ORIGINAL ARTICLE

Improving Outcomes for Type 2 Diabetes Mellitus Patients in Selangor: A Study on Health Literacy Intervention and Its Effectiveness

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ABSTRACT

Introduction: Type 2 Diabetes Mellitus (T2DM) is a metabolic disorder that can be controlled by self-care which includes medication adherence and dietary adjustments. However, health literacy can impede successful self-care, leading to suboptimal blood sugar management and a diminished quality of life. This research aimed to evaluate the impact of a health literacy intervention on enhancing glycaemic control, health literacy, and the quality of life related to diabetes in T2DM patients residing in a rural Malaysian region. **Materials and methods:** A two-armed, single-blinded randomized controlled trial was conducted among 250 diabetic patients on medication, aged 18 years and more who were enrolled from a health clinic in Selangor. The intervention group received a health literacy module, a healthy-plate guide, and a flip chart for self-management. The control group received standard diabetic education. Primary outcomes assessed glycaemic control (HbA1c levels), health literacy (HLS-EU-Q47 tool), and diabetes-related quality of life (DQoL-M) at baseline and three months post-intervention. The study is registered in the Australian New Zealand Clinical Trials Registry (ACTRN12619001725156). **Results:** The result showed a statistically significant improvement in Glycaemic Control in the intervention group (F=4.003, p=0.046), but not in the control group. Health Literacy and the satisfaction domain of Diabetes Quality of Life scores were higher in the intervention compared to the control group, however, the differences between the groups were not statistically significant. **Conclusion:** The intervention in this study improved glycaemic control of diabetic patients. Nonetheless, there is a need for personalized diabetes care, ongoing support, and further research to enhance outcomes.
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Keywords: Type 2 diabetes mellitus, Health literacy intervention, Quality of life, Glycaemic control, Selangor

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INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a significant metabolic disorder that often leads to various complications, especially when glycaemic levels are not well-controlled [1]. The challenge of maintaining effective glycaemic management in Malaysia is notable [2]. This issue is intensified by the widespread problem of limited health literacy, which also contributes to inadequate self-management and poor control of blood sugar [3]. Poor control of blood sugar in T2DM patients not only heightens the risk of serious health complications but also adversely affects their quality of life [4], while the extensive self-management required, including consistent medication intake, dietary adjustments, blood sugar monitoring, and lifestyle changes, places a considerable emotional and psychological strain on patients [5]. The connection between limited health literacy and poor diabetes self-management is well-established, often resulting in negative health outcomes and a higher incidence of diabetes-related complications [6, 7, 8].

Enhancing health literacy and the overall quality of life for diabetic patients can be done through education about diabetes [4]. The educational approach using straightforward communication strategies, such as using clear terminology, emphasizing key points, repeating important information, and utilizing visual aids, can significantly enhance patients' comprehension and implementation of self-care practices. This leads to better disease management and improved glycaemic control [6].

In addition, understanding the patients' behaviour in terms of methods of self-management, the skills involved, and the lifestyle choices made by patients

with Type 2 Diabetes Mellitus (T2DM), is also crucial for both short-term and long-term glycemic control [9]. Combing these two concepts together i.e., education and human behaviour may lead to effective interventions on health literacy, especially when the interventions incorporate elements such as social cognitive theory [10]. Currently, intervention materials such as PRIDE (Partnership to Improve Diabetes Education) are available for low-literacy populations. The PRIDE toolkit was developed in the USA to be a comprehensive set of diabetes education materials intended to assist English- and Spanish-speaking patients in managing their diabetes [1-6].

In Malaysia, several documents for the healthcare professionals, such as Clinical Practice Guidelines for Management of Type 2 diabetes, Practical Guidelines for Type 2 Insulin Treatment, Medical Nutrition Therapy Guideline for Type 2 Diabetes and Screening for Diabetes Retinopathy have been published, but related guideline or toolkit for the patients, on Diabetes Education is limited or non-existent.

This study aimed to assess the effect of health literacy intervention in improving glycaemic control, health literacy, and diabetes quality of life among Type 2 Diabetes Mellitus patients in the context of diabetic patients in a rural area in Malaysia.

MATERIALS AND METHODS

Study design
This study was a randomized controlled trial, registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) under the number ACTRN 12619001725156. Its aim was to determine the effect of health literacy intervention program in improving glycaemic control, health literacy, and diabetes quality of life among in people with T2DM, with a pre and three months post intervention assessment of both the intervention and control groups. This was done by comparing groups before and after the intervention, using a single-blind method and evenly randomizing participants into intervention and control groups. Figure 1 in the study shows a flow diagram, following the CONSORT (Consolidated Standards of Reporting Trials) guidelines, which helps to understand how the study was conducted [1].

The research took place at the Tanjong Karang Government Health Clinic in Kuala Selangor District, in the state of Selangor in Malaysia. From Kuala Lumpur, Tanjung Karang is situated to the northwest. The distance between Kuala Lumpur and Tanjung Karang is approximately 70 kilometres. This region has a notably high number of T2DM cases. The Tanjong Karang Government Health Clinic was chosen for its capacity to serve a wide range of diabetic patients in a rural area. This allowed the study to include participants with

different backgrounds and economic situations, making the findings more relevant to a broader population.

Participants
The participants of this study were drawn from the regular attendees of the Tanjong Karang Government Health Clinic, specifically those diagnosed with Type 2 Diabetes Mellitus (T2DM). On average, the clinic serves about 20-25 T2DM patients daily for their scheduled follow-up care. During the period from December 2018 to February 2019, around 700 T2DM patients visiting the clinic were assessed for eligibility. Patients were included in this study if they were diagnosed with T2DM for at least three months, 18 years or older, have an HbA1c level above 6.5%, Malaysian citizens, and willing to participate in the study. On the other hand, the study excluded T2DM patients facing psychological issues, sensory impairments, those using illicit drugs, having gestational diabetes, or suffering from advanced complications like micro and macrovascular issues. These exclusions were primarily for ethical reasons and to ensure the safety and well-being of the participants.

The decision to exclude individuals with severe health conditions from this study was based on the understanding that these individuals might be more vulnerable. Including them in the research could potentially lead to harm or discomfort. For example, as this research involves discussions about their health, lifestyle, or disease management, it could induce stress, anxiety, or emotional discomfort. Additionally, participation in research such as this often requires time, effort, and compliance with specific protocols, which could be overly taxing for individuals with severe health issues, leading to fatigue or other complications.

For those who met the eligibility criteria and agreed to participate, an information sheet and a consent form were provided. Once consent was given, participants were officially recruited for the study. They were then asked to fill out a baseline questionnaire, marking the beginning of their active participation in the research.

Sample size determination
The study sample size was calculated with consideration for a desired statistical significance level (p = 0.05) and a study power of 80%. The size of the sample was determined based on the findings of a previous research study [7]. The sample size estimation was performed using hypothesis testing by comparing means, as outlined in the Adequacy of Sample Size Determination in Health Studies by Lemeshow, Hosmer, and Lwanga [8]. Considering a 20% dropout rate, the target sample size was established at 250 participants, with 125 participants allocated to both the intervention and control groups.

Randomization and recruitment
The sampling population comprised all T2DM patients

who attended the Tanjong Karang government health clinic for their follow-up appointments between December 2018 and February 2019. The recruitment process involved diabetes nurses conducting eligibility assessments. Once participants were deemed eligible, they met with a researcher who explained the study, its duration, and potential benefits. After agreeing to participate, participants were provided with an information sheet and a consent form to sign before completing baseline data. The consent form outlined the purpose of the study, the process to be followed, and the risks and benefits of participation. The researcher ensured that participants understood the study information and answered any questions. Following this, patients were informed of their next appointment, during which the researcher would contact them. Eligible participants underwent block randomization, employed by the researcher to ensure the generation of comparison groups according to a predetermined 1:1 ratio of control and intervention groups. A randomization sequence was created using a computer random number generator, with selected participants being assigned to either the intervention or control group.

Many RCTs have utilized this form of randomization to reduce bias and achieve balance between the two trial arms. This type of randomization in allocation increased the probability that the two groups contained an equal number of participants, minimizing imbalance and ensuring that treatment groups were as similar as possible [9]. After participants were enrolled in either of the two groups, those assigned to the intervention group were contacted via phone calls to schedule meetings with the researcher for the intervention.

Intervention
In this study, the intervention consists of (1) A T2DM health literacy module (PRIDE toolkit adapted) and (2) take-home material (flip chart & healthy plate concept). The T2DM health literacy module was adapted from the "Partner to Improve Diabetes Education" (PRIDE) toolkit created by Becton Dickinson and Company [1]. The decision to use the PRIDE toolkit, as opposed to other options, is rooted in its adaptability to the cultural and contextual subtleties of the rural population in Malaysia. The T2DM health literacy module consists of 6 education modules involved items concerning: Module 1: General Information about Diabetes, Module 2: Nutrition Information, Module 3: Diabetes Medication, Module 4: Lifestyle Management and Behaviour Change, Module 5: Foot Care, Module 6: Coping with Stress and Depression (Table I).

Table I: Content of the intervention program

Module	Content
Module 1 General information about Diabetes	1.1 What is Diabetes 1.2 Low blood sugar (Hypoglycaemia 1.3 High blood sugar (Hyperglycaemia)

Table I: Content of the intervention program (CONT.)

Module	Content
Module 2 Nutrition information	2.1 Nutrition for Diabetes 2.2 Using plate to controlcarbohydrates 2.3 What can I eat for a snack? 2.4 What should I eat when I eat out?
Module 3 Diabetes Medication	3.1 Diabetes pills 3.2 Taking your medicines
Module 4 Lifestyle management and behaviour change	4.1 How to be active? 4.2 How can losing weight help me
Module 5 Foot care	5.1 Foot care Do's and Don'ts
Module 6 Coping with Stress and Depression	6.1 Stress and Depression
Diabetes Flip Chart & Healthy Plate Concept	Take-home materials for participants

Note: This table shows the content of the intervention program in this study, it presents an overview of the included modules. Each module is explained in detail according to the content, giving participants a clear understanding of the specific topics and content covered throughout the educational program.

With a full range of educational modules covering various aspects of diabetes management, this toolkit has proven essential in delivering comprehensive education on self-management, lifestyle changes, and related topics. The health literacy module for Type 2 Diabetes Mellitus (T2DM) uses simple language, clear communication, and pictures to explain key actions and information. The module is useful for all diabetes patients, regardless of their treatment. For this study, it was carefully translated into Bahasa Malaysia by a professional translator using a back-to-back translation process.

The educational sessions for the intervention were conducted at the health clinic once a week using the T2DM health literacy module, in small groups of 6-8 participants. The intervention group had their sessions on Fridays, while the control groups had their sessions on Wednesdays. Each session lasted approximately half a day. During these sessions, participants learned about diabetes self-care and took part in interactive discussions. The sessions were conducted by postgraduate students who had received specialized training. This training covered the subject content, teaching methods, and presentation skills, aiming to ensure that each session was delivered in a consistent and standardized manner.

In addition to the T2DM health literacy education sessions, participants were given two extra resources to use at home, setting this approach apart from the usual care given by a diabetic nurse. The plate is based on the concept of the Malaysian Healthy Plate, which emphasizes the "Suku Suku Separuh" or "Quarter Quarter Half" (QQH) concept. The plate is a standard round dinner plate, divided into three distinct sections: one-quarter of the plate should contain grains or grain

products, another quarter of the plate should include protein sources, and the remaining half of the plate should be filled with fruits and vegetables. The plate is a simple visual technique to assess if a meal is balanced and healthy.

The second material is a flip chart, provided to each participant for better diabetes self-management. This comprehensive guide covers various topics, including general diabetes information, blood glucose monitoring, nutrition, medication adherence, lifestyle management, behaviour change, foot care, and coping with stress and depression. Developed with clear health communication principles, the flip chart predominantly uses picture-based information, with over 60% of content consisting of images and diagrams for improved comprehension and retention. The chart employs simple language, and concise sentences, and focuses on key points and essential physiological information to enhance participants' understanding of diabetes self-management practices.

Participants assigned to the control group received standard diabetic education administered by a diabetic nurse. Both the baseline and post-intervention assessments for the control group were conducted using identical methodologies as employed for the intervention group, ensuring uniformity and comparability in data collection. Additionally, each participant in the control group was provided with the T2DM health literacy education sessions, a healthy plate and the flip chart in the post-intervention phase.

Measures of study outcomes

There are three outcomes in this study: glycaemic control, health literacy, and diabetes quality of life among Type 2 Diabetes Mellitus patients. To assess glycaemic control, HbA1c readings extracted from a review of the participant's medical records, were used. Classification for HbA1c levels was good glycaemic control (HbA1c $\leq$ 6.5%), and poor glycaemic control (HbA1c > 6.5%) [10]. Health literacy was evaluated using the Malay version of the European Health Literacy Questionnaire (HLS-EU-Q47). The HLS-EU-Q47 follows a conceptual model that covers four key skills in handling health-related information: accessing, understanding, evaluating, and applying this information across three areas: healthcare, disease prevention, and health promotion. This tool is designed to measure individuals' ability to understand and use health-related information. The questionnaire consists of 47 questions. Each question's level of difficulty was scored on a 4-point Likert scale, ranging from 1 (very difficult) to 4 (very easy). The maximum index (combined) scores a person could get was 188 (4 points multiplied by 47 questions), while the minimum score was 47. The mean score for these items can be as low as 1 and as high as 4, giving a score range of 3. Based on the literature [19], health literacy scores were then converted to a scale of

0 to 50 using the formula: Index = (mean − 1) * (50/3). "Index" represents the standardized health literacy score, "mean" is the average score for each participant across all items, "1" adjusts the scale to start at 0, "3" is the total scoring range, and "50" is the set maximum value on the new scale. Consequently, an index value is produced where 0 indicates the lowest level of health literacy and 50 the highest.

Based on this range of 0-50, the scores were categorized into four levels: Adequate (0-25), Problematic (25.1-33), Sufficient (33.1 – 42), and Excellent (42.1-50).

Diabetes Quality of Life was assessed using the Malay revised version of the Diabetes Quality of Life test (DQoL-M) [11]. It consisted of 13 questions in three major domains such as (i) Diabetes Satisfaction Scale (QOL Satisfaction) – 6 items, (ii) Disease Impact Scale (QOL Impact) – 4 items, and (iii) Disease Worry Scale (QOL Worry) – 3 items. All items contained in the 'Satisfaction' Domain are scored on a five-point scale, ranging from 1 (very satisfied) to 5 (very dissatisfied), while all items encompassed in the 'Impact' and 'Worry' domains are scored on a five-point scale, ranging from 1 (never) to 5 (all the time). A more excellent score demonstrates a poorer QOL [12].

Data analysis

Analysis of data was conducted using the Statistical Package for Social Sciences (SPSS) Software Version 23. For the baseline comparison between the intervention and control group, Pearson's Chi-Square test and Fisher's exact test were used for categorical variables and an independent t-test for continuous variables. The repeated measure ANOVA was conducted to analyze continuous data with multiple variables. Significant level was set at a standard value of $p < 0.05$ and a confidence interval of 95%. These studies was chose an intention-to-treat (ITT) analysis. This means that data from participants were analyzed according to the group to which they were initially randomized to address dropouts, non-adherence, protocol deviations, or withdrawal in this study, and Treatment for missing data last observation carry (LOCF) forward was used.

Ethical approval

This study commenced after the ethical approval from the Ethics Committee for Research Involving Human Subjects of Universiti Putra Malaysia (UPM) (UPM/TNCPI/RMC/1.4.18.2 (MREC-JKEUPM-2018-183) and the Medical Research Ethics Committee (MREC) Ministry of Health Malaysia (NMMR-15-2490-28108). Permission was obtained from the Director of the Health Department of the Selangor State and the respective Kuala Selangor District health officers before the study was conducted. This study was also registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) as an RCT trial (registration number: ACTRN12619001725156).

RESULTS

Table II shows a baseline comparison of socio-demographic, socio-economic characteristics, medical profiles, glycaemic control (HbA1c (%)), health literacy, and diabetes quality of life (satisfaction, impact, and worry domain) between the intervention and control groups. The results indicate that at the baseline, there were no statistically significant differences observed for all the studied variables. This suggests that the intervention and control groups were comparable at the outset of the study.

Table II: Socio-Demographic, Socio-Economic Characteristics, Medical Profiles, Glycaemic Control (HbA1c Level), Health Literacy and Diabetes Quality of Life of the Participants at Baseline in Intervention and Control Group (N=250).

Characteristics	Intervention (n=125) Mean (SD) / (%)	Control (n=125) Mean (SD) / (%)	Total (N=250)	Mean Diff (95% CI)	Test Statistics (df)	P-value
Age (Years)	56.09 (9.58)	57.52 (9.60%)	250		-1.180 (247.9) [c]	0.239
< 40 years old	7 (5.6%)	8 (6.4%)	15			0.953[a]
41 – 64 years old	87 (69.6%)	85 (68.0%)	172			
≥ 65 years old	31 (24.8%)	32 (25.6%)	63			
Gender					1.691 (1)[b]	
Male	53 (42.4%)	43 (34.4%)	96			0.193
Female	72 (57.6%)	82 (65.6%)	154			
Marital Status						
Single	5 (4.0%)	7 (5.6%)	12			0.729[a]
Married	118 (94.4%)	115 (92.0%)	233			
Divorced	2 (1.6%)	3 (2.4%)	5			
Ethnic						
Malay	113 (90.4%)	115 (92.0%)	227			0.776[a]
Chinese	9 (7.2%)	6 (4.8%)	15			
Indian	3 (2.4%)	4 (3.2%)	7			
Education Level						
Non-formal	7 (5.6%)	6 (4.8%)	13			0.987[a]
Primary	55 (44.0%)	56 (44.8%)	111			
Secondary	52 (41.6%)	53 (42.4%)	105			
Diploma	3 (2.4%)	4 (3.2%)	7			
Degree	7 (5.6%)	5 (4.0%)	12			
Postgraduate	1 (0.8%)	1 (0.8%)	2			
Occupation						
Government Sector	10 (8.0%)	9 (7.2%)	19			0.470[a]
Private Sector	7 (5.6%)	12 (9.6%)	19			
Self-employed	28 (22.4%)	17 (13.6%)	45			
Retired	21 (16.8%)	25 (20.0%)	46			
Housewife	56 (44.8%)	58 (46.4%)	114			
Unemployed	3 (2.4%)	4 (3.2%)	7			
Income Status						
≤ RM 1000	40 (32.0%)	38 (30.4%)	78			0.643[a]
RM 1001 – RM 1999	59 (47.2%)	60 (48.0%)	119			
RM 2000 – RM 2999	15 (12.0%)	15 (12.0%)	30			
RM 3000 - RM 3999	2 (1.6%)	6 (12.0%)	8			
≥ RM 4000	9 (7.2%)	6 (4.8%)	15			

Table II: Socio-Demographic, Socio-Economic Characteristics, Medical Profiles, Glycaemic Control (HbA1c Level), Health Literacy and Diabetes Quality of Life of the Participants at Baseline in Intervention and Control Group (N=250). (CONT.)

Characteristics	Intervention (n=125)	Control (n=125)	Total (N=250)	Mean Diff (95% CI)	Test Statistics (df)	P-value
	Mean (SD) / (%)	Mean (SD) / (%)				
Duration of having Diabetes Mellitus Type 2 (Years)					3.664 (2)[b]	
1 – 5	63 (50.4%)	48 (38.4%)	111			0.16
6 – 9	20 (16.0%)	24 (19.2%)	44			
≥ 10	42 (33.6%)	53 (42.4%)	95			
Types of Medication						
Oral anti-diabetic agent	66 (52.8%)	60 (48.0%)	126			0.548[a]
Insulin alone	6 (4.8%)	4 (3.2%)	10			
Combination of oral agent and insulin	53 (42.4%)	61 (48.8%)	114			
Glycaemic Control (HbA1c (%))	8.66 (1.72)	8.99 (2.32)		- 0.332 (-0.482, 0.178)	- 1.281 (229)[c]	0.201
Health Literacy	28.73 (9.04)	28.61 (7.37)		0.11 (-0.95 , 1.00)	0.113 (248)[c]	0.91
Diabetes Quality of Life						
Satisfaction Domain	23.91 (3.94)	23.89 (3.90)		0.24 (-0.95 , 1.00)	0.048 (248)[c]	0.961
Impact Domain	5.10 (2.44)	5.09 (2.00)		0.01 (-0.54 , 0.57)	0.057 (248)[c]	0.955
Worry Domain	4.28 (1.21)	4.22 (1.11)		0.06 (-0.22 , 0.35)	0.433 (248)[c]	0.665

Note: a= Fisher's Exact Test, b= χ² (Chi Square) test, c= Independent t- test, SD = Standard Deviation, CI= Confidence Interval, df = degree of freedom, significant p < 0.05.
Note: At baseline, there were no significant differences for all studied variables, suggesting that the intervention and control groups were comparable.

Table III compares outcomes before and after a health intervention in two groups: Intervention (n=125) and Control (n=125). Initially, the Intervention group had slightly better Glycaemic Control but similar Health Literacy and Diabetes Quality of Life compared to the Control group. After intervention, the Intervention group improved Glycaemic Control, had higher Health Literacy, and showed positive changes in Diabetes Quality of Life, especially in Satisfaction.

Table III: Glycaemic control (HbA1c (%)), Health Literacy, and Diabetes Quality of Life (Satisfaction, Impact and Worry Domain) in intervention and control group before and after intervention (N=250)

Outcome	Before Intervention n =125		After Intervention n = 125	
	Intervention Mean ± SD	Control Mean ± SD	Intervention Mean ± SD	Control Mean ± SD
Glycaemic Control (HbA1c (%))	8.66 ± 1.72	8.99 ± 2.32	8.06 ± 1.57	8.67 ± 2.10
Health Literacy	28.73 ± 9.04	28.61 ± 7.37	31.85 ± 5.90	31.24 ± 5.16
Diabetes Quality of Life				
Satisfaction Domain	23.91 ± 3.94	23.89 ± 3.90	24.38 ± 2.67	24.27 ± 2.51
Impact Domain	5.10 ± 2.44	5.09 ± 2.00	5.05 ± 2.48	4.68 ± 1.94
Worry Domain	4.28 ± 1.21	4.22 ± 1.11	3.50 ± 1.22	3.47 ± 1.02

Note: Post-intervention changes were observed within each group. Both the intervention and control groups exhibited significant reductions in HbA1c levels, with the intervention group showing a 0.6% decrease and the control group a 0.3% decrease. Health literacy improved in the intervention group but declined in the control group. The "worry" domain in Diabetes Quality of Life has reductions in both groups, with the intervention group experiencing a more pronounced decrease. The "impact" domain showed minor changes, while the "satisfaction" domain saw increases in both groups post-intervention.

A repeated measures ANOVA was performed to assess the impact of the health intervention in Table IV. No outliers were identified through boxplot analysis. Data showed a normal distribution, and homogeneity of variance was verified using Levene's Test of homogeneity of variance. Mauchly's sphericity test showed that the assumption of sphericity was met for two-way interactions. Since the measurements were carried out between subjects and at two levels (pre-test and post-test), conducting a post hoc test was considered unnecessary.

Table IV: The Effect of Groups (Intervention and Control) on the Glycaemic control (HbA1c (%)), Health Literacy, and Diabetes Quality of Life (Satisfaction, Impact and Worry Domain)

Variables	df	F	p-value
Glycaemic Control (HbA1c (%)	(1 , 248)	4.003	0.046*
Health Literacy	(1 , 248)	0.256	0.613
Diabetes Quality of Life			
Satisfaction Domain	(1 , 248)	0.053	0.818
Impact Domain	(1 , 248)	0.612	0.435
Worry Domain	(1 , 248)	0.195	0.659

*Sig (p<0.05)

Note: Table IV provides a comprehensive analysis of the effect of intervention and control groups on diabetes-related factors, including glycaemic control (HbA1c %), health literacy and different domains of diabetes quality of life (Satisfaction, Impact and Worry.).The table shows that were a significant effect on glycaemic control (HbA1c %), with a p value of 0.046*, indicating a significant difference between the two groups. However, no significant differences were observed in health literacy (p-value = 0.613) or various domains of diabetes quality of life: Satisfaction (p-value = 0.818), Impact (p-value = 0.435), and Worry (p-value = 0.659).

The repeated measure ANOVA test was conducted to investigate the effect of the intervention (Table IV). The effects were as follows: Glycaemic Control $F_{(1,248)}$ = 4.003, P = 0.046, Health Literacy $F_{(1,248)}$ = 0.256, P = 0.613, Diabetes Quality of Life (Satisfaction Domain) $F_{(1,248)}$ = 0.053, P = 0.818, Diabetes Quality of Life (Impact Domain) $F_{(1,248)}$ = 0.612, P = 0.435, Diabetes Quality of Life (Worry Domain) $F_{(1,248)}$ = 0.195, P = 0.659 (Table III).

DISCUSSION

Effectiveness of Health Intervention on Glycaemic Control (HbA1c %)
The study's findings highlight the positive impact of the intervention on glycaemic control, as evidenced by a significant reduction in HbA1c levels within the intervention group compared to the control group. However, it is crucial to emphasize that even though statistical significance was achieved, neither group managed to reach the recommended optimal HbA1c levels essential for effective diabetes management. This result is supported by other research indicating that even a 1% reduction in HbA1c levels among individuals with Type 2 diabetes was associated with a 21% reduction in the risk of diabetes-related mortality and a 37% reduction in the risk of microvascular complications over ten years [13].

The findings of this study can partly be explained by the inherent variability in how individuals respond to diabetes interventions, which is influenced by genetic, lifestyle, and physiological factors. This underscores the significance of tailoring a personalized care plan, as some individuals may have diabetes that demands a more comprehensive approach. Furthermore, achieving ideal glycaemic control is greatly affected by the duration of the intervention, often requiring consistent and prolonged efforts for sustained results.

The key determinant in achieving optimal glycaemic control is the patient's commitment to adhering to prescribed treatment plans, which encompass medications, dietary guidelines, and lifestyle adjustments [14]. Healthcare providers should prioritize patient education, clear communication, and continuous support to enhance adherence, recognizing its crucial role in attaining and sustaining ideal glycaemic control while reducing the risk of diabetes-related complications.

Effectiveness of Health Intervention on Health Literacy
The results of the study show that there is no significant difference in the improvement of health literacy between the intervention and control groups, as shown by the p-value of 0.256. Nevertheless, both groups showed an increase in their average health literacy scores. In particular, the intervention group saw a significant improvement, with their mean health literacy score increasing from 28.73 to 31.85, while the control group's score increased from 28.61 to 31.24. This significant improvement was mainly observed in the intervention group. This finding is in line with previous studies, such as the study, which also found an increase in participants' health literacy after the intervention [15]. However, it is worth noting that even though there was an increase in mean health literacy scores post-intervention, they may have yet to reach a level considered sufficient. This might be attributed to the study's potential focus on short-term effects, whereas significant changes in health literacy could require a longer timeframe to become statistically significant. Extended follow-up periods could reveal more substantial improvements in health literacy.

Importantly, it should be emphasized that, on average, participants in both groups did experience an enhancement in their health literacy despite not achieving statistical significance. These improvements, while not statistically significant, could hold practical importance for individuals with Type 2 Diabetes Mellitus (T2DM) as they could contribute to improved self-management and overall health outcomes.

Effectiveness of Health Intervention on Diabetes Quality of Life
The result of the study finds the impact of a health literacy intervention on Diabetes Quality of Life across key domains, including Satisfaction, Impact, and Worry. The finding of increases in Satisfaction and reductions in Worry post-intervention for both the intervention and control groups indicate a positive influence of the

intervention on these aspects. However, there are no statistically significant differences between the groups, suggesting that the improvements were not uniquely attributable to the intervention. The minor decrease in the Impact Domain, with no significant distinction between groups, further underscores the nuanced nature of the intervention's effects on various dimensions of Quality of Life.

In this study, the impact of a health literacy intervention on Diabetes Quality of Life across several important domains, including Satisfaction, Impact, and Anxiety. Findings show an increase in Satisfaction and a reduction in Anxiety after the intervention for both the intervention and control groups, showing the positive influence of the intervention on these aspects. However, the absence of statistically significant differences between groups suggests that improvements may not be solely attributable to the intervention. The slight decrease in the Impact Domain, with no significant differences between groups, highlights the complex nature of the intervention's effects on various dimensions of Quality of Life.

Regarding the Satisfaction domain, the study did not reveal any statistically significant differences between the intervention and control groups after the intervention. This lack of significant improvement suggests that the intervention has limited effectiveness in improving patient satisfaction with their diabetes management.

It suggests that while interventions may target specific aspects of diabetes care, they may not adequately address the broader factors that contribute to overall satisfaction with disease management. These results underscore the challenge of developing interventions that comprehensively improve the satisfaction of individuals dealing with the complexities of diabetes.

Similarly, the Impact Domain showed no significant improvement in either group. However, what is particularly interesting is the drop in scores in the control group. Even if they do not receive the intervention, their participation in the study may create certain expectations or beliefs about the potential for improvement, potentially triggering a psychological phenomenon known as the placebo effect [16]. The modest improvement observed in the intervention group suggests that the intervention may not fully address the multiple dimensions in which diabetes affects individuals, including physical, emotional, and social aspects.

In the worry domain there was no significant change for either group. These findings suggest that interventions do not effectively address the worry that individuals with diabetes often experience. Worry can significantly impact the quality of life for those managing a chronic condition such as diabetes. The inability to achieve of these interventions to reduce worry underscores the need

for more targeted strategies to address the psychological aspects of diabetes management.

Therefore, this non-significant improvement should be refined by extending the duration of the intervention or exploring innovative approaches to address the unique challenges faced by individuals with diabetes may be necessary.

CONCLUSION

In conclusion, this study reveals a positive effect of this health interventions on glycaemic control compared to the usual care approach, although the optimal HbA1c level still needs to be achieved. Although there was no significant difference in the improvement of health literacy between the intervention and control groups, both showed a slight increase in scores, especially the intervention group. Diabetes quality of life exhibited nuanced changes, with an increase in Satisfaction and a decrease in Anxiety for both groups, but no significant differences between them. The study highlights the complexity of diabetes management and the need for a personalized care plan, ongoing efforts, and ongoing support. Further research and innovative strategies are essential to comprehensively address the psychological aspects of diabetes management and achieve better outcomes for individuals with diabetes.

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