Pharmacist intervention in home care program for diabetes patients[*]

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ABSTRACT

Majority of research reports identified moderate reduction in glycated haemoglobin with education interventions regardless of age group. Our study objective was to evaluate the pharmacist interventions in providing patient home care. A 24-week longitudinal quasi-experimental—pre-test/post-test study design was used to assess the effectiveness of a diabetes education program to enhance self-care practices. A double-blinded randomized study design was considered but was not feasible as the investigator was responsible for implementing the intervention and collecting data on outcomes. Since this was a longitudinal study a 25% attrition rate was included in the calculation of sample size. Hence the sample size for the proposed study was 106 subjects with 53 subjects in each group. All analyses were done using SPSS version 18[®]. The level of significance was set at 0.05. The Research Ethics Committee of hospital and the Malaysian Medical Research and Ethics Committee approved the study. Of the 109 subject who met the study-entry criteria, 3 subjects declined to participate due to lack of time and interest. There was no significant relationship between the demographic and clinical characteristic of participants who completed the study. No significant relationship between the intervention and control groups who completed the study in demographic, clinical and psychosocial contexts. Of the 47 subjects from the intervention group who reported adherent to their daily medication intake after the education intervention, 51 subjects (31.9%) reported taking their medication at the wrong time. The recommended times for oral anti-hyperglycemic medication (OAM) are: sulphonylureas 30 minutes before food, acarbose with food, metformin with or within 30 minutes after food. This research has shown a brief structured education program that incorporated behavior science specifically self-efficacy was effective in enhancing self-care practices (SMBG and medication adherence) and improving glycaemic control in the intervention group.

Keywords: Diabetes Mellitus; Interventional Study; Longitudinal Study; Pharmacist Services

1. INTRODUCTION

It reported that the greatest effect was knowledge improvement with small effects on self-care behavior, metabolic control and psychological well-being [1]. The same author replicated these findings with 35 additional studies which focused on the effects of different educational strategies on patient outcomes reported similar results [1-3]. Recent systemic reviews that examined the effectiveness of self-management training of type 2 diabetes based on randomized controlled trials also found significant findings on knowledge improvement regardless of the educational strategies used [4-6]. With regular reinforcement, knowledge level can be sustained for 24 months [3,6].

Patient education appears more effective in younger patients particularly knowledge outcome [7]. No other demographic variable is reposted in relation to knowledge improvement in the meta-analysis. Whereas health literacy literature indicates older subjects, those with less education, minority ethnic groups and do not speak English are factors associated with low health literacy. These

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subjects often benefit less from education interventions [8-10]. The positive effects of knowledge outcomes via diabetes education must be interpreted within the methodological limitation like possible contamination due to infeasibility of participant blinding, lack of uniform measures of knowledge and the validity of the tools use [6,8,11-13]. Hence the next question is to investigate whether the beneficial effects of education go beyond knowledge.

Majority of research reports identified moderate reduction in glycated haemoglobin with education interventions regardless of age group [8,14-16]. The glycated haemoglobin levels improve between one to six months post-intervention and the level frequently returned to baseline after six months [3,6,11]. Studies with follow up periods longer than one year showed mixed effects on glycaemic control [6,17-21]. Since most positive studies were short-term studies, there is concern about the lack of long-term glycaemic improvement.

Education methodology appears to influence glycaemic control. Compared to didactic interventions, patient collaborative interventions produce more favorable results particularly if the interventions are repetitive and ongoing [15,22-24]. In a meta-analysis, face to face delivery, cognitive reframing teaching and studies that included exercise content explained 44% of the variance in glycaemic control [25]. A meta-analysis reported that if require 23.6 hours of education to reduce 1% of HbA1c [26].

Some researchers have reported improvement of glycaemic control in both the control and study groups. In these studies, the education interventions were usually unblended [6]. In addition, lack of standardized measurements of glycated haemoglobin such as shorter than 12 week duration might not have documented the full effect of the interventions [6,27].

Our study objective aimed on three clinical hypothesis; There will be no difference in medication adherence self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who received standard education, there will be no difference in SMBG self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education, and there will be no difference in glycaemic control measured by glycated haemoglobin (HbA1c) between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

2. METHDOLOGY

2.1. Research Design

The purpose of this study was to examine the effect of an intervention. For logistical reason, this study was necessarily a small one and had to be completed within the study period. A 24-week longitudinal quasi-experimental—pre-test/post-test study design was used to assess the effectiveness of a diabetes education program to enhance self-care practices [28]. A double-blinded randomized study design was considered but was not feasible as the investigator was responsible for implementing the intervention and collecting data on outcomes [28,29].

2.2. Theoretical Framework

Findings from literature reviews have shown the importance of incorporating behavioral theories in Diabetes Self-management Education interventions because they provide an understanding of the cognitive and psychosocial processes that influence health decision-making and behavior. Self-efficacy has been shown to act as the mediating link between cognitive preparation (knowledge and skill) and actual task engagement [30-32]. Furthermore, when comparing self-efficacy to other psychosocial interventions, self-efficacy emerged as better predictor of self-care adherence to diet, exercise and blood glucose monitoring. It shared 4% to 26% of variance of self-care behavior when compared to Health Belief Model, outcome expectancies, autonomous self-regulation and social support in both Type 1 and Type 2 diabetes [30-32]. Hence self-efficacy in-home practice was the choice of theoretical framework for this study.

2.3. Subjects

2.3.1. Inclusion Criteria
Subjects were included if they:
- Were non-pregnant adults >18 years of age regardless of gender or ethnicity;
- Had diabetes for more than a year;
- Spoke and understood Bahasa Malaysia, English, Mandarin or Chinese dialects (Cantonese, Hokkien or Teow-chew) as these were the languages used during the pre-and post-assessments and education interventions;
- Had a medical record showing poor diabetes control*;

*Poor diabetes control in this study was defined as HbA1c of more than 7% for two reasons. First the currently global recommended glycaemic target measured by HbA1c is between ≤6.5% to ≤7%. Second, empirical studies reported that HbA1c of more than 7% is associated with increased micro-vascular complications [33-36].

2.3.2. Exclusion Criteria
Subjects were excluded from the study if they:
- Were above 18 years of age but unable to answer the questionnaire independently due to mental illness, se-

nility, other co-morbidities, unstable medical condition such as in-patients;

- Had hearing impairment as they might have had problems with telephone follow-ups for education and data collection;
- Had vision impairment as they might not be able to assess the portion size of their carbohydrate intake or prescribed medication;
- Were pregnant women with diabetes or diagnosed with gestational diabetes due to the different criteria on standard of control.

2.3.3. Sample Size

The required sample size was calculated with a power analysis using the procedure provided by Polit and Hungler [37]. Self-care practice was the primary outcome. The power was set at 0.7 with an alpha of 0.05. The investigator was unable to calculate the effect size using previous studies as there are no previous studies that measure the four self-care practices together. Hence the convention developed by Cohen (1988 cited in Polit and Hungler) was used (p492) [37]. Based on this, the value of effect size in a two-group test of mean difference was estimated at 0.20 - 0.49 for small effect, 0.50 - 0.79 for medium effect and 0.80 for large effect. To test for a significant difference between the two groups, a medium effect size of Gamma 0.5 was arbitrarily adopted, requiring a sample size of 42 in each group or a total of 84. Since this was a longitudinal study a 25% attrition rate was included in the calculation of sample size. Hence the sample size for the proposed study was 106 subjects with 53 subjects in each group.

2.4. Setting

One hundred and sixty subjects with poor diabetes control were recruited from the general medical outpatients clinics of general hospital in the state of Penang. A general hospital was defined as the main government hospital in the state offering tertiary care. Subjects were not recruited from the private clinics and hospitals for reasons of possible demographic and psychosocial differences which could affect the intervention outcomes. Controls were intervened in their respective homes while controls were observed in the usual appointments at out-patient department of the hospital.

2.5. Research Tools

Three research instruments were used in this study: measurement of glycated haemoglobin, an assessment tools and an education program.

Glycated Haemoglobin (HbA1c) was computed by using reference analogue of serum glucose values analysed by using Johnson-Johnson One-Touch Ultra 2 Me-

ter. Self-monitoring practices in home was performed by the patient and later researcher computed HbA1c on weekly basis.

2.6. Medication Intake Practices

Assessment of medication adherence included the subjects' reported medication intake on dosage and frequency which was compared with the physicians' prescriptions for concordance at the baseline. Compared to DSA questionnaire, 4 items were used to assess adherence to timing of daily medication adherence in the preceding week with a 8-point scale from "0" to "7" day, 4 items were used to assess the insulin users' injection skills and 3 items were added to assess for correct medication timing in relation to food intake. Percentage of medication adherence was calculated based on the data from subjects description of medication intake on dosage and frequency during the preceding 7 days using the formula in table below [38]. For subjects on combined treatment, the adherence percentage is the mean of oral anti-hyperglycaemia medication (OAM) and insulin adherence rates. Medication adherence rate was defined as consuming 90% and above of the prescribed medication in the preceding week.

2.7. Self-Monitoring of Blood Glucose Practice

At baseline, subjects were asked questions about the recommended weekly frequency of self-monitoring. No score was allocated for recommended frequency. The frequency of SMBG and treatment modification was assessed using a 9-point scale from "0" to more than 7 times'. Timing of SMBG was assessed using an 8-point scale from "0" to "7". The scoring system was based on the frequency of SMBG and treatment modification done during the preceding week (questions 4, 8 - 10). Although previous studies unanimously recognized the importance of SMBG in diabetes management, there were discrepancies between the recommended frequency and timing of SMBG [39,40]. Previous researchers reported less than 25% of Malaysians with diabetes practiced SMBG [41,42]. Hence for the purposes of this study, a minimum of four blood glucose testing in the preceding week was considered as adequate SMBG self-care practice.

2.8. Pilot Study

As all patients from the medical out-patient department of the hospital where the investigator was attached had regular HbA1c testing during their follow-ups, a pilot study was conducted there to assess the reliability,

content validity and criterion-related validity of the "Revised Diabetes Self-care Activities Questionnaire".

2.8.1. Subjects

Subjects were recruited using a systematic sampling approach and every second diabetic subject who met the inclusion criteria was invited to participate until a total of 50 subjects were recruited, which included 48 Type 2 diabetic and 2 Type 1 diabetics.

2.8.2. Content Validity

A panel compromising three diabetologists, three diabetes nurse consultants, two dieticians, one pharmacist, two adults with Type 2 diabetes reviewed the questionnaire independently for face and content validity that reflected the daily self-care practices of an individual with diabetes. The content of the questionnaire was also thought to be appropriate with several suggestions given to improve its clarity and precision. An example was re-phasing of "*what is the effect of exercise on diabetes control*?" to "*what is the effect of regular exercise on blood glucose*?" It was also suggested to measure the subjects' *waist circumference* because of the significance to the diagnosis of metabolic syndrome with diabetes [43-45].

2.8.3. Reliability

Internal consistency of the Revised Diabetes Self-care Activities Questionnaire was assessed using Cronbach's alpha analysis after the pilot study. The result of the Cronbach's alpha was 0.8 varying from 0.6 to 0.9.

The low Cronbach alpha value of SMBG could be because it has the least number of items [30] among all sections. According to the formula for Cronbach's alpha calculation, the co-efficient alpha depends on the total number of items and the average inter-item correlation among the items [46,47]. Different timing of SMBG has different significance in diabetes management. [39,40] Hence three further questions to assess the timing of SMBG were added.

2.9. Ethical Consideration

The Research Ethics Committee of hospital and the Malaysian Medical Research and Ethics Committee approved the study.

2.10. Statistical Analysis

Demographic data was analyzed using descriptive statistics. A 2-tailed t-test was used to analyze any difference between the intervention and control groups and within groups for ratio data such as medication adherence rate. Chi-square was used to analyze the relationship between nominal data such as gender. Multiple re-

gressions were performed to predict the variance of different self-care practices after the education with post-HbA1c levels. All analyses were done using SPSS version 18®. The level of significance was set at 0.05.

3. RESULTS

Of the 109 subject who met the study-entry criteria, 3 subjects declined to participate due to lack of time and interest. One hundred and six subjects were randomized to either control or intervention group with 53 subjects in each group. Thirteen subjects withdrew from the study for reasons of lack of interest (n = 9), transferred to either healthcare centre (n = 2), severe anaemia and hence were unable to read the post-HbA1c (n = 1) and one died. The primary result of this study were based on data from the 93 subject who completed the 24-weeks (6 months) follow-up (intervention = 47, control = 46).

There was no significant relationship between the demographic and clinical characteristic of participants who completed the study (**Table 1**).

No significant relationship between the intervention and control groups who completed the study in demographic, clinical and psychosocial contexts. **Table 2** presented the detailed information of analysis.

3.1. Medication Adherence Self-Care

3.1.1. Between Groups

There was no statistically difference in the medication adherence rate between the intervention (M = 83.21, SD = 17.26) and control groups [M = 84.52, SD = 19.79; t(149) = −1.7, p = 0.06] at follow up.

3.1.2. Within Groups

Within the intervention group, however, there was a significant difference in medication adherence rate from baseline (M = 83.21, SD = 17.26) to follow-up [M = 89.50, SD = 17.98, t(77) = −2.19, p = 0.03] with moderate effect size (eta squared = 0.06). This control group did not show any significant difference in medication adherence practices (M = 84.52, SD = 19.79) to follow-up [M = 84.60, SD = 18.16, t(72) = −0.04, p = 0.97].

3.2. Factors Influencing Medication Adherence Self-Care

3.2.1. Hypoglycaemia Episodes

During the study, 11 subjects (23.4%) from the intervention group reported hypoglycaemic episodes that were confirmed by SMBG results. These subjects adjusted their own insulin dosage to avoid further hypoglycaemic episodes. Unpaired t-test was used to assess whether this influenced medication adherence. Subject with no previous hypoglycaemic episodes had higher medication adherence rate (M = 91.10, SD = 15.71)

Table 1. Comparison between demographic data of subject who had and had not completed the study at baseline (n = 106).

Subjects	Participants = 93 mean ± (SD)/percent	Drop-outs = 13 mean ± (SD)/percent	X^2/t	p value
Age (years)	54 (10.03)	53 (11.43)	−0.92	0.34[≠]
BMI (kg/m²)	28.20 (5.58)	27.63 (6.32)	−0.33	0.75[≠]
Waist circumference (cm)	94.55 (11.49)	94.47 (12.8)	−0.07	0.94[≠]
Gender				
-Male	60 (64.5%)	4 (30.7%)	0.05	0.82[‡]
-Female	33 (35.5%)	9 (69.3%)		
Education level				
-Never	5 (5.4%)	1 (7.7%)		
-Primary	51 (54.8%)	7 (53.8%)		
-Secondary	30 (32.3%)	4 (30.8%)	0.81	0.93[‡]
-College	4 (4.3%)	1 (7.7%)		
-Tertiary	3 (3.2%)	0 (0%)		
HbA1c (%)	9.75 (1.75)	10.46 (1.72)	1.68	0.10[≠]
Duration of diabetes (years)	11.41 (8.64)	9.88 (8.87)	−0.63	0.55[≠]
Diabetes type				
-Type 1	5 (5.4%)	2 (15.4%)		
-Type 2	88 (94.6%)	11 (84.6%)		

[≠] analysis by t-test; [‡] analysis by Chi-square.

Table 2. Baseline characteristic of subjects who completed the study (n = 93).

Variables	Intervention (n = 47) mean (SD)/percent		Control (n = 46) mean (SD)/percent		X^2/t	p Value
A. Demographic						
Age (years)	54	(9.81)	54	(10.29)	0.02	0.98[≠]
Gender					0.04	0.1[‡]
Male	31	66.0%	29	63.0%		
Female	16	34.0%	17	37.0%		
Race					4.25	0.22[‡]
Malay	28	59.6%	25	54.3%		
Chinese	11	23.4%	12	26.1%		
Indian	8	17.0%	9	19.6%		
Education					−1.25	0.11[‡]
Never Primary	3	6.4%	2	4.3%		
Primary	25	53.2%	26	56.5%		
Secondary	16	34.0%	14	30.4%		
College	1	2.1%	3	6.5%		

Continued

Tertiarry	2	4.3%	1	2.3%		
Marital status					2.56	0.21[‡]
Single	3	6.4%	4	8.8%		
Married	38	80.9%	37	80.4%		
Divorced	1	2.1%	0	0%		
Separated	1	2.1%	2	4.3%		
Windowed	4	8.5%	3	6.5%		
B. Climical Variables						
Type of Diabetes					1.41	0.14[‡]
Type 1	2	4.3%	3	6.5%		
Type 2	45	95.7%	43	93.5%		
Duration of Diabetes (yrs)	12.09	(8.61)	10.62	(8.82)	0.03	0.030[≠]
Treatment mode					1.03	
OAM[§]	24	51.1%	23	50.0%		
Insulin	6	12.8%	8	17.4%		
OAM[§] and insulin	17	36.1%	15	32.6%		
HbA1c (%)	9.84	(1.75)	9.6	(1.78)	−0.81	0.31[≠]
BMI§ (kg/m^2)	28	(5.41)	28	(5.79)	0.55	0.64[≠]
Male	27	(4.05)	27	(5.70)	1.02	0.14[≠]
Female	29	(6.03)	29	(5.79)	1.07	0.18[≠]
Waist circumtances (cm)	94	(10.01)	95	(12.44)	0.65	0.78[≠]
Male	95	(10.01)	97	(12.80)	1.68	0.35[≠]
Female	93	(11.00)	94	(12.18)	0.86	0.48[≠]
C. Psychosocial Social status						
Living with family					1.59	0.49[‡]
members	45	95.7%	43	93.5%		
Living with friends	0	0%	1	2.2%		
Living alone	2	4.3%	2	4.3%		
Occupation					2.13	0.76[‡]
Office	6	12.8%	5	10.9%		
Factory	18	38.3%	14	30.4%		
Fieldwork	3	6.4%	5	10.9%		
Housewife	12	25.5%	10	21.7%		
Proffesional	1	2.1%	4	8.7%		
Retired	7	14.9%	8	17.4%		

[≠] analysis by t-test; [‡] analysis by Chi-square; [§] OAM means oral anti-hyperglycaemic medication BMI means body mass index.

when compared to those with history of hypoglycaemic episodes [M82.45, SD = 18.48; t(76) = 1.65, p = 0.10]. The finding was not statistically significant.

3.2.2. Demographic Factors

After the education intervention subjects >60 years old (mean adherence rate 88% ± 15.6) adhered the most to their medication intake. Subjects younger than 40 years old adhered the last to medication intake (mean adherence rate 83% ± 21.9, X^2 = 2.22, df = 2, p = 0.04). Post-knowledge assessment, other demographic data self-care practices were not related to medication adherent practices (p ≥ 0.05).

3.3. Medication Self-Care and Hb1Ac Levels Wrong Timing of Medication Intake

Of the 47 subjects from the intervention group who reported adherent to their daily medication intake after the education intervention, 51 subjects (31.9%) reported taking their medication at the wrong time. The recommended times for oral anti-hyperglycemic medication (OAM) are: sulphonylureas 30 minutes before food, acarbose with food, metformin with or within 30 minutes after food [33-35]. Short acting and premix insulin are injected at 30 to 45 minutes before food [36]. Subject who took their medication at times other than the above were classified as taking their medication at the wrong time. To assess the effect of wrong medication timing on HbA1c level, unpaired t-test was used. There was a significant difference in HbA1c results between subjects from the intervention group who took their medication at the correct time (M = 8.29, SD = 1.39) when compared to those who did not (M = 9.94, SD = 2.18; t926.18), df = −0.32, p = 0.003). A similar finding was observed when analysis of wrong time of medication in relationship to HbA1c was done for the whole study group. Subjects who took their medication at the correct time (M = 8.74, SD = 1.74) compared to those who didn't (M = 10.00, SD = 2.17; t(71.38), df = −3.49, p = 0.001).

Subjects who took medication at the wrong time were most frequently found to be those who had never attended formal school (mean rank = 91) and least likely those who had tertiary education (mean rank = rank52; X^2 = 3.38, df = 4, p = 0.41). These findings were not statistically significant.

3.4. Self-Monitoring of Blood Glucose Self-Care (SMBG)

3.4.1. Between Groups

During follow-up there was a statistically significant difference in SMBG practices between the intervention group (M = 2.94, SD = 2.25) and control group [M = 0.47, SD = 1.36; t(127.64) = −8.23, p ≤ 0.001] with mod-

erate effect size (eta squared = 0.06).

3.4.2. Within Groups

Within the intervention group, not all the subjects monitored their SMBG four times a week as instructed. During the 24 weeks the mean number of times this was done was 2.94 (SD = 2.25) ranging between 0-8 test per week. Despite the inconsistent practices, there was a statistically significant difference in SMBG practices from baseline (M = 0.60, SD = 1.39) to follow-up [M2.94, SD = 2.25, t977) = −8.73, p ≤ 0.001] with large effect size (eta squared = 0.32). In addition, there was a significant relationship between total number of SMBG performed and HbA1c result (r = −0.25, p = 0.03), carbohydrate intake (r = −0.24, p = 0.04) and medication adherence practices (r = +0.27, p = 0.03). There was no relationship between SMBG practices with demographic data or post-knowledge assessment or level of physical activity.

As for the control group, there was no significant difference in SMBG practices from baseline (M = 0.70, SD = 1.35) to follow-up [M = 0.47, SD = 1.36, t(72) = 0.97, p = 0.34] and no relationship was found between the number of blood glucose tests done with demographic or clinical variables.

4. DISCUSSION

Concomitant with the increasing global prevalence of diabetes is the increase in medical costs for this population [48,49]. One explanation for the heavy economic burden is that a substantial proportion of the cost of diabetes treatment is spent on treating complications [50,51]. Individuals with diabetes who had not received diabetes education had four times more risk of experiencing chronic diabetes complications due to inappropriate self-care, leading to persistent hyperglycaemic and metabolic perturbations. Hence diabetes self-management education is a critical element of diabetes management.

Despite the high prevalence of poor diabetes control leading to chronic diabetes complications in Malaysia with diabetes, [52-54] most previous studies done in Malaysia have focused on clinical management of the disease and few studies were found on self-care practices and education. Thus this study aimed to examine the effectiveness of a self-efficacy education program to enhance self-care practices and improve glycaemic control of Malaysians with poorly controlled diabetes.

4.1. Major Findings and Their Significance in Clinical Practices

This study showed that a brief diabetes education program incorporating self-efficacy principles had different effects in self-care practices and glycaemic control.

4.1.1. Comparison between Groups

The intervention group showed a statistically improvement in HbA1c levels, self-monitoring blood glucose (SMBG) practices when compared to the control group. Even though not statistically significant, the intervention group has also improved medication self-care practices.

4.1.2. Analysis within Groups

At follow-up, within the intervention group, there was a statistically significant improvement in HbA1c level, SMBG practices and medication self-care. The control group had small improvement in HbA1c levels but none of the self-care practices.

4.1.3. Effects of Diabetes Education

Diabetes education intervention was shown to enhanced SMBG and medication adherence practices. Likewise medication adherence and SMBG practices predicted the HbA1c levels at follow-up. The total education time rather than the number of intervention was associated with the above positive outcomes.

Each of the hypothesis is addressed individually before discussing the effect of diabetes education on self-care practices and glycaemic control.

4.2. Self-Care Practices

4.2.1. Medication Self-Care

Ho1: There will be no difference in medication adherence self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who received standard education.

The findings appeared to support the null hypothesis with no difference between the intervention and control groups. However, within the intervention group there was significant improvement from baseline to week 24. Hence this finding should be interpreted with caution for reasons given below.

One possible reason for the low medication adherence rate (89.5%) of the intervention group at end of study was the hypoglycaemia episodes experienced by 14% of the subjects in this study. Unlike previous studies the cause of hypoglycaemia in the intervention groups was not due to increased insulin dosage because the proposed intervention did not include insulin adjustment [55,56]. The hypoglycaemia episodes were most probably caused by better medication adherent practice, reduction of carbohydrate intake and increased physical activity. These subjects self-reported having to reduce their insulin dosage to prevent further hypoglycaemic episodes. By doing so the mean medication adherent rate of these subjects fell to 82%. Medication adherence in this study was de-

fined as adherent to 90% and more of the prescribed medication. To address the possibility of pseudo-medication non-adherence, another sub-analysis was done on the subjects who did not experience hypoglycaemia from the intervention group. Their medication adherence rate was 91%.

Although adherent in medication intake, 37% of the intervention subjects took their medication (both OAM and insulin) at the wrong time such as more than an hour before or after food intake which had resulted in higher HbA1c as compared to those who took it at correct timing (p = 0.003). Browne (2000) reported 38% of Type 2 diabetes subjects (n = 261) took their OAM incorrectly in relation to food. However, no assessment was done in that study to identify any relationship between wrong timing of OAM with overall glycaemic control [57]. In this study all subjects were prescribed with conventional insulin like Actrapid or Premix 30/70. Previous studies found that most insulin-treated diabetes patients regardless of the type of diabetes did not follow the recommended pre-meal injection time for conventional insulin injection but administered it at an interval shorter than advised [58-60]. This could have resulted in sufficient time to raise serum levels to correspond with the effect of meals which could contribute to post-prandial hyperglycaemia and higher HbA1c levels [58-60]. No research was found on timing of OAM intake of more than an hour before or after meal in relation to glycaemic control. More importantly, future research needs to explore the underlying reasons of this behavior as it could result not only in post-prandial hyperglycaemia but also hypoglycaemia that could endanger life [61,62]. One possible explanation is the subjects lack knowledge about the action mechanism of their prescribed medications. This assumption was supported by the findings that subjects who took their medication at the wrong time were those with less education. Previous studies have shown similar findings [57,63,64]. Another possibility was that wrong advice could have been provided by the healthcare professionals. Findings from previous studies reported that only 30% - 42% of their subjects who were healthcare professionals that included doctors, nurses and pharmacists were knowledgeable on the action mechanism of OAM [57,63-66].

The detailed investigation of the subjects medication intake behavior in relation to medication adherence self-care was indeed the strength of this study. The inquiries had shown that presence of hypoglycaemia could contribute to medication non-adherence practice and wrong timing of medication could lead to poor glycaemic control. Previous studies have commented on the paucity of information regarding such topics. Hence this observation requires futher investigation to confirm the cause and effect.

Existing literature made controversial findings regarding medication compliance and older people. In this study, older subjects were more compliant with medication intake. There are two possible explanations for this finding. First, it was possible that older people were more likely to experience progression of their disease leading to increased awareness of the illness and better motivation to comply with treatment. Second, older people in Malaysia often stay with their families and thus could have received support in medication intake from family members or caretakers. Similar findings were observed in the first study of this portfolio and previous literature [67-69].

4.2.2. Self-Monitoring Blood Glucose Practices

Ho2: There will be no difference in SMBG self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

There was a significant difference between the intervention and control group SMBG practices and therefore the null hypothesis was rejected. The improvement in SMBG self-care in the intervention group was anticipated not only because of the education intervention, but also because the subjects were provided with free test strips. Due to limited supply of free test strips, the advised frequency of monitoring was not based on the current recommendation of 2 - 3 times per day for insulin users and minimum once a day for those with OAM [70]. Despite the free supply of blood glucose test strips, there was substantial variation between 0-8 times of monitoring per week with a mean of 2.94 (SD = 2.25) times per week. Since cost was not a barrier for SMBG among the Intervention subjects, infrequent occurred for other reasons. Previous studies had cited these being: attitude toward SMBG, lifestyle interference, inconvenience, pain, old age and cost [70-73]. These barriers were not investigated in this study and should be explored in the future. Thus this finding only partially supported the assumption of this study that people with diabetes when provided with the opportunity to practice SMBG would improve their self-care practices.

The lack of change in the SMBG practices in the control group mirrored results from the first study of this portfolio [67]. As explained earlier, Malaysian engage in social medicine where the government heavily subsides the cost of medication for patients attending government-run healthcare facilities [74]. The government, however does not finance the cost of SMBG. This could act as a financial to SMBG self-care especially for patients from lower socio-economic backgrounds.

Earlier researcher has reported conflicting findings on the efficacy of SMBG among Type 2 diabetic subjects, especially those prescribed with OAM [75-77]. In this study the intervention group comprised 95% of Type 2 diabetic of which 78% were prescribed on OAM and combination therapy. These subjects had lower HbA1c levels compared to the control group. This could be due to more frequent SMBG practices enhancing intervention subject's medication adherence. In addition, there was also a significant relationship between total number SMBG performed and HbA1c result (p = 0.03) and carbohydrate intake (p = 0.04). The findings of this study are consistent with previous research reporting a negative correlation between frequency of SMBG with HbA1c levels [78,79]. The increased frequency of SMBG had enhanced the self-care practices of the intervention group in dietary and medication intake.

Previous study found improved Hb1Ac levels with self-adjusted of insulin dosage [79]. However, in this study, increases in medication dosage by the attending doctors did not lower the HbA1c of the intervention group (p = 0.57). Instead the intervention subjects were shown on meal-related SMBG to identify excessive carbohydrate intake. It was explained to the subjects that the same meal, if there was a difference between the pre-meal and the 2-hour post-meal blood glucose levels greater than 4 mmol/L, it might indicate excessive carbohydrate intake for that particular meal. For example, if the pre-meal blood glucose was 8 mmol/L and 2 hour later, the blood glucose level was 16 mmol/L, there could be due to excessive carbohydrate intake for that particular meal. However, if the pre-meal blood glucose was 14 mmol/L and 2 hours later, the blood glucose level was 16 mmol/L, the post-prandial hyperglycaemia might not be due to intake of food but other causes. To increase their self-efficacy in dietary management, they were then guided to identify the carbohydrate food items in the meal so as to reduce the carbohydrate intake in the future. At the end of this study, subjects who practiced more frequent meal related SMBG reduced their carbohydrate intake (p = 0.04). Similar findings have been reported in previous studies [80,81]. Furthermore, it was also explained that persistent fasting hyperglycaemia might be due to medication non-adherence and wrong timing of medication intake. With self-efficacy education the intervention group improved its medication intake practices (p = 0.03). The above findings had supported the assumption of this study which argued the beneficial effects of SMBG with treatment modifications.

4.2.3. Glycated Haemoglobin

Ho3: There will be no difference in glycaemic control measured by glycated haemoglobin (HbA1c) between adults with poorly controlled diabetes who received a structured self-efficacy education compared to those who receive standard education.

Compared to the control group, the intervention group

significantly improved its HbA1c levels with a reduction of 1.1% compared to baseline which means the null hypothesis was rejected. This is an important finding as previous clinic trials have reported that reduction of HbA1c by 1% is associated with reduction of diabetes complications by 21% [82]. The proposed intervention of this study was an education program with no change of medication by the investigator. Although the medication prescriptions of some subjects were increased by the attending doctors during the course of study, this has no significant effect on the HbA1c levels of the subjects at the end of the study ($p = 0.57$). Hence it could argued that improvement in HbA1c was due to the education intervention enhancing self-care practices in SMBG ($p = 0.001$), medication adherence ($p = 0.04$), physical activities 9p = 0.002) and dietary intakes. These are the cornerstone of diabetes management. Previous researchers have reported similar findings [83-87]. However, whether the improved self-care practices were due to subject's improved self-efficacy could not be ascertained as no assessment of self-efficacy was done before and after the intervention.

Not all subjects in the intervention group lowered their HbA1c. The glycaemic control of 20% of the intervention subjects deteriorated despite education. This could be due to several reasons. During the data collection process, it was observed that 23% of intervention subject who were older, female and with less education had problem attending education session due to lack of transport thus they received less education ($p = 0.006$). Subjects with transportation problem had statistically higher HbA1c at follow-up ($p = 0.03$). Although the barriers to transportation were not assessed in this study, previous studies found that distance from health facilities was positively correlated to glycaemic control of the subject [88,89]. Other studies have revealed the importance of social support to subject's glycaemic control [90-92]. In view of the increasing incidence of diabetes in Malaysia, social support warrants future research as this may be a barrier to subjects attaining glycaemic control.

Another barrier to education observed in this study was telephone access. Over the last decades in Malaysia, mobile phone have gained in popularity at the expense of landlines. This study was found that although mobile phones were readily available within a family, they were usually used by younger members of the family or the male subjects who were employed. As two-third of the subjects were older women or housewives, they were liable to have problems with phone access during the day. It was observed that subjects with less financial resources were likely to purchase low cost prepaid phone cards (RM 5 or RM 10). This could have contributed to the frequent change of phone numbers which further contributed to telephone access problems. Three previous studies done in Malaysia had used a phone intervention for survey and appointment reminder purposes rather than education [93-95]. Although these studies did not report problems with phone access, one study reported only a 67% success rate. Ten percent of the potential subjects in another study did not have a mobile phone call were answered by caregivers rather than the patients themselves. In addition, the mean age for two of the above three studies was 38.2 years.

Not all subjects in the control group experienced deterioration in their glycaemic control. Some control subjects improved their HbA1c at the end of this study. As discussed earlier, the increased in medication prescribed by the attending doctors did not lower their HbA1c levels ($p = 0.57$). There was also no significant change in the self-care practices among control subjects. Hence the silent question is what could have contributed to improved glycaemic control among the control group without the effect of additional medication or enhanced self-care like as in the intervention group. Previous researchers had reported recruitment to a clinical trial itself improves glycaemic control in patients with diabetes [96]. Another possible reason could be the use of complementary therapy. Previous studies done in Malaysia reported the popular use of the complementary therapy [97-99]. Some complementary therapies may contain anti-diabetis effects [100,101]. This could result in over-medication if the subjects also consumed the doctor's prescription at the same time without informing their attending doctors. Due to limitations of this study, use of complementary medication by both the study groups was not investigated.

The higher frequency of SMBG performed by the intervention group compared to the control group could have influenced the HbA1c improvement as SMBG results provided real time effects of self-care practices./ Subjects in this study improved their medication adherence rate ($p = 0.03$) in within group comparison and reduced carbohydrate intake ($p = 0.04$) based on their SMBG practice results. The results of previous studies supported these findings [102-104].

5. CONCLUSION

This research has shown a brief structured education program that incorporated behavior science specifically self-efficacy was effective in enhancing self-care practices (SMBG and medication adherence) and improving glycaemic control in the intervention group. The brief education implemented in this study appeared to enhance self-efficacy in self-care practices leading to behavioral change and better clinical outcomes.

Practice Implications

The results of this study have implications for patient

education, clinical practice and policy-making.

Subjects who were elderly and with less education in this study did not gain the same benefits from the intervention compared to the younger subjects with more education. This suggests the importance of an individualized approach. When educating the elderly and those with less education, sessions may need to be longer and approaches specifically designed to achieve maximum benefit.

It is usual practice in the study settings that more subjects with Type 1 diabetes and on insulin treatment rather than Type 2 diabetes on OAM are referred for diabetes education. In this study, the difference of knowledge scores between Type 1 and Type 2 subjects in the intervention group had changed from significant at baseline to non-significant after the intervention which suggested that education could benefit all hence everyone diabetes in Malaysia regardless of type of diabetes or treatment mode should be provided with education to enhance their knowledge and self-care management.

In this study despite good overall adherence to medication intake, wrong timing of medication intake in relation to meal-intake was observed to decrease glycaemic control. During the education sessions, medication intake in relation to meal-timing should be emphasized as well as encouraging medication adherence.

With less than 500 registered dieticians in Malaysia, there is a considerable shortage of dietary services provided by dieticians. Since diabetes nurse educators provide most of the teaching for people with diabetes, they are in unique position to assist dieticians in enhancing dietary knowledge and self-care. This could be done by emphasizing meal-related SMBG practices in dietary management and problem solving skills which are an important aspect of diabetes self-care.

In this study, by providing the required resources (blood glucose strip and knowledge) to the interventions subjects, the majority of them regardless of demographic differences were willing to practice SMBG. In addition, the frequency of SMBG in this study was found to correlate with significant clinical improvement and better self-care practices. All individuals with diabetes regardless of treatment mode and age group should be encouraged to practice SMBG.

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