Effect the Pharmaceutical Care and Health Education on Knowledge and Disease Control for Type 2 Diabetes Mellitus Patients: A sample of Iraqi Patients

Al Hussein Safaa Hussein*, Kadhim Ali Kadhim, Sabah Mousa Fadil*****

Department of Clinical Pharmacy, College of Pharmacy, Al-Mustansiriyah University, Baghdad, Iraq.

**** Department of Pharmacy, Al-Yarmouk University College, Baghdad, Iraqq***

*****Ibn al Bitar Hospital specialized center for Cardiac Surgery, Baghdad, Iraq.***

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Corresponding Author email:
Pharm.drkaka75@uomustansiriyah.edu.iq
orcid: https://orcid.org/0000-0002-4040-1808

Abstract:

Objective: To study the effect of Pharmaceutical Care (PC) program and health education delivered by pharmacist on Type 2 Diabetes Mellitus (T2DM) patient's knowledge about diabetes, glycemic control, blood pressure and Body Mass Index (BMI).

Patients and methods: A prospective interventional study including T2DM patients with poor glycemic control, i.e. glycated hemoglobin (HbA1c) more than 7%. Patients receiving PC and education about T2DM and cardiovascular disease by the researcher pharmacist. Patients were followed for 26 weeks. The study parameters included HbA1c, Fasting Blood Sugar (FBS), Systolic Blood pressure (SBP), Diastolic Blood Pressure (DBP), BMI and Diabetes Knowledge Questionnaire (DKQ-24).

Results: Thirty-eight T2DM patients were included in the study. Thirty-two completed the program. A significant decrease in the HbA1c and FBS at the end line measurements (from 9.1% to 7.4%, *P*-value = 0.001) and (from 187.4 to 135.3, *P*-value = 0.001) respectively. A significant decrease occurred in both SBP and DBP (from 129.8 to 125.2, *P*-value = 0.009) and (from 82.0 to 77.9, *P*-value =0.001) respectively. Diabetes knowledge score also showed a significant increase at the end of study (from 52.6 to 63.7, *P*-value =0.001)

Conclusion: Pharmaceutical care and health education with continuous follow up delivered by the pharmacist even for a relatively short period of time in collaboration with specialist physician, resulted in improved T2DM Knowledge plus better glycemic and blood pressure control.

Key words: Type 2 diabetes mellitus, Pharmaceutical care, Glycated hemoglobin, and Blood pressure

تأثير الرعاية الصيدلانية والتثقيف الصحي على المعرفة و السيطرة على المرض في المرضى المصابين بداء السكري – النوع الثاني: عينة من المرضى العراقيين

الحسين صفاء*, كاظم علي كاظم, صباح موسى فاضل*****

***فرع الصيدلة السريرية, كلية الصيدلة الجامعة المستنصرية**

****قسم الصيدلة, كلية اليرموك الجامعة**

*****مستشفى ابن البيطار لجراحة القلب**

الخلاصة:

الهدف من الدراسة: دراسة تأثير برنامج الرعاية الصيدلانية و التثقيف الصحي التي يقدمها الصيدلي على المرضى المصابين بداء السكري من النوع الثاني في السيطرة على نسبة السكر في الدم، ضغط الدم، مؤشر كتلة الجسم و مقدار معرفة المريض بداء السكري.

المرضى والطرق: دراسة تداخلية، تضم مرضى من المصابين بداء السكري من النوع الثاني الغير مسيطيرين على المرض. استمرت الدراسة من أبريل 2018 إلى أبريل 2019. يتلقى المرضى المشاركون بالدراسة و عددهم 32, برنامج الرعاية الصيدلانية والتثقيف حول مرض السكري وأمراض القلب والأوعية الدموية من قبل الصيدلي، وتمت متابعة المرضى لمدة 26 اسبوع. تم تقييم السكر التراكمي، مستوى الكلوكوز بالدم ، مؤشر كتلة الجسم ,(BMI) ضغط الدم ومعرفة المريض بداء السكري .(DKQ-24)

النتائج:اظهرت النتائج انخفاضا ملحوظا في السكر التراكمي و مستوى الكلوكوز بالدم في نهاية الدراسة (من 9.1 ٪ إلى 7.4 ٪ ، (P-value = 0.001و (من 187.4 إلى 135.3 ، (P-value = 0.001على الترتيب. اظهرت النتائج تحسنا في كل من ضغط الدم الانقباضي SBP وضغط الدم الانبساطي) DBP من 129.8 إلى 125.2 ، P-value = 0.009)و (من 82.0 إلى 77.9 ، (P-value =0.001على الترتيب. كذلك تحسنا في معرفة المريض بداء السكري في نهاية الدراسة (من 52.6 إلى 63.7 ، (P-value = 0.001

الاستنتاج: من خلال نتائج هذا البحث توصلنا الى ان تطبيق برنامج الرعاية الصيدلانية مع التثقيف الصحي بواسطة الصيدلي ومن خلال المتابعة المستمرة من قبله حتى وان كانت لفترة زمنية قصيرة نسبيًا وبالتعاون مع طبيب الاختصاص، قد ساهمت في تحسين مستويات السكر بالدم في المرضى المصابين بداء السكري من النوع الثاني بالاضافة الى تحسن في معرفة المريض بداء السكري وكذلك السيطرة على ضغط الدم.

الكلمات المفتاحية: داء السكري - النوع الثاني, الرعاية الصيدلانية, السكر التراكمي, ضغط الدم

Introduction

Worldwide 451 million people age between (18-99years) were estimated to have diabetes.[1] Diabetes is projected to be in 2030, the 7th leading cause of mortality, due to the rapid increase in its prevalence, especially in developing countries.[2,3] In Iraq, The prevalence of diabetes increased from 5% in the year 1978 to 19.7% in 2012, with 48.8% prevalence of dysglycemia.[4] In a study of adults in Basrah in southern Iraq, it was found that every five subjects tested, one had diabetes.[5]

Diabetes mellitus is a heterogeneous metabolic disorder with the main characteristic (hyperglycemia) due to insufficient insulin secretion, impaired action of insulin, or both.[6] This chronic hyperglycemia is associated with many long-term microvascular complications affecting the kidneys, eyes, and nerves, moreover, an increased risk for cardiovascular disease (CVD) to occur.[6] Non-adherence to medications and lifestyle recommendations act as a major barrier for the control of the disease, despite the availability of effective medications [7], leading to decreased treatment efficacy, reduced patient safety, and increased health care costs.[8, 9]

Type 2 diabetes requires treatment with a combination of modalities, including lifestyle changes, medical nutrition therapy, with oral and injectable medication, including insulin.[10] Improving knowledge is another strong approach for better glycemic control among T2DM patients, it can help them achieve more understanding for the risk of diabetes and its complications, motivate them seek suitable care and treatment in order to keep T2DM under control.(11) All mentioned above led to the development of program combining lifestyle intervention and medical therapy for CVD risk in patients with diabetes that proved to be more efficient than either intervention alone.[12-14] another reason is the high cost associated with controlling diabetes, making health care providers participating in the education for diabetes self-management.[15] Systematic reviews of interventions addressing diabetes self-management led by pharmacist show that education increase knowledge, adherence, self-care, and improve glycemic control.[16, 17]

Many trials all over the world that studied the potential role of the pharmacist in the management of diabetes both in hospital and ambulatory care (by providing

pharmaceutical care), all demonstrated positive outcome regarding improved adherence, glycemic control and other risk factors for CVD, especially when working as team member in collaboration with physician, nurse and other medical staff.[7] Pharmaceutical care is defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[18] Since Iraq is facing a significant shortage of physicians, with the excepted rate in 2018 to be about half the rate globally or in the region.[19] Which urge the need for giving the pharmacist more active role in the management of diabetes through the application of pharmaceutical care. Till now, only one trial studied the potential role of the pharmacist in T2DM management occurred in northern Iraq, which showed promising results.[20]

The aim of the present study is to evaluate the effect of PC program and education led by pharmacist on different clinical outcomes (FBG and HbA1c for glycemic control, Blood pressure, diabetes knowledge and BMI), for T2DM patients with poor glycemic control. It was crucial to study the effect of pharmaceutical care in Iraq since the significant increase in disease prevalence in the past years with its subsequent morbidity and mortality and cost on the health care system. There are limited studies that evaluated the effect of pharmaceutical care in different chronic disease in Iraq.

Methods

Thirty-eight candidate T2DM patients with poor glycemic control, working at the Ministry of Oil and Ministry of Science and Technology, were registered in the study. Only thirty-two completed the study.

A prospective interventional study including poorly controlled T2DM patients, to evaluate the effect of PC program and health education delivered by the pharmacist on glycemic control, blood pressure and knowledge about diabetes. The study carried out in the Ministry of Oil and Ministry of Science and Technology clinical departments. During the period of April 2018 and April 2019.

Inclusion criteria for the patients included in the study to be age more than 18 years, T2DM patients with poor glycemic control (HbA1c>7%). Exclusion criteria for the study, on the other hand, are patient with established cardiovascular disease (secondary prevention) such as (MI, stroke, angina.etc), pregnancy and lactation, patient with liver and kidney disease and patients with severe anemia.

Researcher pharmacist interviewed all T2DM patients face – to – face for 10 – 15 minutes, to obtain patient's sociode-mographic data, history of present illness and the medication used. Patient's weight and height were also measured to calculate Body Mass Index (BMI). Blood sample collection and laboratory analysis were done, pre-scheduled before the meeting. Patients with HbA1c less than 7% were excluded directly.

Patients were followed for 6 months, with follow up visit face – to – face in patients work office or the clinical department every 2-3 weeks, with the visit lasting for 15 – 30 minutes, also phone call was done for some patients if direct meeting was not possible on appointment schedule and additional on-demand calls for specific cases.

The T2DM patients received education about diabetes, its complications, cardiovascular disease, risk factors for cardiovascular disease, goals for the treatment, diabetes self-management education (DSME), self-monitoring blood glucose (SMBG) guided with using glucometer supplied by the researcher pharmacist and diary to track patients reading, importance of exercise and healthy eating and most importantly improving correct using of medication and importance of adherence.

All T2DM patients had an appointment with the specialist physician, for examination, adding, adjusting changing any medication needed, the researcher

pharmacist also attended the appointment to share thoughts, ideas with both physician and patients. This appointment was made within the first few weeks of the program, after that the pharmacist kept in contact with specialist physician if help is needed for any patient.

Ethical Considerations

The proposal of the study obtained ethical Approval after being discussed by the Ethics Committee by College of Pharmacy -Mustansiriyah University. An informed written or (verbal) consent was taken from each T2DM patient, after a full explanation of the study aims to gain patient full understating and to ensure reliable data collection.

Statistical Analysis

The data were analyzed using SPSS version 20 and Microsoft Excel software. Because of the collected data were not normally distributed according to Shapiro test. Non-parametric Mann Whitney test and Wilcoxon test were used to finding out the significance of differences between ranks of related variables. *P*-value less than 0.05 was considered as a discrimination point of significance.

Results

This interventional study included 32 poorly controlled T2DM patients, 81.3% of them were males, 34.4% aged less than 50 years, 93.8% are married, the educational level of 37.5% was less than university, 59.4% of the patients had BMI (less than 30), 31.3% were smokers, duration of DM was 5 years or less in 43.8%, while 68.8% of patients got positive family history of type 2 DM and 34.4% had hypertension in addition to diabetes as shown in table (1).

A significant decrease in the HbA1c and FBS at the end line measurements were found in the study group from 9.1% – 7.4%, *P*-value = 0.001, and from 187.4 – 135.3, *P*-value = 0.001 respectively, table (2) Figure (1). Glycemic control (HbA1c and FBS) showed significant reduction at the final measurements regardless of patients; age, duration of the disease, family history of T2DM, history of hypertension and education level (*P*- value <0.05) (table 3-7). Statistically significant reduction in HbA1c at the end of the study occurred regardless of change in DKQ-24 score (*P*–value < 0.05), while FBS showed statistically significant reduction in T2DM patient that showed improvement in DKQ-24 score (P-value = 0.001), but not those with no improvement in DKQ-24 score (P-value = 0.533) (table 8).

Table (1): Patients characteristics.

		Patients n=32 (%)
Gender	Male	26 (81.3%)
	Female	6 (18.8%)
Age Group	<50 years	11 (34.4%)
	=>50 years	21 (65.6%)
Marital Status	Married	30 (93.8%)
	Single	2 (6.3%)
Education Level	less than university	12 (37.5%)
	University	20 (62.5%)
BMI	<30	19 (59.4%)
	=>30	13 (40.6%)
Smoking	Smoker	10 (31.3%)
	not smoker	22 (68.8%)
Duration of T2DM	5 years or less	14 (43.8%)
	> 5 years	18 (56.3%)
Family History of T2DM	Yes	22 (68.8%)
	No	10 (31.3%)
Hypertension	Yes	11 (34.4%)
	No	21 (65.6%)

% = Percentage, BMI= Body mass index, T2DM= Type 2 diabetes mellitus.

Systolic blood pressure measured at the start of the study was significantly decreased at the end time calculation, (from 129.8 – 125.2, *p*-value=0.009). Also, DBP calculated at the start of the study decreased significantly at end time calculation (from 82.0 – 77.9, *P*-value=0.001) (table 2). Systolic blood pressure was significantly decreased at the final measurement only in T2DM patients with positive family history of T2DM, negative history of hypertension, age more than 50 years, education level less than university and duration of diabetes less than 5 years (*P* – value < 0.05). While DBP showed significant reduction in the end line measurement in patient with positive family history of T2DM, age more than 50 years and education level less than university (*P*-value < 0.05), on the other hand significant reduction occurred in DBP regardless of history of hypertension and duration of T2DM (table 3-7).

Diabetes Knowledge Questionnaire (DKQ-24) score calculated at the start point of the study was significantly increased at end time calculation, (*P*-value = 0.001) (Table 2). Diabetes Knowledge Questionnaire (DKQ-24) on the other hand also showed significant improvement in T2DM participants in the study regardless of their; age, disease duration, education level and history of hypertension (*P*-value <0.05), only patients with negative family history of T2DM showed statistically no significant improvement in the DKQ-24 score (*P*-value >0.05) (table 3-7).

No significant difference was found between measurements taken at the start of the study and that measurement taken at the end of the study regarding BMI (*P*-values > 0.05) (table 2)

Table (2): Effect of 26 weeks pharmaceutical care program on (SBP, DBP, HbA1c, FBS, BMI and DKQ-24).

Parameter	Time of Measurement	N	Mean ± SD	N*	Mean ranks	*P*-value
SBP	Baseline	32	129.8±12.97	22[n]	18.3	0.009*
	After 26 weeks		125.2±11.07	10[p]	12.55	
DBP	Baseline	32	82.0±7.13	24	17.21	0.001*
	After 26 weeks		77.9±6.99	7	11.86	
HbA1c	Baseline	32	9.1±1.1	31	16.9	0.001*
	After 26 weeks		7.4±0.6	1	3	
FBS	Baseline	32	187.4±52.3	28	17.5	0.001*
	After 26 weeks		135.3±26.3	4	9.3	
BMI	Baseline	32	29.2±3.8	13[n]	14	0.442[NS]
	After 26 weeks		29.3±3.5	16[p]	15.8	
DKQ-24	Baseline	32	52.6±15.98	5	11.3	0.001*
	After 26 weeks		63.7±13.44	25	16.34	

Data presented as mean ± SD, Mean ranks.

[NS] = No significant differences (P>0.05), * = Significant difference (P<0.05)

[b]= baseline, [e]= end line, [n]=negative rank, [p]=positive rank, SBP=systolic blood pressure, DBP=diastolic blood pressure, HbA1c=glycated hemoglobin, FBS=fasting blood sugar, BMI = body mass index, DKQ-24=Diabetes Knowledge Questionnaire

Wilcoxon rank test used for statistical analysis

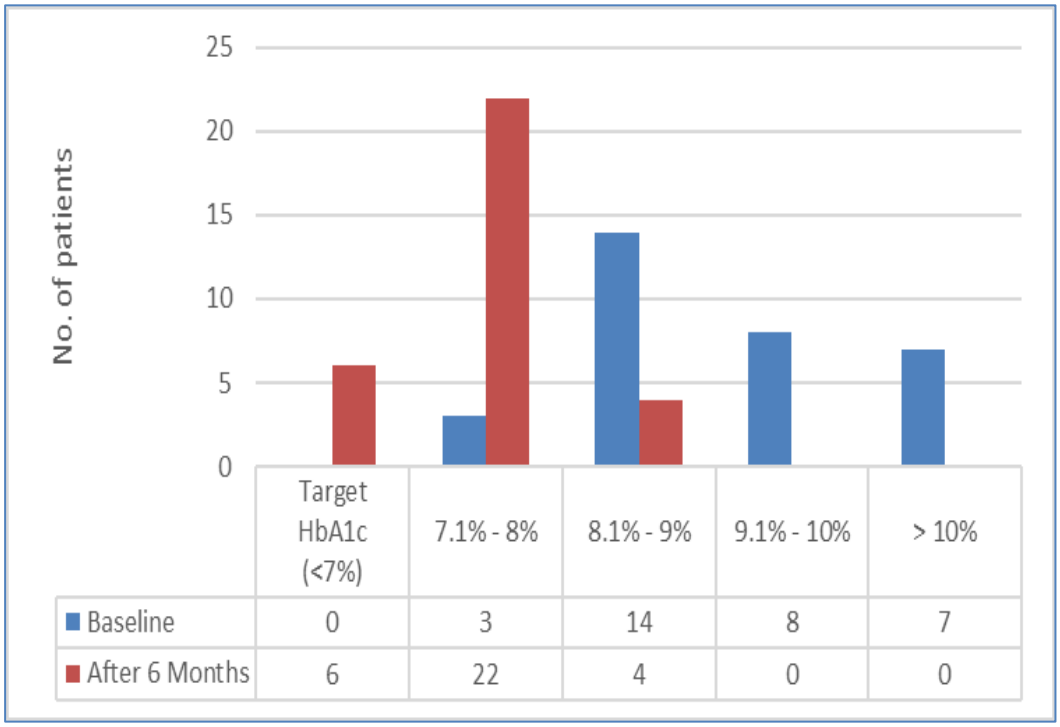

Figure (1): HbA1c of patients at baseline and after 26 weeks.

Table (3): Effect of 26 weeks pharmaceutical care program on (SBP, DBP, HbA1c, FBS, and DKQ-24) regarding to type 2 diabetic patients age category.

Parameter	Age < 50 years (n=11)			*P*-value	Age > 50 years (n=21)			*P*-value
	Mean ± SD	N*	Mean Rank		Mean ± SD	N*	Mean Rank	
SBP^{b}	127.7 ± 16.9	7^{n}	6.14	0.372^{NS}	130.9 ± 10.7	15^{n}	12.47	0.013*
SBP^{e}	126.7 ± 13.4	4^{p}	5.75		124.4 ± 9.9	6^{p}	7.33	
DBP^{b}	80.5 ± 9.1	6^{n}	6.67	0.533^{NS}	82.7 ± 5.9	18^{n}	10.81	0.001*
DBP^{e}	79.5 ± 9.8	5	5.2		77.1 ± 5.1	2^{p}	7.75	
HbA1c^{b}	9.4 ± 1.4	11^{n}	6	0.003*	9.0 ± 0.9	20^{n}	11.45	0.0001*
HbA1c^{e}	7.3 ± 0.7	0^{p}	0		7.4 ± 0.6	1^{p}	2	
FBS^{b}	200.7 ± 60.9	9^{n}	6.61	0.018*	180.5 ± 47.2	19^{n}	11.45	0.0001*
FBS^{e}	142.7 ± 28.9	2^{p}	3.25		131.5 ± 24.6	2^{p}	6.75	
DKQ – 24^{b}	53.8 ± 14.0	0^{n}	0	0.005*	51.9 ± 17.2	5^{n}	7.1	0.009*
DKQ – 24^{e}	66.7 ± 6.7	10^{p}	5.5		62.1 ± 15.8	15^{p}	11.63	

Data presented as mean ± SD, Mean ranks.
^{NS} = No significant differences (P>0.05), * = Significant difference (P<0.05)
^{b}= baseline, ^{e}= end line, ^{n}=negative rank, ^{p}=positive rank, SBP=systolic blood pressure, DBP=diastolic blood pressure, HbA1c=glycated hemoglobin, FBS=fasting blood sugar, DKQ-24=Diabetes Knowledge Questionnaire.
Wilcoxon rank test used for statistical analysis.

Table (4): Effect of 26 weeks pharmaceutical care program on (SBP, DBP, HbA1c, FBS, and DKQ-24) regarding to type 2 diabetic patients' level of education.

Parameter	Education level < university (n=12)			*P*-value	Education level university (n=20)			*P*-value
	Mean ± SD	N*	Mean Rank		Mean ± SD	N*	Mean Rank	
SBP[b]	132.5 ± 12.3	11[n]	6.77	0.005*	128.2 ± 13.41	11	11.59	**0.397[NS]**
SBP[e]	123.0 ± 9.51	1[p]	3.5		126.5 ± 11.95	9	9.17	
DBP	81.7 ± 7.65	10	7.4	0.006*	82.2 ± 7.01	14	10.07	**0.063[NS]**
DBP	75.2 ± 7.51	2	2		79.6 ± 6.31	5	9.8	
HbA1c	9.4 ± 0.99	12	6.5	0.002*	9.01 ± 1.19	19	11	0.0001*
HbA1c	7.7 ± 0.66	0	0		7.2 ± 0.47	1	1	
FBS	193.7 ± 57.84	9	7.67	0.019*	183.7 ± 49.80	19	10.45	0.0001*
FBS	137.5 ± 30.54	3	3		134.1 ± 24.16	1	11.5	
DKQ - 24	44.8 ± 20.36	3	3.5	0.045*	57.3 ± 10.72	2	8.5	0.002*
DKQ - 24	58.7 ± 15.95	8	6.94		66.6 ± 11.06	17	10.18	

Data presented as mean ± SD, Mean ranks.
[NS] = No significant differences (P>0.05), * = Significant difference (P<0.05)
[b]= baseline, [e]= end line, [n]=negative rank, [p]=positive rank, SBP=systolic blood pressure, DBP=diastolic blood pressure, HbA1c=glycated hemoglobin, FBS=fasting blood sugar, DKQ-24=Diabetes Knowledge Questionnaire.
Wilcoxon rank test used for statistical analysis**.**

Table (5): Effect of 26 weeks pharmaceutical care program on (SBP, DBP, HbA1c, FBS, and DKQ-24) regarding to duration of type 2 diabetes.

Parameter	T2DM Duration < 5 years (n=14)			*P*-value	T2DM Duration >= 5 years (n=18)			*P*-value
	Mean ± SD	N*	Mean Rank		Mean ± SD	N*	Mean Rank	
SBP[b]	127.9 ± 10.7	11[n]	8.32	0.014*	131.3± 14.7	11	10.55	0.183[NS]
SBP[e]	121.1 ± 8.5	3[p]	4.5		128.4± 11.9	7	7.86	
DBP	80.2 ± 6.5	11	7.95	0.028*	83.4 ± 7.5	13	9.88	0.014*
DBP	76.3 ± 5.5	3	5.83		79.9 ± 7.9	4	6.13	
HbA1c	9.1 ± 0.9	13	7.92	0.002*	9.2 ± 1.3	18	9.5	0.0001*
HbA1c	7.4 ± 0.7	1	2		7.4 ± 0.6	0	0	
FBS	186.2± 48.9	13	7.46	0.005*	188.4± 56.1	15	10.47	0.002*
FBS	134.8± 28.6	1	8		135.7± 25.2	3	4.67	
DKQ – 24	47.0 ± 15.2	3	5.33	0.022*	56.9 ± 15.6	2	6.75	0.005*
DKQ – 24	58.4 ± 15.1	11	8.09		67.7 ± 10.7	14	8.75	

Data presented as mean ± SD, Mean ranks.
[NS] = No significant differences (P>0.05), * = Significant difference (P<0.05)

[b]= baseline, [e]= end line, [n]=negative rank, [p]=positive rank, SBP=systolic blood pressure, DBP=diastolic blood pressure, HbA1c=glycated hemoglobin, FBS=fasting blood sugar, DKQ-24=Diabetes Knowledge Questionnaire.
Wilcoxon rank test used for statistical analysis**.**

Table (6): Effect of 26 weeks pharmaceutical care program on (SBP, DBP, HbA1c, FBS, and DKQ-24) regarding to family history of type 2 diabetes.

Parameter	Family History of T2DM Yes (n=22)			*P*-value	Family History of T2DM No (n=10)			*P*-value
	Mean ± SD	N*	Mean Rank		Mean ± SD	N*	Mean Rank	
SBP[b]	131.3 ± 11.8	17[n]	12.85	0.003*	126.6 ± 15.5	5	6	0.798 [NS]
SBP[e]	125.3 ± 10.5	5[p]	6.9		124.9 ± 12.8	5	5	
DBP	82.6 ± 6.6	18	12.17	0.003*	80.7 ± 8.5	6	5.42	0.236[NS]
DBP	77.8 ± 5.7	4	8.5		78.3 ± 9.6	3	4.17	
HbA1c	9.2 ± 1.2	21	12	0.0001*	9.1 ± 0.9	10	5.5	0.005*
HbA1c	7.3 ± 0.6	1	1		7.7 ± 0.5	0	0	
FBS	185.9 ± 58.8	20	12	0.0001*	191.0 ± 36.5	8	6.13	0.028*
FBS	129.4 ± 24.5	2	6.5		148.6 ± 26.4	2	3	
DKQ – 24	53.4 ± 14.3	3	7.33	0.002*	50.8 ± 19.9	2	4.25	0.052[NS]
DKQ – 24	64.2 ± 10.9	17	11.06		62.5 ± 18.5	8	5.81	

Data presented as mean ± SD, Mean ranks.
[NS] = No significant differences ($P>0.05$), * = Significant difference ($P<0.05$)
[b]= baseline, [e]= end line, [n]=negative rank, [p]=positive rank, SBP=systolic blood pressure, DBP=diastolic blood pressure, HbA1c=glycated hemoglobin, FBS=fasting blood sugar, DKQ-24=Diabetes Knowledge Questionnaire.
Wilcoxon rank test used for statistical analysis**.**

Table (7): Effect of 26 weeks pharmaceutical care program on (SBP, DBP, HbA1c, FBS, and DKQ-24) regarding to coexistence of hypertension.

Parameter	History of Hypertension Yes (n=11)			*P*-value	History of Hypertension No (n=11)			*P*-value
	Mean ± SD	N*	Mean Rank		Mean ± SD	N*	Mean Rank	
SBP[b]	136.5 ± 10.52	6[n]	7	0.419[NS]	126.3 ± 12.99	16	11.5	0.017*
SBP[e]	132.4 ± 11.50	5[p]	4.8		121.4 ± 8.99	5	9.4	
DBP	84.5 ± 7.24	8	6	0.036*	80.7 ± 6.9	16	11.88	0.009*
DBP	80.9 ± 7.74	2	3.5		76.4 ± 6.23	5	8.2	
HbA1c	9.6 ± 1.25	10	6.5	0.004*	8.9 ± 1.01	21	11	0.0001*
HbA1c	7.5 ± 0.60	1	1		7.4 ± 0.60	0	0	
FBS	211.1 ± 55.24	10	6.5	0.004*	175.1 ± 47.33	18	11.33	0.002*
FBS	132.4 ± 20.75	1	1		136.9 ± 29.14	3	9	
DKQ – 24	55.3 ± 12.08	1	4	0.016*	51.2 ± 17.8	4	8.13	0.007*
DKQ – 24	65.2 ± 13.73	9	5.67		62.9 ± 13.57	16	11.09	

Data presented as mean ± SD, Mean ranks.
[NS] = No significant differences (P>0.05), * = Significant difference (P<0.05)
[b]= baseline, [e]= end line, [n]=negative rank, [p]=positive rank, SBP=systolic blood pressure, DBP=diastolic blood pressure, HbA1c=glycated hemoglobin, FBS=fasting blood sugar, DKQ-24=Diabetes Knowledge Questionnaire.
Wilcoxon rank test used for statistical analysis**.**

Table (8): Effect of 26 weeks pharmaceutical care and health education on HbA1c and FBS in correlation with DKQ-24 score improvement.

Improvement in DKQ-24 Score	Parameter	Mean ± SD	N*	Mean Rank	*P*-value
Yes (n=23)	HbA1c[b]	9.2±1.2	24[n]	13.46	0.001*
	HbA1c[e]	7.3±0.61	1[p]	2	
No (n=9)	HbA1c	8.9±0.86	7	4	0.018*
	HbA1c	7.7±0.43	0	0	
Yes (n=23)	FBS	194.6±54.9	24	13.5	0.001*
	FBS	132.1±21.9	1	1	
No (n=9)	FBS	162.0±32.5	4	4.38	0.533[NS]
	FBS	147.1±38.1	3	3.5	

Data presented as mean ± SD, Mean ranks.
[NS] = No significant differences (P>0.05), * = Significant difference (P<0.05)
[b]= baseline, [e]= end line, [n]=negative rank, [p]=positive rank, HbA1c=glycated hemoglobin, FBS=fasting blood sugar.
Wilcoxon rank test used for statistical analysis

Discussion

Diabetes is a major independent risk factor for CVD when speaking about the death from heart disease and stroke; the risk is drastically increased by 2-4 folds in diabetic patients against non-diabetics.[21] With HbA1c levels above 7.0% associated not only with CVD but also with microvascular complications, that is why correct management of T2DM, regardless of the treatment used, all share one goal (optimal glycemic control).[22] In the present study PC and education led by the researcher pharmacist result in a significant reduction regarding both FBS and HbA1c.

Regarding HbA1c, the findings in the present study comes in agreement with a recently published meta-analyses regarding the efficacy of pharmaceutical care and education in the management of type 2 diabetes, with an average reduction of (-0.85%) in HbA1c.[7]

Whether it was very short study such as; (Farsaei et al.,) in 2011 which last only for 3 months,[23] or studied that continued for 6 months like the present study, such as;(Siaw et al., and shao et al.,)[24, 25] or studies for more extended period 12 months or more such as; (Korcegez et al., and Lim et al.,) [26,27] all these studies shared the same outcome regarding glycated hemoglobin, that is a significant reduction in PC group at the end of their follow up period.

Doucette et al., in 2009, the study found that pharmaceutical care program though was effective in helping patient to engage in more diabetes self-care activities and eat more healthy food choices, after 12 months follow up, did not result in statistically significant improvement in glycated hemoglobin (P-value = 0.27).[28]

When speaking about FBS the findings in the present study comes in agreement with almost all studies that measured this outcome, which is a significant reduction in PC group. [23, 25, 27, 29, 30]

At the beginning of the study mean BMI was about (29.23) with about 85% of patients being overweight or obese, which comes in agreement with the fact that 80% - 90% of

patient with diabetes are obese or overweight.[31]

There was no statistically significant change in BMI the end of the study (*P*-value > 0.05). Among possible reasons for this outcome; short duration of the study. Other reasons for non-significant change in the mean BMI in the present study could be that some of the patient start using insulin or insulin secretagogues to manage their illness which might result in weight gain and finally patient reported a decrease in physical activity and more hunger due to cold weather of winter, note that patients in this study were followed mostly during winter season.

The result of the study came in agreement with, Lim et al., in 2016 both study groups intervention (39 patients) and those receiving usual care (37 patient) did not achieve statistically significant BMI change at the end of study,[32] while other research although continued for a similar period with the present study they did have a statistically significant effect on BMI with PC group against the usual care group such as; Jahangard-Rafsanjani et al., in 2015. [33] Regarding PC programs lasting for a year or more, Ali et al., in 2012, showed significant change at the end of their study regarding BMI.[30]

Pharmaceutical care program result in statistically significant reduction in both SBP (129.8 – 125.2, *P*-value=0.009) and DBP (82.0 – 77.9, *P*-value=0.001) for all T2DM patients. Patient aged more than 50 years, with a level of education (less than university), having a positive family history of T2DM was predictive of a better response to PC and education led by the pharmacist, resulting in a significant reduction of both SBP and DBP. An explanation for the result that patients with less education level had better results regarding SBP and DBP is a study in the United Kingdom (UK), which concluded that patients with lower education have better compliance with recomm-endations.[34]

Regarding studies lasting for similar period of time (6 months), Shao *et al*., Ahmad *et al.*, and Jarab *et al*., all achieved a significant reduction in the intervention group in both SBP with mean reduction (-4.4, -5.8 and -9.9 respectively) and mean reduction in DBP (-1.9, -7.1 and –5.3 respectively), versus non-significant change in the usual care group [25, 35, 36]. The Brazilian RCT Moauro *et al*., in 2013, showed an only significant reduction in SBP with mean reduction (-12.1) in the intervention arm after six months of follow up, while no significant change occurred in DBP [37]. Other studies, such as Krass *et al*., in 2006, revealed no statistically significant change in the means of neither intervention nor usual care arm regarding SBP and DBP at the end of their study. Longer duration studies also got divided result such as; Korcegez *et al*., Al Mazroui *et al*., both lasting for one year, a significant reduction in both SBP and DBP at the end of their study occurred in the intervention arm, with mean reduction (-6.8 and -4.2 in SBP respectively) and mean reduction of (-2.4 and -8.9 in DBP respectively).[26,38] On the other hand, Turkmani *et al*., (9 months) and Lim *et al*., lasting for 1 year they both reported non-significant change in the intervention group after the end of their studies regarding both SBP and DBP [27, 39].

At the end of the pharmaceutical care program and education supported by written information and follow up by the researcher pharmacist resulted in (DKQ-24) score mean to increase significantly from 52.6% to 63.7%, which also correlate with the significant reduction in both HbA1c and FBS (*P*-value = 0.001, 0.001 respectively). Wishah *et al.*, in their study also studied the effect of patient knowledge before and after the pharmaceutical care program application, using “diabetes knowledge test developed by Michigan diabetes research and training center”, the final result regarding intervention group were significant when compared to the start of the program, similar to the finding in the present study [29]. Another research, Mehuys *et al*., after

6 months of follow up, also agreed to the findings in the present study by gaining significant (+12.7%) improvement in diabetes knowledge score in the PC group [40]. These findings come in agreement with Ozcelik *et al*., where they studied the association between glycemic control and knowledge about diabetes, where they concluded that the higher knowledge score, means the better is the glycemic control [41]. Also, Selea *et al*., concluded that supplying the diabetic patient with booklet (printed material) in the education process resulted in the improvement of both knowledge and better glycemic control [42].

Limitations

The Most important limitation is the short period of the study lasting only (6 months intervention), making it impossible to follow long term effect of the program on diabetes-related complications, also whether the effect of pharmaceutical care program effect on glycemic control, blood pressure and knowledge delivered by the pharmacist is sustained after the end of the program or not. The study is also underpowered by the fact that it included only small sample size, relatively small number of patient that visit clinical departments were the study took place, plus having only a single pharmacist (the researcher) to deliver the PC program on the same time funding all the work by himself, were all limitation to have larger sample size. Finally, the study was carried on government employee who visit the medical unit of their workplace; therefore, adherence to advice may be higher than other patients with lower health literacy and lower monthly income, so the intervention methodology must be tested in other clinical settings.

Conclusion

The present study found that PC and health education delivered by researcher pharmacist for T2DM patients with poor glycemic control showed Statistically-significant decrease in FBS, HbA1c, SBP, DBP and significant improvement in diabetes Knowledge. In the study sample regarding glycemic control, benefits from the program occurred in T2DM patients regardless of their age, education level, duration of the disease and family history of T2DM. This study showed a great potential for the involvement of pharmacist as a primary care provider and health educator for chronic disease like diabetes and other chronic diseases, for the government employee in Iraqi ministries with poor glycemic control. With this approach, we can have both patients and pharmacist working in the same place to ease follow up visits and deliver the care during the working hours. Future studies with larger sample size, with follow up periods longer than half a year, plus pharmaceutical care program on other chronic diseases is needed to confirm the need for the pharmacist to perform these roles and find out what is best service model for the delivery of care. More consideration must be given for statistically significant versus clinically important difference; therefore, more extended studies will confirm if these effects are sustained and demonstrate true clinical benefits.

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