Original Article

Effect of Hospital Pharmacist Counseling on Clinical Outcomes of Type 2 Diabetes Mellitus Outpatients

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Abstract

Objective: In Indonesia, the role of a hospital pharmacist in pharmaceutical care is still limited or even absent. This study aimed to determine whether counseling by a pharmacist could improve medication adherence, controlling the glycemic status, lipid profile, and blood pressure of type 2 diabetes mellitus (T2DM) outpatients. **Methods:** We conducted an interventional study at RSUD Kota Depok, a secondary public hospital, Indonesia, from April to October 2018. Counseling was given three times during the 4-month study. The study design was quasi-experimental with pretest-posttest group design on 77 respondents divided into intervention group (IGs) (n = 39 people) who received counseling and booklets from the hospital pharmacist and control group (CG) (n = 38 people) who were only given the booklets. We measured adherence with the Medication Adherence Questionnaire and conducted blood tests for fasting blood glucose (FBG), postprandial blood glucose (PPBG), glycosylated hemoglobin A1, lipid profiles (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and TG), and blood pressure measurements. **Findings:** In the IG, adherence parameters such as HbA1c and lipid profile improved, whereas in the CG, there were no statistically significant changes in clinical parameters and even nonadherence score increased (P = 0.008). IG showed statistically significant improvement in medication adherence, in parameters such as FBG, PPBG, and HbA1c, compared to CG. Based on the Chi-square test, IG also showed a statistically significant improvement in the number of controlled FBG (P = 0.05) and HbA1c (P < 0.001) compared to CG. In addition, a multivariate analysis showed that counseling by hospital pharmacist was 2.764 times (95% confidence interval [CI]: 1.096–6.794) and 9.964 times (95% CI: 3.434–28.917) better than no counseling in improvement of FBG and HbA1c, respectively. However, the significance disappeared after adjusted by type of medicine, duration of diabetes mellitus drug use, and medication adherence. **Conclusion:** Hospital pharmacist counseling is an important and significant factor in improving FBG and HbA1c levels of T2DM outpatients.

Keywords: *Clinical outcomes, diabetic patient, hospital pharmacist, Indonesia, medication adherence*

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Introduction

Indonesia is a country where one in three adults has diabetes and one in three deaths is related to diabetes in this region. Diabetes mellitus (DM) is classified into two categories, type 1 and type 2 diabetes, in which type 2 DM (T2DM) is most common due to lifestyle and genetic factors.[1] Counseling as a part of clinical pharmacy services aims to optimize the results of

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therapy, minimize the risk of adverse drug reactions, and increase cost-effectiveness, which further increases the safety of drug use for patients.[2]

Pharmacists act as a liaison between patients and other health providers by conducting pharmaceutical service programs, especially in terms of education and ensuring patients' adherence to diabetes treatment and treatment programs.[3] The program includes nonpharmacological diabetes education; pharmacological interventions including treatment counseling; and strategies for improving adherence, avoiding drug interactions, and adjusting the treatment.[4]

Diabetes is a chronic disease that requires long-term treatment; thus, patient adherence will have an impact on the success of therapy. A comprehensive reduction in risk factors for cardiovascular disease, including blood pressure and lipid control other than blood glucose, is very important in preventing the development of cardiovascular disease in diabetic patients, as well as for preventing microvascular complications.[5] Education and support for patient's self-management are very important to prevent acute complications and reduce the risk of long-term complications.[6]

The study aims to evaluate the impact of counseling delivered by the researcher who is a hospital pharmacist in an Indonesian secondary hospital. Counseling was given three times on three topics namely diabetes and its management, diabetes mellitus management during Ramadan fasting, and management for acute and chronic complications. We also determined variables on the controlled condition from glycated hemoglobin (HbA1c), fasting blood glucose (FBG), and postprandial blood glucose (PPBG) for glycemic control; lipid profiles including total cholesterol (TC), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglyceride (TG); and also blood pressure measurements at the end of the study (posttest).

Methods

This was a prospective quasi-experimental study with pretest-posttest design. This study obtained ethical clearance from the Ethics Committee of the Faculty of Medicine, University of Indonesia (No. 040/UN2. F1/ETIK/2018). Informed consent was obtained from the individuals before participation. The study was conducted at the Depok City General Hospital (RSUD Kota Depok), West Java, Indonesia, from April to October 2018.

The sample in this study was T2DM outpatients that met the inclusion and exclusion criteria, using consecutive sampling method.[7] The minimum number of samples required was 64. To avoid dropping out, the number of samples was increased by 20% to 78 samples. The study inclusion criteria were T2DM patients who used pharmacological therapy at least 2 months earlier, T2DM outpatients, those aged ≥20 years, individuals who undergo fasting during Ramadan, and those who were willing to be respondents in the study. The study exclusion criteria included pregnant and lactating female patients, those taking birth control drugs, those having other endocrine diseases that are not associated with DM, those with mental illness, who are illiterate, and those who have experienced blood loss or recently transfused and underwent hemodialysis.

The participants were divided into two groups, namely control group (CG) who did not receive pharmacist intervention but only received booklets and intervention group (IG) who received pharmacist intervention, booklets, and counseling. The participants received a questionnaire titled "Sociodemography and Therapy for Type 2 Diabetes Mellitus Patients" and Medication Adherence Questionnaire (MAQ) and underwent measurement of HbA1c, FBG, and PPBG levels, as well as measurements of lipid profile and blood pressure to assess treatment adherence, at the beginning and at the end of the study. Counseling was done three times for 4 months except during Ramadan.

Data were analyzed using Statistical Package for the Social Sciences, version 22.0; IBM Corp, ©Copyright IBM Corporation and other(s) 1989, 2013. $P < 0.05$ was considered statistically significant. The data were presented as mean ± standard deviation [SD]. Differences between pretest and posttest were compared using the Chi-squared test, Pearson's exact test, dependent *t*-test if the data are normal; if the data are not normally distributed, they were analyzed using Wilcoxon signed-rank test. The differences between CG and IG were analyzed using independent *t*-test, if the data are normally distributed, and Mann–Whitney test if the data are nonnormally distributed. A multivariate analysis was conducted using binomial logistic regression test.

Results

A total of 81 patients were enrolled in this study and were divided into two groups: IG (40 patients) and CG (41 patients). Seventy-seven patients completed the study [Figure 1].

The baseline characteristics of the respondents are shown in Table 1. The results showed that there were no statistically significant differences in baseline characteristics between the IG and CG ($P > 0.05$). The majority of respondents were nongeriatric, in the age range between 41 and 60 years old

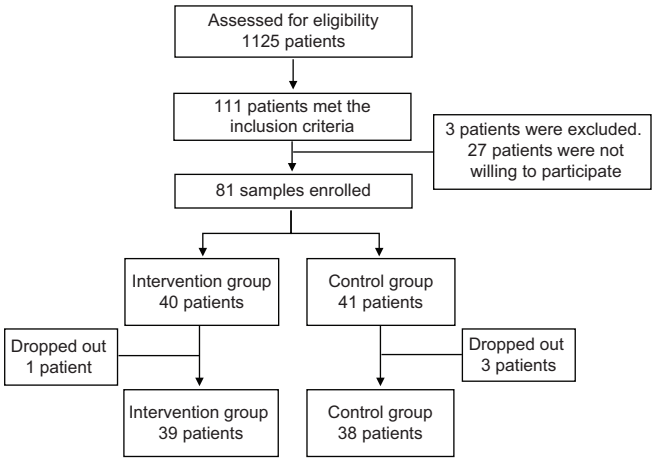

Figure 1: Flowchart of participants selected for this study

comprising 38 people (49.4%), with an average age of 58.65 ± 10.1 years (mean ± SD). The majority of participants were female (48 people, 63.2%), had a secondary level of education (31 people, 40.3%), and were homemakers (40 people, 51.9%).

There were no significant differences in clinical characteristics between IG and CG, except for the types of DM drugs used. Medication adherence was assessed using the MAQ questionnaire that has been validated in Bahasa Indonesia. Both groups at pretest showed comparable medication adherence.

The results of the clinical outcomes of glycemic control measurements (HbA1c, FBG, and PPBG), lipid profiles (TC, HDL, LDL, and TGL), and blood pressure are summarized in Table 2, and the clinical outcome conditions are summarized as proportions in Table 3. IG showed a significant improvement on adherence, in parameters such as HbA1c, TC, HDL-cholesterol, LDL-cholesterol, and TG. In contrary, CG showed a decrease in medication adherence parameters, but no change on all the clinical parameters.

When the posttest results in IG were compared to those of CG, it was reported that adherence, in terms of FBG, PPBG, and HbA1c, was better in IG than CG ($P < 0.05$). In terms of medication adherence, the level of adherence improved after intervention in IG ($P = 0.006$). In contrary, there was a decrease in medication adherence ($P = 0.008$) in CG [Table 2].

Discussion

According to the International Diabetes Federation DM map, nearly half of the 4 million people who died of diabetes in 2017 are under 60 years of age.[8] Two previous studies in China and Malaysia showed similar results as the average age of diabetic patients was <60 years. The research showed that DM patients were mostly female (59.1%), and T2DM patients in China on an average have secondary education (60.80%) and are unemployed (59.29%).[9,10]

The mean body mass index of the patients in both groups was in overweight criteria. The pathophysiology of DM does not only involve insulin and glucose but interference with fat metabolism can also cause T2DM. Excess triglycerides (TGL) in the stomach adipose tissue cause central obesity. Subcutaneous fat has a high basal lipolysis level. The accumulation of visceral fat causes an increase in free fatty acids, causing a buildup of ectopic fat. In the end, it causes the accumulation of ectopic TGL in the muscles, liver, heart, and pancreatic β-cells, which results in insulin resistance at the systemic level by interfering with insulin secretion and insulin signaling.[11]

The IG tends to have a good lifestyle in terms of physical activity. The participants from IG mostly work as housewives that make them sweat every day not because of doing sports but because they undergo their own physical activities by doing household chores such as sweeping, mopping the floor, washing clothes with hands, and carrying their children or grandchildren so that they meet the criteria for physical activity according to the American Diabetes Association (ADA) standard.[12]

Physical activities carried out in accordance with the recommendation (150 min/week) can activate the enzyme pathway in insulin receptors (e.g., adenosine monophosphate-activated protein kinase-AMPK) and protein kinase B substrate to increase glucose transport in skeletal muscle. They may also increase the use of fat reserves as an energy source, and increased performance of mitochondria in the skeletal muscle can increase cell sensitivity to insulin. Muscle contraction as a response to the body during physical activity can increase glucose uptake in cells without using insulin. This activity is thought to involve several major proteins including AMPK, protein kinase C, Ca2+/calmodulin-dependent protein kinase, and mitogen- AMPK, and act as a substrate for 160 kDa (AS160).[13]

This study showed different results from previous studies conducted by Osterberg and Blaschke. Both IG and CG were shown to have behavioral changes, becoming more compliant because each respondent in both groups continued to feel supervised by health professionals during the study period. This symptom is commonly known as white-coat adherence, a result of interactions with health practitioners so that patients tend to improve their habits in taking medicine 5 days before and after they meet health practitioners.[14] Counseling is related to adherence ($P = 0.006$) [Table 2]. The group that received

Table 1: Baseline demographic and clinical characteristics

Characteristics	IG (*n*=39), *n* (%)	CG (*n*=38), *n* (%)	Total (*n*=77), *n* (%)	*P* (inter group)
Age (years)				
20-40	0	4 (10.5)	4 (5.2)	0.109[a]
41-60	21 (53.8)	17 (44.7)	38 (49.4)	
>60	18 (46.2)	17 (44.7)	35 (45.5)	
Sex				
Male	11 (28.2)	18 (47.4)	29 (37.7)	0.134[a]
Female	39 (71.8)	20 (52.6)	48 (62.3)	
Level of education				
None	5 (12.8)	2 (5.3)	7 (9.1)	0.514[a]
Primary	11 (28.2)	7 (18.4)	18 (23.4)	
Secondary	18 (46.2)	24 (63.1)	42 (54.6)	
Bachelor and above	5 (12.8)	5 (13.2)	10 (13.0)	
Working status				
No	11 (28.2)	9 (23.7)	20 (26.0)	-
Yes	5 (12.9)	12 (31.6)	17 (22.1)	
Homemaker	23 (59.0)	17 (44.7)	40 (51.9)	
Smoking				
Yes	4 (10.3)	4 (10.5)	8 (10.4)	0.687[a]
No	35 (89.7)	34 (89.5)	69 (89.1)	
Exercise				
Yes	23 (59.0)	12 (31.6)	35 (45.5)	0.029[a,*]
No	16 (41.0)	26 (68.4)	42 (54.5)	
Risk food consumption				
Not often	16 (41.0)	12 (31.6)	28 (36.4)	0.532[a]
Often	23 (59.0)	26 (68.4)	49 (63.6)	
Duration of DM drug use (months)				
<12	5 (12.8)	0 (0.0)	5 (6.5)	0.990[a]
12-24	11 (28.2)	2 (5.3)	13 (16.9)	
>24	23 (59.0)	36 (94.7)	59 (76.6)	
Number of DM drugs				
Single drug	4 (10.3)	7 (18.4)	11 (14.3)	0.470[a]
Combination of two drugs	19 (48.7)	17 (44.7)	36 (46.8)	
Combination of >2 drugs	16 (41.0)	14 (36.9)	30 (38.9)	
Type of medicine				
Oral antidiabetic	37 (94.9)	7 (18.4)	44 (57.1)	<0.0001[a,*]
Insulin injection	0 (0.0)	17 (44.7)	17 (22.1)	
Combination	2 (5.1)	14 (36.8)	16 (20.8)	
Complications				
Yes	23 (59.0)	23 (60.5)	46 (59.7)	1.000[a]
No	16 (41.0)	15 (39.5)	31 (40.3)	
Family history of DM				
Yes	23 (59.0)	19 (50.0)	42 (54.5)	0.496[a]
No	16 (41.0)	19 (50.0)	35 (45.5)	
BMI	25.90±4.47	25.10±3.66	25.50±4.09	0.396[b]

**P* value based on Chi-square test. [a]Chi-squared test, [b]Mann-Whitney test. Data were expressed in *n* (%) or mean±SD. *P*=Significance of different tests, SD=Standard deviation, BMI=Body mass index, DM=Diabetes mellitus, CG=Control group, IG=Intervention group

counseling had a higher proportion of adherence than controls. Improvement in adherence might be due to an increase in the respondent's understanding as a result of education provided through counseling.

Labrador Barba *et al*. stated that one of the main requirements in order to achieve treatment compliance is by increasing patients' knowledge about their disease and treatment. The majority of respondents understood the importance of taking medication and recognized the importance of getting adequate information about their illness, comorbidity, and benefits of the medicine. In addition, patients' involvement in the selection of the therapy can also increase their adherence to the therapy they undergo, especially patients on insulin therapy.[15]

Table 2: Comparison of clinical parameters in both groups

Variable	IG (*n*=39)			CG (*n*=38)			P^c	P^d
	Pretest	Posttest	P^a	Pretest	Posttest	P^b		
FBG (mg/dL)	122.64±37.98	124.05±49.90	0.485	175.97±84.4	172.89±80.9	0.788	0.003*	0.002*
PPBG (mg/dL)	192.56±72.40	192.13±88.09	0.976	232.82±110.2	240.45±99.87	0.643	0.061	0.027*
HbA1c (%)	7.29±1.35	6.90±1.07	0.003*	9.07±2.06	8.85±2.00	0.318	<0.0001*	<0.0001*
TC (mg/dL)	230.15±57.02	198.72±45.66	0.002*	207.24±38.41	198.687±40.97	0.177	0.093	0.997
HDL-c (mg/dL)	45.187±12.23	51.72±13.16	0.004*	48.97±11.23	52.26±16.42	0.166	0.161	0.873
LDL-c (mg/dL)	132.82±59.46	110.41±40.56	0.026*	112.58±55.32	112.13±38.23	0.37	0.126	0.691
TG (mg/dL)	221.05±192.5	164.15±102.9	0.012*	185.66±132.8	163.08±116.4	0.157	0.169	0.628
SBP (mmHg)	123.59±12.24	122.82±14.31	0.469	122.63±9.78	121.32±10.44	0.286	0.924	0.871
DBP (mmHg)	78.72±6.95	75.38±6.82	0.059	78.687±6.64	78.16±5.12	0.669	0.761	0.071
Adherence	0.79±0.128	0.44±0.088	0.006*	0.84±0.128	1.13±0.132	0.008*	0.743	<0.0001*

**P* value based on *T*-test. Data presented as mean±SD. [a]Before versus after intervention on IG, [b]Before versus after intervention on CG, [c]IG versus CG before intervention, [d]IG versus CG after intervention. CG=Control group, DBP=Diastolic blood pressure, FBG=Fasting blood glucose, HbA1c=Glycosylated hemoglobin A1, HDL-c=High-density lipoprotein-cholesterol, IG=Intervention group, LDL-c=Low-density lipoprotein-cholesterol, SBP=Systolic blood pressure, SD=Standard deviation, TG=Triglyceride, TC=Total cholesterol, PPBG=Postprandial blood glucose

Table 3: Clinical outcomes in category

Clinical parameters	Pretest			Posttest		
	Controlled	Uncontrolled	*P*	Controlled	Uncontrolled	*P*
FBG						
IG	25 (64.1)	14 (35.9)	0.03*	23 (59.0)	16 (41.0)	0.051*
CG	14 (36.8)	24 (63.2)		13 (34.2)	25 (65.8)	
PPBG						
IG	23 (59.0)	16 (41.0)	0.21	22 (54.6)	17 (43.6)	0.304
CG	16 (41.2)	22 (57.9)		16 (42.1)	22 (57.9)	
HbA1c						
IG	22 (56.4)	17 (43.6)	0.003*	27 (69.2)	12 (30.8)	<0.0001*
CG	8 (21.1)	30 (78.9)		7 (18.4)	31 (81.6)	
TC						
IG	13 (33.3)	26 (66.7)	0.428	20 (51.3)	19 (48.7)	0.411
CG	17 (44.7)	21 (55.3)		24 (63.2)	14 (36.8)	
HDL-c						
IG	26 (66.7)	13 (33.3)	0.493	32 (82.1)	7 (17.9)	0.734
CG	29 (76.3)	9 (23.7)		29 (76.3)	9 (23.7)	
LDL-c						
IG	11 (28.2)	28 (71.8)	0.747	14 (35.9)	25 (64.1)	0.643
CG	13 (34.2)	25 (62.8)		11 (28.9)	27 (71.1)	
TG						
IG	19 (48.7)	20 (51.3)	0.908	21 (53.8)	18 (46.2)	0.55
CG	20 (52.6)	18 (47.4)		24 (63.2)	14 (36.8)	
SBP						
IG	23 (59.0)	16 (41.0)	0.574	26 (66.7)	13 (33.3)	0.493
CG	19 (50.0)	19 (50.0)		29 (76.3)	9 (23.7)	
DBP						
IG	34 (87.2)	5 (12.8)	0.963	38 (97.4)	1 (2.6)	0.982
CG	32 (84.2)	6 (15.8)		36 (94.7)	2 (5.3)	

**P* value based on Chi-square test. Data were expressed in *n* (%). CG=Control group, DBP=Diastolic blood pressure, FBG=Fasting blood glucose, HbA1c=Glycosylated hemoglobin A1, HDL-c=High-density lipoprotein-cholesterol, IG=Intervention group, LDL-c=Low-density lipoprotein-cholesterol, SBP=Systolic blood pressure, TG=Triglyceride, TC=Total cholesterol, PPBG=Postprandial blood glucose

Research conducted by Shao *et al*. showed that additional services provided by pharmacists in the form of counseling can improve medication adherence and clinical outcomes of glycemic control, lipid profile, and blood pressure.[10] Similar finding has been proven in a study in Malaysia that the involvement of pharmacists

Table 4: Multiple regression analysis on the influencing factors of fasting blood glucose and glycated hemoglobin

Variable	Type of OR	OR	95% CI		*P*
			Lower	Upper	
FBG					
Model 1					
Counseling	Crude OR	2.764	1.096	6.974	0.031*
Model 2					
Counseling	Adjusted OR	2.062	0.603	7.059	0.249
Type of medicine		1.319	0.605	2.879	0.486
HbA1c					
Model 1					
Counseling	Crude OR	9.964	3.434	28.917	<0.0001*
Model 2					
Counseling	Adjusted OR	2.247	0.51	9.889	0.284
Type of medicine		3.252	1.281	9.706	0.015
Duration of DM drug use		1.302	0.475	3.571	0.608
Medication adherence		2.737	0.786	9.538	0.114
Age		0.559	0.187	1.672	0.298
Model 3					
Counseling	Adjusted OR	3.516	0.880	14.045	0.075
Type of medicine		2.973	1.085	8.147	0.034*
Duration of DM drug use		1.152	0.442	3.002	0.772

**P* value based on Binomial logistic regression test. FBG=Fasting blood glucose, HbA1c=Glycated hemoglobin, OR=Odds ratio, CI=Confidence interval, DM=Diabetes mellitus

in patients' treatment can improve compliance, HbA1c, and quality of life of the patients.[9] Vella and Azzopardi conducted research in Malta, where patients were given pharmacist intervention in the form of counseling and leaflets, and showed that there was an increase in the adherence of respondents after the intervention. In addition, improved the awareness of the treatment they undergo could decreased missed medicine taken.[16]

The categorization of clinical outcomes in a controlled–uncontrolled form in this study was based on the ADA guidelines. Table 2 summarizes that the difference in PPBG between IG and CG was not significant and IG's HbA1c decreased at posttest. The mean results of FBG and HbA1c in both groups were significantly different post test. The mean of HbA1c decreased in small amount (by 0.39%). The results were similar to a study conducted in China, where the decrease in the mean of HbA1c was only 0.9%, possibly because the condition of IG's HbA1c before intervention tended to be close to normal (7.29 ± 1.35).[10]

A systematic review of 118 studies by Chrvala *et al*. showed that the reduction of the mean of HbA1c as a result of diabetes self-management education (DSME) was 0.57%. Improvement of HbA1c was experienced by 61.9% of patients who received DSME compared to those who did not. Decreases were getting better in the study where the total interaction time between educators and patients over the study was more than 10 h.[17] At the end of the study, there was an increase in the proportion of respondents in the IG with controlled HbA1c conditions of 69.2% compared to before-the-pharmacist intervention of 56.4% ($P < 0.05$).

There was no significant difference in lipid profile between IG and CG. However, lipid profile changed in IG, as shown by the decrease of TC, LDL, and triglycerides, and an increase in HDL value ($P < 0.05$). The higher lipid profiles may also be due to the fact that majority (62.3%) of the respondents were female. According to Gupta *et al*.,[18] the average value of lipid profiles in females tends to be higher than that in males.

There was no significant difference in systolic blood pressure (SBP) and diastolic blood pressure (DBP) between IG and CG. SBP and DBP also did not change in each group [Table 2]. The effect of pharmacist's counseling and other independent variables on FBG and HbA1c was analyzed using binomial logistic regression. Bivariate analysis was performed for each independent variable on the dependent variable before performing mutivariate analysis. The results showed that counseling and the type of drugs used by respondents influence the FBG levels. Whereas in HbA1c, the type of the drug was the main factor that affected, while counseling along with other factors as a controlling factor for these changes [Table 4]. In the case of FBG, the IG was 2.764 times more likely to show FBG-controlled results than the intervention without counseling. Whereas in HbA1c, the IG was 9.964 times greater, which showed controlled results than the intervention without counseling.

In line with the results of this study, Shao *et al*. conducted research in China which showed that there is a linear relationship between HbA1c values and patient medication adherence as a result of pharmacist intervention in the form of counseling in a 6-month period.[10]

Nazir *et al*., in a study conducted in Pakistan, looked at the relationship between HbA1c levels, knowledge, and treatment adherence to DM patients and reported that HbA1c has a negative and insignificant relationship with diabetes-related knowledge ($r = -0.036$, $P = 0.404$) and medication adherence ($r = -0.071$, $P = 0.238$). Lack of knowledge related to diabetes among patients results in poor adherence to treatment and ultimately causes poor glycemic control. The causes of poor knowledge or inaccurate understanding of the diseases suffered include the lack of time to interact with medical practitioners, lack of counseling about their illnesses, and various sources of alternative medicine referrals that provide wrong information about DM, whereas the causes of medication noncompliance include poor knowledge; lack of understanding and concern for the illness; and the inability to access health services, which leads to differences in services, facilities, and treatment received by patients. This study suggests that future studies shall be conducted to look at the main causative factors that can affect glycemic control.[19] The present study results showed that pharmacist counseling has a significant effect on improving patient's clinical outcomes and glycemic control of FBG and HbA1c.

Authors' Contribution

Wiwiet Nurwidya Hening participated in design, literature search, clinical studies, data analysis, statistical analysis, manuscript preparation, manuscript editing; Ratu Ayu Dewi Sartika participated in design, definition of intellectual content, statistical analysis, manuscript editing and manuscript review; Rani Sauriasari participated in concept, design, definition of intellectual content, statistical analysis, manuscript editing and manuscript review.

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Conflicts of interest

There are no conflicts of interest.

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