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Full Length Research Paper

Effects of an additional pharmaceutical care intervention versus usual care on clinical outcomes of Type 2 diabetes patients in Nigeria: A comparative study

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The aim of this study was to evaluate the impact of an additional pharmaceutical care intervention on clinical outcomes of Type 2 diabetes patients receiving care in tertiary hospitals. This study was a randomized, controlled and longitudinal study with a 12-month patient follow-up. This study was conducted in two Nigerian University Teaching Hospitals. Patients in 'usual care' received the usual/conventional care offered by the hospitals. Patients in 'intervention' received usual care and pharmaceutical care for 12 months. This additional pharmaceutical care included a stepwise approach: setting priorities for patient care, assessing patient's specific educational needs and identification of drug related problems (DRPs), development of a comprehensive and achievable pharmaceutical care plan in collaboration with the patient and the doctor, implementation of the this plan, monitoring and review of the plan from time to time. By end of 12 months, there were significant reductions in the following clinical outcomes (control vs. intervention): glycosylated haemoglobin (%) (7.77 ± 1.12 vs. 7.23 ± 1.09; P = 0.0009), fasting glucose (mg/dL) (168.7 ± 11.49 vs. 129.34 ± 9.97; P < 0.0001). The results for LDL-C, HDL-C, Triglycerides and Total Cholesterol were 116.28 ± 9.64 vs. 101.43 ± 8.35; P < 0.0001, 45.29 ± 6.68 vs. 53.82 ± 5.81; P < 0.0001, 159.59 ± 8.91 vs. 154.37 ± 10.34; P = 0.0002, 203.75 ± 25.96 vs. 188.71 ± 19.41; P < 0.0001 respectively. The intervention resulted in beneficial improvement of clinical outcomes of Type 2 diabetes patients receiving treatment in tertiary hospitals.

Key words: Pharmacist, pharmaceutical care, intervention, diabetes outcomes, clinical outcomes, Type 2 diabetes, randomized, controlled study.

INTRODUCTION

Diabetes mellitus is associated with considerable morbidity and mortality. Diabetes is also a major risk factor for cardiovascular disease, stroke, and kidney failure (Akanji and Adetunji, 1990). Diabetes mellitus (DM) was once regarded as a disease of the affluent but is now vastly visible as a growing health problem in

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developing economics as almost 80% diabetes death occurs in low and middle income countries (International diabetes federation; Odili et al., 2010). The national standardized prevalence rate of DM in Nigeria is 2.2%, while the crude prevalence rate is 7.4% in those aged 45 years and above who live in urban areas (Nyenwe et al., 2003). Global estimates of the prevalence of diabetes for 2010 and 2030 showed that prevalence of diabetes in Nigeria in 2010 was 4.7% and 3.9% and it would be 5.5% and 4.3% in 2030 when compared with world population and national population, respectively (Shaw et al., 2010).

Pharmaceutical care is the direct, responsible provision of medication related care with the purpose of achieving definite outcomes that improve a patient's quality of life (Hepler and Strand, 1990). The principal elements of pharmaceutical care are that it is medication related; it is care that is directly provided to the patient by pharmacist; it is provided to produce definite outcomes; these outcomes are intended to improve the patient's quality of life; and the provider (pharmacist) accepts personal responsibility for the outcomes (Hepler and Strand, 1990). Diabetes is a disease that desperately needs more pharmacist involvement. Pharmacists who are specialized in this growing chronic condition can make a significant, positive impact on the patient, the health care system and themselves (Davis et al., 2005). Health-care professionals are becoming increasingly aware of the need to assess and monitor the quality of life (QoL) as an important outcome of diabetes care.

Health related quality of life HRQoL is an important outcome on its own right and, because it may influence the patient's self-care activities, which may consequently impact on the diabetes control (Khan et al., 2004). Many pharmaceutical care programs have been established in various countries to enhance clinical outcomes and the health-related quality of life (HRQoL). These programs were implemented by pharmacists, with the cooperation of the physicians and other health care professionals. Pharmaceutical care and the expanded role of pharmacist are associated with many positive diabetes-related outcomes, including improved clinical measures (Jaber et al., 1996), improved patient and provider satisfaction (Sadur et al., 1999; Majumdar et al., 2003), and improved cost of management (Sadur et al., 1999; Coast-Senior et al., 1998). The pharmacist can therefore, in collaboration with physicians and other health care professionals, contribute to the improvement of diabetic patients' quality of life by informing and educating patients, answering their questions and, at the same time monitoring the outcomes of their treatment (Hawkins et al., 2002). Currently in Nigeria, there is no available evidence of impact of pharmaceutical care intervention on clinical outcomes of patients with Type 2 receiving treatment in tertiary hospital.

The aim of this study was to evaluate the impact of an additional pharmaceutical care intervention on clinical diabetes outcomes of patients with Type 2 diabetes receiving care in tertiary hospitals.

METHODS

Study design

This study was a randomized, controlled, and longitudinal prospective study with a 12-month patient follow-up.

Study setting

The study protocol was approved by the Research Ethical Committees of the University of Nigeria Teaching Hospital, ItukuOzalla (UNTH) and NnamdiAzikiwe University Teaching Hospital, Nnewi (NAUTH) in which this study was conducted. These hospitals are tertiary hospitals that serve as referral centers to most of the hospitals in Nigeria.

Inclusion/exclusion criteria

Patients with Type 2 diabetes mellitus who fulfilled the recruitment criteria were identified and included in the study. The inclusion criteria were: patients that were diagnosed of Type 2 diabetes mellitus and/or patients that were receiving oral hypoglycemic therapy, patient who provided written informed consent, patients who expressed willingness to abide by the rules of study, patients who were certified fit for the study by their consulting doctors.

Exclusion criteria were patients who were diagnosed of Type 1 diabetes (to avoid complexity in the study scope), patients who were less than 18 years (they are legally regarded as minor and consequently they cannot take decision of their own), patients who were pregnant (they are generally not allowed to participate in the study of this nature by the institutions used for the study), patients who expressed willingness to withdraw from the study (participation is voluntary). These criteria were according to the guiding principles of the institutional review boards of the hospitals used in this study.

Patients' selection

Following sample size power calculation, a sample size of at least 104 patients in each of the control and intervention groups was required. Based on these data, to ensure sufficient statistical power and to account for 'drop-outs' during the study, a target sample size of 220 patients were recruited (110 patients from each of the hospitals).

The folders of the 110 selected patients in each hospitals (UNTH and NAUTH) were assigned numbers 1 to 110 which represented individual patient, patients were randomly assigned to one of two sub-groups (intervention group-PC or control group-UC) based on the number on their folders using online 'random sequence generator' (Mads-Haahr, 1998) with sequence boundaries of 1 to 110 (boundaries inclusive) set in two columns format: first column was priori designated to sub-intervention group (55 patients) and second column sub-control group (55 patients) see the flow chart in the Figure 1.

Data collection

Each recruited patient was interviewed face-to-face (for approximately 20 min) by the research clinical pharmacist to obtain details of their socio-demographics, family history of diabetes. Patients' files were reviewed to obtain information on medications being used, co-morbidities, patients' hospital visits and admissions. The recruitment lasted for three months. Pharmaceutical care diary

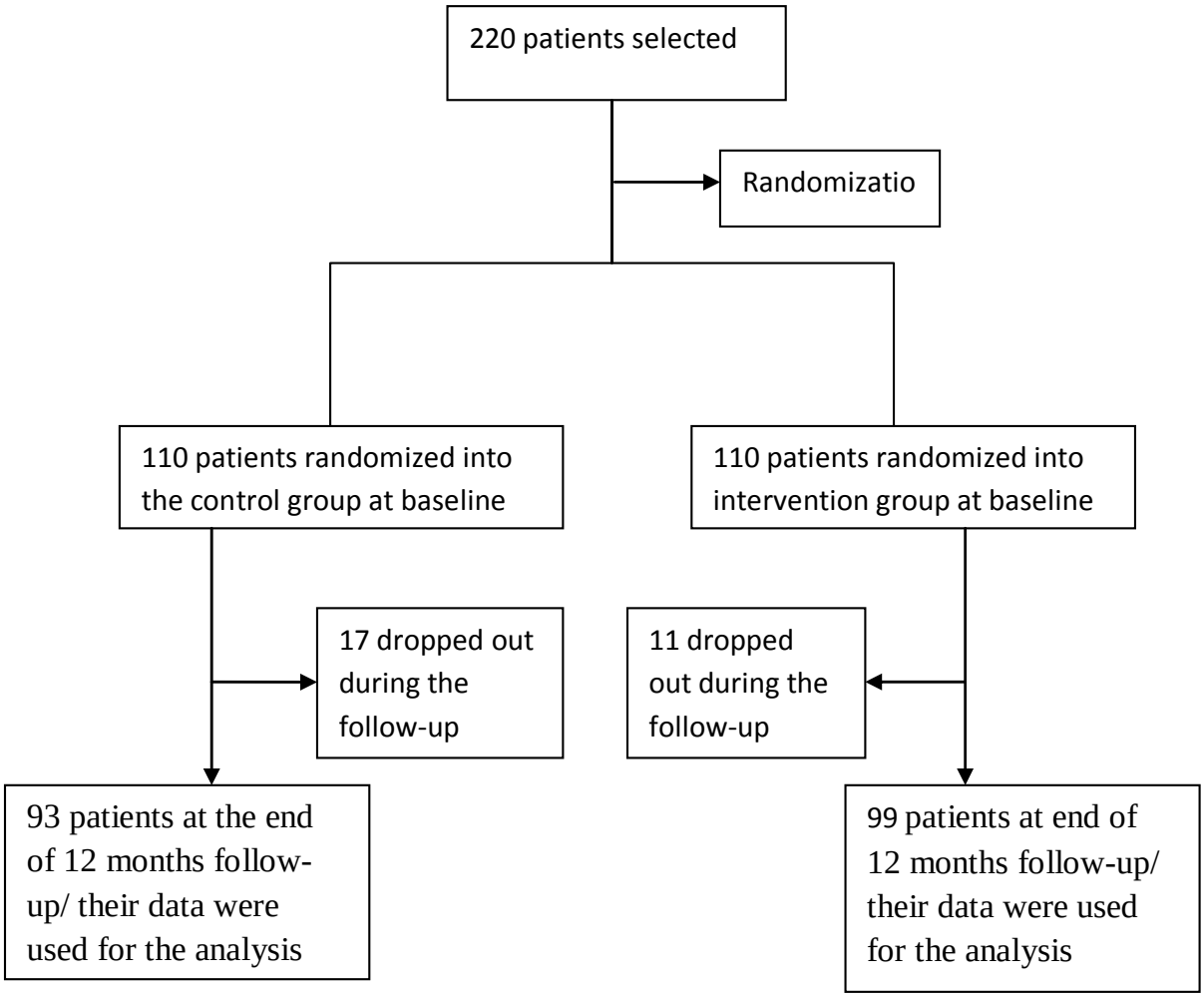

Figure 1. Flow chart of the participants.

was given to each patient to gather data on frequency of continuous home blood glucose monitoring, fasting blood glucose, systolic and diastolic blood pressure, drug-related problems and adherence to medication. There were routine measurements of body weight and body mass index (BMI), HbA1c, serum total cholesterol, serum creatinine, serum HDL-C, serum low density lipoprotein-cholesterol (LDL-C) and serum triglycerides.

Evaluation of training course and teaching materials

The medical and educational contents of the training materials were evaluated by the doctors and nurses in diabetes clinics before the administration of the materials to the patients. They were asked to rate the materials as being excellent, very good, good, fair, poor, and unsuitable for use.

Study procedures

Patients in UC received the usual/conventional care offered by the hospitals which included: hospital visits on appointment or on a sick day, consultations with the doctors, prescription of drugs and routine laboratory tests, review of diagnosis and medications, refilling of prescriptions by patients and referral. This usual care was offered with little or no education/training of the patients on their diseases and drugs and without empowerment of the patients to be fully involved in the self-management of their illnesses.

Patients in PC received usual care and pharmaceutical care for 12 months. This additional pharmaceutical care included a stepwise approach: setting priorities for patient care, assessing patient's specific educational needs and identification of drug related problems (DRPs), development of a comprehensive and achievable pharmaceutical care plan in collaboration with the patient and the doctor, implementation of the this plan, monitoring and review of the plan from time to time (Hepler and Strand, 1990).

The nurses collaborated with the pharmacist in terms of organizing the patients and patients' folders, taking point of care testing, counseling the patients, and reinforcing the information given to the patients during training sections. The physicians provided the visitation/appointment schedule for the patients, and prescription of laboratory tests. They were also involved in implementation of consensus strategies in managing drug related problems in areas of changing, substitution, and withdrawal of medications. All the members of the health care team were trained before the implementation of the intervention.

Table 1. **The treatment goals/targets and therapeutic protocol.

S/N	Parameter	Goals/ Targets
1	HbA_{1c}	< 7%
2	FBG	70-130 mg/ dL
3	RBG	< 200 mg/dL
4	2h-postprandial blood glucose	< 180 mg/ dL
5	BP	< 130/80 mmHg
6	Total cholesterol	< 200 mg/ dL
7	LDL-C	< 100 mg/ dL or ~ 30-40% reduction.
8	HDL-C	>50 mg/dL (Women), > 40 mg/dL (men)
9	Triglycerides	< 150 mg/dL
10	Waist circumference	Male < 94 cm, female < 82 cm
11	Physical activity	1 h brisk walking ≥ 3 times/ week
12	Weight loss	~ 5-10% if overweight
13	Alcohol intake	< 1 (men) and < 0.5 (women) bottle of beer/day (3 units of alcohol per bottle)
14	Smoking cessation	100%
15	Medication adherence	100%
16	Continuous self-monitoring of glucose and BP	100%
17	Medication adherence	100%
18	Appointments/follow-up	100%
	Therapeutic protocol	**Actions**
19	Patient with Hypertension	ACEI/ ARB therapy
20	Dyslipidaemia or age > 40 years with CVD risk.	Statin therapy
21	If HbA_{1c} > 8.5%	Basal insulin therapy
22	Age > 40 years with CVD risk	Aspirin/clopidogrel therapy

** These targets and protocols could be adjusted to meet individual needs of the patients.

The educational/training program for the patients consisted of 4 sessions of 90 to 120 min. The program covered the following areas: diabetes overview and its complications, self-monitoring blood glucose techniques and interpretation of diabetes related tests, medications and their side-effects, life style modification, counseling and effective interaction with health providers. Pharmaceutical care provided ground for the patients to monitor and react to changes in their blood glucose levels, allowing them to integrate their diabetes into the lifestyle they preferred. Glucometer and strips were given to the patients as motivation and to encourage continuous self blood glucose monitoring. Data were collected on baseline (first 3 months), 6, 9 and 12 months. The treatment goals/targets and therapeutic protocol used during the study is shown in Table 1.

Data analysis

Statistical analyses were performed using the SPSS version16. An intention-to-treat approach was used. Two-sample comparisons were made using Student's *t*-tests for normally distributed variables or Mann–Whitney *U*-tests for non-normally distributed data. Comparisons of proportions were done using Chi square or Fisher's exact. The differences in PC and UC were assessed at baseline and 12 months. An a priori significance level of $P < .05$ was used throughout.

Since we used two hospitals, we initially made comparisons of the sub-UC of UNTH and NAUTH, also

sub-PC of UNTH and NAUTH to determine their similarity, or, more specifically, to uncover any problems related to selection, history, or maturation effects. If major differences were identified, we planned to analyze and report the group findings separately. If the groups were found to be essentially similar in these respects, we planned to combine the groups for baselines and 12 months assessments of the effects of PCs (Cranor and Christensen, 2003). The latter condition was applicable to this study.

RESULTS

The medical and educational contents of the training course were rated positively by the 17 doctors and 29 nurses: the majority 38 (82.6%) rated the contents as 'Excellent' and remaining 8 as 'very good' or 'good' and only 3 (6.5%) of them suggested little modification or changes which were effected before the materials were administered.

The number of patients who completed the study and whose data were analysed at 12 months in UC and PC were 93 (84.55%) vs. 99 (90.0%), respectively. With the exception of patients' variables 'number of participants taking hypertensive drugs' and 'smoking', we found no other variable differing significantly at baseline when the sub-UC and sub-PC arms of the two hospitals were compared (Table 2).

The number of patients who completed the study and whose data were analyzed at 12 months in UC and PC were 93(84.55%) vs. 99 (90.0%) respectively. There were significant improvements in all the clinical parameters measured after 12 months of intervention (Table 3).

There were significant changes in number of patients that achieved 'control' in the following parameters (change, % change) after 12 months of intervention: HbA1c < 7%: 17 (18.28%); P = 0.0466; Obesity: -10 (10.75%); P = 0.0364, Overweight: -16 (-17.2%); P = 0.0067, and high-density lipoprotein cholesterol (HDL-C) > 40 mg/dl: 19 (20.43%); P = 0.0195 (Table 4). (For this study, we defined "control" as the normal ranges as reported by ADA (2011).

DISCUSSION

This study revealed that there were significant changes in number of patients that achieved 'control' in the following parameters after 12 months of intervention: HbA1c, overweight, and high-density lipoprotein cholesterol (HDL-C), LDL-C, Triglyceride and total cholesterol.

Patients with Type 2 diabetes are more likely to die from cardiovascular disease than people without diabetes, and modifiable risk factors such as hyperglycemia, dyslipidemia, and hypertension can be targeted to reduce this risk (UKPDS, 1998; Gaede et al., 2000). In addition to community-based care, there is a need for simple, cost-effective programs implemented in the hospital that allows the benefits of improved metabolic and blood pressure control to be realized more widely (Viberti, 2003). Pharmacists could contribute to such programs through pharmaceutical care (PC). This PC intervention comprised elements that are parts or extensions of existing diabetes management namely: individualized patient education and follow-up reinforcement through additional written educational material; use face-to-face interview and appointments; provision of a regularly updated, goal-directed, patient-specific medication profile designed to improve patient compliance and understanding. It was tailored to promote communication of drug-related information between patient, pharmacist, primary care physician, and other health care professionals. Although, the clinical benefits of PC intervention in the present study cannot be assessed in relation to the individual contributions of these factors, they reflect effects of combined strategies (Kennie et al., 1998).

This study demonstrated that a 12-month PC program implemented for Type 2 diabetes patients can produce beneficial reductions in modifiable vascular risk factors, most notably glycemic control (HbA1C), blood pressure and dyslipidaemias. Pharmacist-administered diabetes education and management services have been shown to improve glycemic control over standard treatment, as well as to improve control of blood pressure, hyperlipidemia and increase in the frequency of aspirin use (Keil and McCord, 2005). Garrett and Bluml (2005) demonstrated that patients who participated in the pharmaceutical care intervention had significant improvement in clinical indicators of diabetes management, higher rates of self-management goal setting and achievement, and increased satisfaction with diabetes care.

Glycosylated Haemognobin (HbA1c)

A significant higher mean reduction was noted in PC group when 12-month value was compared to baseline value while there was no significant change in the UC group. This suggests that regular pharmacist contact was beneficial perhaps through encouraging adherence with blood glucose–lowering therapy and a prudent diet.

The HbA1C test is subject to certain limitations: conditions that affect erythrocyte turnover (haemolysis, blood loss) and haemoglobin variants must be considered, particularly when the HbA1C result does not correlate with the patient's clinical situation (DCCT, 1993; Stratton et al., 2000; Sack et al., 2002). In addition, HbA1C does not provide a measure of glycemic variability or hypoglycemia. For patients prone to glycemic variability (especially Type 1 patients, or Type 2 patients with severe insulin deficiency), glycemic control is best judged by the combination of results of self monitoring blood glucose (SMBG) testing and the HbA1C (ADA, 2011).

Blood pressure

This study demonstrated a positive effect of the pharmaceutical care intervention on blood pressure

Table 2. Baseline characteristics of the patients in PC and UC arms.

Demographic data	UC (N=110)	PC (N=110)	p-value
Mean Age (years)	52.8 ± 8.2	52.4 ± 7.6	0.708
Grouped Age: > 53 years, no (%)	81(73.64)	75 (68.18)	0.373
Sex: Male, no (%)	49 (44.55)	44 (40)	0.495
Level of education (%)			0.406
Primary school, no (%)	3 (2.72)	6 (5.45)	
Secondary school, no (%)	71 (64.55)	63 (57.27)	
University, no (%)	36 (32.73)	41 (37.27)	
Marital status (%)			0.409
Currently married, no (%)	37 (33.64)	46 (41.82)	
Widowed, no (%)	71 (64.54)	63 (57.27)	
Single, no (%)	2 (1.82)	1 (0.91)	
Occupation (%)			0.611
Self employed, no (%)	37 (33.64)	34 (30.91)	
Employee, no (%)	35 (31.82)	42 (38.18)	
Retired, no (%)	38 (34.54)	34 (30.91)	
Smoking status: Smoker, no (%)	34 (30.91)	21 (19.09)	0.043*
Dignostic Time- Mean (SD)	4.5±2.2	4.8±2.8	0.378
Dignostic Time: ≥ 5 years, no (%)	62 (56.36)	71 (64.55)	0.215
Family hx of diabetes, no (%)	71(64.55)	62 (56.36)	0.214
Physical Activity/Exercise no (%)	18 (16.36)	23 (20.91)	0.387
Co-morbidities			
Hypertension	60 (54.55)	73 (66.36)	0.073
Congestive heart failure	11 (10.00)	15 (13.64)	0.404
Ischemic heart disease	7 (6.36)	8 (7.27)	0.789
Arthritis	37 (33.64)	43 (39.09)	0.400
≥ 2 co-morbidities: no (%)	72 (65.45)	81 (73.64)	0.187
Overnight hospitalization, no (%)	9 (8.18)	7 (6.36)	0.604
Emergency Room, no (%)	1(0.91)	2 (1.82)	0.561
Use of insulin, no (%)	17 (15.45)	13 (11.82)	0.432
Anti-diabetic medication, no (%)	103 (93.64)	107 (97.27)	0.195
Other medications			
Daily Aspirin, no (%)	43 (39.09)	57 (51.82)	0.058
Diuretics, no (%)	71 (64.55)	84 (76.36)	0.055
Anti-Hypertensives, no (%)	98 (89.91)	78 (70.91)	0.0007*
Lipid lowering, no (%)	23 (20.91)	14 (12.73)	0.105
Complications			
Myocardial infarction, no (%)	2 (1.82)	4 (3.64)	0.408
Stroke, no (%)	9 (8.18)	6 (5.45)	0.422
Foot ulcer, no (%)	2 (1.82)	3 (2.73)	0.651
Blindness, no (%)	1 (0.91)	1 (0.91)	1.000
Renal failure, no (%)	3 (2.73)	8 (7.27)	0.122

levels. The reduction observed in the PC was more pronounced despite having the higher number of patients with hypertension who were in anti hypertensive drugs at baseline. This could be attributed to the effectiveness of pharmaceutical care in identifying and resolving drug-related problems and in optimizing adherence to lifestyle modifications (Machado et al., 2007; Krass et al., 2005; Al-Mazroui et al., 2009). The Fremantle Diabetes Study identified a reduction in mean SBP and DBP values over 12 months (Clifford et al., 2005). Significant reductions in SBP and DBP over 12 months were also reported by Al-Mazroui et al. (2009). In a study conducted by Lee et al. (2006), patients who submitted to a pharmaceutical care program for 18 months significantly reduced their mean

Table 3. Comparison of mean clinical data of PC and UC arms at baseline and 12 months.

Clinical outcomes	Baseline		12 Months		p-value	
	UC (n = 110)	PC (n = 110)	UC (n = 93)	PC (n = 99)	Baseline	12 months
Mean HbA1c (%)	7.785 ± 1.03	7.985 ± 1.06	7.77 ± 1.12	7.23 ± 1.09	0.318	0.0009*
Mean weight (kg)	66.5 ± 5.7	65.05 ± 4.7	66.20 ± 3.24	61.40 ± 5.37	0.148	<0.0001*
Mean body mass index (kg/m^2)	26.6 ± 3.5	27.2 ± 2.8	26.10 ± 4.29	25.28 ± 2.79	0.162	<0.1159
Mean SBP (mmHg)	140.84 ± 10.3	143.91 ± 12.8	141.82 ± 7.84	127.76 ± 6.98	0.051	<0.0001*
Mean DBP (mmHg)	87.32 ± 4.2	88.92 ± 7.9	86.32 ± 4.60	78.45 ± 4.97	0.062	<0.0001*
Mean FBG (mg/dL)	177.43 ± 11.8	180.61 ± 13.5	168.74 ± 11.49	129.34 ± 9.97	0.064	<0.0001*
Mean LDL-C (mg/dL)	112.43 ± 7.9	113.10 ± 10.6	116.28 ± 9.64	101.43 ± 8.35	0.596	<0.0001*
HDL-C (mg/dL)	44.65 ± 4.7	44.85 ± 5.1	45.29 ± 6.68	53.82 ± 5.81	0.763	<0.0001*
Triglycerides (mg/dL)	161.40 ± 11.4	162.41 ± 13.8	159.59 ± 8.91	154.37 ± 10.34	0.555	0.0002*
Total Cholesterol (mg/dL)	211.56 ± 22.3	204.4 ± 24.5	203.75 ± 25.96	188.71 ± 19.41	0.024*	<0.0001*

Table 4. Comparison of percentage of patients that achieved control at 12 months.

Clinical outcomes	Baseline		12th Month		p-value	
	UC(n=110)	PC (n=110)	UC (n=93)	PC (n=99)	baseline	12 months
HbA1c < 7%, no, (%)	42(38.18)	38(34.55)	44(47.31)	61(61.62)	0.575	0.0466*
Obese, no. (%)	17(15.45)	20(18.18)	22(23.66)	12(12.12)	0.589	0.0364*
Overweight, no, (%)	48(43.64)	51(46.36)	51(54.84)	35(35.35)	0.684	0.0067*
BP < 130/80 (mmHg), no. (%)	22(20.00)	17(15.45)	23(24.73)	33(33.33)	0.377	0.1900
LDL-C < 100 mg/dL, no. (%)	76(69.09)	71(64.55)	81(87.10)	86(86.87)	0.474	0.9626
HDL-C > 40 mg/dL, no. (%)	59(53.64)	61(55.45)	58(62.37)	77(77.78)	0.787	0.0195*
Triglycerides < 150 mg/dl), no. (%)	29(26.36)	31(28.18)	27(29.03)	39(39.39)	0.7621	0.1309
Total-C < 200 mg/dL, no. (%)	25(22.73)	28(25.45)	26(27.96)	38(38.38)	0.6362	0.1256

UC = Usual care and PC = Pharmaceutical care intervention.

SBP values but demonstrated no significant differences in DBP. Castro et al. (2006) reported a trend for better blood pressure control in uncontrolled hypertensive patients enrolled in a pharmaceutical care program over 6 months, although the differences were not statistically significant. These variations in results may be attributed to different characteristics of patients enrolled in the studies (age, baseline blood pressure levels, diseases presented, education level, and socio-economic status), study duration, and the characteristics of the health systems where the studies were conducted (availability of medications, availability of medical and nursing consultation, and others).

Lipid profile

The percentage change in number of patients who achieved HDL-C goal in the intervention group was significant after 12 months in comparison with the control group. Interventions to optimize adherence to lifestyle modifications, identify and resolve drug-related problems, particularly the drug-related problems concerning the need for additional therapy such as statins and fibrates (Al-Mazroui et al, 2009; Mazzolini et al., 2005) supported to this result. Other studies had also demonstrated the effectiveness of pharmaceutical care programs in lowering lipid levels, but with varying figures in the results (Al-Mazroui et al, 2009; Clifford et al., 2005; Mazzolini et al., 2005).

Body Mass Index

Significant change in proportion of patients that achieved control in 12 months was observed in the intervention group compared with the control group. Obesity is a well-known risk factor for cardio-vascular diseases and it is associated with increased mortality. Obese (with BMI ≥ 30 kg/m^2) and overweight people (i.e., BMI of 25.0 to 29.9) have an increased risk of death from heart disease, stroke, and cancers. (Al-Mazroui et al., 2009) reported a smaller reduction in BMI (-1.05 kg/m^2) over 12 months in the United Arab Emirates health system. Another study demonstrated that a pharmaceutical care program reduced BMI from 30.0 to 29.4 kg/m^2 in 12 months

(Clifford et al., 2002). These studies demonstrated the effectiveness of pharmaceutical care in reducing BMI though with considerable variability, which may be due to a variety of factors such as diverse health system settings, different patient characteristics, and different study durations.

Limitations

Studies of this kind must address inherent potential threats to internal validity (Campbell and Stanley, 1963; Cook and Campbell, 1979). Several such threats were possible in this study: Missing data presented the most daunting challenge. Among the clinical outcomes measured, HbA1c concentration was the most important. Fortunately, this measure suffered the least from missing data, so it served well as the focus of clinical outcome assessments. Selection bias was a threat because participation was voluntary though the groups were randomized. It remains possible that patients who chose to participate in the program may have differed in some important way from those who did not participate.

Conclusion

The additional pharmaceutical care intervention resulted in beneficial improvement of the clinical outcomes over usual care in the following areas glycoslated haemoglobin (HbA_{IC}), glycemic control, blood pressure control, and lipid profile. The results of this study illustrate a convincing rationale for improving standards of care for patients with Type 2 diabetes through pharmaceutical care intervention. However, further research is needed to improve on the current pharmaceutical care intervention strategies such that the recorded improvements in clinical outcomes will be sustained for a very long time after an intervention.

Conflict of interest

The authors declare that they have no competing interests.

Authors' contributions

MOA and CNA designed the study. MOA carried out the statistical analysis. All the authors were involved in articles write-up. All authors read and approved the final manuscript.

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