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RESEARCH ARTICLE

Evaluation of pharmacist-led structured counselling on glycemic control and clinical outcomes of Type 2 diabetes mellitus patients at a health centre in East Jakarta, Indonesia

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Abstract

Background: The researchers developed structured counselling for Type 2 diabetes mellitus (T2DM) patients, comprised of an introduction to T2DM and how to manage it and its complications. **Aim:** This study aimed to evaluate structured counselling on its ability to improve glycemic control and the clinical outcomes of T2DM outpatients. **Methods:** A quasi-experimental study was conducted from August to December 2019 involving T2DM patients at health centers in East Jakarta, who met the criteria and had completed informed consent. The patients were divided into the intervention group (IG, n = 33), which received counselling and booklets, and the control group (CG, n = 32), which received booklets. **Results:** Counselling showed significant results in decreasing HbA1c levels and improving fasting blood glucose (FBG), total cholesterol (TC), and low-density lipoprotein cholesterol (LDL-c) levels in the IG compared to the CG. Moreover, counselling in the IG reduced HbA1c 7.596 times more than in the CG. **Conclusion:** Pharmacist-led structured counselling significantly improves glycemic control and clinical outcomes in T2DM patients.

Introduction

Indonesia was ranked seventh in the world for the highest number of diabetes mellitus (DM) sufferers in 2015, with a prevalence that increased from 5.7% in 2007 to 6.9% in 2013 (Kementerian Kesehatan Republik Indonesia, 2017). According to the results of the 2018 Basic Health Research (Riskesdas) in Indonesia, conducted by the Ministry of Health of the Republic of Indonesia, the prevalence of DM sufferers who were aged 15 and above increased from 1.5% in 2013 to 2.0% in 2018. In Jakarta, there was also an increase in the prevalence of DM sufferers, reaching 3.4% in 2018, the highest prevalence amongst provinces in the country (Kementerian Kesehatan Republik Indonesia, 2018).

Diabetes is a disease that can be managed by patients with appropriate treatment through education and self-management (Nazar, 2016). However, according to Riskesdas, 50.4% of Type 2 diabetes mellitus (T2DM) sufferers in Indonesia do not routinely take their antidiabetic drugs or insulin injections, either because they feel well or 18.8% forget to take their medication (Kementerian Kesehatan Republik Indonesia, 2018). This can happen due to the patient's lack of knowledge regarding the disease, so there is a need for health services to provide education to patients with T2DM about the importance of adhering to taking medication, especially by pharmacists who provide direct services related to drugs. Education and counselling by pharmacists can also strengthen their role in the treatment of T2DM (Shareef *et al.,* 2015). This study aims to evaluate the ability of pharmacist-led structured counselling to improve glycemic control and clinical outcomes of patients. Structured counselling comprises the introduction of T2DM (symptoms and risk factors),

management of T2DM, and management for acute and chronic complications of T2DM.

Material and methods

This was a quasi-experimental study conducted from August to December 2019 and has been registered and approved by the Ethics Committee Faculty of Medicine, Universitas Indonesia, Dr Ciptomangunkusumo Hospital (No: KET-480/UN2.F1/ETIK/PPM.00.02/2019). Informed consent was collected from all participants before participation.

The study samples were patients from the Pulogadung District Health Center and Duren Sawit District Health Center who met the inclusion and exclusion criteria. For T2DM patients to meet the inclusion criteria, they had to be aged ≥ 20 years, have an HbA1c level of ≥ 7%, have a check-up at the health centre regularly, and be interested in being involved in the study. The exclusion criteria were if patients were suffering from an endocrine disease other than T2DM, heart failure, chronic renal disease, hepatitis, cancer and mental disorders; or patients who were pregnant, breastfeeding, taking birth control drugs (steroids), had performed blood transfusions and hemodialysis, and if they were illiterate. The minimum number of samples was 64. To avoid dropout, the sample size was increased by 25% to 80.

The patients were divided into two groups based on their treatment location. Those from Pulogadung District Health Center where the intervention group (IG) given structured counselling and booklets with different themes every month for three months. The first theme was information about T2DM, symptoms, and its risk factors; the second was the pharmacological and non-pharmacological management of T2DM; and the third was T2DM complications, prevention, and their management. At the end of the counselling, the researcher reviewed the patient's knowledge by asking the patient again about the counselling that had been given. Meanwhile, patients from the Duren Sawit District Health Center constituted the control group (CG). They were only given a booklet every month for three months. Each patient involved received a sociodemographic questionnaire and their HbA1c levels as a representation of the glycemic outcome, fasting blood glucose (FBG), total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-c), high-density lipoprotein cholesterol (HDL-c), systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured both pre-test and post-test. The measurement of HbA1c levels was performed using Alere Afinion AS100 Analyzer (Alere, Oslo, Norway), and lipid profiles were performed using Lipid Pro (Infopia, Gyeonggi, South Korea) at the Drug Development Laboratory of the Universitas Indonesia.

The pre-test and post-test data were compared using a paired t-test if the data were normally distributed; if not, a Wilcoxon signed-rank test was used. To compare the two groups, the researchers used the chi-square test, Fisher exact test, a dependent t-test, or Mann-Whitney U test. Multivariate analysis in the form of a logistic regression test was used to determine the relationship between confounding variables and the dependent variable in the form of primary clinical outcomes. The data were analysed using SPSS version 22, with $p < 0.05$ as the significant value.

Results

The two groups (IG and CG) had the same characteristics, apart from the length of time that drugs were used and the T2DM food consumption risk (Table I). The pre-test HbA1c levels in the IG were significantly higher than those of the CG (Table II). However, in the post-test, HbA1c levels in the IG were significantly lower than in the CG. The median decrease in HbA1c levels in the IG was 2.5% ($p < 0.05$), while the HbA1c levels in the CG did not change ($p = 0.308$). As shown in Table III, the multivariate analysis to assess the effect of counselling by pharmacists on the reduction in HbA1c indicates that there are other variables that also had a significant influence, namely T2DM food consumption risk and physical activity ($p < 0.05$). The analysis showed that patients who did not frequently eat foods that caused a risk of T2DM were 4.2 times more likely to experience a decrease in HbA1c than those who often ate such food. A good level of physical activity of ≥150 minutes/week had a 5.7 times greater effect on reducing HbA1c levels than in patients who did no physical activities. Counselling by pharmacists became the dominant variable, and it had a 7.5 times greater effect on reducing HbA1c than in patients who only received booklets.

In addition, secondary clinical outcomes in the form of FBG, TC, TG, LDL-c, HDL-c, SBP, and DBP need to be considered in patients with T2DM. In the IG, the values of FBG, TC, and LDL-c showed a significant decrease ($p < 0.05$), and a decrease in the median score of pre-test and post-test cholesterol (Table IV). In the CG, a significant difference was shown in TG and SBP levels. On the other hand, other secondary outcomes experienced a change in median values but did not show a significant difference. The comparison between the IG and CG showed a significant difference in TG at the pre-test, which was presumably due to differences in levels of TG in the two groups. In addition, the results of the post-test analysis did not show any significant results other than SBP.

Table I: Baseline demographic and clinical characteristics

Characteristics	CG, n (%)	IG, n (%)	*p*
Age (years)			0.911
≤ 60	17 (53.1)	19 (57.6)	
> 60	15 (46.9)	14 (42.4)	
Sex			0.499
Female	22 (68.8)	19 (57.6)	
Male	10 (31.3)	14 (42.4)	
Level of education			1.000
Basic	12 (37.5)	13 (39.4)	
Advance	20 (62.5)	20 (60.6)	
Working status			0.291
No	26 (81.3)	22 (66.7)	
Yes	6 (18.8)	11 (33.3)	
Nutritional status (BMI)			1.000
Over nutritional status	16 (50.0)	16 (48.5)	
Normal nutritional status	16 (50.0)	17 (51.5)	
Type of medication			0.564
Oral antidiabetic	28 (87.5)	29 (87.9)	
Insulin injection	1 (3.1)	0 (0.0)	
Oral antidiabetic + insulin injection	3 (9.4)	4 (12.1)	
Number of T2DM drugs			0.951
Single drug	7 (21.9)	6 (18.2)	
Combination of ≥ 2 drugs	25 (78.1)	27 (81.8)	
Duration of T2DM drug use (months)			**<0.001**
> 24	2 (6.3)	23 (69.7)	
≤ 24	30 (93.8)	10 (30.3)	
Complications			0.132
Yes	25 (78.1)	19 (57.6)	
No	7 (21.9)	14 (42.4)	
Risk food consumption			
T2DM risk food			**0.017**
Often	9 (28.1)	20 (60.0)	
Not often	23 (71.9)	13 (39.4)	
Hypertension risk food			1.000
Often	9 (28.1)	10 (30.3)	
Not often	23 (71.9)	23 (69.7)	
Dyslipidemia risk food			0.690
Often	12 (37.5)	15 (45.5)	
Not often	20 (62.5)	18 (54.5)	
Physical activity			0.154
Inactive	19 (59.4)	26 (78.8)	
Active	13 (40.6)	7 (21.2)	
Use of herbal medicines			0.511
Yes	9 (28.1)	6 (18.2)	
No	23 (71.9)	27 (81.8)	

p-value by Chi-square test, $p < 0.05$. IG = Intervention group, CG = Control group, n = number of patients, T2DM = Type 2 diabetes mellitus, BMI = Body mass index

Table II: Comparison of adherence level based on HbA1C levels before and after the intervention in both groups

Variable	IG			CG				
	Pre-test	Post-test	p^a	Pre-test	Post-test	p^b	P^c	P^d
HbA1c (%)	9,3 (7.1-12.3)	6,8 (5.7-12)	**<0,001**[e]	7,6 (7-11.6)	7,6 (6.2-11.8)	0.308[f]	**<0.001**[g]	**0.021**[g]

Data were presented as median (minimum-maximum). [a]Pre-test versus post-test on IG, [b]Pre-test versus post-test on CG, [c]Pre-test of IG versus pre-test of CG, [d]Post-test of IG versus post-test of CG; [e]*p*-value based on Paired sample *t*-test, [f]*p*-value based on Wilcoxon signed rank test, [g]*p*-value based on Mann-Whitney U test, $p < 0.05$; IG = Intervention group, CG = Control group, HbA1c = Glycated haemoglobin

Table III: Multivariate regression analysis of variables influencing HbA1c

Model	Variable	OR	95% CI		*P*
			Lower	Upper	
Crude OR Model 1	**Counselling**				
	Control	Reference			
	Intervention	6.842	1.720	27.215	**0.008**
Adjusted OR Model 2	**Counselling**				
	Control	Reference			
	Intervention	7.596	1.676	34.417	**0.009**
	T2DM risk food consumption				
	Often	Reference			
	Not often	4.236	1.049	17.105	**0.043**
	Physical activity				
	Inactive	Reference			
	Active	5.736	1.397	23.551	**0.015**

Significance level and OR were analysed by multivariate logistic regression analysis, $p < 0.05$; OR = odds ratio

Table IV: Comparison of secondary outcomes before and after the intervention in both groups

Variable	IG			CG			p^c	p^d
	Pre-test	Post-test	p^a	Pre-test	Post-test	p^b		
FBG (mg/dL)	195.5 (103.0-361.0)	177.5 (94.0-297.0)	**0.022**	144.5 (91.0-392.0)	145.0 (101.0-307.0)	0.784	**0.008**	0.075
TC (mg/dL)	219.0 (125.0-323.0)	196.0 (100.0-313.0)	**0.001**	206.5 (140.0-295.0)	196.0 (107.0-283.0)	0.360	0.251	0.983
TG (mg/dL)	220.5 (101.0-402.0)	204.0 (103.0-457.0)	0.174	130.5 (57.0-318.0)	157 (78-329.0)	**0.018**	**0.001**	0.158
LDL-c (mg/dL)	135.0 (56.0-223.0)	116.0 (33.0-183.0)	**0.001**	125.5 (84.0-207.0)	120.0 (32.0-214.0)	0.325	0.432	0.853
HDL-c (mg/dL)	42.5 (25.0-75.0)	47.5 (25.0-68.0)	0.114	48.5 (28.0-69.0)	45.0 (25.0-78.0)	0.324	0.065	0.912
SBP (mmHg)	140.0 (90.0-160.0)	131.5 (100.0-159.0)	0.706	135.0 (110.0-160.0)	120.0 (100.0-160.0)	**<0.001**	0.766	**0.006**
DBP (mmHg)	80.0 (60.0-90.0)	80.0 (60.0-90.0)	0.176	80.0 (70.0-90.0)	80.0 (70.0-90.0)	0.285	0.134	0.220

Data presented as median (minimum-maximum). [a]Pre-test versus post-test on IG, [b]Pre-test versus post-test on CG, [c]Pre-test of IG versus pre-test of CG, [d]Post-test of IG versus post-test of CG. a and b = *p*-value based on paired sample t-test for normally distributed data and Wilcoxon signed-rank test for abnormally distributed data, c and d = *P*-value based on Independent sample t-test for normally distributed data dan Mann-Whitney U test for abnormally distributed data; IG = Intervention group, CG = Control group, FBG = Fasting blood glucose, TC = Total cholesterol, TG = Triglyceride, HDL-c = High-density lipoprotein cholesterol, LDL-c = Low-density lipoprotein cholesterol, SBP= Systolic blood pressure, DBP = Diastolic blood pressure.

Discussion

The HbA1c level is an important indicator in determining glucose levels over a longer period. It has the ability to show a cumulative glycemic history for two to three months (Sherwani *et al.,* 2016), so it was the main parameter in this study. The patients involved were those with completely uncontrolled HbA1c levels. The results of the pre-test analysis show a significant median difference in the HbA1c levels in the IG and CG, with those of the IG being higher than those of the CG, which is one of the limitations of this study. This is because the sampling technique used was non-random sampling to avoid bias caused by communication between samples in one research location, so the patients' pre-test clinical outcomes could not be matched. However, the changes that occurred in the HbA1c levels after the intervention can be seen by observing the changes in the median HbA1c post-test value. The provision of counselling produced significant results, with the median HbA1c level being controlled. In line with other studies, intervention in diabetics can influence glycemic control by significantly lowering

mean HbA1c levels (Butt *et al.,* 2016; Shao *et al.,* 2017). This is because the counselling and booklets routinely reminded the patients of the importance of being obedient and continuing to take medication to achieve therapeutic targets and avoid worsening their disease.

Other clinical outcomes that should be considered in patients with T2DM are FBG, lipid profile, and blood pressure because there is a risk of comorbidities. Patients with T2DM can have a two to four times increased risk of coronary artery disease, leading to altered mortality, with dyslipidemia and hypertension being the major risk factors (Bhowmik *et al.,* 2018). Counselling by a pharmacist can minimise the incidence of diabetes complications in T2DM patients (Erku *et al.,* 2017). The clinical outcome comparison between the IG and CG after the intervention of FBG and SBP showed significant results, while this was not the case for the other variables. However, as expected, there were changes in the levels of lipid profiles and blood pressure after the intervention on the IG. This fall in levels indicates an improvement in the levels of lipid profiles and blood pressure.

From the observations, it was found that apart from providing counselling, other variables could influence changes in HbA1c levels, namely consumption of T2DM-risk food and physical activity. This is because the pharmacist-led structured counselling is not only related to pharmacological therapy but also non-pharmacological therapy, namely lifestyle modifications, which include increasing physical activity and limiting the consumption of risky foods. Research in China by Wang and colleagues has shown that a low-carbohydrate diet can significantly reduce HbA1c levels (Wang *et al.,* 2018). Lifestyle modifications such as dietary regulation through using the plate method and 150 minutes of physical activity per week can help reduce HbA1c levels (American Diabetes Association, 2020). Over a period of at least eight weeks, physical activity can reduce HbA1c levels by 0.66% in people with T2DM, even without weight loss (Lambrinou *et al.,* 2019).

Compared with the consumption of T2DM-risk food and physical activity, counselling had the greatest effect, with 7.5 times more influence on reducing HbA1c levels than in the group that only received booklets. Various studies have been conducted in several countries to evaluate the effectiveness of pharmacological interventions in T2DM patients, which in general have shown a positive effect on increasing patient knowledge of the disease and its complications, pharmacological and non-pharmacological T2DM therapy, and self-monitoring (Hughes *et al.*, 2017). The intervention by pharmacists can have a positive impact on patient treatment outcomes, with a significant impact on patient treatment through monitoring therapy and preventing and resolving drug-related problems (Shareef *et al.,* 2015). Appropriate communication between patients and pharmacists contributes to better adherence and clinical outcome (Shao *et al.,* 2017).

Conclusions

Pharmacist-led structured counselling was shown to improve glycemic control and clinical outcomes in T2DM patients.

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