These skills include medication management, provision of drug information to prescribers, counselling patients about medicines and facilitating medication adherence strategies.[8] Pharmacists can also address common misconceptions about antidepressants, and have been shown to influence patients' attitudes towards depression and improve treatment outcomes.[9]

In Nigeria, estimates of depression or depressive symptoms prevalence range from 4% to 22%,[2] and it is estimated that over 7 million people currently living in the country are depressed.[1] In the last decade, Borno State; located in the north-east region of the country is marred with Boko Haram insurgency which has resulted in over 20 000 deaths and the displacement of over 1.8 million people.[10] One of the long-term effects of insurgency among people is the manifestation of depressive symptoms as a result of witnessing the killing of family members, separation from family and displacement, terror attacks, kidnapping and sexual harassment, participation in violent acts, bombardment, physical injuries and extreme poverty.[10]

A study conducted in the north-eastern part of the country also reported suboptimal adherence to medication in patients suffering from severe mental illnesses including depression.[11] Despite this, while some studies[12, 13] have evaluated the impact of pharmacist interventions on medication adherence in other chronic diseases within the country, to the best of our knowledge none has explored the impact of pharmaceutical care in mental health. Therefore, this study aimed at exploring the impact of a pharmacist intervention on antidepressant medication adherence and disease severity in patients with major depressive disorder.

Method

Study design and sample population

The study was a prospective interventional control trial carried out between April 2019 and March 2020 at Federal Neuro-Psychiatric Hospital (FNPH) Maiduguri, Nigeria. It was a multiphase study and data were collected at baseline, 3 months and 6 months. Included in the study were patients aged 18 years or older, who had been diagnosed with major depressive disorder using ICD-10 criteria and had received pharmacological treatment for at least 6 weeks. They also had no history of; bipolar disorder, drug abuse or dependency, cognitive impairment or other conditions that could make it difficult to collect data from them. Primary study endpoints were differences in medication adherence and severity of depression.

Sample size estimation and sampling technique

Sample size was calculated using a formula described by Chan[14] with the following assumptions: a constant (c) was taken as 7.9 for 80% power, the means difference between the intervention and usual care group was taken as 0.3 units and standard common deviation taken as 0.5. Total participants for the intervention and usual care groups were calculated to be 90. Due to anticipated loss to follow up as observed in a previous study[15] and the humanitarian crisis in the study area; which could contribute to loss to follow up, 33% of the calculated sample size was added and a total of 120 participants were included in the study. Systematic random sampling with sampling interval of two (selecting one patient while skipping 2 on the basis of their arrival on clinic days) was used to select depressed patients attending FNPH Maiduguri's depression clinic on clinic days (Mondays, Tuesdays, Thursdays and Fridays). They were approached by the principal investigator and asked some questions to ascertain their eligibility to participate in the study. Patients who met the eligibility criteria were then informed about the study objectives, and asked whether they would be willing to participate. Consenting patients were randomised into a usual-care group (60) or intervention group (60) using computer-generated random numbers. The random numbers (120) which had already been assigned to usual care (60) or intervention group (60) were written on a paper and sealed individually in a non-transparent envelop. Patients were allowed to pick one envelop and assigned into a usual care or intervention group on the basis of the number in the envelop they picked. Fifty-two patients from the intervention group and 49 patients from the usual-care group completed the study and were included in the final data analysis.

Study instruments

Patient medication adherence

The Medication Adherence Rating Scale (MARS) developed by Thompson *et al*.[16] was used. MARS is a 10-item self-reporting instrument, with each question having a 'yes' or 'no' response. Total score on the MARS ranges between 0 and 10, with a higher score indicating better medication adherence. The scale has good psychometric properties, and satisfactorily predicts non-adherence.[17] The instrument has also been validated for use within the Nigerian setting.[17]

Severity of depression

Severity of depression was assessed using the 21 item Beck Depression Inventory (BDI-II) instrument. Each item is scored on a scale of 0 to 3, and the ratings are summed up to yield a total score that ranges from 0 to 63. A score of 18 or above indicates a depressive disorder, and the higher the total score, the more severe the depressive symptoms. It is widely used and has also been validated for use in Nigeria by an earlier study.[18]

Pharmacist's intervention

The pharmacist intervention included educational counselling sessions of between 15 and 30 min, delivered by the principal researcher through one-on-one discussions with individual patients

(once) after baseline and 3 months' data collection. Patients were also contacted once in every month within the 6 months' period through mobile-phone calls; to know how they were doing with their medications, reinforce information given during the educational counselling sessions, answer their questions if any and remind them of their appointment days. Patient counselling included educating patients about the purpose of their medication, reinforce when and how to take medication, the need for long-term use, the importance of medication adherence and how to deal with possible side effects. Other content of these sessions consisted of strategies to cope with forgetfulness which included; habit-based strategies or involvement of family members, and improving knowledge on what to do when a dose was forgotten. Counselling to cope with lack of motivation was done by reducing the patients' concerns about the potential side effects of their medications and improving medication necessity beliefs. Other drug-related problems were solved by offering solutions/alternatives when possible. Usual care delivered by pharmacists working in the hospital includes: prescription review to ensure that prescribed medications are appropriate, drug dispensing and responding to patient questions if any. Structured guide of the pharmacist intervention is shown in Table 1.

Data collection procedure

Data on medication adherence and severity of depression were collected at baseline, at 3 months and 6 months' periods, by interviewing patients using the data collection instruments in a consulting room at the hospital. Patients in the usual-care group received the usual care offered by the hospital, which included hospital visits on appointments or on sick days, consultations with doctors, review of medications and refilling of prescriptions by patients. This usual care was offered without any additional pharmacist interference. Patients in the intervention group received usual care plus the intervention for 6 months.

Data analysis

Statistical analyses were performed using Statistical Package for Social Science (SPSS) version 20 software (SPSS Inc, Chicago, Illinois, USA). Two-sample comparisons were computed using Student's *t*-tests. Comparisons of proportions were done using chi-square or Fisher's exact tests. A repeated measure ANOVA was used to quantify changes over time. The differences in intervention group and usual-care group were assessed at baseline, 3 months and 6 months. Significance level of $P < 0.05$ was used throughout.

Ethical considerations

Ethical approval for the study was received from the Research and Ethics Committee of Federal Neuro-Psychiatric Hospital Maiduguri (Approval number: FNPH/012019/REC002). Written consent from the participants was also obtained.

Results

Flow of participants through the study

During this study period, out of 140 eligible patients, 120 agreed to participate and 20 were excluded (5 were in critical condition and 15 refused to participate). A total of 49 (81.6%) and 52 (86.6%) participants completed the six months follow-up in the usual care and intervention groups respectively. Reason for loss to follow-up of 19 participants was not known because connection to participants or their care givers was lost (Figure 1).

Participants' socio-demographic characteristics and disease severity

Socio-demographic characteristics of participants revealed that majority of participants in both the usual care (83.7%) and intervention (76.9%) groups were females (Table 2). Most of the participants also fell within the 30–50 year age group (73.4% versus 61.5%), were married (57.1% versus 42.2%), had no formal education (44.9% versus 55.8%) and had moderate (55.1% versus 57.7%) to severe (40.8% versus 38.5%) depression in both the usual care and intervention groups, respectively. No statistically significant differences existed between the groups in terms of their socio-demographic characteristics and disease severity (Table 2).

Participants' responses to the medication adherence rating scale questions

Participants' responses to the MARS questions at baseline, 3 months and 6 months are shown in Table 3. A reduction in the number of participants whose responses demonstrated that they were non-adherent to their medications at 3 months and 6 months was observed in the intervention group when compared to the usual-care group. At baseline, 21 (42.9%) participants in the usual-care group reported that they sometimes forgot to take their medications (question 1). The number increased to 33 (67.3%) and 24 (49.0%) at 3 months and 6 months, respectively. In the intervention group on the other hand, 32 (61.5%) participants reported that they sometimes forgot to take

Table 1 Structured guide of the pharmacist intervention

Intervention	Strategy
Educational counseling sessions	Educational counseling sessions of between 15 and 30 min were delivered by the principal researcher through one-on-one discussions with individual patients (once) after baseline and 3 months' data collection.
Treatment information	This includes educating patients about the purpose of their medication, reinforce when and how to take their medication, the need for long-term use, the importance of medication adherence and how to deal with possible side effects.
Copping with forgetfulness	This was done using habit-based strategies or involvement of family members, and improving knowledge on what to do when a dose was forgotten.
Counseling to cope with lack of motivation	This was done by reducing the patients' concerns about the potential side effects of their medications and improving medication necessity beliefs.
Other drug-related problems	Other drug-related problems were solved by offering solutions/alternatives when possible.
Follow-up contacts	Patients were contacted once in every month within the 6 months' period through mobile phone calls. This is to know how they were doing with their medications, reinforce information given during the educational counseling sessions, answer their questions if any and remind them of their appointment days.

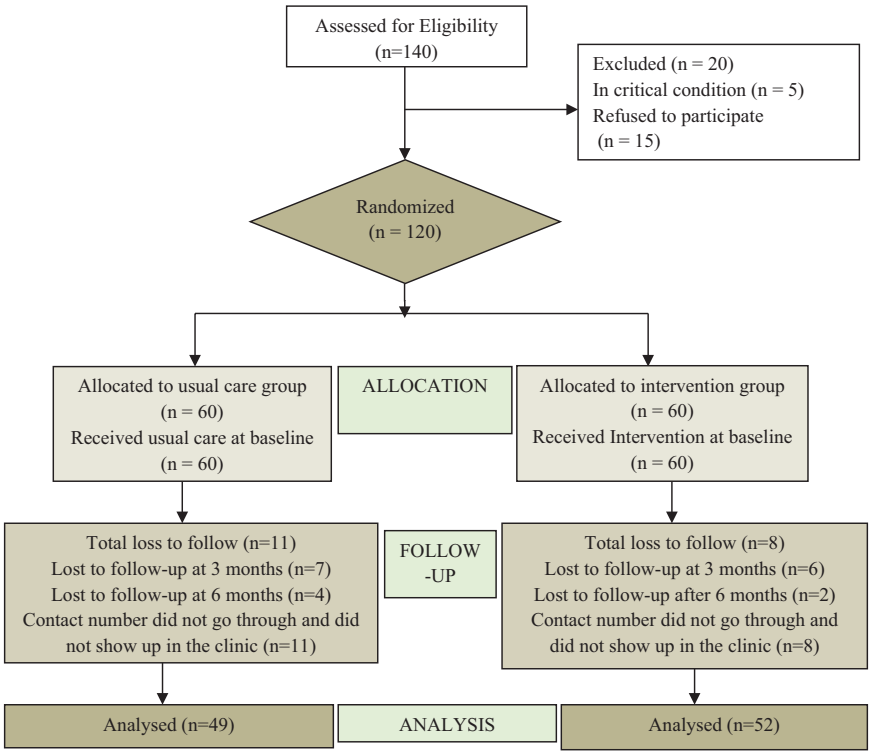

Figure 1 Flow of participants through the study.

their medications at baseline, but the number reduced to 24 (46.2%) and 4 (7.7%) at 3 months and 6 months, respectively (Table 3).

Mean medication adherence and depression severity scores at baseline, 3 months and 6 months

Mean medication adherence and disease severity scores of study participants at baseline, 3 months and 6 months are presented in Table 4. After the intervention, significant improvements in mean medication adherence scores of study participants in the intervention group were observed at 3 months ($P < 0.001$) and 6 months ($P < 0.001$) respectively, while a significant improvement in mean depression severity score ($P < 0.033$) was only observed in the same group at 6 months (Table 4).

Medication adherence and depression severity scores with consideration for time and group

To further evaluate the impact of the intervention on medication adherence, repeated measures ANOVA analyses with consideration for time and group were conducted. Significant improvements in medication adherence and depression severity with time and in groups were observed (Table 5). It was observed that medication adherence significantly changed with time ($P < 0.001$), and this accounted for 27.9% (Partial eta squared = 0.279) of the change depicted. However, the direction of this change depended on the participant group ($P < 0.001$) and 27.6% (Partial eta squared = 0.276) of this change could be explained by interactions between time and group.

Severity of depression also changed with time ($P < 0.001$) and 17.0% (Partial eta squared = 0.170) of the change was explained by time. Even though severity of depression changed with time, the direction of the change also depended on the group ($P = 0.001$) and 7.5% (Partial eta squared = 0. 075) of this change was explained by interactions between time and group (Table 5).

Discussion

This study evaluated the impact of a pharmacist intervention on medication adherence and disease severity in patients with major depressive disorder, at a Neuro-Psychiatric Hospital in fragile north-eastern Nigeria.

Most of the participants in this study were female, were within the age group of 30–50, were married and had either moderate or severe depression. This is consistent with what was observed in a previous study conducted on medication knowledge and beliefs in patients with major depressive disorder.[2] Also, the lack of significant difference between the socio-demographic characteristics and disease severity; of the two groups is an indication that any bias as a result of these variables has been excluded.

Adherence to antidepressant treatment is essential for the effective management of major depressive disorder. Despite this, a large proportion of depressed patients are poorly adherent, with up to 52% of patients discontinuing their medication after 3 months.[19] At baseline, several participants in both the usual care and intervention groups in this study reported that they sometimes forgot to take their medications. They also reported that they stopped taking their medications if they felt worse after taking them or if the medications made them feel tired or sluggish. It has been reported that patients who forget to take their medications are less likely to adhere to their antidepressant medication.[7] Furthermore, poor compliance to antidepressant treatment may be seen after only 15 days if patients develop an adverse effect, or after 20 days if their condition worsens or after 40 days if the response is less than they expected.[7] An appreciable reduction in the number of patients in this study with these complaints was observed in the intervention group after 3 and 6 months respectively.

In this study, there were statistically significant differences between the mean medication adherence scores in both groups, and these changes were also significantly different over time.

Table 2 Socio-demographic characteristics and disease severity of study participant

Variables	Usual care (n = 49)	Intervention (n = 52)	P value
	n (%)	n (%)	
Gender			
Male	8 (16.3)	12 (23.1)	0.395[1]
Female	41 (83.7)	40 (76.9)	
Age group			
<30 years	4 (8.2)	12 (23.1)	0.122[1]
30–50 years	36 (73.4)	32 (61.5)	
>50 years	9 (18.4)	8 (15.4)	
Marital status			
Single	8 (16.3)	16 (30.8)	0.148[2]
Married	28 (57.1)	23 (44.2)	
Divorced	9 (18.4)	5 (9.6)	
Widowed	4 (8.2)	8 (15.4)	
Level of education			
No formal education	22 (44.9)	29 (55.8)	0.063[2]
Primary	9 (18.4)	7 (13.4)	
Secondary	2 (4.1)	8 (15.4)	
Tertiary	16 (32.6)	8 (15.4)	
Working status			
Unemployed	36 (73.5)	44 (84.6)	0.168[1]
Employed	13 (26.5)	8 (15.4)	
Monthly income			
No income	36 (73.4)	44 (84.6)	0.278[2]
<20 000 NGN	4 (8.2)	4 (7.7)	
20 000–50 000 NGN	9 (18.4)	4 (7.7)	
Severity of depression[3]			
Mild	2 (4.1)	2 (3.8)	0.938[2]
Moderate	27 (55.1)	30 (57.7)	
Severe	20 (40.8)	20 (38.5)	

NGN, Nigerian Naira (1 US$ ≈ 360 NGN).
[1]Chi-square test.
[2]Fisher's exact test.
[3]Severity of depression as obtained in patients' folder.

This suggests that pharmacist interventions can improve medication adherence in patients with major depressive disorder. This finding is consistent with results from a systematic review conducted by Rubio-valera *et al.*[20] on the effectiveness of pharmacist care in improving adherence to antidepressants, and another study by Aljumah and Qureshi[6] Both of these studies indicated that pharmacist interventions in the care of patient treated with antidepressants can significantly improve adherence to medication. This study's findings are also similar to results obtained from a randomised controlled study conducted by Aljumah and Hassali[19] on the impact of pharmacist intervention on adherence and measurable patient outcomes among depressed patients in Riyadh, Saudi Arabia.

On the other hand, no significant differences in mean depressive symptom scores were seen in this study's intervention group until after 6 months. Changes in severity of depressive symptoms were also significant over time; however, the effect size was very small. This is an indication that while pharmacist interventions may significantly reduce the severity of depressive symptoms, a minimum of a 6-month intervention may be required to achieve significant improvements. And if a larger effect size is required, a longer duration may be required. This finding is consistent with a study conducted by Canales *et al.*[21] on the outcomes of clinical pharmacy services in a psychiatric inpatient setting, where a significant improvement in severity of depression after pharmacist intervention was observed. Other studies have not reported improvements in severity of depression after pharmacist interventions.[6, 15]

This study has some limitations. Firstly, the study was carried out in one neuropsychiatric hospital (the only federal neuropsychiatric hospital in the north-east region) in Nigeria which may limit the generalizability of the result. Nonetheless, most of our findings are consistent with studies conducted in other settings.[6, 19–21] Secondly, we use subjective methods (self-report scales) to measure patient outcomes which may be subject to social desirability bias. However, we selected all scales carefully and subjective methods appear reliable and correlate with the clinical state of psychiatric patients in clinical practice.

Table 3 Participants' responses to the medication adherence rating scale (MARS) questions

SN	Items	Usual care (n = 49)			Intervention (n = 52)		
		Non-adherent			Non-adherent		
		T0	T1	T2	T0	T1	T2
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
1.	Do you ever forget to take your medicine?	21 (42.9)	33(67.3)	24 (49.0)	32 (61.5)	24 (46.2)	4 (7.7)
2.	Are you careless at times about taking your medicine?	8 (16.3)	4 (8.2)	16 (32.7)	12 (23.1)	8 (15.4)	4 (7.7)
3.	When you feel better, do you sometimes stop taking your medicine?	20 (48.8)	24 (49.0)	16 (32.7)	4 (7.7)	0 (0.0)	0 (0.0)
4.	Sometimes if you feel worse when you take your medicine, do you stop taking it?	21 (42.9)	12 (24.5)	8 (16.3)	16 (30.8)	8 (15.4)	0 (0.0)
5.	I take my medication when I am sick.	36 (73.5)	32 (65.3)	36 (73.5)	36 (69.2)	16 (30.8)	8 (15.4)
6.	It is unnatural for my mind and body to be controlled by medication.	20 (40.8)	25 (51.0)	33 (67.3)	28 (53.8)	20 (53.8)	12 (23.1)
7.	My thoughts are clearer on medication.	20 (40.8)	20 (40.8)	24 (49.0)	24 (46.2)	16 (30.8)	4 (7.7)
8.	By staying on medication I can prevent getting sick.	12 (24.5)	17 (34.7)	12 (24.5)	12 (23.1)	4 (7.7)	0 (0.0)
9.	I feel weird, like a 'zombie', on medication.	40 (81.6)	20 (40.8)	28 (57.1)	39 (75.0)	4 (7.7)	4 (7.7)
10.	Medication makes me feel tired and sluggish.	36 (73.5)	32 (65.3)	37 (75.5)	31(59.6)	24 (46.2)	8 (15.4)

Patients are non-adherent if they respond 'Yes' to items 1–6 and 9–10 and 'No' to items 7–8, T0 = Baseline, T1 = 3 months after baseline, T2 = 6 months after baseline.

Table 4 Mean medication adherence scores and depression severity scores of participants at baseline, 3 months and 6 months

	Usual care	Intervention	*p* value
	Mean (SD)	Mean (SD)	
Medication adherence			
Baseline	5.22 (1.51)	5.46 (1.46)	0.417
3 months	5.53 (2.03)	7.46 (1.34)	$P < 0.001$*
6 months	5.22 (1.90)	9.15 (1.62)	$P < 0.001$*
Depression severity			
Baseline	24.16 (13.50)	27.07 (16.12)	0.392
3 months	23.63 (14.79)	19.71 (10.35)	0.124
6 months	21.40 (11.52)	17.34 (6.96)	0.033*

Independent samples *t*-test: SD, standard deviation.*Significant at $P < 0.05$.

Table 5 Medication adherence and depression severity scores of study participants with consideration for time and group

Source	Baseline	3 months	6 months	*P* value	Partial eta squared
	Mean (SD)	Mean (SD)	Mean (SD)		
Medication adherence					
Time	5.34 (1.45)	6.52 (1.96)	7.24 (2.64)	<0.001*	0.279
Time × group					
Usual care	5.22 (1.51)	5.53 (2.03)	5.22 (1.90)	<0.001*	0.276
Intervention	5.46 (1.40)	7.46 (1.34)	9.15 (1.62)		
Depression severity					
Time	25.66 (14.91)	21.61 (12.79)	19.31 (9.62)	<0.001*	0.170
Time × group					
Usual care	24.16 (13.50)	23.63 (14.79)	21.40 (11.52)	0.001*	0.075
Intervention	27.07 (16.12)	19.71 (10.31)	17.34 (6.96)		

Repeated measures: ANOVA, SD, standard deviation. *Significant at $P < 0.05$.

Conclusion

Pharmacist's intervention significantly improved antidepressant medication adherence and disease severity in patients with major depressive disorder in this study. Enhancing pharmacist involvement in the long-term management of these patients, especially with respect to interventions to optimize adherence will go a long way towards reducing depressive symptoms and improving patient outcomes.

Author Contributions

Hadiza Yusuf- Research concept and design, data collection, data analysis and interpretation, writing the article and final approval of article. Mohammed G. Magaji- Research concept and design, data interpretation, critical revision of the article and final approval of article. Bilkisu B. Maiha- Research concept and design, data interpretation, critical revision of the article and final approval of article. Sani I. Yakubu- Research concept and design, data interpretation, critical revision of the article and final approval of article. Wazis C. Haruna- Research concept and design, data interpretation, critical revision of the article and final approval of article. Shafiu Mohammed- Research concept and design, data interpretation, critical revision of the article and final approval of article.

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Conflict of Interest

The Authors declare that they have no conflicts of interest to disclose.

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