Original Research

Impact of pharmacist-led care on glycaemic control of patients with uncontrolled type 2 diabetes: a randomised controlled trial in Nigeria

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Abstract

Background: Diabetes mellitus is a chronic, degenerative disease, requiring a multi-dimensional, multi-professional care by healthcare providers and substantial self-care by the patients, to achieve treatment goals.

Objective: To evaluate the impact of pharmacist-led care on glycaemic control in patients with uncontrolled Type 2 Diabetes

Methods: In a parallel group, single-blind randomised controlled study; type 2 diabetic patients, with greater than 7% glycated haemoglobin (A1C) were randomised into intervention and usual care groups and followed for six months. Glycated haemoglobin analyzer, lipid analyzer and blood pressure monitor/apparatus were used to measure patients' laboratory parameters at baseline and six months. Intervention group patients received pharmacist-structured care, made up of patient education and phone calls, in addition to usual care. In an intention to treat analysis, Mann-Whitney U test was used to compare median change at six months in the primary (A1C) and secondary outcome measures. Effect size was computed and proportion of patients that reached target laboratory parameters were compared in both arms.

Results: All enrolled participants (108) completed the study, 54 in each arm. Mean age was 51 (SD 11.75) and majority were females (68.5%). Participants in the intervention group had significant reduction in A1C of -0.75%, compared with an increase of 0.15% in the usual care group (p<0.001; eta-square= 0.144). The proportion of those that achieved target A1C of <7% at 6 months in the intervention and usual care group was 42.6% vs 20.8% (p=0.02). Furthermore, intervention patients were about 3 times more likely to have better glucose control; A1C<7% (aOR 2.72, 95%CI: 1.14-6.46) compared to usual care group, adjusted for sex, age, and duration of diabetes.

Conclusions: Pharmacist-led care significantly improved glycaemic control in patients with uncontrolled T2DM.

Keywords

Diabetes Mellitus, Type 2; Glycemic Control; Pharmacists; Pharmaceutical Services; Patient Education as Topic; Blood Glucose; Glycated Hemoglobin A; Intention to Treat Analysis; Randomized Controlled Trials as Topic; Nigeria

INTRODUCTION

Type 2 Diabetes mellitus (T2DM) is a complex, chronic, multi-dimensional, degenerative disease, requiring multi-professional approach by healthcare providers and a substantial self-care practice by the patients, to achieve desired care outcomes.[1] Approximately 463 million people were affected globally in 2019 and the disease is projected to increase by 2045 to 700 million, with 79% adults (20-79 years) living with diabetes in low- and middle-income countries (LMICs).[2] The prevalence of diabetes mellitus (DM) in African was 3.9% as at the end of 2019 and is expected to rise by 2045 to 47 million.[2,3] Approximately 5.8% of Nigerians had DM as at 2018.[4] Systematic reviews and meta-analysis of randomised controlled trials have demonstrated the effects of pharmacist-led care in patients with T2DM, but majority of these studies were conducted in high income countries (HICs) and only complimented by few from LMICs.[4-12] Literature search identified four published randomised-controlled trials among patients with DM in Nigeria within the last decade.[13-17] None of the study was done in the northern part of the country.[18] The study conducted in southwest Nigeria was a quasi-experimental non randomised clinical trial to assess adherence among T2DM Patients.[13] Adibe and colleagues in southeast Nigeria focused on the impact of pharmacist intervention on patients' quality of life and cost-utility analysis of pharmaceutical care interventions while the two studies from the south zone compared intensive diabetes self-management education (DSME) programme with conventional education model and assessed pharmacist intervention using 2 hours post-prandial glucose control, in addition to mean fasting blood sugar. The methods are subject to poor reproducibility and glucose variability errors.[14-19] This study aimed at assessing the impact of pharmacist-led care on glycaemic control of patients with uncontrolled T2DM, receiving care in a teaching hospital in northern Nigeria.

METHODS

Study design

This was a concurrent parallel group single-blinded randomised controlled study, consisting of 108 subjects with uncontrolled T2DM. Fifty-four participants each were randomly assigned to intervention and usual care groups, using computer random number generator.

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Study setting

This study was conducted at the out-patients diabetic clinic of Abubakar Tafawa Balewa University Teaching Hospital (ATBUTH), Bauchi State Nigeria. The hospital is a tertiary health facility, with 700 bed spaces and serves as a referral centre to other hospitals in the state and beyond. The clinic holds every Wednesdays, with nine medical doctors, two nurses and four auxiliary staff, attending to an average of 100 patients. The study was conducted between November 2017 and January 2019, with 6-month follow-up period.

Study population or participants

Inclusion criteria:

i. clinically diagnosed T2DM patients with greater than or equal to 7% glycated haemoglobin (A1C)[20]

ii. patients with atleast 6 months regular clinic attendance prior to recruitment

iii. patient who were 18 years of age or older

iv. patients taking one or more anti-diabetic medication for atleast 6 months

Exclusion criteria:

i. critically ill or unconscious patients

ii. patients with blood disorders (lymphocytic leukaemia, haemolytic anaemia, haemoglobinopathy, chronic)

iii. patients undergoing haemodialysis, and on erythropoietin therapy or haematinic medications

iv. pregnant women with diabetes mellitus

v. patients without mobile phone number

Description of interventions

Participants randomised to intervention group received two consecutive 30 to 45 minutes face-to-face interview and educational sessions. The lead researcher, a clinical pharmacist and qualified diabetes educator (International Diabetes Federation Certified), had exclusive interview and structured teaching sessions with eligible subjects at baseline and month three (3rd month) in a consulting room at the diabetic clinic of the hospital. A few of the participants were accompanied by family members. Each participant in the intervention group was provided with diabetes-related information, risk factors, complications, importance of healthy diet, physical activity, self-monitoring of blood glucose, adherence to prescribed medications, lifestyle modifications and management of hypoglycaemia. Furthermore, a copy of the educational package was given to each participant for reference and guidance (Online appendix). They were followed up via mobile phone calls/text messages every 6 weeks to review previous session(s) and to be reminded of their clinic appointment date for data collection.

Participants in the usual care group received care from physicians, nurses and medication refill at the pharmacy department. They were interviewed by the clinical pharmacist and assessed at baseline, but were not provided with active intervention. Phone calls were made to remind them of their clinic appointment for data collection.

Data collection

Baseline socio-demographic (age, gender, marital status, level of education, occupation, height and weight), clinical and biochemical characteristics of participants were obtained using a pre-designed data collection form via face-to-face interview session.

Alcohol consumption was rated as non- or occasional drinkers for participants who ingest less than 1 bottle of alcohol in a month, moderate drinkers for individuals who consumed three bottles or less per week while heavy drinkers referred to those who ingested more than three bottles weekly. All participants who have ever smoked were classified as smokers while non-smokers were those who never smoked in their lifetime. Physical activity was stratified into three: low activity (<30 minutes per week), moderate activity (30 to 60 minutes per week) and regular activity (≥150 minutes per weekly), while the family history of diabetes referred to participants whose father, mother, uncle or aunt were ever diagnosed with diabetes.

Each patient's blood pressure reading was measured using sphygmomanometer and stethoscope. Glycated haemoglobin and lipid profile tests were conducted by the research pharmacist using a Clover A1C Analyzer (EuroMedix®) and lipid profile analyzer (Lipidplus®). A skilled laboratory scientist took a 5ml sample of venous blood from each patient, which was immediately processed by the research pharmacist, and the results were entered in the data collection form. Patients' weight and height were measured with a weighing scale and a stadiometer, and the body mass index (BMI) was calculated by dividing weight in kilograms (kg) by height in meters squared (m^2).[21] Data was collected at baseline and six months into the intervention period.

Primary outcome measure

Glycaemic control was the primary outcome of this study, as measured by change in glycated haemoglobin (A1C) from baseline (0 month) to 6 months after intervention and proportion of patients achieving target A1C of <7% at 6 months.[20] The baseline A1C was measured during the initial interview session for all patients, and the next values were obtained 6 months after the trial began and noted in the pre-designed data collecting form.

Secondary outcome measures

The secondary outcomes included fasting blood glucose (FBG), systolic blood pressure (SBP), diastolic blood pressure (DBP), total cholesterol, high density lipoproteins (HDL-C), low density lipoproteins (LDL-C), triglycerides, BMI (height and weight) and prescribed medications.

Sample size determination

The sample size was determined using RCT-specific formula as shown below:

$$m = \frac{2c + 1}{\partial^2}$$

Where:

m = sample size per group

δ =|μ2-μ1|/σ = the standardized effect size

|μ-μ| = the means of the 2 treatment groups (difference the investigator wishes to detect)

σ = the common standard deviation

c = 7.9 for 80% and 10.5 for 90% power: 7.9 represent the factor for estimation at 80% power.[22]

Evidence in literature suggests that 0.9% mean difference in A1C at 1.5 standard deviations could be detected using 80% (7.9) power for 0.05 level of significance.[23-25] Thus, using a sample frame of approximately 200 patients with uncontrolled T2DM, a sample size of 45 participants each was estimated for intervention group and usual care group respectively, making a total of 90 participants. However, an attrition rate of 20% was anticipated leading to the estimation of 108 participants which were randomly assigned to intervention group and usual care groups.[26]

Randomisation and blinding

Participants were recruited based on the study inclusion criteria and given unique identity numbers generated using Microsoft Excel. Numbers having a maximum of six digits were labeled as 'A', while those with fewer than six digits were labeled as 'B'. The intervention group was assigned to one arm, while the usual care group was assigned to the other. The participants were interviewed individually by the lead researcher, but they were not told who would get an intervention. They were just given general information about the study in order to obtain their consent and cooperation for the duration of the investigation. Participants were unaware of their group allocation, but

Table 1. Socio-demographic and clinical characteristics

Characteristics	Treatment group; n (%)		Total n (%)	Chi-square (p-value)
	Intervention	Usual care		
Gender				0.10
Female	33 (61.11)	41 (75.93)	74 (68.52)	
Male	21 (38.89)	13 (24.07)	34 (31.48)	
Age in years				0.52[a]
Mean (SD)	51.54 (11.75)	50.09 (11.66)	50.81 (11.67)	
Marital status				0.28
Single	6 (11.11)	10 (18.52)	16 (14.81)	
Married	48 (88.89)	44 (81.48)	92 (85.19)	
Education				0.25
NFE	24 (44.44)	26 (48.15)	50 (46.3)	
Primary	4 (7.41)	10 (18.52)	14 (12.96)	
Secondary	12 (22.22)	8 (14.81)	20 (18.52)	
Tertiary	14 (25.93)	10 (18.52)	24 (22.22)	
Occupation				0.73
Unskilled worker	9 (16.67)	8 (14.81)	17 (15.74)	
Skilled Worker	13 (24.07)	11 (20.37)	24 (22.22)	
Student	0 (0)	1 (1.85)	1 (0.93)	
No paid Job	32 (59.26)	34 (62.96)	66 (61.11)	
DOD (years)				0.78[b]
Median (IQR)	7 (3-9)	5.5 (3.8-9.0)	6 (3.0-9.0)	
BMI (Kg/m^2)				0.94
Underweight	2 (3.7)	2 (3.7)	4 (3.7)	
Normal Weight	17 (31.48)	14 (25.93)	31 (28.7)	
Over weight	23 (42.59)	25 (46.30)	48 (44.44)	
Obese	12 (22.22)	13 (24.07)	25 (23.15)	
Alcohol Consumption				0.60
Occasional/Non-Drinker	52 (96.3)	53 (98.15)	105 (97.22)	
Light Drinker	1 (1.85)	1 (1.85)	2 (1.85)	
Heavy Drinker	1 (1.85)	0 (0.00)	1 (0.93)	
Smoking Status				
Non-Smoker	54 (100)	54 (100)	108 (100)	
Activity level				0.58
Low activity	45 (83.33)	43 (79.63)	88 (81.48)	
Moderate Activity	9 (16.67)	10 (18.52)	19 (17.59)	
Regular Activity	0 (0.00)	1 (1.85)	1 (0.93)	
Family History of DM				
Not Present	13 (24.07)	20 (37.04)	33 (30.56)	0.32
Present	31 (57.41)	27 (50.00)	58 (53.7)	
Not sure	10 (18.52)	7 (12.96)	17 (15.74)	
Hypertension				1
Not Present	14 (25.93)	14 (25.93)	28 (25.93)	
Present	40 (74.07)	40 (74.07)	80 (74.07)	
Dyslipidemia				0.14
Not Present	11 (20.37)	15 (33.33)	26 (26.26)	
Present	43 (79.63)	30 (66.67)	73 (73.74)	

[a]Independent t-test, SD – Standard Deviation, NFE – No Formal Education
[b]Mann-Whitney U test, DOD: Duration of Diabetes, BMI: Body Mass Index

Table 2. Medication utilization at baseline		
	N	**%**
Anti-diabetes medication		
Metformin	183	91.5
Glibenclamide	98	49.0
Pioglitazone	63	31.5
Glimeperide	39	19.5
Insulin	24	12.0
Metformin/Sitagliptin	10	5.0
Glicazide	8	4.0
Anti-lipidaemic medication		
Rosuvastatin	2	1.0
Atorvastatin	9	4.5
Blood pressure medication		
Atenolol	1	0.5
Spironolactone	2	1.0
Carvedilol	2	1.0
Losartan	13	6.5
Nifedipine	16	8.0
Bendrofluazide-Furosemide	21	10.5
Amlodipine	65	32.5
Lisinopril	111	55.5

those in the intervention group were recognized by the pharmacist using their unique IDs and given the comprehensive pharmacist intervention package. They were also told not to tell other patients about their knowledge.

Ethical consideration

The study protocol was approved by the research and ethics committee of the hospital (REC No. 08/10/2017). All participants signed the informed consent form and were assigned unique identification numbers to ensure confidentiality of their personal information.

Trial Registration: This trial was registered with the Pan African Clinical Trial Registry and was assigned trial registration number PACTR202010543945594.

Statistical analysis

Statistical package for social sciences (SPSS) Version 23.0 (IBM Corp, Armonk, NY, USA) was used to assess baseline and final data. After an initial exploratory analysis with normality test, the continuous variables were reported as median and interquartile ranges. Categorical variables were expressed in frequencies/proportions and compared using Chi square test. In a six-month intention to treat analysis, group comparison of median change from baseline in the primary outcome measure (A1C) and secondary outcomes of fasting blood glucose, blood pressure, total cholesterol, triglycerides, LDL-C and HDL-C was performed using Mann-Whitney U-test. Effect size was computed using an online epidemiological calculator and the proportion of patients that reach goal laboratory values of outcomes (<7% A1C, <7.0 mmol/L fasting blood glucose, <140/90mmHg blood pressure, <5.2 mmol/L total cholesterol, <1.7mmol/L triglycerides, <2.6mmol/L LDL-C and >1.3 mmol/L HDL-C) were compared and odds ratio computed.[20,27] Finally, a multivariable logistic regression model was used to correct the effect of several non-modifiable independent factors such as age, gender, and diabetes duration on the dichotomized dependent variable A1C (<7% A1C and ≥7% A1C)). The confounders were chosen based on an understanding of their impact on glycaemic control.

RESULTS

A total of 200 patients with hyperglycaemia (FBG ≥7mmol/L) were assessed for eligibility using glycated haemoglobin (A1C) measure and 108 patients with 7% or higher A1C measure were recruited for the study, comprising 54 subjects in intervention and 54 subjects in usual care group. Ninety-eight participants were excluded based on various reasons; 63 had less than 7% A1C, 15 did not have mobile phone for communication, 9 had type 1 diabetes and 5 were newly diagnosed diabetic patients (less than six months before the commencement of study).

Table 1 shows that there was no difference in the demographic and baseline clinical characteristics of participants in the intervention and usual care group. More females participated in the study compared to males (68.5% vs 31.5%) and 85.2% were married, with a mean age of 51.8 years. Majority (46.3%) had no formal education and 61.1% denied engagement in a paid job.

Majority of the study participants have had diabetes for more than five years, with 67.6% being overweight/obese and less than 1% engaged in regular physical activity. Hypertension (73.7%) and dyslipidaemia (74.1%) were commonly reported among the patients and more than half (53.0%) had family history of diabetes mellitus (Table 1).

Metformin was the most prescribed anti diabetes agent in the studied population (91.5%), closely followed by sulphonylureas (72.5%) comprising of glibenclamide (49.0%), glimepiride (19.5%) and gliclazide (4.0%). Pioglitazone was more prescribed (31.5%) ahead of insulin injection (12%) and fixed-dose combination (5.0%) of sitagliptin-metformin (Table 2). Over 60% of the participants received anti-hypertensive medications, while only 5.5% had anti-lipideamic prescriptions (Table 2).

All participants had higher than normal levels of A1C (>7%) at baseline, but at the end of six months. The intervention group achieved a significantly greater reduction in A1C level while patients in the usual care group experienced an increase (-0.75% vs +0.15%; p<0.001), with a large effect size of eta-square=0.144. Patients in the intervention group achieved slight, but not significant improvement in low density lipoproteins and high-density lipoproteins while a significant reduction (p=0.02) was observed in the triglycerides of patients in the usual care group at six months (Table 3)

The proportion of patients who achieved the American Diabetes Association (ADA) goal of <7% A1C in the intervention group was significantly higher compared to usual care group (42.6% vs 20.8%; p=0.02; p<0.001), but the proportion of patients who achieved ADA goal of <7.0mmol/L FBG was not significant (0.24%) between the groups. The percentage of patients who achieved JNC-8 standard blood pressure for diabetic patients (<140/90mmHg) were equal (57.4%; 57.4%) for both groups, while the proportion of intervention patients on target for total cholesterol (81.1%; n=43) and triglycerides (64.8%; n=35) at 6 months post intervention were significantly higher (p<0.05) compared to usual care patients (Table 4)

The adjusted odds ratio of factors associated with glycaemic control at six months follow-up showed that

Table 3. Comparison of change in biochemical parameter at six months

Parameter	N	Median (IQR) change from baseline (Baseline value minus six months value)	Type of change	Mann-Whitney U	p-value	Eta-squared
A1C (%)				815.500	<0.001*	0.144
Intervention	54	0.75 (0.2 - 1.5)	Decrease			
Usual care	54	-0.15 (-0.95 - 0.5)	Increase			
FBG (mmol/L)				786.500	<0.001*	0.158
Intervention	54	2 (0.98 - 5.88)	Decrease			
Usual care	54	0.05 (-1.23 - 1.95)	Decrease			
SBP (mmHg)				1267.500	0.234	0.013
Intervention	54	0 (-10 - 10)	Decrease			
Usual care	54	0 (-10 - 10)	Decrease			
DBP (mmHg)				1184.500	0.082	0.026
Intervention	54	-5 (-10 - 0)	Increase			
Usual care	54	0 (-10 - 6.25)	Decrease			
LDL-C(mmol/L)				1232.500	0.165	0.018
Intervention	54	0.3 (-0.33 - 0.53)	Decrease			
Usual care	54	-0.1 (-0.33 - 0.4)	Increase			
TG (mmol/L)				1070.000	0.017*	0.053
Intervention	54	-0.15 (-0.3 - 0.2)	Increase			
Usual care	54	0.1 (-0.2 - 0.4)	Decrease			
HDL-C(mmol/L)				1178.500	0.082	0.027
Intervention	54	-0.1 (-0.3 - 0.1)	Increase			
Usual care	54	0 (-0.2 - 0.2)	Increase			
TC (mmol/L)				1415.000	0.791	0.001
Intervention	54	-0.05 (-0.43 - 0.3)	Increase			
Usual care	54	0.1 (-0.53 - 0.2)	Decrease			

Interpretation of Eta squared 0-0.003, no effect; 0.01-0.022, small effect, 0.06-0.110, 0.14-0.2, large effect.*Statistical significance, FBG: Fasting Blood Glucose, A1C: Glycated Haemoglobin, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, LDL-C: Low Density Lipoprotein-Cholesterol, Triglycerides, HDL-C: High Density Lipoprotein-Cholesterol, TC: Total Cholesterol, Increase or Decrease signifies higher levels or reduction in the proportion of a given parameter

patients who received pharmacist care were approximately 3 times more likely to have better glucose control compared to the usual care group (aOR 2.718; 951CI: 1.143-6.461) (Table 5).

DISCUSSION

This study was a randomised controlled trial led by a clinical pharmacist and qualified diabetes educator (International Diabetes Federation Certified), who provided diabetes-related educational intervention, adherence counseling and follow up support to patients with uncontrolled T2DM. This study provided for the first time in northern Nigeria evidence of the impact of pharmacist-led care on glycaemic control in diabetic patients after 6 months follow-up. There was a significant reduction observed in A1C levels of patients in the intervention group, from 8.05% to 7.3% (-

Table 4. Proportion of participants with target level of biochemical parameter at six months stratified by intervention and usual group

Parameter (Normal value)	N	Normal level of parameter N (%)	High level of parameter N (%)	p-value	OR (95%CI)
A1C (< 7%)				0.020*	2.83 (1.2 - 6.66)
Intervention	54	23 (42.6)	31 (57.4)		
Usual care	53	11 (20.8)	42 (79.2)		
FBG(<7mmol/L)					
Intervention	54	3 (5.6)	51 (94.4)		
Usual care	54	0 (0.0)	54 (100)		
BP (<140/90 mmHg)				1.0	1 (0.46 - 2.14)
Intervention	54	31 (57.4)	23 (42.6)		
Usual care	54	31 (57.4)	23 (42.6)		
LDL-C (mmol/L)				0.610	0.82 (0.38 - 1.77)
Intervention	54	24 (44.4)	30 (55.6)		
Usual care	53	21 (39.6)	32 (60.4)		
TG (mmol/L)				0.030*	0.43 (0.2 - 0.94)
Intervention	54	35 (64.8)	19 (35.2)		
Usual care	54	24 (44.4)	30 (55.6)		
HDL-C(mmol/L)				0.35	0.64 (0.26 - 1.63)
Intervention	54	14 (25.9)	40 (74.1)		
Usual care	54	10 (18.5)	44 (81.5)		
TC (mmol/L)				0.010*	0.33 (0.14 - 0.81)
Intervention	54	43 (81.1)	10 (18.9)		
Usual care	54	32 (59.3)	22 (40.7)		

*statistical significance
OR=Odds ratio; CI=Confidence interval

Table 5. Adjusted analysis of factor associated with glycaemic control at six months			
Exposure variable	**aOR**	**95%CI. for aOR**	***p*-value**
Females compared to males	0.755	0.302 - 1.886	0.547
Age in years	1.015	0.977 - 1.054	0.449
Duration of diabetes in years	0.967	0.876 - 1.069	0.515
Group (Intervention compared to control)	2.718	1.143 - 6.461	0.024
aOR, adjusted odds ratio; CI, confidence interval			

0.75%), with a remarkable effect size. A greater proportion of participants in the intervention group also achieved less than 7% A1C (0% at baseline to 42.6% at six months). This outcome was consistent with results of studies conducted in both developed and developing countries.[5,6,10,28-34] Particularly, some systematic reviews and meta-analysis conducted between 2014 and 2020, reported mean difference in A1C between -0.18% and -2.33% and FBG reduction of between -2.4 mmol/L and -2.9mmol/L respectively, in patients who received pharmacist intervention.[32-35] The result of this study was slightly better than that of another study conducted in Northern Cyprus, where patients who received pharmacist-led care had -0.74% A1C reduction and only 16% achieved good glycaemic control.[30] Similar to the current study, Adibe and colleagues observed 0.755% mean A1C reduction in research conducted 2014 in Southeast Nigeria, but the proportion of patients who attained A1C target was less compared to what was observed in this study (42.6% vs 27.07%).[28] The improvement observed in this study may be attributed to the inclusion of phone calls to the face-to-face educational sessions, and provision of educational booklet to each patient in the intervention group. Unlike this study which ensured that all participants were strictly patients with uncontrolled glycaemic status, other studies had patients with good glycaemic control at baseline, which might have led to reporting and selection bias.[15,16] The proportion of patients with target blood pressure in both group were equal at the end of six months. Blood pressure control is a critical component in the management of diabetes mellitus and very essential in preventing cardiovascular complications, which is a leading cause of death in patients with diabetes mellitus.[32,38] There was slight but not significant improvement in low-density lipoproteins and high-density lipoproteins, which could be related to study duration (not long enough to produce a significant effect) or some participants not fully adhering to the intervention provided. However, this represents a fairly better outcome compared to the result of another randomised controlled trials (RCTs), where patients in pharmacist intervention program had no significant effect on the low density lipoproteins or no improvement at all on lipid profile of participants.[15,30,39-42]

Overall, the adjusted odds ratio in this study showed that patients who received pharmacist care were approximately three times more likely to achieve glucose control compared to patients in usual care group, which is suggestive of better quality of life, lower risk of complications, less morbidity and mortality as observed in other studies.[8-11]

Metformin and sulphonylureas were the most prescribed anti-diabetes agents while fixed-dose combination and insulin were the least utilized. The prescription pattern complies with the recommendations in the standard treatment guidelines for T2DM and consistent with previously published literature in Nigeria.[20,43-45] This difference may be attributed to the study setting (exclusively diabetic clinic and not a general out-patient). The use of anti-hypertensive agents in this study was similar to the results obtained by Ukwe and colleagues in 2012, where angiotensin-converting enzyme inhibitors (ACEIs) were the most prescribed anti-hypertensive.[46] Furthermore, a recent study conducted in southwest Nigeria also had ramipril (ACEI) as the most utilized drug for hypertension.[47] However, diuretic or calcium channel blockers were more favoured in other studies as recommended by the Eight Joint National Committee (JNC 8).[44,45] The guideline states that the initial antihypertensive treatment for the general black population including those with diabetes should comprise of a thiazide-type diuretic or calcium channel blocker.[48,49]

Limitations

RCTs are revered as gold standard in clinical research and the cornerstone of Evidence-Based Medicine (EBM), but quite expensive and tedious to undertake. In this study, it was ensured that bias associated with selection of participants was minimised through randomisation, information bias was reduced through blinding of participants while bias related to confounding factors was avoided by having a usual care group as control. However, there were some limitations associated with the study. Limited number of T2DM patients participated in the study and report on patient adherence to medication was not available. Moreover, it was possible that the participants who received intervention discussed the details of their educational sessions with other diabetic colleagues who did not receive intervention and thus introduced information bias. The authors also admit that it was quite tough and expensive to have sustained the participants through the study period.

CONCLUSIONS

Pharmacist-led care significantly reduced A1C and improved glycaemic control in patients with uncontrolled T2DM, highlighting the need to engage well-trained clinical pharmacists in diabetes care teams, especially in LMICs like Nigeria. Funding for a multiple-site and double or triple-blinded pharmacist-led RCT is recommended in Nigeria and other LMICs in Africa, with a longer duration of follow-up.

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CONFLICT OF INTEREST

Authors declare no conflict of interest associated with this research work.

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Investigation: EAD
Methodology: EAD, RIA-W, ROS
Project administration: EAD, RIA-W, ROS
Resources: EAD, RIA-W, ROS
Software: EAD, IOA
Supervision: RIA-W, ROS
Validation: EAD, RIA-W, ROS
Visualization: EAD, IOA, RIA-W, ROS
Writing – original draft: EAD
Writing – review & editing: EAD, RIA-W, IOA.

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