African Journal of Nephrology
Official publication of the African Association of Nephrology
Volume 26, No 1, 2023, 127-134

ARTICLE

Effectiveness of pharmacist intervention in improving medication adherence in patients with chronic kidney disease: a randomised controlled trial in Nigeria

Roland Nnaemeka Okoro[1], Ibrahim Ummate[2], John David Ohieku[1], Sani Ibn Yakubu[1], Maxwell Ogochukwu Adibe[3]

[1]Department of Clinical Pharmacy and Pharmacy Administration, Faculty of Pharmacy, University of Maiduguri. Maiduguri, Nigeria; [2]Department of Medicine, Nephrology Unit, University of Maiduguri Teaching Hospital, Maiduguri, Nigeria; [3]Department of Clinical Pharmacy and Pharmacy Management, University of Nigeria, Nsukka, Nigeria.

ABSTRACT

Background: Chronic kidney disease (CKD) is a global health concern associated with a high risk of cardiovascular disease, end-stage renal failure, and premature death. The interventions of pharmacists in chronic disease management have been promising. However, there is little evidence of their participation in managing CKD, particularly in developing countries. The objective of this study was to evaluate the influence of pharmacists' interventions in improving medication adherence in patients with CKD.

Methods: This double-arm randomised controlled study was carried out at the nephrology outpatient departments of two Nigerian hospitals. Patients with stage 1 to 4 CKD who visited the hospitals between November 2019 and February 2020 were enrolled. Pharmacists' interventions included CKD education, dietary suggestions, medication adherence counselling, and telephonic consultations. The usual care (UC) group served as the control and received only ordinary hospital treatment, whereas the pharmaceutical care (PC) group received usual care in addition to pharmacists' interventions. The influence of pharmacists' engagement was assessed by recording improvements in adherence scores and creatinine levels after 6 and 12 months, respectively. Using standard statistics, the PC and UC groups were compared at the $P < 0.05$ significance level.

Results: A total of 147 patients (74 in the UC and 73 in the PC group, respectively) completed the study. Baseline variables were comparable between the two groups. Pharmacists' interventions achieved significant improvement in mean adherence scores at 12 months in the PC group compared to the UC group (0.2 ± 0.6 vs 0.7 ± 1.3, $P= 0.003$). Also, serum creatinine levels significantly improved in the intervention group compared to the control group at the end of the study (245.9 ± 101.7 µmol/L vs 291.7 ± 140.7 µmol/L, $P = 0.025$). In the adjusted analysis, participants in the PC group were 2.11 times ($P = 0.038$) more likely to achieve excellent medication adherence than their counterparts in the UC group.

Conclusion: Our findings indicate that pharmacists' interventions have the potential to improve medication adherence among patients with CKD.

Keywords: Chronic kidney disease; counselling; education; medication adherence; Nigeria; pharmacist intervention; pre-dialysis.

INTRODUCTION

Chronic kidney disease (CKD) is a significant hazard to global public health due to its rising incidence and prevalence, particularly in poorer countries [1]. An estimated prevalence of 10–13.2% has been reported in Nigeria [2]. CKD is a progressive disease that requires patients to invest considerable time into managing their health, including modifying their diet and lifestyle, taking numerous medications, and attending to medical appointments.

Received 09 February 2022; accepted 21 August 2023; published 14 December 2023.
Correspondence: Roland Nnaemeka Okoro, orolandn@gmail.com.

DOI: https://doi.org/10.21804/26-1-5037.

The medical management of pre-dialysis and dialysis patients involves complex and highly variable pharmacotherapy, including frequent monitoring and evaluation to ensure optimal pharmacotherapy, and adherence to medications. Widespread suboptimal adherence to medications has been reported among patients with CKD in Nigeria [1].

Poor medication adherence, among other factors, may contribute to drug-related problems (DRPs) and morbidity in patients with CKD [3,4]. The documented factors associated with poor adherence among patients with CKD are lack of knowledge of medication, the complexity of the medication regimen, polypharmacy, frequent adjustment to medications, lack of trust in patient perceptions, poor relationship with the physician, lack of family support, and patients' myths and beliefs, among others [5-7]. These findings underscore the need for the involvement of clinical pharmacists in renal care to help improve the health outcome of patients with renal diseases. Improving adherence to medications with a clinical pharmacist is a desirable outcome with this particular patient population. Interventions that advocate the importance of adhering to CKD treatment are shown to achieve better health results [8].

A pharmacist is a critical health professional who can bridge the gaps between patients, providers, and healthcare systems that contribute to suboptimal adherence to medications and other DRPs. The pharmacist can positively influence the overall care of the patient with CKD through the provision of clinical services targeted at the use of safe and appropriate medications. The benefits of pharmacist-led interventions have been recorded in various studies where adherence to medications is broadly evaluated in haemodialysis patients all over the world [5,9,10]. Previous studies in Nigeria have been limited to cross-sectional studies, with the primary goal of determining the prevalence and risk factors for CKD [1,11-16]. The objective of the current study therefore was to evaluate the effect of pharmacists' interventions in improving medication adherence in patients with CKD at to two Nigerian hospitals.

METHODS

Study sites, design and sample size

From November 2019 to January 2021, a prospective, double-blind, randomised, controlled trial was conducted at two major hospitals in Maiduguri, Nigeria. The sample size was calculated online using the Sealed Envelope® power sample size calculator [17]. Based on the available literature at the time of writing the study proposal, the goal was an absolute difference of 40% increase in medication adherence between the two groups at 6 months and 12 months, respectively (60% in the PC group vs 20% in the UC group). Each study group required 33 participants (total sample size = 66) to test this difference with a power of 95% and a two-sided risk of 0.05. At 20% attrition in both groups, the minimum sample size of 66 was revised to yield an adjusted total sample size of 136.

Ethical considerations

The Health Research and Ethics Committees of the two hospitals in the study provided ethical approval. All participants who volunteered to take part in this study provided written informed consent. Patient data confidentiality was maintained at all times, as was complete anonymity.

Study population

Patients who were recruited were aged 18 to 85 years, with CKD at stages 1 to 4, gave voluntary written informed consent, expressed willingness to abide by trial rules, and agreed to be available for the duration of the trial. In contrast, patients with acute renal failure and at CKD stage 5 were excluded. Pregnant or lactating women, post-renal transplant patients as well as those who were HIV-infected, critically ill, and cognitively impaired were also excluded.

Randomisation and masking

Participants were randomised in a 1:1 ratio to usual care (UC) and pharmaceutical care (PC) groups (Figure 1), using computer-generated random numbers stratified by CKD stage by an online Sealed Envelope random number generator [18]. A pharmacist, who was not involved in the study that generated the random numbers, enrolled the participants and assigned them to groups. Enrolled patients were blinded to the profession of the investigators and study groups, and outcome assessors were blinded also to the interventions and groups. The final-year pharmacy students that served as the study assistants were not blinded in any way, but were trained to treat both groups of patients in the same manner. Their roles were to deliver educational interventions to the PC group, and administer the study questionnaire to both UC and PC groups.

Usual care and intervention administered

Participants in the UC group received the hospitals' usual/conventional care from their physicians, pharmacists and nurses, whereas those in the PC group also received usual care from the hospital physicians, pharmacists and nurses plus pharmacists' interventions from the study team for 12 months. The PC group therefore received usual care as well as in-person CKD education, dietary recommendations, and medication adherence counselling and a CKD infographic leaflet at baseline (group education) and after 6

months and 12 months (individualised according to each patient's needs). Additionally, reminders about medication were delivered every two weeks by text messages via cell phone throughout the trial period; participants' phone-in queries and phone-out reinforcement interventions were also addressed throughout the study period. Medication reviews were also performed as needed. All participants came to the research clinic for screening and enrollment, as well as at 6 and 12 months for follow-ups, when they were also re-assessed for serum creatinine and medication adherence.

Definitions

Chronic kidney disease is defined as a decline in kidney function [estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m2] or signs of kidney damage (albuminuria ≥3 mg/mmol or abnormalities in urine sediment or renal imaging) lasting more than three months [19].

Study instrument

The 4-item Morisky–Green–Levine (MGL) scale [20] – which is a self-reporting questionnaire with four questions (items) with yes/no response options – was used to assess medication adherence. The copyright holders granted us permission to use this instrument.

Data collection

At the outset, demographic data such as age, sex, education level, marital status, religion, and employment status were collected. The serum creatinine values were obtained from blood samples collected from participants at baseline, at 6 and 12 months follow-ups, and self-reported medication adherence data were gathered using the MGL questionnaire at each research visit.

Data processing

The estimated glomerular filtration rate was computed using the Modification of Diet in Renal Disease Equation for Adults using serum creatinine for CKD staging. In terms of medication adherence, the response was graded as either "yes", which received one point, whereas a "no" response received zero points. The overall score varied from 0 to 4. Adherence levels were then classified into three categories based on the total score. Zero scores were categorised as excellent (high) adherence, whereas scores of 1–2 and 3–4 were categorised as moderate and low adherence, respectively [20]. For logistic regression analysis, moderate and low adherence categories were pooled together to form a sub-optimal adherence category. Excellent adherence was scored one point, whereas sub-optimal adherence was scored zero.

Data analysis

The study data were analysed using the intention-to-treat (ITT) and per-protocol (PP) approaches. Continuous variables were reported by means ± standard deviation (SD), and categorical variables were represented as crude counts and percentages. Proportional comparisons were carried out using chi-squared or Fisher's exact tests where applicable. The mean values of the two study arms were compared using an independent-sample t-test. A paired-sample t-test was used to examine the mean change within an arm. The multivariable logistic regression analysis was performed to identify potential predictors of excellent medication adherence. In all, P values less than 0.05 were considered statistically significant (2-sided). SPSS for Windows version 21 was used for all analyses.

RESULTS

The UC group received 74 (50%) of the 147 eligible recruited individuals, whereas the PC group comprised 73 (50%). At 6 months, 67 (91%) and 65 (89%) participants in the UC and PC groups, respectively, completed the study. In addition, 50 (68%) and 52 (71%) of the study participants in the UC and PC groups completed the study at 12 months, and only their data were included in the analysis (Figure 1).

The average age of all participants was 53.6 ± 11.9 years (53.3 ± 12.1 years in the UC group vs 53.8 ± 11.7 years in the PC group, P = 0.796). The majorities were within 40–64 years of age (67% in both the UC and PC groups). Eighty-three were females (53% in the UC group and 60% in the PC group). Most were at CKD stage 4 (68% and 69% in the UC and PC groups, respectively). Overall, the baseline characteristics of the study participants in both groups were similar as shown in Table 1.

Outcomes

Changes in medication adherence from baseline to 6 and 12 months were the primary outcomes. Altered serum creatinine levels from baseline to 6 and 12 months were secondary outcomes.

The ITT analysis indicated significantly improved medication adherence in the PC group compared to the UC group at the end of the study (0.2 ± 0.6 vs 0.7 ± 1.3, P = 0.003). Also, the mean creatinine value was significantly improved in the PC group compared to the UC group (245.9 ± 101.7 µmol/L vs 291.7 ± 140.7 µmol/L, P = 0.025). The PP analysis at the end of the study indicated also that the PC group had significantly improved medication adherence compared to the UC group (0.3 ± 0.6 vs 1.0 ± 1.5, P = 0.002) (Table 2).

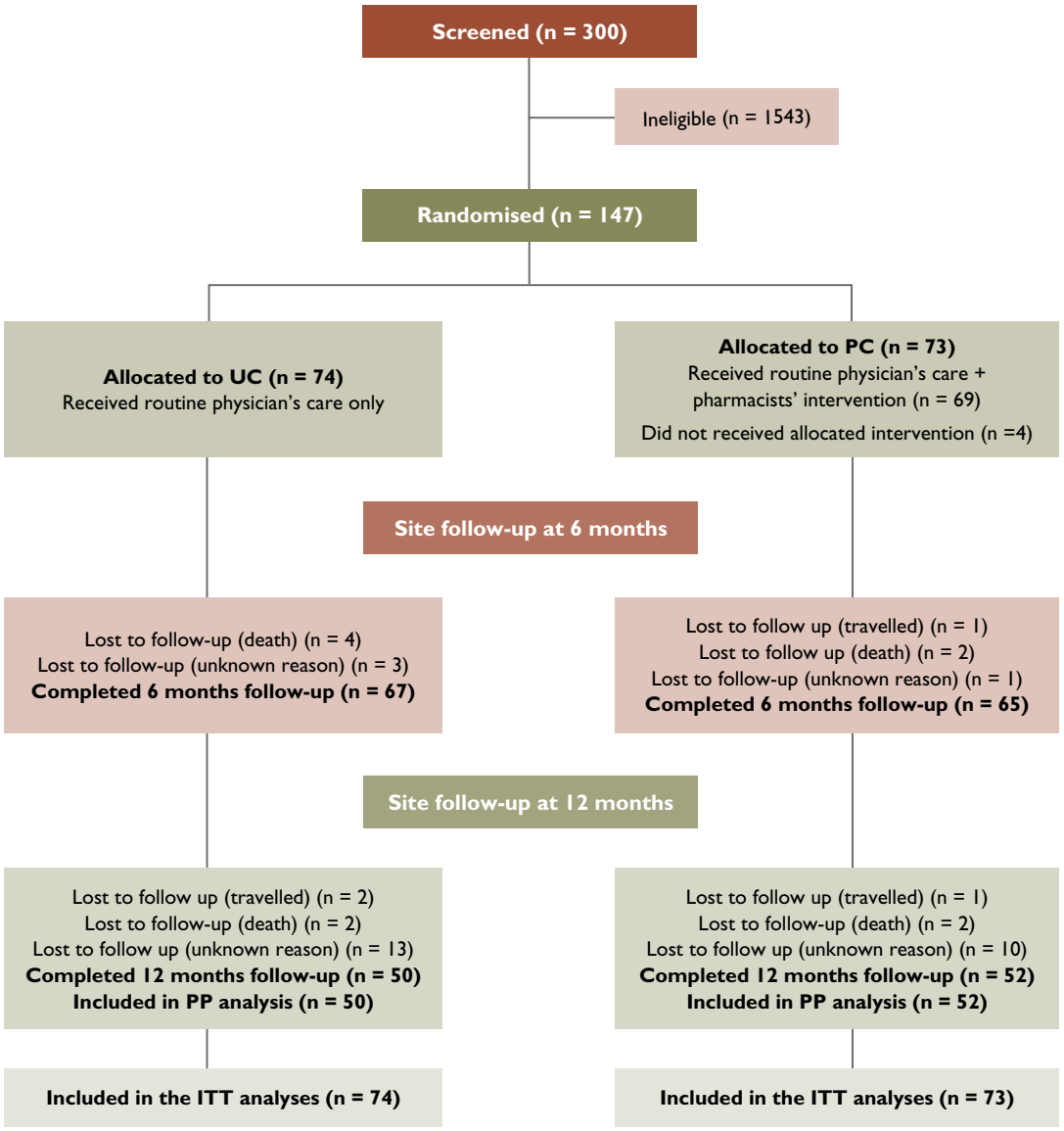

Figure 1. Study flow chart.

Comparison within the PC group indicated that the mean adherence score was significantly improved by 0.51 from baseline to the end of the study. Also, the mean adherence score improved significantly by 0.43 from 6 months to the end of the study. Similarly, the proportion of participants with excellent adherence increased by 80% and 47% from baseline to the end of the study and from 6 months to the end of the study, respectively. Within the UC group, the mean serum creatinine value significantly decreased by 14.85 µmol/L from baseline to 6 months. Conversely, the mean serum creatinine value significantly increased by 49.15 µmol/L from 6 months to the end of the study (Table 3).

Comparisons between groups from baseline to 6 months and 12 months, and from 6 months to 12 months did not reveal any significant increase or decrease in the mean adherence score and mean serum creatinine values in the PC group (Table 4).

In the adjusted analysis for confounders of medication adherence, the study group was found to be a significant predictor of excellent medication adherence with participants in the PC group being 2.11 times (P = 0.038) more likely to achieve excellent adherence than their counterparts in the UC group (Table 5).

Table 1. Baseline characteristics of the study participants.

Variable	Total (n = 147) n (%)	Groups UC (n = 74) n (%)	PC (n = 73) n (%)	P value
Sex				
Male	64 (44)	35 (47)	29 (40)	0.355
Female	83 (57)	39 (53)	44 (60)	
Age group (years)				
<40	21 (14)	10 (14)	11 (15)	0.957
40–64	99 (67)	50 (68)	49 (67)	
≥65	27 (18)	14 (19)	13 (18)	
Marital status				
Single	19 (13)	8 (11)	11 (15)	0.442
Married	128 (87)	66 (89)	62 (85)	
Religion				
Islam	99 (67)	50 (66)	49 (67)	0.954
Christian	48 (33)	24 (32)	24 (33)	
Educational level				
None	47 (32)	24 (32)	23 (32)	0.499
Primary	22 (15)	14 (19)	8 (11)	
Secondary	28 (19)	14 (19)	14 (19)	
Tertiary	50 (34)	22 (30)	28 (38)	
Employment status				
Unemployed	77 (52)	37 (50)	40 (55)	0.561
Employed	70 (48)	37 (50)	33 (45)	
CKD stage				
1	1 (1)	0 (0)	1 (1)	0.818
2	5 (4)	2 (3)	3 (4)	
3	41 (28)	22 (30)	19 (26)	
4	100 (68)	50 (67)	50 (69)	

Table 2. Medication adherence and serum creatinine outcomes of pharmacists' interventions at various times.

Variable	Groups UC (n = 74) Mean (SD)	PC (n = 73) Mean (SD)	P value
ITT (includes LOCF)			
Baseline			
Adherence score	0.8 (1.1)	0.7 (0.9)	0.657
Creatinine (μmol/L)	285.9 (129.2)	274.3 (102.2)	0.548
6 months			
Adherence score	0.7 (1.1)	0.6 (1.0)	0.536
Creatinine (μmol/L)	271.0 (137.7)	255.3 (98.0)	0.427
12 months			
Adherence score	0.7 (1.3)	0.2 (0.6)	0.003
Creatinine (μmol/L)	291.7 (140.7)	245.9 (101.7)	0.025
PP			
End of the study	**n = 50**	**n = 52**	
Adherence score	1.0 (1.5)	0.3 (0.6)	0.002*
Creatinine (μmol/L)	292.4 (109.8)	345.0 (170.5)	0.068

*Independent samples t-test is significant at $P < 0.05$.
Abbreviations: ITT, intention-to-treat; LOCF, last observation carried forward; PP, per protocol; SD, standard deviation.

DISCUSSION

To the best of our knowledge, this is the first study in Nigeria to assess the impact of pharmacists' interventions on medication adherence in pre-dialysis CKD patients. At 12 months, the intervention group had significantly improved mean medication adherence score compared to the UC group. Also, the multivariable logistic regression analysis at the end of the study indicated pharmacists' intervention as an independent significant determinant of excellent medication adherence among patients with CKD.

Table 3. Difference analysis of outcome variables within a group after 6 and 12 months, respectively (n = 147).

Variable	UC						PC					
	0–6 months	P value	0–12 months	P value	6–12 months	P value	0–6 months	P value	0–12 months	P value	6–12 months	P value
Adherence score, mean	0.04	0.820	0.08	0.680	0.04	0.837	0.08	0.535	0.51	0.0001*	0.43	0.002*
Excellent adherence, n (%)	3 (7.5)	–	14 (35.0)	–	11 (25.6)	–	8 (22.9)	–	28 (80.0)	–	20 (46.5)	—
Creatinine, mean (µmol/L)	–14.85	0.045*	34.30	0.153	49.15	0.045*	0.19	0.284	0.28	0.117	9.43	0.539
Target creatinine, n	5	–	2	–	3	–	7	–	9	–	2	—

*Paired sample t-test is significant at P < 0.05.
Abbreviations: UC = usual care; PC = pharmaceutical care.

Table 4. Difference-in-difference analysis of outcome variables between arms at 6 and 12 months, respectively (n = 147).

Variable	0–6 months	P value	0–12 months	P value	6–12 months	P value
Mean adherence score diff. (PC–UC)	–0.04	0.851	–0.43	0.066	–0.38	0.108
High adherence diff. (PC–UC), n	5	–	14	–	9	–
Mean creatinine diff. (PC–UC), µmol/L	4.16	0.827	34.26	0.090	30.26	0.080
Target creatinine diff. (PC–UC), n	2	–	7	–	2	–

*Independent samples t-test is significant at P < 0.
Abbreviations: UC = usual care; PC = pharmaceutical care.

Table 5. Factors associated with medication adherence at the end of the study (multivariable logistic model) (n = 147).

Variable	Crude OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Age group (years)				
<40	1.00		1.00	
40–64	1.26 (0.45–3.53)	0.656	1.28 (0.41–4.02)	0.666
≥65	0.96 (0.28–3.28)	0.954	0.74 (0.19–2.92)	0.671
Sex				
Male	1.00		1.00	
Female	0.77 (0.40–1.49)	0.44	0.59 (0.28–1.24)	0.165
Educational level				
None	1.00		1.00	
Primary	0.61 (0.20–1.80)	0.367	0.60 (0.19–-1.91)	0.387
Secondary	1.01 (0.40–2.55)	0.98	1.12 (0.40–3.17)	0.829
Tertiary	0.80 (0.36–1.79)	0.59	0.79 (0.32–1.96)	0.614
Marital status				
Single	1.00		1.00	
Married	0.74 (0.28–2.00)	0.552	1.53 (0.50–4.61)	0.455
Religion				
Islam	1.00		1.00	
Christian	0.66 (0.34–1.29)	0.226	0.62 (0.30–1.30)	0.205
Employment status				
Unemployed	1.00		1.00	
Employed	1.08 (0.57–2.07)	0.808	0.93 (0.44–1.98)	0.851
CKD stages				
1–2	1.00		1.00	
>2	0.91 (0.48–1.75)	0.781	0.97 (0.48–1.95)	0.932
Study groups				
UC	1.00		1.00	
PC	1.88 (0.98–3.62)	0.059	2.11 (1.04–4.27)	0.038*

*Independent samples t-test is significant at P < 0.
Abbreviations: UC = usual care; PC = pharmaceutical care.

Within the PC group, medication adherence improved significantly from baseline to 12 months. Similarly, the intervention group had significantly improved mean serum creatinine values compared to the UC group at the end of the study.

The PC group showed improved mean medication adherence scores at the end of the study following pharmacists' interventions. These findings reflect previous results indicating correspondingly increased medication adherence [5,6,21,22]. Also, the adjusted regression analysis revealed pharmacists' intervention as an independent significant determinant of excellent medication adherence. Participants in the PC group were 2.11 times more likely to show excellent medication adherence at the end of the study than those in the UC group. Our findings, which are consistent with earlier data, highlight the critical role of pharmacists in chronic disease management. In chronic diseases, poor medication adherence is seen as a major drug-related issue, as it is connected with an increase in emergency room visits, hospitalisations, and unsatisfactory clinical outcomes, all of which place additional strains on the healthcare system. We believe that involving clinical pharmacists in CKD management through pre-dialysis education programmes could enhance patients' medication adherence, which in turn could lead to a better prognosis, improved quality of life, and a lower healthcare burden.

Furthermore, it is worth noting that significant improvement in serum creatinine was noted at the end of the study in the PC group compared to the UC group. This finding may be linked to improved medication adherence observed at this time. This result is in agreement with that of a previous study on pharmacist-led interventions in a CKD population [22], which reinforces the case for the inclusion of a renal pharmacist as a critical member of a hospital's renal care team.

Within the PC group, medication adherence significantly improved from baseline to 12 months; there was also a slight increase in the mean creatinine value, which was not significant. This result shows that pharmacists' interventions have the capacity to improve medication adherence in the long term.

Strengths and limitations

This is Nigeria's first report on medication adherence strategies in CKD involving pharmacists. The minor differences in baseline demographics between the two study groups support the internal validity of their comparison, implying that the study findings might be applied to a similar population. This investigation was strengthened by the use of a randomised procedure for classifying patients into groups, which helped to remove or reduce participant selection bias. Also, the study's strengths were the long period of follow-up and the multi-centred study design. Furthermore, the follow-up of patients with CKD via telephone to reinforce medication adherence was used for the first time in Nigeria. Despite these positive attributes, the study has limitations. Medication adherence data were self-reported, although the reporting tool used was valid and accurate. The possibility that participants in the intervention group may have discussed the nature of the interventions with their counterparts in the control group cannot be totally ruled out, which may have introduced information bias. However, our study's findings will be critical in promoting the role of clinical pharmacists in renal care in Nigeria, in ways which are currently ignored. Future research is needed to confirm the efficacy of such interventions in clinical pharmacy practice.

CONCLUSION

Our findings show that pharmaceutical care as described here improves medication adherence among patients with CKD. Because dialysis facilities and transplant treatments are limited in Nigeria, pharmaceutical care of this kind may help patients with CKD to live longer without dialysis. Pharmacist involvement in renal care will not only improve patient health outcomes but will also help to recognise the importance of renal pharmacists in the Nigerian healthcare delivery system. Future research should investigate the cost-effectiveness of pharmacists' interventions among CKD patients.

Acknowledgements

The authors extend their heartfelt appreciation to all participants, particularly those who finished the study, for their dedication and diligence. We also thank pharmacists Lahai Umar, Zimboh Adamu and Emmanuel Peters for their help with intervention and data collection at each research clinic visit. Mr Obinna Okereke is also appreciated for his assistance in data gathering and patient bleeding.

Conflict of interest

The author has no conflict of interest to declare.

Funding

This study was funded by the Tertiary Education Trust Fund of the Ministry of Education of Nigeria.

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