

Booklet handout to improve glycemic control in type-2-DM patients and comparison with other models

Daniek Viviandhari^{*}, Nora Wulandari, Nur Rahmi

Faculty of Pharmacy and Science, Universitas Muhammadiyah Prof. Dr. HAMKA,

Delima II Street, Klender, East Jakarta, Indonesia

Submitted: 05-08-2020

Reviewed: 21-01-2021

Accepted: 06-04-2021

ABSTRACT

Non-adherence is still a major issue in the management of diabetes in Indonesia which leads to complication problems. Medication adherence in diabetes mellitus is related to better glycemic control, better control of risk factors, lower risk of hospitalization, lower health care cost, and lower risk of mortality. Many educational models are applied to achieve the patient's glycemic control. There were two research purposes in this study. The first one was to determine the booklet handout's effectiveness in improving glycemic control in type-2 diabetes mellitus patients in Malaka Jaya Primary Healthcare Centre, Jakarta. The second aim was to compare two different educational models, which were done simultaneously at Pondok Kelapa Primary Healthcare Centre and Duren Sawit Primary Healthcare Centre. A quasi-experimental study design was applied in these prospective studies. A total of 30 patients met the inclusion criteria. The intervention was a booklet handout that was given and presented to the respondent once every month for three months. The parameter used was the A1C (glycated hemoglobin). For patients exposed to booklet handout, 20.0% of them had the A1C level <6.5% initially, then the A1C level <6.5% significantly increased to 73.34% ($p=0.005$). For patients who were given public counseling, the number of respondents who had the A1C level <6.5% was 16.7%, then the A1C percentage rose to 76.7% ($p=0.005$). Meanwhile, for patients who were educated with video, the A1C level <6.5% was 6.67% initially, then the A1C level <6.5% increased significantly to 90.0% ($p=0.005$) in 12 weeks after the intervention. Either booklet handout, public counseling, or video are effective to improve glycemic control in type-2 diabetes mellitus patients.

Keywords: booklet handout, public counseling, educational video, comparison, A1C

***Corresponding author:**

Daniek Viviandhari

Faculty of Pharmacy and Science, Universitas Muhammadiyah Prof. Dr. HAMKA

Delima II Street, Klender, East Jakarta, Indonesia

Email: daniek.viviandhari@uhamka.ac.id



INTRODUCTION

Diabetes mellitus is defined as a chronic illness caused by an absolute deficiency of insulin (type-1 diabetes mellitus) or relative deficiency of insulin (type-2 diabetes mellitus) due to impaired insulin activity. The clinical characteristics are hyperglycemia and lipid and protein metabolism. These abnormalities result in the development of cardiovascular disease (Aldredge et al., 2013). Based on national data, the number of diabetes mellitus prevalence (based on clinician diagnose on population age ≥ 15 years) has increased from 1.5% in 2013 to 2.0% in 2018, where Jakarta occupies the highest prevalence (3.4%) (Riskasdas, 2018).

Type-2 diabetes mellitus patients often receive multiple medications to control hyperglycemia and comorbidities such as hypertension. Medication adherence is one of the significant determinant factors of diabetes mellitus outcomes. Medication adherence in diabetes mellitus is related to better glycemic control, better control of risk factors, lower risk of hospitalization, lower health care cost, and lower risk of mortality (Care, 2019; Kirkman et al., 2015). The A1C measurement was used mainly in glycemic management, which showed the benefits of increased glycemic control in a previous study (Care, 2019).

Non-adherence is still a major issue in the management of diabetes in Indonesia which leads to many problems (Alfian et al., 2016; Nanda et al., 2018). Diabetes mellitus complications (microvascular and macrovascular) and extra cost to the health system are results of poor adherence to the treatment for diabetes mellitus (Geest and Sabaté, 2003). Some research in Indonesia showed that most patients exhibited low adherence (ranging from 44.1 to 53.8%). Patients with low adherence tend to have uncontrolled glucose levels (Alfian et al., 2016; Nanda et al., 2018; Rasdianah et al., 2016). Some research conducted in another country stated that the level of non-adherence to diabetes mellitus medication was high. Around 45% patient fail to manage glycemic control (A1C level $> 7\%$). These findings emphasize the need for education to ensure medication adherence (Alqarni et al., 2019; Polonsky and Henry, 2016; Sharma et al., 2014).

Research conducted in South India stated that improved diabetes medication adherence reduces peripheral diabetic neuropathy severity. Patient education ought to be implemented to improve patient adherence. Health care professionals, including pharmacists, play a significant role in educating diabetes mellitus patients regarding therapy management (Samu et al., 2017).

The goal of education is to empower patients to be active and involved in their treatment and prevent complications (Contreras et al., 2017). Many educational models are applied to achieve patient compliance and patient's glycemic control, such as counseling, booklet handout, and educational video. Research stated that individual counseling is more effective in controlling glycemic index than group education (Fan et al., 2016). Another study conducted in Norway found that group-based diabetes self-management education increase clinical, lifestyle, and psychosocial outcomes (Steinsbekk et al., 2015).

The fact that the number of pharmacists in Indonesia's primary health care centers is limited encourages the search for appropriate and effective educational models for patients. Hence, this research aimed to compare the effectiveness of three different educational models (booklet handout, public counseling, and educational video) in improving glycemic control in type-2 diabetes mellitus patients in three Primary Health Care Centers in Jakarta.

MATERIALS AND METHOD

Materials

The A1C level reader (i-Chroma TM) was the tool used in this research to collect data.

Methods

This study used a prospective method, and samples were collected with the total sampling method. This study was conducted at Malaka Jaya primary healthcare center from July 2017 to

October 2017. The population of type-2 DM patients in the Malaka Jaya primary healthcare center was 65 patients; with the total sampling method, the respondents should be 65 patients, but only 30 patients were willing to follow until the end of the study. The participants of this study were type-2 DM patients who joined the "Prolanis" program. Quasi-experimental research was designed to assess the impact of booklet handouts during the study period. During the 12 weeks of the study, the intervention was given three times. The A1C data were collected two times during the pre-test and post-test.

The inclusion criteria of this research were: adult patients (>18 years old), experienced DM at least one year, speak and understand Bahasa Indonesia, fasting blood sugar level >126 mg/dL in 3 months in a row, consume oral antidiabetic drugs (OAD), and visit the primary healthcare center for a check-up regularly. Fasting blood sugar levels were used in this study because A1C examination was rarely performed on patients at Malaka Jaya primary healthcare center. The exclusion criteria of this research were patients with gestational diabetes.

The research proposal received Ethical Approval from the Research Ethics Committee of Faculty of Medicine, University of Indonesia (protocol number 17-03-0285). After the research permit was granted from the primary healthcare center, the researchers conducted the patient screening. Patients were asked to sign an informed consent as a form of agreement to participate as research respondents.

Lifestyle characteristics are dietary habits, smoking, exercise, and herbs. Dietary habit in type-2 DM patients means people with DM need to understand the importance of regularity of meal schedules, types, and calorie content quantities (PERKENI, 2015). Exercise in type-2 DM patients means physical exercise done regularly 3-5 times per week (30-45 minutes each session). For 150 minutes per week, the pause between workouts should be less than two consecutive days (PERKENI, 2015). Smoking in patients with type-2 DM means patients smoked during the study period. Herbs' use means patients consumed herbal medicines that were empirically used to treat diabetes mellitus during the study period.

Research procedure

Patients who agreed to take part in the research filled out the informed consent form. The data were collected using the total sampling method. The samples were all respondents who followed the entire research process and met the inclusion criteria. The measurement of A1C levels (this is considered as the pre-test data) was done before the intervention.

Respondents were given booklet handout as a form of education intervention as many as three times during the study period (3 months). The booklet handout was given to patients during the "Prolanis" (Chronic Disease Control Program) meeting. Patients were asked to read the booklet once (in the forum) and were asked to ask questions if there are things that cannot be understood at that moment. Patients were also educated to reread at home. The booklet handout materials were divided into three sections: the first one was a general explanation of diabetes mellitus, diabetes mellitus complications (microvascular and macrovascular), pharmacotherapy of diabetes mellitus, and also about patient adherence; the second one was an explanation of diabetic diet plan and repeated explanation of pharmacotherapy of diabetes mellitus; the third one was an explanation of physical exercise plan and repeated explanation of pharmacotherapy of diabetes mellitus. The re-measurement of A1C levels (this is considered as the post-test data in the 3rd month) was done after the intervention.

Data Analysis

A frequency distribution was analyzed descriptively. The variables assessed were the sociodemographic characteristics, the clinical characteristics, and the lifestyle characteristics. Statistical analysis using Wilcoxon's t-test was used to assess the changes in A1C level. Meanwhile, the Chi-Square test was performed to determine the correlation between the patient's

characteristics and A1C level. Statistical Package for Social Sciences (SPSS) version 22.0 was used in this research.

RESULT AND DISCUSSION

Two prior studies have been published, i.e., the study of public counseling and educational video separately. This research has mainly discussed education with a booklet handout and also compare the three different educational models.

The population of diabetes mellitus patients in the Malaka Jaya primary healthcare center was 65 patients, but only 30 patients met the inclusion criteria.

Patient characteristics

Based on the sociodemographic characteristics shown in [Table 1](#), the respondents' distribution showed most of the respondents with booklet handout were male (53.3%). This data is different when compared to patients given education with public counseling and video, where most respondents were female (63.3% and 76.7%, respectively) ([Viviandhari et al., 2018](#); [Wulandari et al., 2020](#)). The prevalence of type-2 DM showed that most of type-2 DM patients are females ([Badan Penelitian dan Pengembangan Kesehatan, 2013](#)). The majority of the patients were more than 60 years old (90.0%). Similar results were found in patients with public counseling and video. Geriatric patients are at risk for type-2 diabetes mellitus development due to impaired pancreatic islet function and increased insulin resistance and aging ([Kirkman et al., 2012](#)). Most patients were in the middle levels of education (60.0%). These data were different in all three primary health care. Based on a study held in Jakarta, the level of education and type-2 DM incidence had no significant correlation ([Trisnawati and Setyorogo, 2013](#)). Conversely, a study in China found that a low level of education was associated with a high incidence of diabetes ([Shang et al., 2013](#)). More than 85% of all respondents at three primary healthcare centers were unemployed.

Table 1. The sociodemographic characteristics

The Sociodemographic Characteristics		n = 30	%
Sex	Male	16	53.3
	Female	14	46.7
Age	< 60 years	3	10.0
	≥ 60 years	27	90.0
Level of education	Low	6	20.0
	Middle	18	60.0
	High	6	20.0
Occupation	Unemployed	28	93.3
	Employed	2	6.7

Table 2. The clinical characteristics

The Clinical Characteristics		n = 30	%
History/duration of type-2 DM	< 5 years	12	40.0
	≥ 5 years	18	60.0
The numbers of oral antidiabetic drug (OAD)	1	14	46.7
	> 1	16	53.3
Comorbidity	No	3	10.0
	1	16	53.3
	2 or more	11	36.7
Other medicines	Yes	27	90.0
	No	3	10.0
Adverse Drug Reaction	Yes	5	16.7
	No	25	83.3

Clinical characteristics summarized in [Table 2](#) showed that around 60% of the respondents had a history/duration of type-2 DM for ≥ 5 years. Similar results were found on respondents who were educated with public counseling and even higher on respondents educated with video (80%). A study in Kenya found out that patients with 2-10 years of diabetes mellitus (OR = 2.07, CI = 1.01- 4.22) were factors related to poor medication compliance ([Waari et al., 2018](#)). Another research claimed that the duration of DM was adversely associated with the patients' adherence ([Elsous et al., 2017](#); [Gimenes et al., 2009](#)). Research in South West Ethiopia stated that patients who had diabetes for a long period were more likely to have poor glycemic control ([Mamo et al., 2019](#)). Most respondents received >1 oral antidiabetic drug (OAD) (53.3%). The finding in Pondok Kelapa and Duren Sawit primary healthcare center reinforced these data. A combination of an oral antidiabetic drug can be used if needed; the main principle is the combined drugs should have a different mechanism ([PERKENI, 2015](#)). Usually, patients with a combination of OAD were those whose glycemic control was not well managed when using single therapy only. The majority of the respondents had one comorbidity (53.3%). Data from respondents with educational videos were slightly different (60.0% of patients had 2 or more comorbidities) ([Wulandari et al., 2020](#)). The most common comorbidity in this study was hypertension and found in two other primary healthcare centers. Hypertension increases the risk of diabetes mellitus complications (macrovascular and microvascular) ([American Diabetes Association, 2003](#)). Most of the respondents (90.0%) used other drugs (similar data were found in 2 other primary healthcare centers). This condition was caused by comorbidities (in which more than 50% of patients in this study had at least one comorbidity). This also made the drug regimens even more complex, which further reduced the patient's compliance ([Geest and Sabaté, 2003](#)). In contrast, a research stated that patients on multiple medicines were reported to have high medication adherence rates regardless of the number of medicines taken ([Grant et al., 2003](#)). The efficacy of drug combinations in geriatrics has been shown in some clinical research. Monotherapy simplifies the medication regimen; combined therapies offer benefits, such as giving a lower risk of complications (macrovascular and microvascular) ([Munger, 2010](#)). There were only 16.7% of the patients who experienced side

effects. This finding was less than what we found in Pondok Kelapa primary healthcare centre (26.7%). Some of major side effects of antidiabetic drugs which were experienced by respondents are hypoglycemia and gastrointestinal disturbance (Chaudhury et al., 2017). A research explains that the major factors contributing to non-compliance are financial limitation (37.1%) and side effect of the drug being experienced by the patients (29.2%) (Wabe et al., 2011).

Table 3. The lifestyle characteristics

The Lifestyle Characteristics		n = 30	%
Dietary habit	Adjusted	27	90.0
	Not adjusted	3	10.0
Smoking	Yes	0	0
	No	30	100.0
Exercise	Yes	28	93.3
	No	2	6.7
Herbs	Yes	2	6.7
	No	28	93.3

Table 3 represents the respondent's distribution based on lifestyle characteristics. Only post-test data were shown in this table. Adjusting dietary habits (including carbohydrate and sugar restriction) was applied to 90.0% of respondents. Type-2 DM patients need to restrict calorie intake to lose weight (DiPiro et al., 2015). Overall, all respondents in three primary healthcare centers claim to manage their diet (on post-test), and the number of patients who adjust their habit was increased compared to pre-test data. This finding indicated that the education given affects patients' behavior in dietary control. Patients should understand about diabetes mellitus and proper diet; therefore, the health care professional (including pharmacist) must inform the patients to change their food preparations and nutritional habits. Effective education about dietary habits may prevent diabetes complications (Sami et al., 2017). No respondents were smoking. Similar data were found in respondents who were given with educational video. There was only one respondent in Pondok Kelapa primary healthcare center who was smoking. The research was made to understand the relation between smoking and the risk of diabetes. Inflammation and oxidative stress caused by cigarette smoke increased the risk of diabetes. Smoking is also related to a high risk of abdominal obesity, which is already known as a significant risk factor for developing diabetes. Nicotine in some studies made insulin less effective. Smoking is also related to cardiovascular disease, retinopathy, and peripheral neuropathy (CDC, 2014; Chang, 2012). The Indonesian Association of Endocrinologists and The American Diabetes Association stated that exercise is a critical aspect in DM management (if nephropathy was absent). The recommendations vary depending on patient characteristics and health status. Exercise should be regularly done (3-5 times a week for about 30-45 minutes each). Some types of exercise are walking, jogging, cycling, and swimming (Colberg et al., 2016; PERKENI, 2015). Only 6.7% of respondents used herbal medicines. A similar result was seen on the patient with an educational video. According to a research, the effect on the A1C level using herbs which are known empirically as an antidiabetic agent was not significant since the information regarding the herb's duration, dose, and administration may be unclear (Puspitasari et al., 2013).

The effectiveness of booklet handout

A1C level was the laboratory data used to measure type-2 DM patient's glycemic control. Glycemic management was mainly measured with the A1C test. The A1C level in DM management's primary target is $\leq 6.5\%$ (American Diabetes Association (ADA), 2017). A1C demonstrates the benefits of better glycemic control. A1C reflects the average of glycemic over three months (Care, 2019). Some research stated that increasing medication adherence means improvements in A1C (Aikens and Piette, 2013; Alqarni et al., 2019; Gordon et al., 2018).

Table 4. The Mean A1C Levels (Pre-Test and Post-test)

The A1C levels	Before intervention (Pre-test)		After intervention (Post-test)	
	n = 30	%	n = 30	%
<6.5%	6	20.0	22	73.3
$\geq 6.5\%$	24	80.0	8	26.7
Mean A _{1C} \pm SD	7,56 \pm 1,17		5,67 \pm 1,07	
<i>p</i>	0,005 ^a			

SD = standard deviation

^aThe statistically significant differences according to the paired t-test

The measurement of A1C level on this research was conducted at the Indonesian Centre for Health Laboratory, Ministry of Health (ISO/IEC 17025:2005 accredited). The analysis used was the HPLC method (High-Performance Liquid Chromatography) (Sacks et al., 2011).

Based on Table 4, as much as 80.0% of patients still had high levels of A1C ($\geq 6,5\%$) at the beginning. Then, the number declined to 26.7% after patients received an education with the booklet handout. The result indicated that the A1C levels before the intervention were significantly different from the A1C levels after the intervention ($p = 0,005$). The mean A1C level was $7,56 \pm 1,17\%$ at the beginning and decreased after education using booklet handout ($5,67 \pm 1,07$). This can be concluded that education with the booklet handout improves the A1C level and increase medication adherence in patients with type-2 DM. The research conducted in two other primary healthcare centers was similar in results. The patient's glycaemic controls were mostly considered poor before the intervention (mean HbA1c 7.83 ± 1.59 and 7.93 ± 1.26) and rose significantly ($p=0.005$) after three months of intervention's period (mean HbA1c 5.41 ± 1.34 and 5.52 ± 0.64) (Viviandhari et al., 2018; Wulandari et al., 2020).

The relationship between patient's characteristics and A1C level

A Chi-Square test was performed to assess the relationship between the patient's characteristics (sociodemographic, clinical, and lifestyle characteristics) and A1C levels. This test was used to assess the factors that influence the A1C levels.

Table 5. The factors affecting A1C level

Type	Characteristic	P value
Socio-demographic Characteristic	Gender	0.295
	Age	0.099
	Level of education	0.600
	Occupation	0.377
Clinical Characteristic	History/duration of type-2 DM	0.064
	The numbers of oral antidiabetic drug	-
	Comorbidity	0.724
	Other medicines	0.783
	Adverse Drug Reaction/side effect	0.460
	Lifestyle Characteristic	Dietary habit
Smoking		-
Exercise		0.440
Herbs		0.377

In this study, there was no factor from patient's characteristics related to A1C level. This may be due to the limited number of samples. Many pieces of research stated that patient's characteristics were associated with glycemic control. A study stated that poor glycemic control was found in young patients (<30 years old) (Feldman et al., 2014). Unemployed patients prove to have lower glycemic control (Haghighatpanah et al., 2018). Other researches stated that patients without comorbidities had better glycemic control; patients with poor glycemic control had been suffering from type-2 DM for more than 5 years; and patients with a high number of drugs have poor glycemic control (Haghighatpanah et al., 2018; Kassahun et al., 2016).

Prior studies were conducted in two different places (primary healthcare center [2016] and hospital [2017]). A combination of public counseling and booklet handout was used as an education model at Kebon Pala and Makasar primary health care centers in East Jakarta. The research found out that 63.3% of respondents who followed the study period had A1C level >7% initially. After 3 months of study, the number of respondents who had A1C level >7% significantly decreased to 23.3% ($p < 0.05$), respectively. It can be concluded that education intervention with public counseling and booklet handout is effective to improve the type-2 DM patient's glycemic control (Wulandari et al., 2017).

A study in 2017 at Pondok Kopi Hospital, which assessed patient's glycemic control with the help of a family member as a drug supervisor, found out that the mean A1C level of the respondents before the education intervention was 7.2%. The mean A1C level was significantly declined after the education intervention to 5.5% ($P < 0.05$) (Viviandhari and Wulandari, 2017). This study and prior study recruited respondents from primary health care centers in East Jakarta but used different education intervention models. Booklet handout alone also improves the patient's glycemic control significantly.

Compliance with diabetes mellitus therapy is considered one of the critical aspects of type-2 DM management. Medication adherence in diabetes mellitus is related to better glycemic control, better control of risk factors, lower risk of hospitalization, lower health care cost, and lower risk of mortality (Care, 2019; Kirkman et al., 2015). Implementing diabetes management services requires many aspects such as effort, resources, communication skills, and time commitment. Giving routine education to increase the patient's understanding about the disease itself and the medication to patients made glycemic control achievable. The vital roles of pharmacists in diabetes management are: to screen the patients who are at high risk for developing diabetes, determining

patient's health status and compliance to diabetes therapy, informing patients with understanding the illness and diabetes mellitus therapy to empower them to self-manage their disease in partnership with health care professionals so that the patients involved and being responsible with their monitoring and therapy outcomes (Hughes et al., 2017).

Research in Indonesia found a limited number of pharmacists in Indonesia's primary healthcare center (Supardi and Susyanti, 2012). This finding made personal education by the pharmacist to patients through personal counseling become difficult to be implemented. Research by Merakou et al. (2015) in a primary health care center in Greece showed that group-based education is more effective in diabetes self-care than individual-based education for type-2 DM patients. In other words, booklet handout, public counseling, and educational video become an effective and cost-efficient alternative in diabetes mellitus education.

This research limitation was the sample size, which is considered inadequate to generalize the Jakarta population's; therefore, bigger sample size and wider coverage area of the healthcare center are needed. Another limitation of this study was that there were no parameters used to ensure that the patients reread the booklet handout at home and understand the information given; therefore, knowledge level analysis is needed.

CONCLUSION

Booklet handout as an educational intervention effectively improves glycemic control in type-2 diabetes mellitus patients. Either booklet handout, public counseling, or video effectively improve glycemic control in type-2 diabetes mellitus patients.

ACKNOWLEDGEMENT

The authors acknowledge all pharmacists and other health professionals at Malaka Jaya Primary Healthcare Centre involved in this research.

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