

IMPACT OF PHARMACIST-LED EDUCATION SESSION (PLES) ON QUALITY OF LIFE AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN HOSPITAL BESUT

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ABSTRACT

Type 2 diabetes mellitus (T2DM) is a chronic and progressive disease that has reached an epidemic level. To achieve a better quality of life among diabetic patients, patient education has become an essential role. Quality of life (QOL) is used as an important health outcome measure. Thus, this interventional study aimed to determine the effect of pharmacistled education sessions (PLES) on QOL among T2DM patients in Hospital Besut and the association of sociodemographic factors with QOL. T2DM patients attending the Medical and Nephrology Clinic from July until November 2021 were recruited and randomised into the PLES and control groups. A guided questionnaire was used to evaluate their QOL in the satisfaction, impact and worry domains. The educational session was provided by the pharmacist via counselling, and all outcomes pre- and post-intervention were evaluated after a 3-month interval. Data were analysed using paired and independent t-tests, with p < 0.05 considered statistically significant. A total of 70 patients were enrolled in this study, with around half being female (52.8%) and a mean age of 58.6 ± 9.7. The increase in QOL after the intervention in the PLES group for all domains was significantly higher than that in the control group (p < 0.001). The mean QOL scores in the PLES group in terms of satisfaction, impact, and worry domains before intervention were 40.48 ± 14.1, 49.86 ± 17.84 and 45.14 \pm 18.72, respectively, while the overall score was 44.44 \pm 13.60. There was a significant improvement of QOL after PLES in satisfaction 31.43 ± 10.61 (p < 0.012). impact 38.86 ± 10.95 (p < 0.001), worry domain 36.76 ± 12.56 (p < 0.040) and an overall score of 35.25 ± 9.04 (p < 0.022). No significant improvement was observed in the control group (p = 0.447). There was no significant association between sociodemographic factors and QOL (P > 0.05). This study suggested that PLES had a positive impact on the quality of life of patients with diabetes.

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Keywords: Pharmacist, Education session, Quality of life, Type 2 diabetes mellitus, Diabetic patients

INTRODUCTION

Diabetes is a common public health problem worldwide. According to Malaysia National Diabetes Registry (NDR) 2020 (Zakariah and Chandran 2021), there was a total of 1,698,683 patients enrolled in the registry and there were 902,991 active diabetes patients in the NDR at the end of the reporting year for 2020. Nearly all the patients enrolled in the NDR were diagnosed with *Type 2 diabetes mellitus* (99.33%), followed by *Type 1 diabetes mellitus* (0.59%) and others (0.06%).

It is estimated that in 2025 the number of patients could reach about 7 million if not contained. This figure makes Malaysia not only rank first in the Southeast Asia region but also one of the countries with the highest number of diabetic patients in the world. Malaysia had spent around USD600 million a year. Overall diabetes in Malaysia recorded the highest among people aged 60 years and above with 33.46% (Akhtar *et al.* 2022).

In addition, uncontrolled diabetes mellitus (poor glycaemic control) can result in complications such as renal, ocular, cardiac and vascular diseases, and increased hospitalisation and mortality (Niroomand *et al.* 2015). A previous study done by Saleh *et al.* (2014) showed that the increasing number of diabetic patients will need more specialised diabetic care, education and motivation. The failure to provide these may lead to more complications such as increased treatment costs and reduced their quality of life. Manan *et al.* (2014) revealed the numerous factors that affect medication adherence, such as quality of life, side effects and complexity of medications, healthcare system issues, demographic, behavioural, treatment and clinical variables.

A study done by Khan *et al.* 2022, found that the pharmacist-based diabetes intervention model is effective in improving patients' lives in aspects such as self-care practices, medication adherence and glycaemic control. Although those parameters are often used to assess disease control and clinical outcomes, quality of life is also the main aspect that must be prioritised. This is supported by a study done by Didarloo and Alizadeh, 2016 which mentioned that diabetic patients with diabetes have lower quality of life (QOL) compared with non-diabetic individuals. Thus, optimising quality of life has now become one of the ultimate goals in pharmaceutical care, as it can represent the effectiveness of the treatments and evaluate the effects of chronic diseases on patients' lives.

Based on data from diabetes registry list in Hospital Besut, the number of patients diagnosed with T2DM has continued to increase over the years. Therefore, this interventional study aimed to investigate the impact of educational intervention in improving the quality of life of patients with T2DM in Hospital Besut. Specifically, this study was conducted to determine the effect of pharmacist-led education sessions (PLES) on QOL among T2DM patients in Hospital Besut in terms of satisfaction, impact, worry and total QOL domains.

METHODS

This is an interventional study, which included T2DM patients presented to Medical and Nephrology clinics in Hospital Besut between July 2021 and November 2021. This study was approved by the Medical Research and Ethics Committee of the Ministry of Health Malaysia (KKM/NIHSEC/P21-461[12]). Patients were selected based on these criteria:

1. Inclusion Criteria

- T2DM patients of age 18 years and above
- Able to comprehend Malay/English language
- Diagnosed with T2DM at least 5 years and received pharmacological treatment (irrespective of types of anti-diabetic treatment given)

2. Exclusion Criteria

- Patients with cognitive impairment (such as intellectual disability and severe psychosis)
- Unable to comprehend Malay/English language
- Incomplete questionnaire
- Patients recruited under Diabetes Medication Therapy Adherence Clinic (DMTAC)

The simple random sampling technique was used from a list of random numbers of eligible patients, which was compiled using the patients' hospital identification numbers. After recruitment, the patients were requested to handpick an envelope from the basket, indicating allocation to either the control or intervention group with 1:1 randomisation. After the initial assessment, the control group received usual care in terms of medication dispensing, whereas the interventional group was provided with the structured intervention.

Questionnaires were distributed to the patients and forms were filled out after consent was obtained. A revised, Malay-translated version of the Diabetes Quality of Life (DQOL) questionnaire that had been specifically validated for the Malaysian adult population with T2DM from a study by Bujang *et al.* (2017), was adopted (permission granted on March 4, 2020). This questionnaire consisted of four sections that inquired about the respondent's demographic information, satisfaction, impact and worry domain of DQOL.

Four pharmacists were trained by certified DMTAC pharmacist about the implementation of educational intervention in the recruited participants in addition to the medical treatment they received. They were required to complete two sessions of two hours training. They were assigned to briefly describe the patients and caregivers and obtained consent for participation in this study. Participants were requested to fill in the DQOL questionnaire before their involvement in the educational intervention session. The settings for the pharmacist's educational intervention in this study were private counselling rooms at medical clinics and an outpatient pharmacy in Hospital Besut. The details about demographic characteristics, self-care behaviours and disease knowledge of intervention and control group participants were collected at the start (baseline) and the end (3 months) of the intervention.

After the initial assessment, the control group received usual care in terms of medication dispensing, whereas the intervention group received structured intervention. The intervention group was being counselled on the following issues:

- Brief overview on diabetes (definition, symptoms, complications)
- Therapeutic goals, specifically blood glucose (HbA1c, FBG)
- Medication use/adverse effects with the patient (insulin and hypoglycaemic agents)
- Self-monitoring of blood glucose (SMBG), if applicable
- Signs and symptoms of hypo/hyperglycaemia, sick day management and course of action to be taken
- Medication storage at home
- · Cardiovascular education (lipids, blood pressure, peripheral vascular

- disease and goals)
- Advice on smoking cessation
- · Benefits, risks and options for improving blood glucose controls
- · Benefits of exercise
- Prevention of complications (macro and micro complications)
- Foot care
 (Counselling points were adapted from Garis Panduan Kaunseling Ubat-ubatan Edisi ke-3 Kementerian Kesihatan Malaysia, 2019).

Each participant was required to complete the DQOL questionnaire three months after their routine follow-up. Pre- and post-intervention data in terms of scores for quality of life were compared and recorded between the interventional and control groups. Data was analysed and interpreted using the Statistical Packages for Social Version 25. The descriptive, independent, and paired t-tests were used, with a *p*-value < 0.05 was considered statistically significant.

RESULTS

A total of 80 patients who met the study criteria were enrolled in the study. Of these, only 70 patients completed the study (one follow-up at three-month intervals each), with 35 patients in the intervention group and 35 patients in the usual care group. Ten patients were excluded from the study for several reasons (passed away, unreachable). Among the 70 patients, 33 were males (47.14%) and 37 were females (52.86%). The mean ages of the patients were 56 years (control group) and 59 years (PLES group). Overall, 77.1% of the patients were married, 52.8% had a household monthly income of less than RM1,000 and 57.3% of them had an educational level up to secondary school. The control and PLES groups were comparable (p > 0.05), and the results showed not statistically significant.

Table 1: Socio-demographic characteristics of the respondents (n = 70).

S	Control Group Number (%)	PLES Group Number (%)	<i>p</i> -value
< 60 years	20 (57.1)	19 (54.3)	0.421
> 60 years	15 (42.9)	16 (45.7)	
Mean	56.53	59.17	
Male	13 (37.1)	20 (57.1)	0.462
Female	22 (62.9)	15 (42.9)	
Married	26 (74.3)	28 (80.0)	0.248
Unmarried	9 (25.7)	7 (20)	
	< 60 years > 60 years Mean Male Female Married	(%) < 60 years	(%) (%) < 60 years

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Table 1: (continued)

Characteristic	cs	Control Group Number (%)	PLES Group Number (%)	p-value
Household monthly	<rm 1000<="" td=""><td>21 (60.0)</td><td>16 (45.7)</td><td>0.293</td></rm>	21 (60.0)	16 (45.7)	0.293
income	> RM 1000	14 (40.0)	19 (54.3)	
Educational Level	≤ Secondary	23 (65.7)	20 (57.1)	0.499
	≥ Tertiary	12 (34.3)	15 (42.9)	

The mean QOL scores in the PLES group in terms of satisfaction, impact and worry domains before intervention were 40.48 \pm 14.1, 49.86 \pm 17.84 and 45.14 \pm 18.72, respectively, while the overall score was 44.44 \pm 13.60. There was a significant improvement of QOL after PLES in satisfaction 31.43 \pm 10.61 (p < 0.012), impact 38.86 \pm 10.95 (p < 0.001), worry domain 36.76 \pm 12.56 (p < 0.040), and the overall score of 35.25 \pm 9.04 (p < 0.022). On the other hand, no significant improvement in satisfaction, impact, and worry domains was observed in the participants of the usual care group (control group).

Table 2: The Mean Score of QOL Across PLES and Control Group Before and after The Intervention (n = 70).

Category	Domain	Mean Score (Pre) ±Sd	Mean Score (Post) ±Sd	<i>p</i> -value
Ples	Satisfaction	40.48 (14.10)	31.43 (10.61)	0.001
	Impact	49.86 (17.84)	38.86 (10.95)	0.001
	Worry	45.14 (18.72)	36.76 (12.56)	0.001
	Total Qol	44.44 (13.60)	35.25 (9.04)	0.001
Control	Satisfaction	42.57 (20.18)	41.14 (13.42)	0.509
	Impact	46.85 (13.72)	45.28 (14.08)	0.408
	Worry	47.80 (19.43)	47.23 (16.35)	0.720
	Total Qol	45.09 (13.91)	43.82 (10.39)	0.447

Notes: Statistical analysis by using paired t-test, p < 0.05 statistically significant

In addition, the study found significant improvement (p < 0.05) in QOL after the intervention in the PLES group for all domains compared to the usual care group (control group). As lower scores indicate better QOL, a larger negative mean difference indicates a greater improvement in QOL.

Table 3: The Changes of QOL in PLES and Control Group after 3 Months of Intervention (n = 70).

Domain	Category	Mean Difference (%)	Standard Deviation	p-value
Satisfaction	Ples	-9.0476	7.60854	0.003
	Control	-1.4286	12.66165	
Impact	Ples	-10.0000	11.31111	0.002
	Control	-1.5714	11.09925	
Worry	Ples	-8.3810	11.35786	0.002
	Control	-0.5714	9.34053	
Total Qol	Ples	-9.1868	7.49508	0.001
	Control	-1. 2747	9.80482	

Notes: Statistical analysis by using independent t-test, p < 0.05 statistically significant

DISCUSSIONS

This study showed that 47.1% (33/70) of patients were males and 52.9% (37/70) patients were females. This figure is similar to that reported in a previous study that found no significant difference in the prevalence of the disease between males and females (Zhang et al. 2019). The mean ages of the patients in this study were 56 years (control group) and 59 years (PLES group) which is also consistent with another study that found most of the T2DM patients were in the age range of 56–65 years and older (Syarifuddin et al. 2019).

Several factors can affect T2DM patients' QOL. It can be due to diabetic care regimes, the occurrences of hypoglycemia and hyperglycemia, as well as anxiety of or experience with complications. Comorbidities would worsen a person's QOL even further (Jannoo et al. 2017; Trikkalinou et al. 2017). A study from Dhillon, Nordin and Ramadas (2019) found that important solutions for a better QOL among Malaysians with T2DM were lower diabetes complications and severity, better medication adherence and psychosocial well-being through direct and indirect ways. QOL is multifactorial and quite complex. Medication adherence was not the only key to improve quality of life (Nazmi et al. 2021). Thus, based on this study, showed that PLES really can optimise patients' QOL.

Pharmacists are regarded as trustworthy healthcare workers and easily accessible to patients. Patients usually worry about their diabetes and have unpleasant experiences regarding the disease. By reassuring patients, offering them emotional support, and educating them concurrently, pharmacists may help to overcome negative views (Ramzi and Farah 2022). Our study found significant improvement in QOL in all domains of satisfaction, impact and worry after PLES. Shareef et al. (2016) proved that pharmacist interventions improved QOL in terms of family life, physical appearance, motivation and social life. This study coincided with Simon et al. (2021), which revealed that pharmacist-provided counselling improves satisfaction with care in diabetic patients by reducing medication discrepancies and errors, and improving adherence. Shrestha and Tamrakar (2019) mentioned that incorporating regular counselling sessions was beneficial in promoting health-related QOL of diabetic patients. This was supported by another study which concluded that the combination of pharmacist counselling followed by short reminders and motivational messages was able to help patients with T2DM improve their QOL (Ginanjar, Akrom and Endang 2016).

A study in Indonesia concluded that pharmacist counselling intervention improved the QOL of T2DM patients by increasing the European Quality of Life 5 Dimensions 5 Levels (EQ-5D-5 L) index score (Fajriansyah *et al.* 2020). However, the findings of this study contradicted those of Puvvada and Muthukumar (2018), who concluded that counselling did not affect the mental component summary of the patient's QOL. This was also supported by a previous study done by Mateti, Ummer and Kodangala (2016), a pharmacist's intervention did not significantly improve QOL.

STUDY LIMITATIONS

This was a single-centred study that limited the cause-effect interpretation and generalisability of the findings. In addition, only one follow-up session after the counselling session was conducted because of limited resources and time.

CONCLUSION

This study suggested that PLES had a positive impact on the quality of life in diabetic patients. Significant improvement in quality of life was observed in all domains of satisfaction, impact and worry.

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