



Pharmaceutical Care Impact on Quality of Life in Type 2 Diabetic Patients: A Study in a Nigerian Tertiary Hospital Setting

Sabiu Adamu¹, Wetkos D. Dayom², Comfort N. Sariem³

¹Zinnia College of Health Science and Technology, Keffi, Nigeria

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

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ABSTRACT

The aim of this study was to evaluate the impact of pharmaceutical care intervention on the quality of life as a health outcome in patients with type 2 diabetes in a 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 a structured education programme from clinical pharmacists, while the control group participants received normal care without any special training from the clinical pharmacists. Domains of quality of life (QoL) were assessed at the baseline, 3rd month, 6th month and 12th month for both intervention and control groups using the Short Form (SF)-36 Questionnaire, and compared. The differences were analysed with appropriate statistical tools. **Results:** After twelve months of follow-up, higher changes were achieved in domains of QoL in the intervention group than the control group, and they were statistically significant (p -value < 0.05). **Conclusion** The study demonstrated the effectiveness of pharmaceutical care intervention in improving quality of life in patients with Type 2 diabetes mellitus. As such, appropriate policies and guidelines should be adopted to integrate pharmaceutical care intervention in the management of diabetes mellitus, and also to make the clinical pharmacist an integral part of medication therapy in diabetes mellitus.

Keywords : Pharmaceutical Care Intervention; Quality of Life; Type 2 Diabetes Mellitus; Clinical Pharmacists; Tertiary Hospital; Keffi.

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder characterized by chronic hyperglycemia due to defects in insulin secretion, insulin action, or both ^[1]. This impaired insulin secretion can either be absolute or relative. The absolute impairment due to autoimmune destruction of pancreatic beta cells leads to type 1 diabetes mellitus (T1DM) ^[2], while the relative impairment due to insulin resistance and relative insulin deficiency, often associated with obesity and physical inactivity results in type 2 diabetes mellitus (T2DM) ^[1]. The impaired insulin secretion will cause chronic hyperglycaemia which leads to inability of tissues to carry out routine metabolic functions on carbohydrates, fats and proteins, leading to microvascular complications such as diabetic retinopathy, nephropathy, and neuropathy ^[3] and macrovascular complications like cardiovascular disease, stroke, and peripheral artery disease ^[4]. The microvascular complication, primarily due to chronic hyperglycaemia on small blood vessels affects the eyes, teeth/gums, kidney and nerves, affecting the digestive system, sexual organ and feet. On the other hand, the macrovascular complication, due to chronic hyperglycaemia on large blood vessels affects the brain, heart and lower limbs, and this can lead to stroke, heart attack and blockade of blood flow to the extremities particularly the leg. As such, DM accounts for about 80% of amputations ^[5] and high rate of erectile dysfunction in men ^[6].

DM is a global health issue, with an estimated 537 million adults living with diabetes worldwide in 2021, projected to increase to 643 million by 2030 and 783 million by 2045 ^[7]. DM is a common cause of morbidity and mortality in Nigeria ^[8,9,10] with an overall pooled prevalence of 5.77% ^[11].

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. The economic burden is as high as 45% in Nigeria. The global health expenditure on diabetes was expected to total to at least 376 billion USD in 2010 and 490 billion USD in 2030 ^[12,13].



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 ^[14]. In addition to the emotional and social burdens associated with diabetes mellitus, it is a general observation that patients with type II diabetes mellitus (T₂DM) experience reduced health-related quality of life (HRQoL) due to treatment intensification from diet alone to oral agents and eventually to insulin injection.

Furthermore, Social functioning refers to an individual's ability to engage with and fulfill their roles in their environment—including work, social activities, and family relationships—and may be impaired in chronic illnesses like diabetes ^[15], while physical function is the ability to perform both basic and instrumental activities of daily living. All these are attributes or domains of quality of life (QoL).

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. The fundamental difference between quality of life (QoL) and health-related quality of life (HRQoL) is in the scope. While QoL is a broader concept that encompasses all aspects of life, including non-health-related factors like financial stability, personal relationships, and environmental factors, HRQoL, on the other hand, is narrowly focused on the effects of health and illness on an individual's quality of life.

At the moment, there is a growing global evidence on the effectiveness pharmaceutical care (PC) on health outcomes of patients with type 2 diabetes mellitus (T2DM). For instance, a study reported the addition of PC to usual care (UC) improved the quality of life in patients with type 2 diabetes ^[16]. Therefore, this study evaluated the impact of pharmaceutical care intervention on the quality of life as a health outcome in patients with type 2 diabetes.

LITERATURE REVIEW

Quality of Life

Quality of life (QoL) is the general well-being of individuals and societies outlining negative and positive features of life. It also refers to an individual's overall perception of their position in life, encompassing various domains such as physical health, psychological state, social relationships, and environment. QoL is a broad, multidimensional concept that reflects a person's satisfaction with life and their ability to achieve personal goals. It observes life satisfaction, including everything from physical health, family, education, employment, wealth, religious belief, finance and environmental status ^[17]. Quality of Life (QoL) does not only reflect peoples' physical, mental, or emotional functioning or disease status, but also expresses their ability to participate in the world around them, which means they can participate in activities that are common to most people in a society. On this premise, a person with a functional limitation such as vision loss, mobility difficulty or intellectual disability can live a long and productive life and enjoy a good quality of life ^[18].

Quality of life (QoL), according to Britannica, is the degree to which an individual is healthy, comfortable, and able to participate in or enjoy life events. The World Health Organization (WHO) defines QoL as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." Standard indicators of the quality of life include wealth, employment, the environment, physical and mental health, education, recreation and leisure time, social belonging, religious beliefs, safety, security and freedom. Quality of life is important to everyone. Although the World Health Organization (WHO) defined health very broadly as long as a half century ago, health in the United States has traditionally been measured narrowly and from a deficit perspective, often using measures of morbidity or mortality. But health is seen by the public health community as a multidimensional construct that includes physical, mental, and social domains. As medical and public health advances have led to cures and better treatments of existing diseases and delayed mortality, it was logical that those who measure health outcomes would begin to assess the population's health not only on the basis of saving lives, but also in terms of improving the quality of lives.

Health-Related Quality of Life (HRQoL)

This is another assessment term used to evaluate health outcomes is health-related quality of life. HRQoL is a multidimensional concept that includes domains related to physical, mental, emotional, and social functioning. It goes beyond direct measures of population health, life expectancy, and causes of death. It also focuses on the impact health status has on quality of life. HRQoL serves as a useful and valid indicator for health system evaluation in different countries, especially when it seeks to measure the level of health and disease ^[19]. The Centre for Disease Control and Prevention ^[20] (CDC, 2022) defines HRQoL as an individual's or group's perceived physical and mental health over time. It is also defined as the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy.



On the individual level, HRQoL includes physical and mental health perceptions. On the community level, HRQoL includes community-level resources, conditions, policies, and practices that influence a population's health perceptions and functional status. HRQoL measures make it possible to demonstrate scientifically the impact of health on quality of life, going well beyond the old paradigm that was limited to direct measures of population health, life expectancy, and causes of death.

Measuring Health-Related Quality of Life

The estimation of the relative impact of chronic diseases on HRQoL is necessary in order to better plan and distribute health care resources aiming at a better HRQoL ^[21]. HRQoL is related to both self-reported chronic diseases such as diabetes and their risk factors that may include body mass index, physical inactivity and smoking. Measuring HRQoL helps determine the burden of preventable disease, injuries, and disabilities, and can provide valuable new insights into the relationships between HRQoL and risk factor. It also helps to monitor progress in achieving the nation's health objectives. For the purpose of measuring HRQoL, Health Utility Index questionnaires have been developed to extract responses from research subjects which will appropriately form relevant data in clinical studies.

Diabetes and Quality of Life

Type 2 diabetes mellitus (T2DM) significantly affects HRQoL due to its long-term complications, treatment burden, and psychosocial implications. Factors influencing HRQoL in diabetes include disease duration, insulin use, and the presence of complications. Interestingly, low HbA_{1c} levels have sometimes been associated with lower QoL, while longer diabetes duration correlates inversely with QoL ^[22]. Cardiovascular disease, kidney failure, and other complications remain major contributors to reduced QoL in diabetic patients ^[23].

Comorbidities compound these effects. Patients with both diabetes and kidney disease or heart failure experience particularly low QoL, with up to 50% reporting significant impairment ^[24,25,26]. Moreover, studies suggest diabetes has a stronger negative effect on QoL compared to many other chronic diseases ^[27,28].

Another important factor is health literacy. Research indicates that 30–40% of patients with T2DM experience low QoL due to poor health literacy and inadequate self-care behaviors ^[29,30,31]. Higher health literacy is consistently associated with better QoL outcomes in diabetes ^[32]. Interventions targeting education, social support, and empowerment, particularly for vulnerable groups such as women and those with vision loss, are essential for improving QoL among diabetic patients ^[33].

Pharmaceutical Care Intervention and Quality of Life

Pharmaceutical care interventions (PCI), which include patient education, lifestyle counselling, and medication management, have been shown to significantly improve quality of life (QoL) in patients with type 2 diabetes mellitus (T2DM).

In Nigeria, a randomized controlled study found that adding pharmaceutical care to usual care led to notable improvements in health-related quality of life (HRQoL) over 12 months, with utility scores rising significantly ^[34]. Moreover, the intervention was shown to be cost-effective, yielding additional quality-adjusted life-years (QALYs) at an acceptable incremental cost ^[34].

Similar findings have been reported in other regions. In South India, a pharmaceutical care program involving diabetes education, medication counselling, and lifestyle modification significantly improved QoL scores, glycaemic control, and fasting blood glucose levels ^[35]. In Indonesia, pharmacist interventions resulted in a significant improvement in quality of life scores over a six-month period ^[36]. Studies in Brazil also found that pharmaceutical care led to measurable improvements in QoL, particularly in satisfaction and impact domains ^[37].

In Nigeria, pharmacist-led interventions have also been shown to enhance medication adherence, dietary behavior, physical activity, and glycaemic control among T2DM patients, with only a minimal increase in direct management costs ^[38]. A related collaborative care study similarly demonstrated significant improvements in glycaemic indices and patient self-management awareness ^[39].

The literatures reviewed, revealed limited geographical focus as not many of such studies were conducted in Northern Nigeria, as such, there was lack of region-specific data. This translates to limited implementation of pharmaceutical care in the region. The most fundamental gap identified in this review is low health literacy among T2DM patients which makes a leading cause of low QoL in that population. These gaps highlight the need for deliberate studies to address the specific context of northern Nigeria and to justify the implementation of PCI in tertiary hospitals in the country.



STATEMENT OF THE PROBLEM

Diabetes is a global health problem with an increasing prevalence. A study revealed that one in ten adults has diabetes, one in three has prediabetes and even a greater number of people remained undiagnosed or are at the pre-diabetic stage ^[20]. It is a significant public health challenge on the globe, including Nigeria, with a high burden of disease and poor health outcomes. Patients with T2DM often experience reduced Quality of Life (QoL) due to factors such as poor health literacy, inadequate self-care behaviors, and limited access to effective healthcare interventions ^[31].

Pharmaceutical Care Intervention (PCI) has been shown to improve QoL in patients with T2DM in other contexts, but there is a scarcity of studies on the impact of PCI on QoL in patients with T2DM in Nigeria, particularly in northern Nigeria and also in tertiary hospital settings. This knowledge gap hinders the development of effective strategies to improve QoL and health outcomes for patients with T2DM in Nigeria.

RESEARCH QUESTIONS

1. Is there a difference in QoL scores between patients with T2DM who receive PCI and those who receive usual care?
2. How does health literacy moderate the impact of PCI on QoL in patients with T2DM?

AIM AND OBJECTIVES

Aim

The aim of this study was to assess the impact of pharmaceutical care intervention on the quality of life of patients with type 2 diabetes mellitus.

Specific Objectives

1. To evaluate the difference in QoL scores between patients with T2DM who receive PCI and those who receive normal care.
2. To assess the impact of health literacy of PCI on QoL in patients with T2DM?

JUSTIFICATION FOR THE STUDY

Reports from several studies suggest that health outcomes for patients with diabetes are still suboptimal, since blindness, renal failure, lower-extremity amputations, ischemic heart disease and stroke are common in these patients. These constitute significant factors for low quality of life. Low health literacy is a significant issue in Nigeria, and PCI can help address this by empowering patients with the knowledge and skills necessary to manage their condition effectively. It is then expected that enhancing health literacy of diabetic patients will positively influence self-care management skills, glycemic control and patient's QoL.

On the other hand, the study will help in understanding the impact of PCI on QoL within the local context (Northern Nigeria) since there is a limited region-specific data, resulting from scarcity of studies and data on the impact of PCI on QoL in patients with T2DM in the region.

It will also be an evidence-based intervention if the PCI improves QoL in patients with T2DM in Keffi, and the study will provide valuable insights to inform healthcare policy and practice.

Again, by evaluating the impact of PCI on QoL in patients with T2DM, this study can provide evidence on the effectiveness of this intervention in improving health outcomes and reducing the burden of T2DM in Nigeria.

Therefore, DM management will need pharmaceutical care (PC) as an intensive intervention program to enhance health literacy and monitor the disease progression with outcomes that are measurable. These justifications highlight the significance and relevance of the study, demonstrating the need for research on the impact of PCI on QoL in patients with T2DM in Nigeria.

THEORETICAL/CONCEPTUAL FRAMEWORK

The theoretical framework of this study was based on Health Belief Model (HBM) which states that an individual's health behaviour is influenced by their perceived susceptibility to a health condition, perceived severity of the condition, perceived benefits of taking



action, perceived barriers to taking action, and cues to action. In the context of this study, the participants, having known their likelihood of developing complications (susceptibility) and severity (consequences) of the complications (stroke, amputation, erectile dysfunction and so on), got motivated and changed their behaviours through:

- a. Reversal of sedentary life or engaging in physical activities
- b. Moderating consumption of food with high glycaemic index (GI)
- c. Adherence to medication
- d. This ultimately led to enhanced and improved QoL.

SCOPE OF THE STUDY

The study evaluates the impact of Pharmaceutical Care Intervention (PCI) on QoL in patients with T2DM attending a tertiary hospital in Keffi, Nigeria. The study assesses the QoL of patients with T2DM using a validated QoL instrument over a period of 12 months.

METHODOLOGY

Study setting

Patients were recruited from the endocrinology and outpatient clinics of Federal Medical Centre, (FMC) Keffi which is a Tertiary Health Institution with a 400-bed capacity, situated about 50 km away from Abuja, the capital city of Nigeria. It serves as a referral centre for all the secondary healthcare facilities in Nasarawa state and also other healthcare facilities at the outskirts of Abuja. The hospital, being a referral centre for diabetes mellitus, has consultant diabetologists and qualified clinical pharmacists who render pharmaceutical care services to patients with chronic diseases.

Study design

The study is a randomized controlled two-arm parallel prospective study with a 12- month patient follow-up.

Study Participants

The study participants were patients with Type 2 DM who were 18 years and above, drawn from endocrinology and general outpatient clinics, and already on oral hypoglycemic agents' prescription (but not on insulin injection).

Ethical Approval

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

Data Collection

Sociodemographic data and clinical parameters of all the recruited participants from both the control and test groups were taken at baseline, at 3rd month, at 6th month and at 12th month. The scores of domains of quality of life in the study participants in both the control and the intervention groups were measured through administration of SF-36 Questionnaire at the same intervals.

Sample Size

Published data on the variability of HbA1c in T2DM patients dictated that to detect an absolute difference of >1% in HbA1c (a clinical effect), with $\alpha = 0.05$ and a power of 0.90 (90%), a sample size of 104 patients in each of the control and intervention groups was required ^[40]. This was adopted and used. Based on these data, to ensure sufficient statistical power and to account for 'drop-outs' during the study, a target sample size of 240 patients (120 control and 120 intervention) was used.



Randomization

Participants were recruited and randomized into the two groups using systematic randomization. Patients in the intervention group received pharmaceutical care interventions through Structured Education Program (SEP) by clinical pharmacists while patients in the control group received only usual or normal care devoid of any special training session from the clinical pharmacists. Scores of the domains of quality of life were measured at the baseline, at three months, at six months and at 12 months intervals for both intervention and control groups.

Normal Care Process (NCP)

NCP defines the usual process through which patients with T2DM pass in FMC Keffi to assess health care. Firstly, patients go to Medical Records Department to activate their personal data in the electronic medical record (EMR). Secondly, they go to triage nurses for taking of vital signs, and thirdly, they go to the clinic for consultation and prescription by the physician. And lastly, they go to pharmacy for prescription filling. The patient normally spends an average of 8-10 minutes each with the physician and the pharmacist. The normal care received by patients from the physician usually does not go beyond prescription and an instruction to go to pharmacy to access medication and an information for a new date of next appointment. For participants in the NCCG in this study, who served as the control, they received only this normal care without any special training in form of structured education program (SEP) by the clinical pharmacists.

Pharmaceutical Care Intervention Process (PCIP)

PCIP is the 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 pharmacists, in addition to NCP. In this study, participants in PCIG received SEP at enrolment, at 2nd encounter (after one month), and at 3rd encounter (after two months). There was also repeated counseling by the clinical pharmacists during every encounter with patients at each hospital visit on the components of the SEP.

The Structured Education Program (SEP)

At Enrolment

Participants were asked several questions on lifestyle modification, the disease and the medication with the aim of identifying their education needs. The responses were documented as the identified education needs of the participants.

Education Needs of the Participants

The following indices were identified as the education needs of the participants and they were appropriately addressed:

- Knowledge on the disease and its process
- 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.

Diabetes and its complications

Participants were briefly educated on what diabetes is all about and were made to understand that it is the long-standing hyperglycemia that is responsible for the irreversible complications such as retinopathy (blindness), neuropathy (amputation) and nephropathy (kidney failure) usually associated with diabetes.



Diabetes medications and their side effects

Participants were briefly educated on the commonly used medications in the management of diabetes and their side-effects so that they would be able to manage the unavoidable ones and avoid the ones that can be avoided. They were discouraged from missing any dose of their medication and also encouraged to use family members clock or phone alarm to remind them on the time of taking their medication. This point was re-emphasized to them at every encounter with the clinical pharmacists.

Life style modifications

Participants were educated on the significance of lifestyle modifications in diet and physical activities (exercise). They were encouraged to modify the types of food they eat and their quantities, avoid sedentary life and adopt one form of physical exercise to practice.

Self-monitoring of blood glucose (SMBG)

Participants were introduced to the concept of SMBG. They were educated on its importance in diabetes management and were encouraged to measure their sugar level at least three times a week.

Self-monitoring of the disease (SMD)

Participants were introduced to the concept of SMD through identification of common signs and symptoms of DM. They were trained to differentiate symptoms of hyperglycemia (extreme thirst, dry mouth, nausea, blurred vision and shortness of breath) and hypoglycemia (hunger, sweating, confusion, fast heartbeat, dizziness and slurred speech).

Second Encounter (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

Participants were encouraged to reduce intake of saturated fats and increase the intake of mono and polyunsaturated fats such as olive oil, as dietary control. The saturated fats to reduce include butter, fatty red meat, fast foods etc.

They were educated on foods with high glycemic index (GI) > 70 and were advised to reduce or moderate them. Foods with high glycemic index (GI) > 70 include maize, white rice, cassava etc. But they were advised to increase intake of foods with low GI such as beans and carrots.

Participants were advised to engage in aerobic exercise such as brisk walking for about 90-150 minutes per week.

Third Encounter (after 2 months)

Sharing experiences

Participants were subjected to an interactive session to share the difficulties experienced and how to overcome them 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

Skin, Foot and Dental Care

Participants were educated on the need to observe skin, foot and dental care. They were encouraged to minimize the contact of hard objects with such parts to avoid causing injuries as healing of injuries is always slow in DM. They were encouraged to use soft tooth brush and room slippers to avoid being injured.

Follow Up and Appointments

Participants were counselled and encouraged not miss their clinic appointments for proper review and monitoring, and they were equally counselled to make sure they see their clinical pharmacists on each hospital visit so that they receive pharmaceutical care education.

All these counselling points as they relate to lifestyle modification, medication adherence and self-monitoring of glucose were repeatedly mentioned to the participants in the intervention group at every encounter with the clinical pharmacists. The scores of domains of quality of life of the participants were assessed at baseline, 3rd, 6th and 12th month.

Materials used

- a. Diabetes Diaries
- b. Training Manuals for Research assistants
- c. Data Collection Booklets for documenting:
- d. Patients' Demographic Data
- e. SF-36 Questionnaire

Outcome Measures

The changes from baseline to 3rd, 6th and 12th month in the scores of domains of QoL of participants in both the control and intervention groups were measured.

Data Analysis

Socio-demographic data of the participants in both the control and intervention groups were generated, analyzed and compared. Scores of domains of QoL of the participants in both the control and intervention groups were assessed, analyzed and compared at baseline, at 3rd month, at 6th month and at 12th month. 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 and percentages. Comparison of frequencies and proportions was carried out using χ^2 or Fisher's exact, as appropriate. $P \leq 0.05$ level of significance was used throughout.

RESULTS

At baseline, similarities and differences were observed in the sociodemographic characteristics of the study participants in both the control and the intervention groups, but the differences were statistically not significant. Similar findings were revealed in the quality of life of the study participants at baseline. At the end of the 12th month, higher changes were observed in the domains of quality of life in the intervention group than the control group.

Sociodemographic Data of Participants

From the 240 study participants randomized into intervention (120) and control (120) groups, 4 and 2 participants were lost to follow-up in the intervention (n=116) and control (n=118) groups respectively. Tables 1 and 2 represent sociodemographic characteristics of the study participants which revealed that majority of the participants were females (54.2%); a good majority had their diabetes duration falling within the age range of 1-5 years (65.8%); majority of participants 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 take alcohol (95.8%). A good number of them were either unemployed (40.4%) or had 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. Statistical analysis of the sociodemographic characteristics for the study participants revealed similarities as the little differences observed were not statistically significant.

Table 1

Socio-demographic Characteristics of Participants in NCCG and PCIG at Baseline

Variables	NCCG (120)	PCIG (120)	Total (240)	P-value
Age (Years)				0.075
20 – 39	17 (14.1)	12 (10.9)	20 (12.6)	
40 – 59	82 (68.4)	69 (57.4)	151 (62.8)	
60 – 79	19 (15.8)	36 (30.0)	55 (22.9)	
Above 79	2 (1.7)	2 (1.7)	4 (1.7)	
Mean \pm Sd	50.73 ± 11.95	53.98 ± 11.73	52.36 ± 11.93	
Gender				0.092
Female	58 (48.3)	71 (59.2)	129 (53.8)	
Male	62 (51.7)	49 (40.8)	111 (46.3)	
Duration of Diabetes (years)				0.134
≤ 5	87 (72.5)	71 (59.1)	158 (65.8)	
6 – 15	26 (21.7)	35 (29.2)	61 (25.4)	
16 – 25	6 (5.0)	8 (6.7)	14 (5.9)	
26 – 35	1 (0.8)	4 (3.3)	5 (2.1)	
36 – 40	0 (0.0)	2 (1.7)	2 (0.8)	
Mean \pm Sd	4.73 ± 2.84	5.25 ± 3.24	4.99 ± 3.05	

NCCG = Normal Care Control Group, PCIG = Pharmaceutical Care Intervention Group, * $P < 0.05$, ** $P < 0.001$. Chi square test or Fisher's exact as appropriate.

Table 2

Socio-demographic Characteristics of Participants in NCCG and PCIG at Baseline

Variables	NCCG (120)	PCIG (120)	Total (240)	P-value
Educational status				0.080
None	23 (19.2)	28 (23.3)	51 (21.2)	
Primary	25 (20.8)	21 (17.5)	46 (19.2)	
Secondary	42 (35.0)	27 (22.5)	69 (28.8)	
Tertiary	30 (25.0)	44 (36.7)	74 (30.8)	
Occupation				0.111
Employed	57 (47.5)	73 (60.8)	130 (54.2)	
Retired	8 (6.7)	5 (4.2)	13 (5.4)	
Unemployed	55 (45.8)	42 (35.0)	97 (40.4)	
Marital status				0.342
Divorced	6 (5.0)	2 (1.7)	8 (3.3)	
Married	94 (78.3)	94 (78.3)	188 (78.3)	
Single	7 (5.8)	10 (8.3)	17 (7.1)	
Widowed	13 (10.9)	14 (11.7)	27 (11.3)	

NCCG = Normal Care Control Group, PCIG = Pharmaceutical Care Intervention Group, * $P < 0.05$, ** $P < 0.001$. Chi square test or Fisher's exact as appropriate



Quality of Life Data of Study Participants

Table 3 represents inter-group comparison of domains of quality of life of study participants in the control and intervention groups at baseline. The results revealed some little differences among the participants of the two groups which were not statistically significant (p-value >0.05 in each of the domains).

Table 3

Comparison of Domains of Quality of Life (QoL) in Both NCCG and PCIG at Baseline

Activities	NCCG (N=120)	PCIG (N=120)	P-value
Physical Functioning	80±11.0	78±10.0	0.142
Role limitation due to physical health	89±12.0	88±21.0	0.651
Role limitation due to emotional problem	91±17.0	89±10.0	0.268
Energy/Fatigue	86±25.0	83±18.0	0.265
Emotional wellbeing	77±18.0	80±11.0	0.121
Social functioning	88±11.0	85±15.0	0.079
Pain	89±12	90±19	0.626
General Health	68±11.0	70±9.0	0.125

NCCG=Normal Care Control Group, PCIG=Pharmaceutical Care Intervention Group. Two sample independent test.

Table 4 represents inter-group comparison of domains of quality of life among the study participants in the control and the intervention groups at the 3rd month. The result indicated some changes in most of the domains among participants in the intervention group. with differences that were statistically significant (p-value <0.05), except in two domains in which the differences were not statistically significant (p-value >0.05). Such statistically significant changes did not occur among the participants in the control group.

Table 4

Comparison of Assessment of Domains of Quality of Life (QoL) Among Participants in NCCG and PCIG at 3rd Month

Activities	NCCG (N=119)	PCIG (N=119)	P-value
Physical Functioning	80 ± 11.0	75 ± 10.0	0.001
Role limitation due to health	89 ± 12.0	88 ± 21.0	0.651
Role limitation due to emotional problem	91 ± 17.0	87 ± 10.0	0.027
Energy/fatigue	86 ± 25.0	79 ± 18.0	0.014
Emotional wellbeing	77 ± 18.0	81 ± 11.0	0.039
Social functioning	88 ± 11.0	84 ± 15.0	0.019
Pain	89 ± 12	90 ± 19.0	0.626
General health	66 ± 11.0	70 ± 9.0	0.002

NCCG = Normal Care Control Group, PCIG = Pharmaceutical Care Intervention Group, Significance level P<0.05.

Table 5 represents inter-group comparison of domains of quality of life among the study participants in the control and the intervention groups at the 6th month. The result revealed nearly similar findings to the effect of intervention after 3rd month where the differences were statistically significant (p-value <0.05) in all most all domains, except three with p-values > 0.05.

Table 5

Comparison of Assessment of Domains of Quality of Life (QoL) Among Participants in NCCG and PCIG at 6th Month

Activities	NCCG (N=118)	PCIG (N=118)	P-value
Physical Functioning	85±8.0	96±10.0	0.001
Role limitation due to physical health	92±16.0	95±17.0	0.161
Role limitation due to emotional problem	92±9.0	95±12.0	0.030



Energy/Fatigue	86±16.0	89±24.0	0.256
Emotional wellbeing	85±14.0	91±9.0	0.001
Social functioning	85±21.0	92±8.0	0.001
Pain	95±11.0	97±13.0	0.200
General Health	73±12.0	83±14.0	0.001

NCCG=Normal Care Control Group, PCIG=Pharmaceutical Care Intervention Group, Significance level $P < 0.05$

Table 6 refers to intergroup comparison of the study participants at the 12th month. At the end of the 12th month, the intervention group had significantly higher scores in most QoL domains compared to the control group, indicating better QoL. The only domain in which statistically significant difference was not achieved is 'role limitation'.

The possible reasons why there was no significant difference between the control and the intervention groups in the role limitation could be attributed to duration of intervention. The 12-month duration of the intervention might not have been adequate to impact physical health limitations significantly. Improvements in physical health and reductions in role limitations due to physical health might require longer-term interventions or follow-up periods. Another reason could be attributed to the nature of the intervention. The pharmaceutical care intervention might have focused more on educational and medication management aspects rather than physical rehabilitation or interventions directly targeting physical health limitations. Again, another reason could be baseline physical health status. If participants in both groups had similar baseline physical health statuses and existing physical limitations, the intervention might not have been able to differentially impact this particular domain of QoL within the study timeframe (Table 6).

Table 6

Comparison of Assessment of Domains of Quality of Life (QoL) Among Participants in NCCG and PCIG at 12th Month

Activities	NCCG	PCIG	P-value
Physical Functioning	82 ± 11.0	99 ± 9.0	0.001
Role limitation due to physical health	94 ± 12.0	98 ± 19.0	0.053
Role limitation due to emotional problem	91 ± 8.0	96 ± 9.0	0.001
Energy/Fatigue	86 ± 7.0	96 ± 8.0	0.001
Emotional wellbeing	81 ± 10.0	95 ± 20.0	0.001
Social functioning	85 ± 13.0	97 ± 11.0	0.001
Pain	87 ± 8.0	97 ± 12.0	0.001
General Health	68 ± 15.0	86 ± 9.0	0.001

NCCG=Normal Care Control Group, PCIG=Pharmaceutical Care Intervention Group, Significance level $P < 0.05$

DISCUSSION

The study participants in the control and intervention groups have similarities in sociodemographic profile as the mean differences of all their sociodemographic characteristics were not statistically significant at baseline, as depicted by tables 1 and 2. Some few empirical differences observed, that were not significant, could be due to sociocultural differences, time of diagnosis, low physical activities in females than males. The findings in the study were also consistent to the findings of Alfayez et al. (2017)⁴¹ which reported that majority of the patients with T2DM were female (64.29%) and the mean age of the participants was 52.07 years which is relatively comparable to 52.36 years of this study (Table 1).

They also have similarities at baseline in the outcome of interest, namely, quality of life, as the mean differences of their indices were not statistically significant, as depicted by table 3. This lack of significant differences in the mean values of data in all the study participants of the two groups at baseline, implies that the impact of the normal care process was the same on all the study participants before intervention and also strengthens the internal validity of the study.

The improved quality of life observed in the intervention group at the 3rd, 6th and 12th months of pharmaceutical care intervention.

The improvement in quality of life observed in the intervention group at the 3rd, 6th, and 12th months (Tables 4, 5 and 6), following pharmaceutical care intervention is consistent with findings from previous studies. Evidence from controlled trials indicates that structured pharmaceutical care and patient education interventions significantly enhance health-related quality of life among



individuals with T2DM when compared to usual care ^[42]. In this study, QoL was significantly better in the intervention group following intervention, compared to the control group. Similarly, quality of life outcomes have been shown to be significantly better in intervention groups than in control groups following pharmacist-led care. Studies focusing on pharmaceutical care interventions report improvements across multiple quality-of-life domains, reinforcing the role of pharmacists in improving patient-reported outcomes in diabetes management ^[43].

Essentially, the study revealed that after 12 months, the control group showed no significant changes in quality of life. On the other side, the intervention group produced statistically significant improvements in the health outcome of interest. In other words, the intervention group produced better changes than the control group in quality of life. This is consistent with the findings of ^[44]. This suggests that the pharmaceutical care intervention effectively improved most aspects of QoL for participants in the PCIG.

The improvement in QoL can be attributed to the structured pharmaceutical care which likely empowered patients with better knowledge and practices, contributing to an overall better QoL. This is consistent with several studies regarding significant improvements after specialized training.

Overall, the statistically significant improvements observed in the intervention group align with broader evidence demonstrating that educational and clinical pharmacist interventions lead to better health outcomes than standard care. Systematic reviews of randomized controlled trials confirm that pharmacist-provided education and follow-up are associated with improvements in glycaemic control, medication adherence, and quality of life across various patient populations ^[45]. Also, a systematic review by ^[46] reported that educational interventions by clinical pharmacists were associated with improved health outcomes in various patient populations.

All these achievements in this pharmacist-led pharmaceutical care intervention study, are products of the structured education program (SEP), delivered by the clinical pharmacists to the intervention group which focused on diabetes and its complications, medications and their side effects, medication adherence and lifestyle modifications on diet and exercise.

These findings may have some potential implications such as healthcare policy in which policymakers might consider integrating pharmaceutical care interventions into standard diabetes management protocols to improve patient outcomes. They can also be considered in clinical practice in which healthcare providers could adopt structured education program as a useful tool for pharmaceutical care interventions to empower patients and enhance their self-care skills. Again, these findings also can lead to patient empowerment which underscores the importance of patient-centred care, suggesting that empowering patients through education can lead to improved QoL and better health outcomes. Finally, they may compel resource allocation in which healthcare systems might allocate resources to support pharmaceutical care interventions, taking into consideration, their potential to improve outcomes and reduce long-term complications.

SUMMARY OF FINDINGS

At the end of the 12-month study, findings revealed that pharmaceutical care intervention (PCI) significantly improved quality of life in patients with T2DM providing evidence of the effectiveness of PCI in diabetes management. The findings can be summarized as:

1. Better QoL scores were achieved in patients with T2DM who received PCI than those who received normal care.
2. Health literacy, a significant component of PCI improved QoL of patients with T2DM.

LIMITATIONS OF THE STUDY

1. The study focused only on quality of life, which is a humanistic outcome, limiting its ability to assess clinical outcomes that will evaluate glycaemic, lipid and BP controls.
2. Its ability to assess the cost-effectiveness of the pharmaceutical care intervention is also limited. This implies that the study has limited ability to inform decision-makers about the economic implications of implementing such an intervention.
3. The study was conducted in only one centre, and this may limit its ability to detect the influence of geographic locations and cultural diversity on health outcomes.



RECOMMENDATIONS

1. Healthcare policymakers should integrate pharmaceutical care into National Health Policy of Nigeria, and it should be adopted and integrated into routine practice in secondary and tertiary hospitals to improve health outcomes for patients with Type 2 diabetes mellitus.
2. Clinical pharmacists should be integrated in the management of diabetes in health institution with the primary mandate of enhancing health literacy in the population.

CONCLUSION

The findings of this study revealed that pharmacist-led pharmaceutical care intervention is effective in improving quality of life of patients with type 2 diabetes mellitus. These positive outcomes resulting from clinical pharmacists' professional involvement in direct patient care are indicators that incorporating pharmaceutical care intervention into the healthcare process within healthcare institutions will optimize treatment goals and outcomes.

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