International Journal of Pharmaceutical and Clinical Research
www.pharmaceuticaljournal.in
Online ISSN: 2664-7605, Print ISSN: 2664-7591
Received: 29-08-2021, Accepted: 14-09-2021, Published: 29-09-2021
Volume 3, Issue 2, 2021, Page No. 06-14

Adherence to medication among type 2 diabetes mellitus patients in a tertiary hospital in Keffi, Nigeria: The impact of pharmaceutical care intervention

Sabiu Adamu[1], Wetkos D Dayom[2], Hasan Abdullahi[3], Kamal A Ibrahim[1], Rukaiya Adamu[1], Ezekiel Gwamna[3]

[1] Department of Pharmaceutical Services, Federal Medical Centre Keffi, Nigeria

[2] Department of Clinical Pharmacy and Pharmacy practice, Faculty of Pharmaceutical Sciences, University of Jos, Nigeria

[3] Research unit Federal Medical Centre Keffi, Nigeria

DOI: https://doi.org/10.33545/26647591.2021.v3.i2a.24

Abstract

The primary aim of this study was to evaluate the impact of pharmaceutical care intervention on medication adherence as a health outcome in patients with type 2 diabetes in tertiary hospital in Keffi.

Methods: A randomized controlled study was conducted on 240 patients with type 2 diabetes accessing care in the diabetes clinic and general out-patient clinic of FMC Keffi. Patients were randomized into control and intervention groups. Participants in the intervention group received pharmaceutical care intervention administered through non-pharmacological approach, from clinical pharmacists while the control group patients received normal care without any special training from the clinical pharmacists. Medication adherence was assessed at the baseline, at three months, six months and at 12 months for both intervention and control Groups using an 8-item Morisky Medication Adherence Scale.

Results: After twelve months follow-up, statistically significant changes were achieved in medication adherence in the intervention group, from baseline to 3 months (p-value 0.001), 6 months (p-value 0.001) and 12 months (p-value 0.001). Again, number of hospitalised patients in the intervention group (13), is proportionately minimal and the difference ($p<0.001$) is statistically significant compared to 97 in the control group, within the study period.

Conclusion: The study has demonstrated and proved the effectiveness of pharmaceutical care intervention in increasing medication adherence and reducing hospital admissions in patients with Type 2 diabetes mellitus. As such, appropriate policies and guidelines should be advocated in order to make clinical pharmacists an integral part of medication therapy in diabetes mellitus and other chronic diseases.

Keywords: pharmaceutical care intervention; medication adherence; type 2 diabetes mellitus; clinical pharmacists; tertiary hospital; keffi

Introduction

Diabetes mellitus (DM) is a heterogeneous group of disorders that are secondary to various genetic predispositions and precipitating factors. DM is a spectrum of conditions that includes hyperglycemia as a common finding. It is a chronic disease characterized by disorders in carbohydrate (CHO), protein and fat metabolism caused by an absolute or relative deficiency in the action of insulin and possible abnormally high amounts of glucagon and other counter regulatory hormones such as growth hormones, sympathomimetic amines and corticosteroids.

It is a chronic disease that has affected 463 million people within the age range of 20-79 years in 2019 globally, and this figure is expected to rise to 700 million by the year 2045.[1] In Africa, DM affected 19 million people in 2019 and it was projected that 47 million people will be affected in 2045.[1] In Nigeria, the overall pooled prevalence of DM was 5.77%.[2]

DM as a common non-communicable disease forms a major risk factor for cardiovascular diseases like stroke and kidney failure, and is associated with considerable morbidity and mortality [3]. It is also a common cause of morbidity and mortality in Nigeria. [3, 4, 5] Diabetes mellitus is generally associated with emotional and social burdens which may be compounded by acute physical distress of hypoglycemia or hyperglycemia and by the chronic physical distress of diabetes – related complications. This naturally affects the patient's quality of life (QoL), his ability to function and to derive satisfactions. [6,7] The ultimate aim of care is preventing the patient's QOL from getting worse. [8] In addition to the emotional and social burdens associated with diabetes mellitus, it is a general observation that patients with type II diabetes mellitus (T_2DM) experience reduced health-related quality of life (HRQoL) due to treatment intensification from diet alone to oral agents and eventually to insulin injection. Health-related quality of life (HRQoL) is one of the important outcomes used to evaluate the effect of management of a chronic disease on health and it reflects a patient's physical and psychosocial wellbeing. Furthermore, DM also affects social and physical functioning of patients. Social functioning defines an individual's interactions with their environment and the ability to fulfill their role within such environments as work, social activities, and relationships with partners and family [7]. While Physical function is the ability to perform both basic and instrumental activities of daily living. Optimal

glycaemic control goes a long way to retain normal physical functioning.

Another devastating effect of DM is on the economy. It imposes a huge burden on individuals, communities and healthcare systems with estimated direct cost accounting for 2.5% to 15% of health care budget depending on prevalence and available treatment.[8,9] The economic burden is as high as 45% in Nigeria.[10]

Physical exercise is beneficial for health in any domain (recreation, transportation and so on) and is recommended by the WHO. [11] Exercise has clinical benefits, such as improved insulin sensitivity, reductions in glycosylated hemoglobin (HbA1C) and increased peak oxygen consumption (PO_2 peak) which are definitely preventive toward diabetes.

Non-adherence to treatment regimen is a prevalent problem of patients with chronic disorders. About half of the patients with a chronic disease have problems following their prescribed regimen to the extent that they are unable to obtain Optimum Clinical Benefit. Adherence to Treatment is a process that begins with alertness about the disease and has to end with staying in treatment [12]. Adherence to medications for chronic diseases has continued to remain low due to various factors [13]

In discussing adherence problems in chronic diseases, the following should be noted:

- Poor Adherence to treatment of chronic diseases is a worldwide problem of high magnitude.
- The impact of poor adherence grows as the burden of chronic diseases increases worldwide.
- Better adherence can produce better health outcomes and limit healthcare expenditures.
- Patient-tailored interventions are necessary.
- The family, the community, and patient's organizations are key to improving adherence.
- A multidisciplinary approach towards adherence is needed.

Adherence, according to [14] is defined as the extent to which patients are able to follow the recommendations for prescribed treatments. Non-adherence can occur at different stages of their treatment. These include:

a. Not starting the treatment at all,
b. Decision not to fill their prescription in the Pharmacy
c. Taking the wrong dose
d. Discontinuing the treatment earlier than the last date.

Other Key factors that result in poor medication adherence include:

a. Perceived Treatment Efficacy: The more firmly the patients believe that the prescribed medication is not really necessary the more non-adherent they are likely to be.

b. Hypoglycaemia: Patients choose to be non-adherent in order to keep their blood glucose levels in a higher range where hypoglycaemic events will be less likely.

c. Treatment Complexity and Convenience: Medication adherence and persistence is more challenging when the treatment itself is perceived to be more difficult.

d. Physician Trust: Adherence is poor if there is perceived distrust.

Statement of the Problem

At the moment, the magnitude of the problem of diabetes is such that one in ten adults have diabetes; one in three have prediabetes and even a greater number of people remained undiagnosed or are at the pre-diabetic stage.[15]

Another disturbing problem is that the risk of developing Coronary Heart Disease and stroke in patients with DM is 2-4 times higher than in normal subjects [16] and patients with DM have increased risk of Stroke and Stroke-related dementia. [17] Furthermore, adults with DM have a 50% higher risk of death from any cause than adults without diabetes, in addition to risk for myriad complications. [18] DM accounted for an estimated 4 million deaths globally among people between 20–79 years old. [4, 5, 6]

Another significant problem associated to DM is the neuropathic complication which affects the feet and nerves resulting in various forms of abnormalities such as blindness, sexual dysfunction and amputation. This autonomic neuropathy associated with DM accounts for a high rate of erectile dysfunction in men [19] and accounts for about 80% of amputations. [20]

Justification of the Study

Among patients with chronic illness, approximately 50% do not take medications as prescribed.[21]. This translates to poor adherence to medication which leads to the devastating microvascular and macrovascular complications associated with DM which have become public health challenge. The health outcomes for patients with diabetes who fail to adhere do appear to be suboptimal and blindness, renal failure, lower–extremity amputations, ischemic heart disease and stroke are common in these patients.[22]

Therefore, there is need for an intensive intervention program to monitor its progression with outcomes that are measurable through PCI. Pharmaceutical care intervention (PCI) has been reported to be associated with reduced mortality, morbidity and increased health related quality of life. [23]

Aim

The study aims to evaluate the impact of pharmaceutical care intervention (PCI) on medication adherence in patients with type 2 diabetes mellitus

Method

Figure 1 represents the flow of participants within the study period of 12 months. Initially, 260 patients with Type 2 diabetes mellitus were enlisted for the study. 14 patients out 260 declined consent for participation in the study. 6 patients were dropped from the list for being either pregnant or having HIV/TB infection. 240 patients were eventually recruited as participants for the study. These were randomised into control (120) and intervention or test groups (120). Eventually, 6 participants were lost to death, 2 from the NCCG (control group) and 4 from the PCIG (intervention or test group), leaving 118 and 116 participants in the two groups respectively.

Study design and setting

This is a randomized controlled, longitudinal and two-arm parallel prospective study with a 12-month patient follow-up

conducted in a single centre (FMC Keffi) to assess the impact of pharmaceutical care intervention (PCI) on medication adherence in patients with type 2 diabetes mellitus. FMC Keffi is a referral centre for many chronic diseases including diabetes mellitus with consultant diabetologists. The hospital also has qualified clinical pharmacists who are Fellows of the West African Postgraduate College of Pharmacists (WAPCP) who provide various clinical services to patients and drug information to staff

Ethical Approval
Ethical approval was given by the Health Research Ethics Committee of Federal Medical Centre, Keffi with reference number NHREC/ 21/12//2012, dated 12th September, 2017

Study Participants
260 patients with Type 2 diabetes mellitus who were 18 years and above, already taking oral hypoglycaemic agents (and not on insulin injection) were recruited from endocrinology and medical outpatient departments for the study. 14 patients out 260 declined consent for participation in the study while 6 patients were dropped from the list for being either pregnant or having HIV/TB infection.

Randomization
A systematic random sampling method was used to divide the participants into 2 groups of 120 each. The first number 2 was randomized into the control group while the next count of two was randomized into the test or intervention group. This alternate randomization continued in this pattern to the last number 240. The control group was named Normal Care Control Group (NCCG) while the test group was named Pharmaceutical Care Intervention Group (PCIG). In the intervention group patients received pharmaceutical care interventions through patient care education by clinical pharmacists while the control group patients received only usual care without any special training from the clinical pharmacists.

Normal Care Process (NCP)
Normal process of care for patients with T2DM in FMC Keffi consists of activation of patient information at the Medical Records Department, taking of vital signs at the triage room by the triage nurses, consultation/prescription by the physician and prescription filling at pharmacy with normal medication counseling. The patient usually spends an average of 8 minutes each with the physician and the pharmacist. In the normal care process, what the patient receives from the physician is usually the prescription and an instruction to go to pharmacy for his /her medication and a reminder for a new date of his next appointment. This process is repeated every month. Participants in the NCCG received only this normal care without any special training education by the clinical pharmacists. They served as the control group.

Pharmaceutical Care Intervention Process (PCIP)
Pharmaceutical Care Intervention Process, includes in addition to the NCP, structured education program (SEP) on the disease and its complications, the medications and their side effects, lifestyle modifications in diet and physical exercise, cessation of smoking and moderation of alcohol consumption, delivered to the participants by the clinical pharmacists. Participants in PCIG received SEP at enrolment, at 2nd visit (after one month), and at 3rd visit (after two months).
PCIP also consists of routinely repeated talk by the clinical pharmacists on medications including dosage, frequency and special precautions as well as balanced diet, regular exercise and need for smoking cessation, on each hospital visit.

The Structured Education Program (SEP)
At Enrolment
Education needs of the participants were identified through an interactive session with the participants that lasted for about an hour. During the session, several questions that border on the disease, medication and lifestyle modification were asked. The various responses were documented, analyzed and interpreted.

The Identified Education Needs of the Participants
The responses to the questions during the interactive sessions revealed the following education needs:
- Knowledge on the disease and its prognosis
- Knowledge on the signs and symptoms
- Knowledge on the complications and their causes
- Knowledge on the medication and side effects
- Knowledge on how to monitor blood glucose
- Knowledge on exercise and its pattern
- Knowledge on how to differentiate between hypoglycemia and hyperglycemia

Participants in this group were educated on the identified educational needs above.

Diabetes and its complications
A brief rundown of diabetes and its complications was given to the participants especially on retinopathy (blindness), neuropathy (amputation) and nephropathy (kidney failure) as end organ complications of diabetes.

Diabetes medications and their side effects
Participants were briefed on the commonly used medications and their side-effects in such a way that they would be able to cope up with the unavoidable ones and avoid the avoidable ones and the benefits of medication adherence.
Use of clock or phone alarm to remind them on the time of taking their medication was encouraged.
They were discouraged from missing any dosage of their medication and the consequences of doing so were explained to them in details. This point was re-emphasized to them at every hospital visit. They were made to always remember this slogan: ***missing my drug, missing my health!***

Life style modifications
Participants were taught the significance of lifestyle modifications, diet and physical activities (exercise) to adopt.

Self-monitoring of blood glucose (SMBG)
Participants were introduced to the concept of SMBG and its importance. They were made to realize that SMBG is an integral part of their diabetes management and were encouraged to measure their sugar level at least three times a week.

Self-monitoring of the disease through identification of common signs and symptoms

Participants were trained to differentiate symptoms of hyperglycemia from hypoglycemia**.** Symptoms of hyperglycemia include: extreme thirst, dry mouth, nausea, blurred vision and shortness of breath while those of hypoglycemia include: hunger, sweating, confusion, fast heartbeat, dizziness and slurred speech.

At 2nd Visit (after 1 month)

Participants were carried through:

- Advanced discussions on complication and how to avoid them
- Advanced discussions on medications and their side-effects
- Advanced discussion on adherence to medication
- Advanced discussion on lifestyle modification

On dietary control, participants were advised to reduce intake of saturated fats such as butter, fatty red meat, fast foods etc. But they were advised to increase the intake of mono and polyunsaturated fats such as olive oil.

Participants were advised to avoid foods with high glycemic index (GI) of > 70 such as maize, white rice, cassava etc. But they were advised to increase intake of foods with low GI such as beans, moi-moi, carrot etc.

At 3rd Visit (after 2 months)

Sharing experiences

Participants were engaged in an interactive session to share their experiences on the challenges of:

- Lifestyle modification
- Adherence to medication
- Target setting to achieve good glycemic controls and other clinical parameters used in monitoring diabetes
- Self-monitoring of blood glucose level

Participants were encouraged to endure to overcome all the challenges as posed by the above-mentioned parameters.

Skin, Foot and Dental Care

Participants were detailed on the importance of skin, foot and dental care. They were enlightened on the dangers of injuries to such parts. They were encouraged to use soft tooth brush to avoid injury and also to use room slippers to avoid being injured by any hard object.

Follow Up and Appointments

Participants were counseled to be abreast with their appointment dates of returning to diabetic clinics for further management by their physicians and diabetologist. They were also counseled to make sure they see their clinical pharmacists on each hospital visit so that they receive pharmaceutical care education.

All the identified education needs were briefly addressed again to make sure every participant was at home with the teaching sessions.

Clinical parameters of the participants in this group were assessed at baseline, 3rd, 6th and 12th month.

Participants in this group also received continuous counselling on lifestyle modification, medication adherence and self-monitoring of glucose at every visit to the GOPD pharmacy**.**

Data Collection

Sociodemographic data of all the recruited participants from both groups (NCCG and PCIG) were taken at baseline. Medication adherence of all the participants was also recorded at baseline by the administration of an 8-item Morisky Medication Adherence Scale Questionnaire (MMASQ). The MMASQ administration and assessment was repeated for all the participants in both groups in the 3rd, 6th and 12th month. For participants with low educational background, pharmacists assisted them in responding to the questions. This helps to overcome the non-responsiveness by some participants and this practice has been reported to be acceptable in the literature. [24]

Outcome Measures

The changes of the medication adherence in both NCCG and PCIG from baseline to 3 months, 6 months and 12 months and number of times participants from the 2 groups were admitted in hospitals were the primary outcome measures considered.

Data Analysis

Statistical analysis was performed using the IBM SPSS Statistics for Windows Version 25. (IBM Corp., Armonk, N. Y., USA). Quantitative data were summarized as Mean and Standard deviation, while Categorical data were reported in proportions.

Socio-demographic characteristics of the participants in both groups, PCIG and NCCG were generated, analyzed and compared.

Medication adherence characteristics of the participants in both groups, were assessed, analyzed and compared at baseline, 3rd month, 6th month and 12th month.

Data were presented as mean±SD or as percentages within groups. Baseline characteristics of the two groups were compared using chi-square and student's sample t-test. The differences in the change of Morisky scores among the two groups were analyzed using repeated measures ANOVA

Results

Sociodemographic findings in the study (tables 1 and 2) revealed the following about the participants: majority of them were females (54.2%); majority had their diabetes duration falling within the range of 1-5 years (65.8%); majority were within the age range of 40-59 years (62.9%); majority of them had strong family history of diabetes (84.2%), were married (78.3%) and neither smoke cigarette (93.8%) nor drink alcohol (95.8%). A good number of the participants were either unemployed (40.4%) or retired (5.4%) from active public service; and a good number of them had no any formal education (21.2%) or had only primary education (19.2%); mean age of the control and the intervention groups are 50.73±11.95 and 53.98±11.73 respectively. While there were statistically significant differences in the family history (p-value 0.003), marital status (p-value 0.025, duration of DM (p-value <0.001 and gender (p-value 0.002) of participants in the study groups, the differences in age (p-value 0.075), education status (p-value 0.080), occupation (p-value 0.111), smoking (p-value 0.790) and alcohol consumption (p-value 0.179) were not statistically significant.

Table 1: Socio-Demographic Characteristics of the Study Participants

Variables	NCCG (120)	PCIG (120)	p-value
Age (years)			
20 – 39	17 (14.1)	12 (10.9)	**0.075**
40 – 59	82 (68.4)	69 (57.4)	
60 – 79	19 (15.8)	36 (30.0)	
Above 79	2 (1.7)	2 (1.7)	
Mean ±SD	50.73 ±11.95	53.98 ±11.73	
Gender			0.002
Female	53 (44.2)	77 (64.2)	
Male	67 (55.8)	43 (35.8)	
Duration of diabetes (yrs.)			<0.001
</=5	99 (82.5)	59 (48.7)	
6 – 10	10 (8.3)	32 (26.9)	
11 – 15	6 (5.0)	13 (10.9)	
16 – 20	3 (2.5)	5 (4.2)	
21 – 25	1 (0.8)	5 (4.2)	
26 – 30	0 (0.0)	3 (2.5)	
31 – 35	1 (0.8)	1 (0.8)	
36 – 40	0 (0.0)	2 (1.7)	
Mean ±SD	4.67 ±4.91	8.78 ±8.45	
Educational status			0.08
None	23 (19.2)	28 (23.3)	
Primary	25 (20.8)	21 (17.5)	
Secondary	42 (35.0)	27 (22.5)	
Tertiary	30 (25.0)	44 (36.7)	
Occupation			0.111
Employed	57 (47.5)	73 (60.8)	
Retired	8 (6.7)	5 (4.2)	
Unemployed	55 (45.8)	42 (35.0)	
Marital status			0.025
Divorced	6 (5.0)	2 (1.7)	
Married	94 (78.3)	94 (78.3)	
Single	12 (10.0)	5 (4.2)	
Widowed	8 (6.7)	19 (15.8)	

NCCG=Normal Care Control Group, PCIG= Pharmaceutical Care Control Group

Table 2: Family History and Social Habits of the Study Participants

Variables	NCCG (120)	PCIG (120)	p-value
Family history of diabetes			**0.003**
Yes	108 (90.0)	94 (78.3)	
No	12 (10.0)	16 (13.3)	
Don't know	0 (0.0)	10 (8.3)	
Smoking			**0.79**
Yes	7 (5.8)	8 (6.7)	
No	113 (94.2)	112 (93.3)	
Alcohol consumption			**0.197**
Yes	3 (2.5)	7 (5.8)	
No	117 (97.5)	113 (94.2)	

NCCG=Normal Care Control Group, PCIG=Pharmaceutical Care Control Group

Adherence Scale (Table 3) revealed that while statistically significant changes were achieved in the intervention group (PCIG) from baseline to 3 months, 6 months and 12 months all with p=0.001. There was no statistically significant change in the control group (NCCG) except in the 12th month (p= 0.015) as seen in table 4.

At baseline, participants in the control group (table 4) had relatively more medium adherence (40.8%) and high adherence (2.5%) than the intervention group (table 3) which recorded 39.2% and 0.0% respectively. However, on a general note, participants in both the intervention and control groups showed poor adherence to medications (p<0.2) at baseline. At the 3rd, 6th and 12th months, the intervention group had more number of participants with high adherence to medication compared to the control group. While the former recorded 31.9%, 32.2% and 27.6% at the 3rd, 6th and 12th months, the latter had only 5.0%, 6.8% and 7.7% respectively. On the other hand, the number of participants in the control group with low adherence to medication was consistently higher in the 3rd month (49.6%), 6th month (45.8%) and 12th month (39.8%) compared to the intervention group that recorded only 16%, 13.6% and 10.3% respectively.

Table 3: Intra-Group Comparison of Medication Adherence Assessment with 8-Item MMAS for PCIG

LEVEL	Baseline	3rd month		p-value
Adherence Level				
Low	73 (60.8)	19 (16.0)		<0.001
Medium	47 (39.2)	62 (52.1)		
High	0 (0.0)	38 (31.9)		
Adherence Level	Baseline	6th month		
Low	73 (60.8)	16 (13.6)		<0.001
Medium	47 (39.2)	64 (54.2)		
High	0 (0.0)	38 (32.2)		
Adherence Level	Baseline	12th month		
Low	73 (60.8)	12 (10.3)		<0.001
Medium	47 (39.2)	72 (62.1)		
High	0 (0.0)	32 (27.6)		

PCIG=Pharmaceutical Care Intervention Group

At baseline, participants in the control group (table 4) had relatively more medium adherence (40.8%) and high adherence (2.5%) than the intervention group (table 3) which recorded 39.2% and 0.0% respectively. However, on a general note, participants in both the intervention and control groups showed poor adherence to medications (p<0.2) at baseline. At the 3rd, 6th and 12th months, the intervention group had more number of participants with high adherence to medication compared to the control group. While the former recorded 31.9%, 32.2% and 27.6% at the 3rd, 6th and 12th months, the latter had only 5.0%, 6.8% and 7.7% respectively. On the other hand, the number of participants in the control group with low adherence to medication was consistently higher in the 3rd month (49.6%), 6th month (45.8%) and 12th month (39.8%) compared to the intervention group that recorded only 16%, 13.6% and 10.3% respectively. However, on a general note, the changes were statistically significant with p-values of 0.001 in each of the 3 months (table 3).

Table 4: Intra-Group Comparison of Medication Adherence Assessment with 8-Item MMAS for NCCG

Level	Baseline	3rd month	p-value
Adherence Level			
Low	68 (56.7)	59 (49.6)	0.391
Medium	49 (40.8)	54 (45.4)	
High	3 (2.5)	6 (5.0)	
Adherence Level	Baseline	6th month	
Low	68 (56.7)	54 (45.8)	0.115
Medium	49 (40.8)	56 (47.4)	
High	3 (2.5)	8 (6.8)	
Adherence Level	Baseline	12th month	
Low	68 (56.7)	47 (39.8)	0.015
Medium	49 (40.8)	62 (52.5)	
High	3 (2.5)	9 (7.7)	

NCCG=Normal Care Control Group

Table 5 shows the number of hospital admissions the participants from the two groups had during the study period. While the control group had 34 (28.6%), 37 (31.4%) and 26 (22.0%) hospitalizations in the 3rd, 6th and 12th months, the intervention group only had 7(5.9%), 5(4.2%) and 1(0.9%) respectively, with P-values < 0.001 in each of the three months.

Table 5: Inter-Group Comparison on Adherence Assessment by 8-items MORISKY Scale Patients Compliance to DM care

	PCIG	NCCG	p-value
Baseline	(n:120)	(n:120)	0.2
Low adherence	73 (60.8)	68 (56.7)	
Medium adherence	47 (39.2)	49 (40.8)	
High adherence	0 (0.0)	3 (2.5)	
3rd month	(n:119)	(n:119)	<0.001
Low adherence	19 (16.0)	59 (49.6)	
Medium adherence	62 (52.1)	54 (45.4)	
High adherence	38 (31.9)	6 (5.0)	
6th month	(n:118)	(n:118)	<0.001
Low adherence	16 (13.6)	54 (45.8)	
Medium adherence	64 (54.2)	56 (47.4)	
High adherence	38 (32.2)	8 (6.8)	

12th month	(n:116)	(n:118)	<0.001
Low adherence	12 (10.3)	47 (39.8)	
Medium adherence	72 (62.1)	62 (52.5)	
High adherence	32 (27.6)	9 (7.7)	

DM=Diabetes mellitus, NCCG=Normal Care Control Group, PCIG=Pharmaceutical Care Intervention Group,

Table 6 shows the number of hospital admissions the participants from the two groups had during the study period. While the control group had 34 (28.6%), 37 (31.4%) and 26 (22.0%) hospitalizations in the 3rd, 6th and 12th months, the intervention group only had 7(5.9%), 5(4.2%) and 1(0.9%) respectively, with P-values < 0.001 in each of the three months.

Table 6: Inter-Group comparison of number of hospital admissions during the Study Period

	Number of patients		**Number of admission**		
	NGGC	PCIG	NGGC	PCIG	p-value
Baseline	120	120	0 (0.0)	0 (0.0)	----
3rd month	119	119	34 (28.6)	7 (5.9)	<0.001
6th month	118	118	37 (31.4)	5 (4.2)	<0.001
12th month	118	116	26 (22.0)	1 (0.9)	<0.001

Discussion

While there were statistically significant differences in the family history (p-value 0.003), marital status (p-value 0.025, duration of DM (p-value <0.001 and gender (p-value 0.002) of participants in the study groups, the differences in age (p-value 0.075), education status (p-value 0.080), occupation (p-value 0.111), smoking (p-value 0.790) and alcohol consumption (p-value 0.179) were not statistically significant. This implies that the participants in the study groups have similarities to a certain extent and also differ to a certain extent in sociodemographic characteristics. The statistical differences in the sociodemographic data could be due to sociocultural differences, time of diagnosis, low physical activities in females than males.

On the other hand, participants in this study from both the control and the intervention groups displayed poor adherence to medication at baseline, though not statistically significant. This could be due to low socioeconomic status as a result of relatively high unemployment and enormous family responsibilities, as most of the participants were married. Similar finding was reported by. [25] In resource settings where healthcare involves direct, indirect, variable and fixed costs, full healthcare will be inaccessible, and non-adherence will be an inevitable occurrence for patients with low socioeconomic power as a result difficulty in refilling medication at pharmacy. This translates to increased difficulty in adhering to treatment. This was reported by Seligman *et al*., 2012[26] in ''Food insecurity and glycemic control among low-income patients with type 2 diabetes''

From the results the study demonstrated an improvement in medication adherence and reduction in hospital admission from baseline to 3rd, 6th and 12th months in the intervention group more than the control group. This translates to enhanced adherence to medication after the study period. The enhancement could be ascribed to the focused patient education on the disease and its complications, lifestyle modifications on diet and exercise, and the repeated counseling on medication use as it relates to timing and consistency, delivered to the participants in the intervention group, by the clinical pharmacists, times and again, as detailed in the structured education program. This consistent bonding of clinical pharmacists with the patients over a period of 12 months, could have led to the development of a strong patient-pharmacist professional relationship. This also could have improved the problem-solving skills of the pharmacists and might have increased the confidence of patients, which would result in improved medication adherence. Similar findings were reported by other studies demonstrating the impact of pharmaceutical care intervention in improving medication adherence in chronic medical conditions.[27] A systematic review of randomized control trials on improving the adherence of type 2 diabetes mellitus patients with pharmacy care by Antoine *et al*., 2014 [28] also reported similar findings. Again other studies also reported that patient education sessions by pharmacists resulted in improvements in medication adherence in diabetes.[29, 30] All these are consistent to the findings of this study. Pharmacotherapeutic knowledge of pharmacists confers them unique roles in different patient care services and disease management including PCI which proves to be an effective tool in improving adherence to antidiabetic medications and health outcomes. Pharmaceutical care is a product of the global paradigm shift in pharmaceutical education and practice, which gives a pharmacist a patient-centred training that specially positions him to educate, implement and monitor patients on medication therapies, which ultimately lead to better health outcomes [31]

This study demonstrated greater glycaemic control and reduction in hospital admission in the intervention group over the control group. This could be attributed to the acceptance by the participants in the intervention group, of the concepts of self-monitoring of blood glucose (SMBG) and self-monitoring of disease (SMD) through identification of common signs and symptoms such as hypoglycemia and hyperglycemia which often lead to hospitalization. The work of [32] proved that self-care practice training and consistent pharmacist counseling reduced patient hospitalization. The SEP appeared to have helped the patients to make self-behavioral changes that improve medication adherence.

Conclusion

The findings of this study revealed that pharmaceutical care intervention improves medication adherence and also minimizes hospitalizations in patients with type 2 diabetes mellitus. The improvement in these two outcomes resulting

from clinical pharmacists' professional role, incorporating pharmaceutical care intervention into the healthcare process within healthcare institutions will optimize treatment goals and outcomes.

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