SELF-CARE PRACTICES OF ADULTS WITH POORLY CONTROLLED DIABETES MELLITUS IN MALAYSIA

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Portfolio Introduction

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SIGNED STATEMENT

This portfolio contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person except where due reference has been made in the text.

A final draft of this portfolio was edited by Mr. Philip Thomas. Mr Thomas is an Information Technologist and librarian, not a Health Professional. He was advised to restrict his assistance to the Australian Standards for Editing Practice (ASEP) concerning language and illustraions and completeness and consistency.

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(Tan Ming Yeong)

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DEDICATION

This Doctoral Portfolio is Dedicated

to all the People with Diabetes Mellitus

in Malaysia

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PORTFOLIO STRUCTURE AND OVERVIEW

Portfolio Structure

This doctoral portfolio presents two separate but related research study reports on 'self-care practices of adults with poorly controlled diabetes in Malaysia'. It is comprised of five sections.

Section one which is the introduction begins with a general discussion on diabetes mellitus (henceforth referred to as diabetes), a common, growing, serious and costly health problem. The importance of self-care in the management of diabetes and its many disabling long-term complications are emphasised. This is followed by a specific discussion of diabetes in Malaysia - its prevalence, the quality of care, cost and the need for research to uncover new information to improve the care provided to Malaysians with diabetes.

Section two is the report on the first research study that investigates the four cornerstones of diabetes self-care practices, namely: dietary intakes, medication adherence, physical activity and self-monitoring of blood glucose in Malaysian adults with poorly controlled diabetes. It also explores the factors that influence these self-care practices.

Section three is the report on the second research study that assessed the efficacy of an out-patient diabetes educational program based on a self-efficacy theoretical approach to improve firstly, self-care practices and secondly, clinical outcomes of adults with poorly controlled diabetes in Malaysia. It also identified some of the factors that facilitate or impede such a programme in the Malaysian context.

Section four integrates the findings of the two related research studies - the first defining the problem and the second providing possible solutions in the Malaysian context. It points out limited diabetes knowledge on self-care can compromise or create problems regarding self-care practices for Malaysians with poor glycaemic control. It also identifies possible areas of research that can uncover new knowledge that may improve the quality of diabetes care and enhance the quality of life of Malaysian with diabetes.

Section five includes publication originating from this work.

The Journey Begins with a true story

Mr. Chong (pseudonym) was diagnosed with Type 2 diabetes in 1987 when he was 30 years old. During his initial years of diabetes, he was treated with oral anti-hyperglycaemic medications (OAM) and he monitored his glycaemic control with urine sugar. When blood glucose monitoring was introduced in 1990 in Malaysia (1978 in the United Kingdom), his doctor recommended that for better accuracy he should monitor his blood glucose instead. As his diabetes control continued to be unsatisfactory, his doctor persuaded him in 2001 to begin twice daily conventional insulin injection. However, this did not improve his diabetes or metabolic control. He remained obese with a BMI of 33 kg/m^2 and continued to smoke 20 cigarettes daily. He also complained of occasional hypoglycaemic symptoms which could be due to skipping his lunch because of frequent travelling. With the introduction of newer insulin, his doctors changed his regimen to Glargine once in the morning and Novorapid before each main meal and advised him to monitor his blood glucose levels more frequently. He claimed he monitored his blood glucose levels at home, but his glucose log showed he tested only 1-4 times a month perhaps due to inconvenience and having a busy schedule. Hence his glycaemic control remained poor with HbA1c frequently more than 9%. He also had high blood pressure and dyslipidemia. He

had to scale down his business ventures in 2005 after being diagnosed with End Stage Renal Failure which required him to be dialysed three times a week. He had a stroke in 2007 that left him bed ridden at 50 years of age.

The Journey Continues with 'If not, Why not?'

The investigator has worked in the field of diabetes education for over 20 years. During these two decades, there have been many advances in the clinical management of diabetes such as new anti-hyperglcaemic medications, numerous advances in monitoring technologies and landmark studies that provided evidence that improvement in glycaemic control in both Type 1 and Type 2 diabetes can prevent the onset and delay the progression of the devastating microvascular complications of diabetes. Despite these advances in diabetes care, the investigator and other diabetes educators in Malaysia who care for patients like Mr. Chong ask themselves many questions including:

- *'Why don't new diabetes management strategies prevent the onset or delay the progression of diabetes complications?'*
- *'Why is it that advances of medical technologies do not seem to promote self-care practices in diabetes management?'*
- *'Why is research in diabetes self-care so limited and lagging behind other advances in diabetes care in Malaysia?'*

These and other questions provided an impetus and formed the basis of the two research studies: firstly, 'What are the self-care practices of Malaysians with poorly controlled diabetes?' and secondly, 'What nursing interventions could be promoted to enhance self-care practices with the aims to prevent or delay the progression of the chronic complications of diabetes?' In the section below the investigator will now discuss the challenges of diabetes and its management in general and in Malaysia specifically.

Diabetes Mellitus

What is Diabetes or 'Kencing Manis/Sweet Urine'?

Diabetes is a chronic progressive metabolic disease characterised by hyperglycaemia due mainly to absolute insulin insufficiency (in Type 1 diabetes) or relative insulin deficiency and insulin resistance (in Type 2 diabetes). Partly due to the metabolic perturbations caused by hyperglycaemia, diabetes affects virtually every system of the body with long term and severe damage if diabetes control over time proves to be suboptimal.[1]

How Common is Diabetes?

There is a global epidemic of diabetes with its prevalence expected to increase from 5.1% in 2003 to 6.3% in 2025. This increase in diabetes is occurring in all nations, however, developing nations are particularly at risk. It spares no group and affects men, women, the elderly, the young and people from every racial and socio-economic background. Nevertheless, certain ethnic groups including Asians are affected more than Caucasians. Nearly half of all diabetes cases occur in people older than 65 years of age.[2-4] Although Type 2 diabetes is predominantly a disease of adults, during the last few decades, the number of Type 2 diabetes children and adolescents has increased globally and particularly in some parts of the Asian-Pacific regions. In some countries in these regions, Type 2 diabetes in the young outnumbers Type 1 diabetes by a ratio of 4:1.[5,6]

What are the Chronic Complications of Diabetes?

There are 2 categories of vascular complications in diabetes: microvascular (retinopathy, nephropathy and neuropathy) and macrovascular (coronary heart disease [CHD], cerebrovascular disease [CVD] and peripheral vascular disease [PVD]).

Microvascular Complications of Diabetes

Diabetic Retinopathy

Diabetes retinopathy is the leading cause of new blindness in adults aged 20-74 years. Ninety percent of people with diabetes of 20 years duration have some diabetic retinopathy. Diabetic retinopathy is categorised as non-proliferative or proliferative and/or macular edema.[7] Early diabetic retinopathy is asymptomatic. Based on the Early Treatment Diabetic Retinopathy Research Study (ETDRS), it is not until the visual acuity assessment of a person with diabetes reaches 20/40 on the ETDRS visual acuity chart that it impairs reading and the ability to drive a motor vehicle. This level of acuity already reflects moderate severe non-proliferative diabetic retinopathy.[8] Furthermore the Wisconsin Epidemiology Study of Diabetic Retinopathy found a significant relationship between glycated haemoglobin and proliferative retinopathy. For every 1% increase in glycated haemoglobin, retinopathy frequency almost doubled with an increase of 30% in frequency of visual loss.[9] If people with diabetes are educated about the need for annual eye examination and achieve near nomoglycaemic control, diabetic retinopathy can be treated early and reduced.[10]

Diabetic Nephropathy and End-stage Renal Disease

Diabetes nephropathy occurs in 20-40% of people with diabetes and is the single leading cause of end-stage renal disease (ESRF). Early diabetic nephropathy is detected by testing for microalbuminuria.[11] Hypertension and hyperglycaemia are two causes of diabetic nephropathy. Controlling hypertension and achieving near-nomoglycaemia have been shown to prevent the onset and delay the progression of diabetic nephropathy.[12,13]

Even at the stage of ESRF, glycaemia control has been reported to be significantly associated with the prognosis and survival rates among diabetics on renal replacement therapies. The major cause of death among diabetics with ESRF is cardiovascular disease. Other predictors of mortality include heart

failure, infection, hypercholesterolemia, age of subjects, low albumin, low dialysis delivery dosage due to poor vascular access and hyperglycaemia.[14-16] All the above studies were observation-based. Hence large clinical trials are needed to confirm this observation which is important in future management of diabetes complications.

Diabetic Neuropathy and Amputation of Lower Extremities

Diabetes neuropathy is common and ultimately affects about half of all people with diabetes. It appears to parallel the duration and severity of hyperglycaemia. The most common among the neuropathies are distal symmetrical polyneuropathy (DPN) and autonomic neuropathy. The autonomic neuropathy may involve every system in the body and can be incapacitating. The distal symmetrical polyneuropathy, especially painful diabetic neuropathy can be very annoying. When DPN is coupled with peripheral vascular disease, loss of sensation in the lower extremities leads to foot ulcer and eventually gangrene. Patient education has shown to improve foot care practices and prevent amputation.[7,11]

Can Microvascular complications of Diabetes be Reduced?

Large randomised clinical trials have shown that improvement in glycaemic control, together with management of diabetes-related risk factors like blood pressure and lipid control significantly reduce the micro- and macrovascular complications in individuals with Type 1 and Type 2 diabetes. These trials demonstrated that for every 1% absolute reduction in glycated haemoglobin, microvascular complications fell by 30-35% and macrovascular complications by 14-16% as shown in Table 1.[12,13,17]

Table 1: Effect of Intensive Glycaemic Control in Reduction (%) of HbA1c and Corresponding Reduction (%) in Complications

	Type 1 Diabetes	**Type 2 Diabetes**	**Type 2 Diabetes**
Study	**DCCT**[12]	**Kumamoto**[17]	**UKPDS**[13]
A1c	9.0% →7.2%	9.4%→7.1%	7.9% →7.1%
Retinopathy	63%	69%	17% - 21%
Nephropathy	54%	70%	24% - 33%
Neuropathy	60%		
Cardiovascular Disease	41%*	52*	16%*

*not statistically significant

Note: UKPDS means United Kingdom Prospective Diabetes Study and DCCT means Diabetes Control and Complication Trial

More good news came from the Epidemiology of Diabetes Interventions and Complications study (EDIC) which was a cohort study with a 10 years follow-up with the Diabetes Control and Complication Trial (DCCT) cohort. This study examined the influence of intensive diabetes treatment versus conventional treatment during the trial period. The effects of cardiovascular disease risk factors was measured by coronary artery calcification as an index of atherosclerosis on 1205 EDIC Type 1 patients at approximately 7-9 years after the end of the DCCT. It reported that previous intensive diabetes treatment was associated with less atherosclerosis changes.[18] A similar beneficial effect on microvascular complication, namely retinopathy and nephropathy was also reported.[19] Researchers from both studies concluded that the benefits of 6.5 years of intensive treatment with reduction of HbA1c extended well beyond the period of its most intensive implementation. Similar beneficial findings were reported on risk reduction for microvascular complications, myocardial infarction and death from any cause during the 10 years of United Kingdom Prospective Diabetes Study (UKPDS) post-trial follow-up for 3277 Type 2 diabetics.[20]

Macrovascular Complications of Diabetes

Two out of three people with diabetes die either of CHD (~50%) or CVD (~17%). Meta-analysis and prospective population studies have shown diabetes is an independent risk factor for cardiovascular disease with two to three-fold increased risk for cardiovascular death regardless of the types of diabetes as compared to persons without diabetes.[21-24] Dyslipidemia (high LDL-cholesterol, high triglycerides and low HDL-cholesterol) and hypertension are more prevalent in people with diabetes. It also contributes to this increased risk for CHD and CVD.[10,11,25]

Diabetes and Coronary Heart Disease

People with diabetes and no history of myocardial infarction have the same risk of getting a myocardial infarction in the next 7 years (18-20%) as people without diabetes who have already had a myocardial infaction.[26] This evidence led to the National Cholesterol Education Program Adult Treatment Panel III to classify diabetes as a coronary artery disease risk equivalent.[27] In 2004, The Global Registry of Acute Coronary Events from 14 countries reported that approximately one in four patients admitted for coronary events had a history of diabetes.[28]

People with diabetes more often have three-vessel disease (40%-53%) and more diffuse coronary artery disease resulting in diabetes being a strong independent predictor for death and myocardial infarction.[29-31] Although percutaneous transluminal coronary angioplasty (PTCA) improves outcomes, clinical trials continue to report that diabetic individuals who undergo coronary interventions - whether under stable or unstable conditions - have a significantly higher risk of mortality and re-infarction in both short-term (<30 days) and long-term (6 months - 4 years) in comparison to non-diabetic subjects.[30-33]

Around 20% of individuals with diabetes undergo coronary artery bypass surgery (CABG). Several studies have reported the short-term outcomes after CABG with conflicting results. Those studies which found diabetes to be an independent predictor for early post-operative death were retrospective and did not match diabetic and non-diabetic groups nor were they comparable with regards to other factors.[34,35] Some researchers have found no difference between the short-term prognosis (<30 days). However, the long-term survival was significantly lower in the diabetic group as compared to the non-diabetic group. Cumulative 5- to 10-year survival rates were 89% and 71% in diabetics and 94 and 84% in non-diabetics.[32,34]

Diabetes and Cerebral-vascular Disease

Prospective population studies have shown that having diabetes increases cerebral-vascular disease incidence by four to five-fold when compared to non-diabetics.[22,36] Epidemiological researchers also reported the detrimental effects of diabetes appeared to result in poorer outcomes after stroke than non-diabetics.[21,37-39] Furthermore the severity of the cerebral-vascular disease correlated with the level of hyperglycaemia at diagnosis.[40-42]

Diabetes and Peripheral Vascular Disease

Twenty to sixty percent of people with diabetes have peripheral vascular disease (PVD). Because PVD and neuropathy co-exist in people with diabetes, 15%-25% of them will eventually have foot ulcers during their lifespan.[43] Diabetic foot complications are the most common cause of non-traumatic lower extremity amputations. The risk of lower extremity amputation is 15-46 times higher in diabetics than in people without diabetes.[44,45]

Can Macrovascular Complications be reduced in Diabetes?

Patient education plays a crucial role in the prevention of diabetic foot problems. In Geneva, the rate of lower limb amputations was reduced by almost 75% after

an educational intervention.[46] In another study of 242 Type 2 diabetic patients, there were fewer recurrences of ulcers and the healing process was faster in subjects adhering to the foot care advice, when compared to those who did not follow the advice.[47] However, there is no convincing evidence based on randomised clinical trials that improving glycaemic control can decrease CHD/CVD morbidity and mortality as shown earlier in Table 1.[48-50] The evidence is largely based on epidemiological studies that 1% increase of A1c is associated with a 15%-18% increase in the relative risk of CVD for patients with Type 1 and Type 2 diabetes,[10,12,24] whereas lowering hypertension has been shown to decrease morbidity and mortality associated with CHD and CVD.[51,52] Many clinical trials report decreased morbidity and mortality due to CHD in people with diabetes when their dyslipidemia (high LDL cholesterol or lower HDL cholesterol) is treated.[25,53,54] In the management of dyslipidaemia and hypertension, patient education leading to self-care can play a critical role.

Other Problems in Diabetes

Diabetes and Dental Problem

Diabetes is an important risk factor for more severe and progressive periodontitis disease, infection and/or lesions resulting in the destruction of tissues and supporting bone that form the attachment around the tooth.[55-57] Periodontitis affects both Type 1 and Type 2 diabetics.[58-60] A study in the United States that examined 700 children for the presence of periodontitis compared diabetic children aged between 6-18 years with a same age-controlled group. They reported that children with diabetes in all age groups had increased gingival inflammation and attachment loss. This and other studies show that even very early in life and regardless of the type of diabetes in children, it affects dental health.[58,61] Furthermore in a national survey in Taiwan of deaths from oral and maxillofacial infection, it was reported that approximately 1 in 150 cases admitted for oral and mixillofacial infections died. Sixty-seven percent of these deaths were patients with diabetes who were older than 40 years.[62] These findings corroborated previous studies.[63-65]

Some researchers suggest that diabetes and periodontitis share a common pathogenesis that involves an enhanced inflammatory response that was mainly caused by the chronic effects of hyperglycaemia and specifically the formation of biologically active glycated proteins and lipids that promoted inflammatory responses.[59,61,66,67] There is evidence that control of periodontal infection has an impact on improving glycaemic control and decrease insulin dosage.[56,67]

Hyperglycaemia in Surgical Patients

Researchers who have conducted a cohort study to determine the relationship between pre-operative blood glucose levels and perioperative mortality in non-cardiac, non-vascular surgery with 108,593 patients from 1991-2001 found that pre-operative hyperglycaemia (diabetic) was associated with 1.7 fold increased mortality risk when compared with normal glycaemic levels (control group).[68] Another study that assessed the impact of having diabetes on patient outcomes after ankle operation (n=160 598) in the United States reported patients with diabetes were more likely to suffer increased mortality, postoperative complications and higher healthcare costs compared to those without diabetes. However, no mention was made concerning the levels of blood glucose of the study subjects.[69] Though another study did not confirm the above[70], control of hyperglycaemia in surgical patients in the peri-operative period is now standard practice because the benefits outweigh the risk.[71]

Diabetes and Pregnancy

Women with diabetes have higher incidence of birth defects in their offspring. Pre-gestational diabetes, whether in Type 1 or Type 2 is associated with a two to eight-fold increase in major congenital defects. This association is probably secondary to the teratogenic effect of hyperglycaemia in early pregnancy. Studies that examined glycaemic control and birth defects have demonstrated a dose-response effect: the poorer the pre-conception and early pregnancy (first 10 weeks) blood glucose control, the greater was the risk of congenital defect.[72] In addition, an outcome analysis of pregnancies in 182 women with Type 2 diabetes

reported that infants borne by mothers with diabetes had 6 times the risk of death within the first year and 11 times the risk of congenital malformation compared with regional and national figures.[73]

A meta-analysis of 14 published studies of preconception care with diabetes that assessed 1192 children whose mothers had received preconception care and 1459 children whose mothers had not received such care, reported the rate of major congenital malformations among preconception care recipients was less than one third of those who did not receive preconception care (2.1% versus 6.5%).[74] Hence the most important step is to improve the glycaemic control of women with diabetes before conception. Diabetes education leading to better self-care practices can make a difference.

Diabetes and Depression

Multicentre studies have shown that depression is common among people with diabetes.[75] Depressive symptoms had been shown to be associated with poor self-care practices and glycaemic control, functional impairment and higher health care costs.[76-78]

Socio-economic Impact of Diabetes

The complications of diabetes are not only serious but also costly. In 2007 the total estimated cost of diabetes in the United States was $174 billion of which $58 billion was used for treating the chronic complications of diabetes.[79] Studies from other countries reported a similar burden of diabetes healthcare cost.[80-82]

Diabetes Mortality

The World Health Organization has announced that the average life expectancy of individuals with diabetes is shortened by 10-15 years.[1] Diabetes is one of the top ten leading causes of death in many countries around the world. Roglic

(2000) reported that burden of mortality attributed to diabetes in the year 2000 was 2.9 million deaths, equivalent to 5.2% of all deaths globally. The excess mortality attributed to diabetes accounted for 2%-3% of deaths in poorest countries and over 8% in the United States, Canada and the Middle East.[83] This situation was worsened by the fact that diabetes increased premature mortality. In individuals younger than 35 years of age and with diabetes, 75% of all deaths were attributed to this disease. In individuals with diabetes aged 35-64 years, 59% of deaths were attributable to diabetes while in individuals with diabetes and older than 64 years, diabetics accounted for 29% of all deaths. This makes the burden in terms of Disability Adjusted Life Years (DALYs) and Year Lost Disability (YLD) heavier in poorer countries, which doubles the burden of communicable and non-communicable diseases in developing countries.[84] In a global population-based study that analysed 959 000 deaths directly caused by diabetes, more than three-quarters were cardiovascular deaths attributable to higher than optimum blood glucose levels.[85]

Diabetes Management

Diabetes mellitus is a chronic disease that requires lifelong medical treatment and lifestyle adjustment. The main treatment goals are to prevent or minimise the acute and chronic complications of diabetes. In those unfortunate enough to already have the vascular complications of diabetes, the challenge is to delay their progression. This lifelong need to manage diabetes is challenging and daunting for people who have to manage their disease alone or with family members for more than 95% of their life span. Not only are they required to adhere to their lifelong daily medication intake but also lifelong lifestyle adjustment. Individuals with diabetes need to follow their meal plans daily, to lose weight if they are overweight or obese, engage in appropriate physical activity, monitor their blood glucose levels regularly, if not daily. They also need to make decisions regarding the adjustment of diet, physical activity level or medication if necessary, to avoid hypoglycaemia or hyperglycaemia and perform daily foot care and quit smoking if they are current smokers.

Diabetes Self-care or Self-management

People with diabetes must acquire the knowledge and skills through education to provide daily self-care in diabetes management which involves maintenance of healthy living, recognition and management of diabetes problems when they arise and taking preventive measures. To complicate self-care in diabetes management, the relationship between self-care and clinical outcomes are constantly influenced by multiple factors as shown in Figure 1. These factors include patients' biomedical variables; the psychosocial environment; the knowledge, attitudes and beliefs of patients themselves, home carers and health care providers; healthcare systems' accessibility and availability and even the national political context may influence these self-care behaviours.

Although self-care plays a critical role in successful diabetes management, most people with diabetes do not have the advantage of having continuous assistance and supervision from health professionals such as during the DCCT or UKPDS trials. Instead they spend more than 95% of their life outside their doctors' office to manage their self-care.[86,87] Helme (2004) and Legman (2005) found that only 7% to 25% of people with diabetes fully adhered to all aspects of the regimen.[88,89] Previous researchers reported that 40% - 60% of people with diabetes failed to comply with diet.[90,91] The frequency of non-adherence to glucose monitoring ranged from 30%-80% and non-adherence to exercise programmes was as high as 70%-80%.[90,92-94] Hence people with diabetes, their family members, and carers need to thoroughly understand the goals of diabetes management in order to successfully carry out the complex management strategies. It is important for health professionals to understand the factors that influence the self-care behaviours (dietary and medication intake, physical activity and SMBG) of people with diabetes. The above findings and needs form the rationale of the first research study which aimed to describe the problem of self-care practices in Malaysians experiencing poor glycaemic control. Since diabetes self-care includes increasing patient's skills and confidence in managing

their health problems, in this portfolio the terms 'self-care' and 'self-management' are used interchangeably.

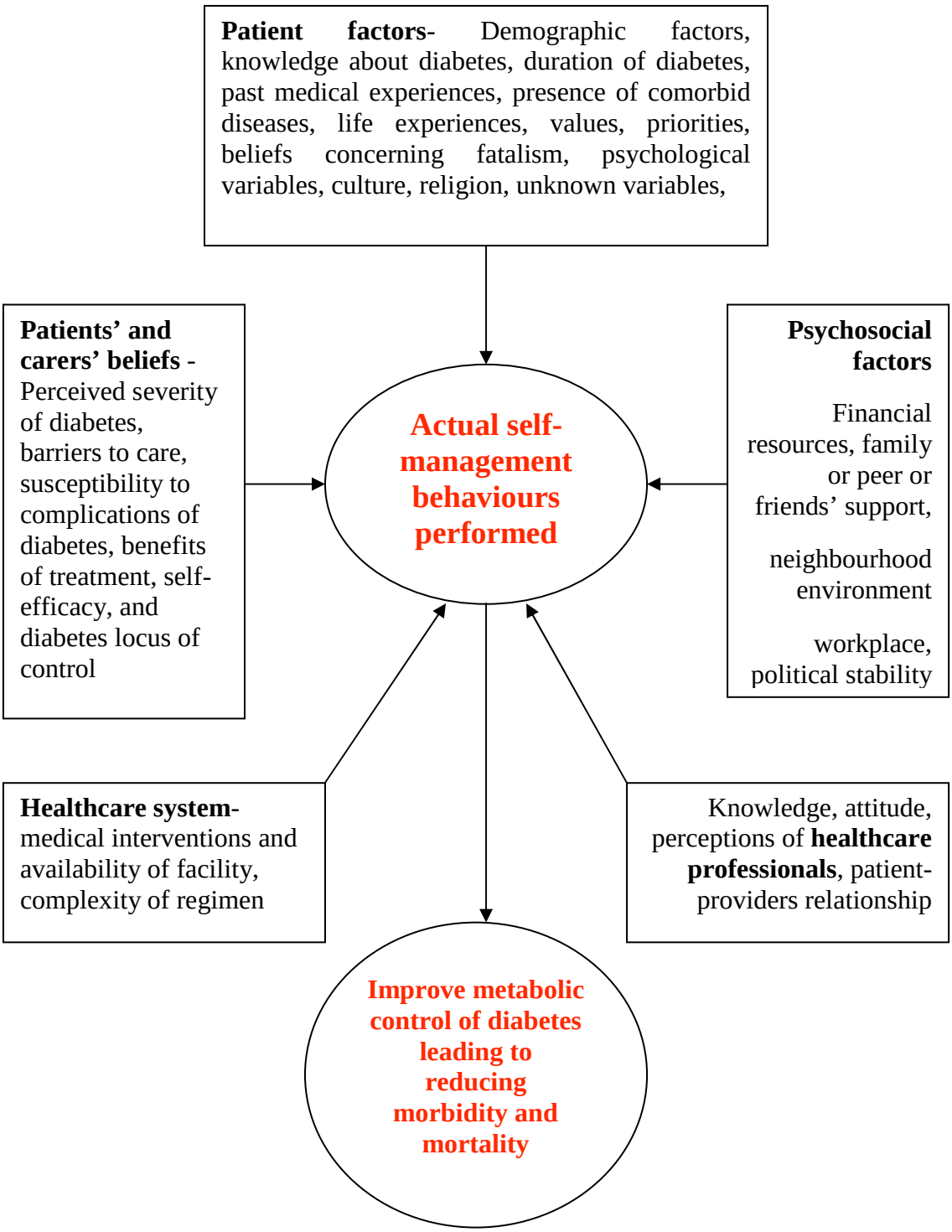

Figure 1: Complexity of Diabetes Management - Factors that Influence Self-management Behaviours and Metabolic Control of Diabetes

The Roles of Diabetes Education

The knowledge and skills needed for good self-care practices are acquired through diabetes education. Patient education has transformed and reinvented itself many times since its origins as early as Zulus Cornelius Celsius (25 BC to 50 AD) who promoted exercise and exhorted '*people with diabetes should try to be his own doctor'*. In 1921, Dr. Elliott Joslin from the Joslin Clinic in the United States was one of the first physicians to start diabetes education and emphasised to his patients the importance of monitoring urine glucose at home.[95]

Since then the traditional approach to diabetes education was for the healthcare professionals to teach people with diabetes about the disease and to demonstrate the skills necessary to monitor the condition and administer their own medications. This traditional diabetes education focuses on the transfer of information which often does not result in the desired change in behaviour or clinical outcomes.[96,97] This reflects a gap between what is being taught and what is being practiced by people with diabetes. To be effective, health professionals must change their approach to influence the self-care behaviour of people with diabetes.

As mentioned earlier, self-care in diabetes is constantly influenced by psychosocial, cultural beliefs and attitudes of people with diabetes and their carers. To be successful, people with diabetes have to plan strategies, set goals, implement treatment plans and motivate themselves to continue this life-long process. Hence the American Association of Diabetes Educators and the Australian Diabetes Educators Association have advocated that diabetes self-management education involving daily medication and dietary intake, SMBG and physical exercise is insufficient. People with diabetes should also be taught problem-solving skills, setting goals and practicing risk reduction behaviours by applying behavioural theory.[98,99] Since the 1980s many behaviour science theories had been incorporated in the management of diabetes and diabetes

education such as empowerment, Locus of Control, the Health Belief Model and self-efficacy. In the second research study of this portfolio, self-efficacy was incorporated in the education program to enhance self-care practices and clinical outcomes.

Diabetes in Malaysia

Malaysia is a multiethnic nation (principally Malays, Chinese and Indian) with a population of 27 million and is experiencing a diabetes epidemic.[100] In 2006, the second National Mortality and Morbidity Survey reported the prevalence of diabetes had reached 11% of the adult population as compared to the prevalence rate of 0.6% in the 1960s.[101] Many factors influence this massive increase in diabetes. With rapid economic growth in the last four decades, Malaysian society has followed the path of urbanisation, industrialisation and motorisation. This has resulted in the population becoming more overweight/obese and sedentary.[101] This is especially common in the young as well as the Malay and Indian female population.[101-103] Malaysian are living longer now because of improvements in nutrition and public health coupled with advances in medicine. The number of Malaysians aged 65 years and over increased by an average of 2.5% per annum between 1991 and 2000.[104] It is estimated that 4.5% of the 27 million Malaysians are 65 years of age and older.[100] In this age group, one in 3-4 people have glucose intolerance/diabetes. By living longer, the number of people with diabetes also increases.[4]

Problems of Diabetes Care in Malaysia

Vascular complications are common in Malaysians with diabetes.[41,105-108] The 14th National Renal Registry reported that 57% of all patients who required dialysis in Malaysia did so because of diabetic nephropathy.[109] Researchers who compared and evaluated the prevalence of strokes in Malaysia reported that 55% were diabetics[39,41] Previous studies done in Malaysia reported the majority of these individuals had poor glycaemic control regardless of types of diabetes, age or treatment centres.[106,110,111]

In a cross-section survey of diabetes care, glycaemic control and complication in children with Type 1 diabetes from the Asia and Western Pacific region, Malaysia contributed 8% of the study population. The total mean HbA1c of the 11 participating countries was 8.3%. In the same study, the Type 1 diabetics in Malaysia had the second highest HbA1c levels of 10.4%. Furthermore, when assessing the incidence of diabetes ketoacidosis, an acute complication, Malaysia tops the list with 26.3 events per 100 patient-years. Hence it was not surprising that only 36.6 events per 100 patient-years for hypoglycaemia event were reported by Malaysian subjects.[112]

The Economic Burden of Diabetes in Malaysia

With regards to some indirect costs, the Malaysian Burden of Disease and Injury Study reported that the total years of life lost (YLL) for the Malaysian population in 2001 was 1.7 million. Almost two thirds of this burden of premature deaths resulted from non-communicable diseases. Diabetes mellitus was eighth in the top ten causes of years of life lost (YLL) in Malaysia in 2001. In addition**,** the total burden of disability in the Malaysian population in 2000 amounted to 1.1 million years. More than four-fifths of this disability burden is due to non-communicable disease. Diabetes emerged as top fifth of the causes of Disability Adjusted Life Years (DALYs)[113]

The economic burden of diabetes in Malaysian healthcare cost is escalating. One study estimated the direct cost of outpatient treatment for the 60,000 diabetics registered with the Ministry of Health in Malaysia amounted to approxiamtely RM 14.5 million per year (equivalent to US $4 million).[114] The cost of haemodialysis and continuous ambulatory peritoneal dialysis (CAPD) in the Ministry of Health Malaysian centres has been estimated to be RM 169 per haemodialysis and RM 2180 per patient month for CAPD (US $1= RM 3.80). Each dialysis patient required three sessions of haemodialysis per week or 156 dialysis sessions per year, which accounts for RM 33,958 for haemodialysis and RM 32,343 for CAPD per patient each year.[115] The above estimated cost only

involved the basic dialysis treatments which did not include other treatment modalities of dialysis patients like the Erythropoietin injections. These accounted for RM 66,000 every year per patient to maintain the haemoglobin level between 8g/dl-10g/dl, prescribed medications, investigations, procedures or hospitalisation costs not to mention patients'own indirect cost, for example transportation to and from dialysis centres and loss of income.[116]

Summary

People with diabetes have hyperglycaemia which causes metabolic perturbations that lead to long-term vascular complications of the disease. Landmark clinical trials have provided convincing evidence that improving glycaemic control prevents the onset and delays the progression of microvascular complications. Lowering hypertension also does the same in addition to decreasing CHD and CVD. Lowering LDL-Cholesterol and raising HDL-Cholesterol in people with diabetes decrease CHD morbidity and mortality. To achieve these treatment goals, people with diabetes must not only be educated about them but also practice self-care to implement the strategies of the treatment plan.

In 2006, more than one in 10 Malaysian adults had diabetes. Published studies show that the majority have poor glycaemic control and have acute and chronic complications of diabetes. To reduce the high burden of diabetes and improve quality of life in Malaysians with diabetes, some effective and meaningful interventions to improve glycaemic control must be implemented. One approach is to enhance positive self-care in people with diabetes to improve their glycaemic control. Before developing a pragmatic and practical plan, the magnitude of the self-care practice problem in Malaysians with poor glycaemic control must be defined and studies demonstrating effective intervention must be conducted. These formed the rationale and basis of the two research studies described in this portfolio.

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Section 2

Research Study 1

Self-care Practices of Adults with Poorly Controlled Diabetes

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ABSTRACT

Purpose: The purpose of this study was to investigate the self-care practices of adults with poorly controlled diabetes.

Background: Previous studies done on Malaysians with diabetes have reported suboptimal diabetes control and a high prevalence of acute and chronic complications. Lack of self-care practices had been reported as a major contributor to poor diabetes control.

Research design and methods: This descriptive study explored the self-care practices of 126 adults with poorly controlled diabetes from two urban and two rural settings. Using a one-to-one interviewing approach, assessment was based on a 75-items questionnaire which included diabetes knowledge on diet, medication, exercise, self-monitoring of blood glucose (SMBG), diabetes complications and practices of self-care in the preceding seven days. To identify the relationship between diabetes knowledge or self-care practices with demographic data, Pearson's correlation or Spearman's rho correlation coefficient was used. Chi-square, Mann-Whitney U, Kruskal-Wallis test and ANOVA were used to detect any differences between the above variables.

Results: Most subjects perceived the importance of diet (96%), medication adherence (99%), exercise (94%) and SMBG (67%) in diabetes management. Subjects also stated that they had been advised on diet (96%), exercise (87%) and SMBG (59%). Yet, 53% of subjects scored poorly (less than 50% correct) in diabetes-related knowledge assessment. Only 6%, 61%, 64%, 34% and 79% of them achieved above 50% scores in diet, medication, exercise, SMBG and diabetes complication knowledge assessment respectively. The above suggested a discrepancy between diabetes education and self-care practice.

In dietary self-care, 80% of subjects consumed four and more meals daily and 80% did not include their regular sweetened food intakes in their daily meal plan.

Subjects in the above two groups had higher mean fasting blood glucose levels (p=0.04). Forty-six percent of subjects did not adhere to their medication intake and these subjects tended to have higher fasting blood glucose levels. Fifty-four percent of subjects were inactive in daily life and they had higher fasting blood glucose level (p=0.04). Only 15 % of subjects practiced SMBG and of these only 4% tested four or more times during the preceding week. There was no statistical difference in mean fasting blood glucose levels between those who practiced SMBG and non-testers. Subjects who were advised on exercise and SMBG were more likely to practice it (p=<0.01).

Predictors of knowledge deficit and poor self-care were low level of education (p=<0.01), older subjects (p=0.04) and Type 2 diabetes subjects on oral medication (p=<0.01).

Conclusion: The results of this study indicated that there were diabetes-related knowledge deficits and inadequate self-care practices for most of the diabetic patients with poor glycaemic control. While they perceived the importance of various aspects of self-care and had received advice on self-care, they did not practice them.

Keywords: Diabetes; Poor control; Self-care

Chapter 1

INTRODUCTION

Context of the Study

The previous chapter discussed the rapid increase in global incidence and prevalence of diabetes especially in Asia. Malaysia has not been spared from the epidemic due to its rapid socio-economic growth. This is reflected in the increase in diabetes in Malaysia over the last few decades rising from 0.65% in 1960 to 2.1% in 1982, 8.4% in 1996 and 11% in 2006.[1,2] In response to the diabetes epidemic over the last decade, the government has increased resources such as diabetes and nutritional education facilities mainly located in the urban hospitals and main rural healthcare centres.[3] However, there are less than 500 trained diabetes nurse educators or dieticians in the current healthcare system for about 2 million Malaysians with diabetes. Previous studies done in Malaysia have shown a high prevalence of suboptimal diabetes control and also high incidence and prevalence of chronic diabetes complications among the study subjects.[4,5]

Despite advances in the management of diabetes, one reason identified in other studies for the high prevalence of suboptimal diabetes control is lack of self-care and adherence to medical treatment.[6,7] Self-care practices of individuals are influenced by a complex interaction of biological and psychosocial factors, attitudes and beliefs of the individuals with diabetes. Despite the abundance of studies on self-care practices, little is known about self-care practices of individuals with diabetes in Malaysia. One approach to improve glycaemic control and reduce diabetes microvascular complications is to focus on individuals with poorly controlled diabetes because they are at higher risk of developing diabetes complications.[8,9] Before designing an intervention such as a diabetes self-management education program to enhance self-care practices, it is important to understand the current self-care practices of Malaysians with diabetes. Hence this study was undertaken at urban and rural healthcare centres in Malaysia to explore the different aspects of self-care practices that are related to glycaemic control.

Purpose of the Study

The purpose of this study was to investigate the four daily self-cares practices which are important cornerstones of overall diabetes management, namely dietary intake, medication use, physical activity and self-monitoring of blood glucose (SMBG) of adults with poorly controlled diabetes. The study findings may provide healthcare providers with a better understanding of the daily self-care practices of individuals with diabetes in Malaysia where little research has been done.

Statement of the Research Questions

This study addressed the following research questions regarding Malaysians with diabetes and poor glycaemic control.

Research Question One:

1. Is there a knowledge deficit about diabetes self-management among diabetic adults with poor glycaemic control?

Research Question Two:

2. What are the dietary practices of diabetic adults with poor glycaemic control?

Research Question Three:

3. What are the medication adherence practices of diabetic adults with poor glycaemic control?

Research Question Four:

4. What are the physical activity practices of diabetic adults with poor glycaemic control?

Research Question Five:

5. What are the self-monitoring blood glucose practices of diabetic adults with poor glycaemic control?

Significance of the Study

It is hoped that the study findings will provide important insights into the self-care practices regarding poor glycaemic control in Malaysians with diabetes. Specifically this study analyses knowledge deficit contributes to poor self care, as knowledge is an important prerequisite for positive self-care practices in diabetes management. In addition, it may help to identify specific characteristics, facilitators and barriers to each self-care practice. This information will assist nursing staff to develop effective strategies for improving the current self-care education in Malaysia.

Assumptions

Three principle assumptions that underpin this research study are:

Individuals with diabetes are inclined to perform self-care to improve their clinical outcomes.

Hunt and colleagues (1998) reported that 51 Mexican-Americans with Type 2 diabetes were all concerned about their diabetes and made efforts to control it. However, none were able to follow the recommended treatment completely, not because of lack of interest in self-care but due to the complexity of the regimen.[10] Other researchers have reported similar findings with variation in the degree of self-care which forms the first assumption of this study.[11-13]

Lack of self-care behaviour in poorly controlled diabetes is related to knowledge and skill deficits.

Self-care directed at the maintenance and promotion of health is a learned activity that requires specific knowledge and skills. Hence diabetes knowledge is a prerequisite in diabetes self-care. With limited resources in Malaysia's healthcare

system, diabetes education is not available to all. There is a reliance on general practicing nurses and doctors to deliver diabetes education, despite the fact that they may lack the necessary knowledge, skills and experience. This observation is supported by the results of three audits on diabetes management in 22 primary care settings in Malaysia. They reported lack of education facilities with knowledge deficit in both doctors and patients which form the second assumption of this study.[14,15]

Self-care conduct is a complex issues influenced by both external and internal factors

This assumption is based on the investigator's 20 years experience working in the field of diabetes in Malaysia. In the current healthcare system, referral by physicians for diabetes education is not a standard practice.[16] Furthermore, health education in the government healthcare system is usually conducted in the national language - Bahasa Malaysia. Being a multi-ethnic society, 35% of the Malaysian population is non-Malay. Many non-Malay patients aged 50 years and more are functionally illiterate in Bahasa Malaysia which poses a language barrier during diabetes education sessions. Furthermore, most patients who attend government healthcare facilities are relatively poor. Hence costly monitoring equipment is beyond their means.

The above assumptions underline the need to examine self-care practices of adults with poorly controlled diabetes from a holistic view in order to understanding their problems better.

Definition of Terms

Certain terms, which are used extensively in this study, are defined below

Type 1 Diabetes Mellitus

Type 1 diabetes is caused by autoimmune damage to the pancreatic beta cells resulting in failure of insulin production and secretion leading to absolute insulin deficiency. Hence individuals with Type 1 diabetes are prone to ketosis in the

basal state and depend on life long exogenous insulin injection to prevent ketosis and sustain health. It involves about 1% to 15% of the diabetic population worldwide depending on geographical locations. It occurs primarily in persons younger than 40 years but can also occur at any age.[17]

Type 2 Diabetes Mellitus

Type 2 diabetes occurs as a result of insulin resistance with relative insulin deficiency. Patients with Type 2 diabetes are not ketosis-prone under normal condition. Environmental factors such as obesity and sedentary lifestyle play an influential role. Genetics play a major role. Type 2 diabetes constitutes 85% to 95% of the diabetic population globally. The majority of Type 2 diabetics are adults above 40 years of age. However, it may also occur in younger age groups. The global prevalence of young Type 2 diabetes has increased in the last two decades.[17]

Self-care or self-management

Diabetes self-care or self-management behaviour is an active, cognitive process in which individuals with diabetes adhere to treatment regimens, exercise preventive measures to avoid or delay complications and to improve general well-being.[18]

Glycoslated haemoglobin (HbA1c)

Glycoslated/glycated haemoglobin results from linkage of glucose to erythrocyte haemoglobin. Because the average erythrocyte lifespan is 120 days, the HbA1c level is proportional to ambient blood glucose level during the previous 2 to 3 months. Hence, HbA1c level has been used as an index of long-term glycaemic control and has been associated with decreased incidence of microvascular diabetes complications. The recommended goal of HbA1c is ≤6.5%. HbA1c correlates with the mean daily blood glucose.[19]

Poor Diabetes Control

Glycated haemoglobin (HbA1c) is the gold standard of glycaemic assessment. However due to lack of availability of the HbA1c results in study settings, in this study, poor diabetes control is defined as the mean of minimum three fasting blood glucose levels of more than 7mmol/L in the last year.[20-22] The normal fasting blood glucose level ranges from 4 - 5.6 mmol/L.[21] Monnier *et al* (2003) showed that when the HbA1c is greater than 8.4% in people with diabetes, fasting blood glucose influences HbA1c more than postprandial blood glucose.[23] In the absence of mean daily blood glucose, fasting blood glucose is an acceptable surrogate.

Good Diabetes Control

Good diabetes control is defined as the mean of minimum three fasting blood glucose levels of 7 mmol/L and less in the previous year.[20-22]

Summary

There is increasing incidence and prevalence of diabetes in Malaysia and high prevalence of suboptimal diabetes control lead to diabetes complications. A possible contributing factor to poor glycaemic control is lack of self-care practices among the individuals with diabetes. However there is paucity of information on self-care behaviour of such people in Malaysia. This chapter discussed the need to understand the self-care practices of people with poorly controlled diabetes. Five research questions were identified and their underlying assumptions discussed. The next chapter will review the relevant literature and Chapter 3 will discuss in detail the methods and choice of statistical analysis used in this study. The results of the data analysis are reported in Chapter 4. In Chapter 5, the major findings of this study and their significance in nursing practice are presented and discussed.

Chapter 2

LITERATURE REVIEW

Introduction

This chapter aims to review the contemporary issues surrounding self-care practices in diabetes management. It begins by reviewing the significance of self-care in diabetes management. This is followed by an analysis of self-care in diet, medication intake, physical activity and self-monitoring of blood glucose (SMBG) in relationship to glycaemic control. Each area is reviewed separately because different factors affect different self-care practices. It then summarises the data by examining the implications for this study.

The literature review was undertaken using the following database: MEDLINE, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Psychological Literature Database (PsycINFO) and Cochane library. Data housed at the Joanna Briggs Institute was accessed and dissertations on this subject were also utilised. The search strategy used the terms: 'self-care or self-management' linked to 'adult and Type 2 diabetes or non-insulin-dependent-diabetes or Type 1 diabetes or insulin-dependent diabetes and 'poor glycaemic or diabetes control'. Subsequently, each of the self-care practices was searched separately using 'adherence or compliance or concordance' with 'diet or nutrition'; 'exercise or physical activity or leisure activity or non-leisure activity'; 'medication intake or consumption'; and 'self- or home monitoring of blood glucose'. The articles included in this review were published from 1980 to 2006 due to changes in self-care practices with advances in diabetes management such as SMBG becoming popular after 1980.[24] Only English language journals were reviewed due to limited translation facilities.

Significance of Self-care in Diabetes Management

The results of the Diabetes Control and Complication Trials (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) had shown that

individuals who adhere to daily self-care of diabetes followed a meal plan, take medication as prescribed, exercise regularly and monitor their blood glucose levels usually achieved better short- and long-term health outcomes.[8,9] This is because more than 95% of diabetes self-care tasks involved the individuals with diabetes and/or their family members.[25,26]

Despite positive outcomes from self-care interventions, the incidence and prevalence of low adherence to self-care in diabetes management has not changed over the decades. Several possible explanations have been explored. The process of self-care for diabetes is different from acute illness because it involves both maintenance and management. Besides maintaining daily self-care as previously discussed, the management phase requires individuals with diabetes to recognise signs or symptoms of diabetes complications, respond and treat symptoms, evaluate and monitor the effectiveness of the chosen treatment.[27] It is necessary to integrate all these behavioural tasks into a person's daily routine which is constantly influenced by available resources, priorities, social responsibilities, health literacy and level of autonomy.[12,28-30] However, the beneficial clinical outcomes of diabetes self-care practices are not seen immediately. This is unlike arthritis, where self-care improves daily function and quality of life thus increasing the adherence rate.[31] Furthermore compared with self-care management of asthma, hypertension or heart failure, self-care practices in diabetes are more numerous, complex, involving lifestyle changes, expensive in terms of SMBG and restrictive especially in dietary self-care.[10,32-34]

To do diabetes self-care in daily life, diabetes knowledge is necessary. Studies of British Pakistani women and illiterate patients have indicated a gradient of improved diabetes knowledge with better self-care and glycaemic control.[35,36] Other researchers reported knowledge explained 16%-17% of the variance in HbA1c.[37-39] In contrast, some researchers have reported increased diabetes knowledge correlated with poorer self-care and glycaemic control.[40,41] One possible explanation was that patients with greater access to education were also those with longer duration and advanced complications.

Summary

Diabetes self-care is complex and often leads to difficulty with adherence to regimens. In view of the controversial findings that diabetes knowledge enhances self-care and glycaemic control, in this study the first research question explored these issues.

Previous researchers reported that different factors influence different self-care practices in diabetes management.[42-44] Hence each self-care practice was examined separately to assess its role in glycaemic control, prevalence, facilitating or barrier factors that influence the self-care practice.

Dietary Self-care

Dietary glucose from carbohydrates contributes to the prevailing blood glucose level. Nutritional intervention improves glycaemic control of individuals with diabetes.[45-47] Subjects with the lowest dietary adherence had the poorest glycaemic control.[48,49] Additionally, lifestyle modifications (nutritional and exercise interventions) reduce diabetes complications by improving cardiovascular risk factors like hypertension, dyslipidemia and weight reduction.[50-53]

Prevalence of Dietary Adherence

Researchers in the United States, Europe and Asia reported that 40%-90% of individuals with diabetes had received dietary education. However across these continents less than 40% of both Type 1 and Type 2 people with diabetes followed strict dietary requirements and 10% -25% did not follow any meal plan. The majority sought to balance their dietary habits with some recommendations. This illustrates the widespread difficulty in adhering to dietary recommendations and the discrepancy between diabetes knowledge and self-care practices.[6,54-59] It also implies other factors influence dietary behaviour.

Factors Affecting Dietary Adherence

Several researchers have reported that some women with diabetes were more obsessed with food and practiced binge-eating when experiencing times of depression.[49,60] Furthermore the multiple care roles that women accept requires them to balance their personal needs with those of the family resulted in less adherence to dietary habit.[49,61,62] A study with predominantly male subjects supported the above findings, with its subjects listing emotional factor and food craving as minimal dietary barriers.[63] In contrast the results of another male dominated study (n=242) indicated an association between dietary non-adherence and depression, but the finding was not statistically significant.[48]

Some researchers have reported that there is no gender difference in dietary adherence. It is postulated that female subjects with better family and social support are able to follow the recommended diet.[7,13,49,52,61,64] Another study that used both survey and focus group interviews to assess the association of family support and dietary adherence reported significant findings from focus group interviews, but not survey. However, it was not clear whether both the survey and focus group subjects were from the same study population.[63]

Several researchers reported age was inversely associated with poor dietary adherence with no cause inferred due to study design limitation.[13,48,54,55] Irregular meal patterns and lack of consistency of day-to-day carbohydrate intake in conventional diabetes regimens contribute to poor glycaemic control.[46,65] Thus rigid meal schedules with lack of self-efficacy in time management of meal schedules during working and social hours pose dietary problems especially among the younger subjects.[13,48,63,66]

Researchers have reported a high prevalence of depression amongst the diabetic population globally. Subjects who were depressed had problems with acceptance of diabetes. They considered self-care to be a low priority resulting in little dietary adherence leading to poor metabolic control.[49,55,60,67-69]

Researchers studying the physician-patient relationship have reported its contribution to dietary adherence through increased understanding and

satisfaction.[67,70] This finding is supported by other studies that have observed a positive association between poor physician-patient relationship and dietary non-adherence behaviour.[58,63,64,71,72]

Sherman and colleagues (2000) discussed the unique issues and barriers to dietary adherence in contrast to adherence to physical activity or medication regimen. Throughout history, diet has been closely associated with social, cultural and religious assumptions and it varies widely with seasons and holidays.[67] Traditional South Asia diets are often high in fat and sugar content.[73-75] Although diet self-care behaviour is deeply rooted in culture, few studies have explored this issue. Among male Kashmiri men in the United Kingdom, there was a cultural norm that overweight figures reflected prosperity and well-being. The attitude of the study subjects was to enjoy life and 'leave the rest to Allah'. The limitation relating to this study was predominantly male subjects. Thus the results could not be generalised to women.[76] Other studies that involved the South Indian Asian Muslim did not find the same religious beliefs. The issue may not have been directly explored.[77,78] Prior eating practice has been shown to be a strong indicator of dietary behaviours.[58,64]

Summary

Poor dietary adherence leads to poor glycaemic control. Due to cross-sectional designs and most previous studies being done on convenience samples, causality could not be determined. Longitudinal studies on random samples are needed to assess the relationship of the above barriers to dietary self-care over time. Few studies were found on Malaysian dietary habits especially among diabetic.[79,80] Despite the similarity of cultural and religious influence in dietary practice for Muslim patients in previous studies and the local Malay population, the Malays constituted 65% of the Malaysian populations only.[81] Other dietary barriers like cost of green vegetables are not a local problem due to climate.[61,63,64] Hence there is a pressing need to explore the dietary behaviour of local subjects in order to understand the cause of poor glycaemic control.

Physical Activity

Physical activity increases glucose utilisation in muscles and fats and thereby influencing the prevailing blood glucose level.[82] In people with diabetes (Type 1 and Type 2), regular aerobic exercise has been shown to improve glycaemic control, reduce cardiovascular risk factors, weight reduction and improve general well-being.[83-85] A recent study on geriatric fitness program for diabetics over 65 years of age showed reduced mortality over a 10-year period. However, the small sample size and supervised research setting limit the generalisation of these findings to other clinical settings.[86]

Prevalence of Physical Activity

National surveys on physical activities of individuals with Type 2 diabetes in the United States (n=1985) and the United Kingdom (n=406) showed that 31% had no regular physical activity. Another 34%-38% of these individuals' exercised less than recommended levels and only 9% exercised sufficiently to achieve clinical benefits.[57,87-90] Similar findings were reported in South Korea (n=400), Taiwan (n=700), Canada (n=49), Australia (n=8881) and Greece (n=3042).[54,91-94] The actual non-adherence practice could be over-inflated as most studies were based on self-reported data.[95] On the other hand, studies that assessed only leisure physical activities such as walking and gardening could underestimate the findings if the subjects were poorer or predominantly female.[57,88,90,94,96] Therefore the results of these studies must be interpreted with caution.

Factors Influencing Physical Activity Self-care

Predictors for inactivity include negative attitude towards exercise like physical discomfort or illness, lack of family and social support, lack of confidence and time, depression and environmental barriers.[89,97-100] These findings' validity is supported by researchers who also reported that self-efficacy and family supports are important predictors for performing physical exercise.[13,88,91,92,98,101,102] Other predictors of exercise were previous experience with exercise and perceived benefits. The cross-sectional design, however, prevents causality being determined in the above studies.[13,88,91,92,98,101-103] Another survey (n=375)

reported that only 38% of the subjects were given advice by their healthcare providers on exercise in comparison to 90% being advised on diet and weight loss. Lack of direct comparison between perceived advice and actual advice received weaken the validity of this finding[104]

Studies done on Pakistanis and Indians with Type 2 diabetes in the United Kingdom have highlighted other social and cultural barriers to exercise self-care. Amongst Pakistani and Indian families, family welfare was valued higher than individual self-care. Taking time out to exercise could be interpreted as a selfish and culturally inappropriate act. Many women in the study also found it difficult to increase their physical activities due to lack of socialisation skills and culturally sensitive exercise facilities.[62]

Demographic factors reported mixed results as determinants of exercise. Several studies found younger subjects exercise more than older subjects.[88,90,94,102,105] Plontikoff and colleagues (2000) reported no significant difference between age groups. However 90% of their study subjects (n=69) were under 55 years of age. [92] Lower socio-economic status was found to have significant association with inactivity in studies reported by Nelson and colleagues (2002) but not by Hays and Clark (1999). Seventy-eight percent of the subjects in Hays and Clark's study were socio-economically poor in comparison to 20% of subjects in Nelson *et al* [57,88] Several studies using the survey approach found women exercised less than men. This could be due to assessment bias as only leisure activities instead of total daily activities were measured.[57,66,88,90,106]

Recent studies found ethnicity correlated to level of physical activity.[10,62,107-109] These studies showed lower levels of physical activities and fitness among diabetic and non-diabetic Asian populations compared to the general or Caucasian population. Although the sizes of the different reports varied across studies, they were broadly consistent and not related to method of measurement. No reason was stated due to observational design.

<u>Summary</u>

The evidence regarding the prevalence of exercise has to be interpreted with caution as many studies only included leisure activities. To improve glycaemic control, achieving recommended exercise intensity, duration and frequency are essential. Since few studies on physical activities of general or diabetic people in Malaysia were found and Asian people have been reported as being less active in contrast to Caucasians, further investigation is warranted. Bearing in mind the limitations in previous studies, to enhance study validity in Malaysia, the assessment tool needs to include both leisure and non-leisure activities.

Medication Intake

In people with diabetes, depending on the anti-hyperglycaemic medication prescribed, different medications reduce the blood glucose level via different mechanisms. For example, metformin primarily decrease the hepatic production of glucose. Thiazolidinediones primarily decrease insulin resistance and increase utilization of glucose in muscles and fats. Insulin and sulphonylurease increase insulin secretion and decrease hepatic glucose production and increase glucose utilisation. Alpha glucosidase inhibitors slow the digestion of complex carbohydrate and delay their absorption. Adherence of medication intake therefore can influence the prevailing blood glucose in many ways.

Prevalence of Medication Adherence

Results from studies on diabetes medication non-adherence vary widely between 36%-93% depending on measurement method, number of medications assessed and treatment mode.[54,110-114] More studies had been conducted on adherence to oral anti-hyperglycaemic medication (OAM) rather than insulin usage due to difficulty in assessing insulin accuracy. This in term is due to self-adjustment and wastage during insulin preparation.[111-113] When comparing the two treatment modes among Type 2 diabetic subjects, some researchers reported a lower adherence rate with insulin injection (73%) as compared to OAM (84%)[114,115] However one study found no difference between the two modalities.[116] The difference between the findings could be a methodological difference.

Relationship of Medication Adherence and Glycaemic Control

Earlier studies found no association between medication adherence and HbA1c reduction.[117,118] In recent years, both prospective and retrospective studies had shown significantly better adherence to glycaemic control ($p<0.05\%$) regardless of measurement approach and number of medications administered.[119-122] The negative findings in earlier studies were probably due to small study population samples and shorter follow-up period of less than 24 weeks compared to the later findings.[121] Despite these known consequences, adherence rates have remained unchanged since the 1970s which means that exploring other factors concerning medication adherence is justified.

Factors Related to Medication Adherence

Most people with Type 2 diabetes eventually require multiple medications to achieve glycaemic control because of its progressive deterioration of beta-cell function.[110,114,123] Medication adherence is influenced by the patient, medication and the healthcare system factors.

Patient Factors

Lower–socioeconomic status leading to depression, financial problems, lack of knowledge and poor social support are significant factors in medication non-adherence.[114,124-128] The relationship between medication non-adherence and demographic variables is inconclusive. Some studies have shown that younger patients are more compliant than older ones,[113,116] but other studies have contradicted the findings.[122,129] No causative relationship was ascertained due to lack of information. Some researchers reported shorter duration of disease was associated with better adherence but the findings were not statistically significant.[111,113,116]

Previous qualitative studies have highlighted different psychosocial factors related to medication non-adherence among Asian people in Western countries. In these studies the subjects were worried about drug dependence, tolerance, addiction, interacting with traditional medication and potential harm with long-

term usage. Hence they only used medicine symptomatically and replaced the medication with alternate remedies to reduce cost.[62,109,130]

Medication Factors

There is a consistent finding of decreased medication adherence with complexity of treatment like polypharmacy therapy, multiple daily dosing and medication side-effects.[111,113,115,116,120,127,128,131] In contrast, Grant and colleagues (2003) reported high medication adherence rate (6.7 ± 1.1days/7days) despite polypharmacy therapy (4.1 ± 1.9 pills daily) in 123 subjects. In this study the subjects were predominantly Caucasians with little or no financial difficulties. In addition, the subjects were informed that their responses would be communicated to their primary care physicians which could have resulted in over-reporting.[132] A systematic review assessing medication adherences based on the gold standard of electronic-cap monitoring reported that mean dose-taking compliance was 71%. This declined as the number of daily doses increased and subsequently confirmed the validity of earlier findings.[133]

Healthcare System

A study conducted in New Zealand found good patient-physician communication improved medication adherence by one-third when compared to control group.[134] Other researchers reported the same findings, although the validity of most of these studies was limited by self-report.[121,128,135,136]

Summary

Low adherence to medication intake undermines the effect of care. Although previous studies had examined the medication intake behaviour of migrant Asian populations in the developed countries, these findings cannot be generalized to the local population due to differences in healthcare systems and psychosocial factors.[62,130] Health care cost in Malaysia is highly subsidised in the public sector where this present study was conducted thus cost-related factor are less likely to be a concern. Few studies were done on Malaysians' medication intake behaviour. One study assessed the medication adherence behaviour among Malaysian hypertensive patients. The findings in this study were biased by its inclusion

criterion of hypertensive patients without other co-morbidity which could have limited the number of medication taken.[137] Current diabetes management encourages early initiation of insulin treatment to reduce morbidity and mortality.[138,139] However, few studies on insulin treatment adherence were reported due to factors addressed earlier. Finally, there is little data on medication intake in Malaysians with poorly controlled diabetes.

Self-monitoring of Blood Glucose

A revolution in diabetes management was the introduction of self-monitoring with blood glucose meters in the 1970s. It allowed people with diabetes to participate actively in their own care and improve how they controlled their health.

Prevalence of Self-monitoring of Blood Glucose

The Third National Health and Nutritional Examination Survey (NAHNES III) in the United States reported that 30% of insulin users, 65% of OAM users and 80% of diet control diabetics never practice SMBG or test less than once per month. Only 39% of patients on insulin and 5%-6% of those on oral drugs, tested more than once a day.[140] Several population-based studies in Italy, the United Kingdom, United States and the Netherlands revealed the same scenarios.[141-145] In contrast, a recent study from two rural health centres (n=698) with 69% of native Americans reported good adherence to SMBG practices (77%) in the previous four weeks. The difference in monitoring frequency between the studies could be due to the availability of insurance reimbursement and recommendation from the healthcare providers in the later study.[146] During the survey of NAHNES III in the early 1990s, only insulin users received insurance reimbursement for testing materials. A review of national data collected between 1994 and 2002 in the Behavioural Risk Factor Surveillance System had shown a consistent increase in SMBG prevalence from 36% in 1994 to 57% in 2002 when insurance coverage was extended to subjects on OAM.[146] Most of the above studies used surveys and thus the results need to be interpreted with caution.

Effectiveness of Self-monitoring of Blood Glucose

Type 1 Diabetes

Consistent findings of improved glycaemic control with increased frequency of SMBG with Type 1 diabetes subjects have been reported.[142,147,148]

Type 2 Diabetes on Insulin Therapy

Earlier studies did not find a beneficial effect from self-monitoring among Type 2 diabetes subjects on insulin treatment.[140,142,149,150] The authors of these studies acknowledged several limitations which included small sample sizes, inconsistencies in recommended monitoring frequency, lack of advice given on modification of therapy, insufficient duration and substantial loss to follow-up. A randomised controlled trial with 62 insulin users with Type 1 and Type 2 diabetes found improvement in HbA1c over 12 months compared to the control group (8.7% versus 9.9%). However, the small sample size and 34% attrition rate weakened the findings.[148]

More recent studies found increased frequency of SMBG and treatment modification were associated with better glycaemic and metabolic control. Yet the findings were limited by lack of information of other confounders like dietary change or exercise effects.[141,151,152] A longitudinal survey over 12 months with intensive SMBG four time daily for eight weeks followed by less intense frequency for 44 weeks reported significant reduction of HbA1c among those who adhered to >75% of SMBG practices. However, it did not report the glycaemic control of those who tested less frequently which could have affected the overall results.[48]

Type 2 Diabetes on Oral Anti-hyperglycaemic Medication

An earlier systematic review based on 11 studies found no association between SMBG with glycaemic control for patients on OAM. All the studies in this systematic review had small samples, 12-73 subjects, with only one study having longer than 6 months follow-up.[153] Another retrospective study using pharmacy databases (n=970) also reported SMBG was not associated with glycaemic

control. This study only reported the medium usage of 0.56 test strip per day with no information on frequency of testing. The subjects' baseline HbA1c ranged from 7% -7.7% which might have contributed to the negative outcomes.[154]

Two recent systematic reviews on the relationship of SMBG with glycaemic control using randomised controlled trials have been reported. The first by Sarol in 2005 analysed eight studies which included 1307 subjects with duration of 12-44 weeks reported SMBG as part of a multi-component management produced a mean reduction of HbA1c by 0.42%. Wlesch in his 2005 systematic review which included six studies also reported a 0.39% decrease in HbA1c with treatment adjustment compared to control group. Both systematic reviews were methodologically sound and included studies from several databases. However they were limited by the quality of the primary studies.[155,156] Two randomised control trials reported reduction of HbA1c by 1% compared to 0.54% for the control group with meal modification based on SMBG readings.[157,158] Although the role of SMBG in Type 2 diabetes regarding both OAM and insulin treatment is inconclusive, recent evidence is emerging that it has a beneficial effect.

Factors Affecting the Effectiveness of SMBG

Karter and colleagues observed an association between increased frequency of monitoring with better glycaemic control in a managed care population (n= 23 312) regardless of type of diabetes or therapy.[147] Similar findings were reported in other community-based studies.[158-160] In contrast, other studies found glycaemic deterioration with increased monitoring frequency among poorly controlled individuals with Type 2 diabetes on insulin treatment.[140,141] No cause-effect could be determined due to cross-sectional study designs. A randomised control trial (n=453) also reported non-significant glycaemic difference between Type 2 diabetes subjects who practiced frequent SMBG and standard care over 12 months' duration. This could be due to the baseline mean HbA1c of the subjects being 7.5%.[161]

Factors Affecting Adherence to SMBG

The prevalence of SMBG is consistently correlated with treatment mode. Insulin users practice more testing than subjects on oral medication and the least users were those on diet control.[140,149,159,162] Patients with Type 1 diabetes test more often than those with Type 2 diabetes.[144,145,147] Some studies found decreased testing frequency with depression and fewer physician visits.[41,163] Family support and self-efficacy were noted to increase testing frequency.[147,148,160,164,165] Cost is another significant predictor of less frequent monitoring.[147,148,160,164,165] Although Harris (2001) found no association between socio-economic status and SMBG frequency, 90% of his subjects had health insurance.[140] Other demographic factors were inconclusive. Cross-sectional design of these studies prevents causal inferences.

Summary

It appears that adherence to SMBG is suboptimal. The majority of previous studies were done in the Western countries. Information is poor regarding either the prevalence or factors associated with SMBG in Asian countries such as Malaysia.

Discussion and Limitations of Previous Studies

Previous literature frequently cited dietary and medication intakes, physical activity levels and SMBG as the cornerstone of diabetes management.[166-168] The reasons are the blood glucose level in any person is influenced by three major factors: [1] the glucose that originates from carbohydrates in the food digested, [2] the production of glucose from the liver in the person, and [3] the utilisation of glucose by the person's muscles and fats.[82] Dietary intake of carbohydrates allows assessment of the first factor. Medication intake allows assessment of the second and third factors. Physical activity allows partial assessment of the third factor. Self-monitoring of blood glucose allows the person to know his/her blood glucose and adjust his/her diet, medication and physical activity accordingly.

This literature review has shown that different factors influence different self-care practices in diabetes management. However, certain common characteristics were also found in the four self-care practices leading to poor glycaemic control. First, negative perception and depression were frequently reported to worsen all the 4 self-care practices.[41,70,169,170] Second, lack of family and psychosocial and economic factors were also associated with poor self-care practices in both healthy adults and diabetes population.[160,164,171] Third, observational studies have shown there is a relationship between inactivity with poor dietary habits in both the healthy and diabetic population.[99,170]

Various aspects of self-care practices in diabetes have been widely studied. However, most of these studies examined self-care practices in isolation. From the above reviews, it is shown that every aspect of self-care practice influences the glycaemic control of an individual with diabetes. Hence to achieve maximum clinical benefits, it is necessary to incorporate all the self-care practices in everyday life. However, there are few studies done on all aspects of self-care combined. Furthermore it is necessary to identify the problems involved in incorporating all self-care practices in daily life.

It may be argued that the practices of Asian populations in the developed countries like the United Kingdom or United States are also applicable in developing countries. However, it is clear that psychosocial and cultural factors influence self-care behaviour. This is illustrated by studies done in Sweden. In this research, male and female of Yugoslavs and Arabs in Sweden were more concerned about being employed and economically independent. Furthermore their migratory experience and former tradition influenced their self-care practices when compared to their Swedish counterparts who actively participate in self-care.[172,173] Since most studies on diabetes self-care were done in developed countries and few in the developing countries, this again demonstrated a need for research.

Despite unsatisfactory glycaemic and metabolic control among the diabetic population in Malaysia,[4,174,175] limited information was found on self-care practices in this country. To date, no study has been conducted on the self-care

practices of individuals with poorly controlled diabetes in Malaysia. Hence, this study was proposed to improve our understanding of the factors that contribute to the self-care practices of poorly controlled diabetes in a local context. It is particularly pertinent as firstly, these individuals are in greatest need of diabetes care. Second, it is evident that neglect of self-care leads to poor glycaemic control. Third, factors specifically associated with poor self-care can be identified. Finally, understanding these factors will help to improve future care for this subgroup diabetic population with increased morbidity and mortality.

Conclusion

Despite the vast number of studies done on self-care in diabetes, this chapter has highlighted a number of areas in our current understanding of self-care practice that warrant further investigations. Although empirical studies had shown that every aspect of self-care practice influences the glycaemic control of individuals with diabetes, there is a paucity of studies that include all aspects of self-care practices and the problems associated with incorporating them into everyday life. Furthermore, most studies had been done in developed countries and few in developing countries. Thus this study aimed to identify the self-care practices of adults with poorly controlled diabetes in Malaysia - a developing country. The next chapter will discuss the methods used in this study.

Chapter 3

METHODS

Introduction

This chapter describes the research design, framework, research methods and type of statistical analysis used in this study

Method

Design

This study aimed to describe the four important aspects of self-care, to understand and to identify any specific characteristics attached to the subjects with poorly controlled diabetes via their self-care behaviour. Hence a non-experimental descriptive cross-sectional design was chosen. A correlation study was considered but was not applicable due to the definition of poor glycaemic control as used in this study. No cause and effect relationship was intended.

Framework

Managing diabetes is a lifelong process and requires total commitment from individuals with diabetes. Hence the framework of this study was based on the principle of self-care which involved maintenance and management categories. The maintenance category of self-care in diabetes involves adherence to positive health practices. The management category of self-care involves recognition of signs and symptoms, implementing treatment options and monitoring the effectiveness of the treatment chosen. In this study, only the maintenance and not the management category of self-care was investigated because the later was not commonly practiced by local people with diabetes.

Setting

As 70% of people with diabetes in Malaysia receive treatment in the government healthcare system,[176] data were collected from four government healthcare settings: one urban general hospital, one district hospital and the two rural healthcare clinics in the state of Melaka. In the urban general hospital and the district hospital, subjects were recruited from both the medical in-patient wards and medical out-patient clinics. Subjects from the two rural healthcare clinics were recruited from the out-patient clinics only. The general hospital is the main government hospital in the state and is situated within the city area offering tertiary care. The district hospital offers secondary care and is situated in a smaller township more than 30 kilometres away from the city. The two rural healthcare clinics are primary health centres situated in different geographical directions within the state and more than 50 kilometres away from the city. Subjects were not recruited from private clinics and hospitals due to problems with accessibility and differences in socio-economic status which could bias the outcomes.

Sample

Sample Size

The required sample size was calculated with power analysis using the procedure provided by Polit and Hungler.[177] The power was set at 0.80 with alpha being set at 0.05. Since the value of the effect size (Gamma), was unavailable from previous similar studies and the pilot study sample size was small (19 subjects), the investigator chose to use the conversion based on the effect size convention table in Polit and Hungler (2004, p495).[177] Polit and Hungler (2004) advise to use medium effect size ranging from 0.2-0.3 for nursing studies.[177] This provided a range of sample size from 88-197 subjects. For logistical reasons the study had to be a manageable size within the period of study, so the investigator chose the sample size using the medium effect size of Gamma y = 0.25. To achieve a power of 0.8 with alpha set at 0.05, 126 subjects were required for the study.

Inclusion Criteria

Subjects who met the following criteria were recruited. They were:

- non-pregnant adults with either Type 1 or Type 2 diabetes regardless of gender and ethnicity
- 18 years and above (legal age for consent)
- diagnosed with diabetes a year or more
- speaking and understanding either English, Bahasa Malaysia, Mandarin, Chinese dialects (Cantonese, Hokkien, Teow-chew) because these were the languages used during the interview.
- having poor diabetes control during the last one year*

*Even though glycated haemoglobin (HbA1c) is the gold standard for glycaemic assessment, it was not consistently measured for all diabetic patients in the healthcare system where the study was done. Therefore for the purpose of this study, poor diabetes control was defined as the mean of minimum of three fasting blood glucose (FBG) readings of more than 7 mmol/L in the last year. Prior studies have shown that FBG of more than 7 mmol/L is associated with increased micro- and macro-vascular complications.[178-180]

Exclusion criteria

The following subjects were excluded. They:

- were adults 18 years of age and more with either Type 1 or Type 2 diabetes but unable to answer the questionnaires independently, such as having unstable medical condition, mental illness, senility or hearing impairment. This was to avoid assistance from family members or carers that could introduce bias in data collection
- had poor vision and unable to assess visually the portion sizes of their carbohydrate food intake during dietary assessment.
- were women who were pregnant or had gestational diabetes due to different criteria on standard of control
- had record of random blood glucose only because the definition of poor control was based on fasting blood glucose readings.

Research Instrument

Instrument Design

Several validated instruments have been used to assess the self-care practices of individuals with Type 1 or/and Type 2 diabetes. An example was 'The Summary of Diabetes Self-care Activities for Type 2 Diabetes'.[59] Although it measured the self-care practices of diet, exercise, blood glucose testing, foot care and smoking, the questionnaire was not culturally appropriate for local people as it used terms like 'meal plan' or 'exchanges' which were not familiar to them and the exercise assessment was tailored to leisure activities only. Another example was the 'Self-care Inventory' scale in which the assessment included insulin adjustment, food label reading, ketone testing which did not reflect the exact practices of the Malaysian population due to limited exposure to previous diabetes education.[181] Cultural, psychosocial and environmental factors influence self-care practices especially in regard to dietary habit and physical activity.[36,172] Hence, the validated self-care scales from the literature were unsuitable for local inhabitants. Since no previous self-care practice scales were found for the local people with limited diabetes education, a 70-item, diabetes self-care activities scale was designed by the investigator. It incorporated culturally appropriate items from some tools published in the literature.

The design of the tool 'Diabetes Self-care Activities Questionnaire' was guided by the 'Michigan Diabetes Research and Training Centre',[182] the 'Gordin Leisure-Time Exercise' questionnaire,[183] the 'Health Insurance Plan of New York Activity' questionnaire,[184] the 'Beacke Questionnaire of Habitual Physical Activity',[185] the 'Diabetes Self-care Activity Measure',[59] the 'Brief Diabetes Knowledge Test',[186] the 'Medication adherence chart' by Wong and colleagues [187] and guidelines on design of questionnaire.[188-190] The 'Diabetes Self-care Activities Questionnaire' consists of four major sections. (Appendix 1) The first section was previous glycaemic control within the last year (1 item) and the second section concerned the demographic data (8 items). No score is allocated for these two sections.

The third section assessed diabetes knowledge with 20 items. Knowledge relating to diet was assessed with 9 items. Medication, physical activity and self-monitoring of blood glucose knowledge were assessed with 2 items each. Knowledge on diabetes complications was assessed with 5 items. Thirteen items had multiple choice answers and the remaining 7 items used a Yes/No/Not Sure selection. One point was given for each of the correct answer with a maximum score of 20 points. No point was allocated for wrong or unsure answer.

The fourth section assessed the actual self-care practices that directly influenced the subjects' glycaemic control during the previous 7 days. It had 4 sub-sections namely dietary, physical activity, medication intake and SMBG practices. Assessment of all the self-care activities began with their perceived importance on each of the self-care activities. According to the perceived benefits of the Health Belief Model, if a subject's beliefs regarding the effectiveness of a treatment mode are solid then there is a higher chance of performing the activity.[191,192] Five-point Likert scales with '1' indicating 'Strongly Disagree' and '5' for 'Strongly Agree' were used to assess the perceived importance of each self-care practice. No score was allocated for perceived importance of self-care practices. The subjects were asked on their previous diabetes education and comprehension of the education received using open-ended questions. No score was allocated for previous advice given.

Dietary Self-care (14-items)

Due to many variables of dietary intake practices, only carbohydrate intake was assessed because this study was designed to identify the association between self-care practices with glycaemic control and not metabolic control. Studies have shown that consistent quantity and even distribution of carbohydrate food intake is important for people with diabetes on OAM or conventional insulin regimen.[193] Hence carbohydrate intake was assessed on both quantity and frequency in the preceding seven days using a number from '0' or '1' to '7' for items 3-11. Items 12-14 were assessed with a 5-points Likert scale.

Daily quantity of carbohydrate intake was assessed with items 4-11. Depending on the individual energy requirement, on average, good dietary habits were reflected on score of '3 to 5' for item 4-6, '0-2' for items 7, 8, 10 to 12. The score on item 12 was reversed. Any score above '5' for items 4-6, above '2' for items 7, 8, 10 to 12 indicated excessive carbohydrate intake as compared to recommendation. Items 3 and 13 assessed the frequency of carbohydrate intake. A score of '3-4' for item 3 and a score of '4-6' for item 13 indicated acceptable distribution of carbohydrate intake daily. Item 14 reflected the subjects' regular dietary habits over the last 3 months.

Medication Intake (11-items)

Medication self-care behaviour was assessed in three phases. First, the subjects' description of prescribed medication dosage and frequency was compared with the physician's prescription for concordance. Then the frequency of adherence (item-9) and self-efficacy (item-10) to medication intake in the preceding seven days were assessed using 8-point scale from 0-7. Lastly, the medication adherence percentage was calculated based on the actual total medication intake during the preceding week over the total prescribed dosage of the preceding week.[110] Most studies used 80% as medication adherence rate. However, previous studies have shown that each 10% of non-adherence to medication intake increased HbA1c by 0.14% to 0.16% which could significantly compromise the clinical outcomes.[120,122] Hence in this study medication adherence was defined as adherence to 90% or more of the prescribed medication in a day.

Physical Activity (16-items)

Physical activity assessment was divided into two sub-sections. The first section assessed non-leisure activities done during occupation/housework/college hours, which included their transportation to non-leisure activities. The second section assessed the subjects' leisure activities during the preceding seven days. For both sub-sections, a 5-point scale from 1-5 was allocated for each activity done. A '1' indicated least activity done and '5' reflected most activity done. The score of

item 3 and 12 were reversed. Activity levels for both sections were categorised as 'least active', 'moderately active' and 'most active' according to the score totals.

Self-monitoring of Blood Glucose (5-items)

The subjects' frequency of SMBG practices and any treatment modification done based on the blood glucose results were assessed using an 8-points scale from 0-7. High score indicates positive self-monitoring behaviour and low score reflects poor self-monitoring practices.

Common terms used in the questionnaire are defined in Table 1.

Content Validity

A panel of three diabetologists, three diabetes nurse consultants, three dieticians and two adult with Type 2 diabetes and one adult with Type 1 diabetes reviewed the questionnaire independently for face and content validity, relevancy and clarity prior to pilot project. All of them agreed that the questionnaire had good face validity as it reflected the daily self-care practices of an individual with diabetes. The contents of the questionnaire were appropriate with suggestions to improve its clarity such as, 'How many days did you miss your medication last week?' to 'Last week, how many times did you miss your medication?' as some people might miss one or two doses in a day but not the whole day. Common terms were defined such as 'gardening means digging and mowing the lawn and not watering pots or plants'. As 'meal plan' was not commonly understood by the local subjects, this item was changed to more culturally sensitive language such as 'control your diet'. To enhance validity of dietary assessment, the panel suggested the inclusion of the subjects' regular dietary history.

Table 1: Definition of Terms used in Diabetes Self-care Activities Questionnaire

Terms	Definition
Carbohydrate food and drinks	Food and drinks prepared with carbohydrate content regardless of its source
Carbohydrate serving	Measurement of the quantity of carbohydrate food consumed based on food exchange system. One carbohydrate serving is equivalent to 15 gm of carbohydrate.[193,194]
Sweetened food or drinks	Food and drinks with added glucose or sucrose.
Non-leisure physical activities	Activities related to occupation or house work or study and mode of transportation to the non-leisure physical activity.
Leisure physical activities	Sports- and exercise-related or non-sport- and non-exercise-related physical activities done during relaxation or hobbies or after working hours or housework.
Regular exercise	Physical activity done during leisure hours with moderate or vigorous intensity of minimum 30 minutes duration for at least 5 times a week. Moderate intensity physical activity includes brisk walking, bicycling, leisure swimming, popular and folk dancing that mildly increased heart beat or breathing. Vigorous intensity physical activity includes jogging, long distance bicycling, vigorous swimming, tennis, squash with rapid heart beats and breathing.[21,108]
Physically active	Involved in moderate or vigorous physical activity during occupational or housework that includes walking and lifting heavy items or heavy manual labour with increased heart rate and sweating.[85]

Pilot Project

A pilot study with 15% of the study population was conducted in the outpatient clinic of the private hospital where the investigator was attached. Nineteen subjects (17 Type 2 subjects and 2 Type 1 subjects) who met the inclusion criteria were invited to pilot test the questionnaire. All the subjects in the pilot study were interviewed after obtaining their consent to participate. The results of the pilot study were not included in the main study.

All the subjects said that medication self-care and SMBG questions were easily understood. The elderly and subjects with less education had problems quantifying their non-leisure physical activities, calculating the total meals and snacks taken per day or meal-time interval or number of carbohydrate drinks and sweetened food consumed in a day. To ensure accuracy and consistency, the investigator converted all carbohydrate quantity and frequency of food intake for all the participants. After the pilot study, four of the questions were rephrased. Findings of the pilot study showed that the interviewing time ranged from 24-40 minutes. The majority of subjects thought that the length of the questionnaire was just right. Five of them said that it was too long.

To standardise data collection for non-leisure activities, a visual analogue scale (VAS) with indicators of ‘0’, ‘25’, ‘50’, ‘75’, ‘100’ on a 210 mm horizontal line was developed to enhance the subjects’ conceptual understanding of quantifying their non-leisure activities in sitting, standing and walking. On the VAS, ‘0’ indicated minimum time spent; ‘25’ indicated less than half of the time spent; ‘50’ indicated half of the time spent; ‘75’ indicated more than half of the time spent and ‘100’ indicated maximum time spent on a particular activity. The above written answers in 4 different languages were placed directly below the respective numbers from 0-100 (Appendix 2). One study has shown that analogue lines shorter than 100mm increase error variance.[195]

Reliability

Internal consistency estimate was computed for knowledge assessment and the 4 sub-scales of self-care practices using Cronbach’s alpha from the data of the pilot

project and the present study. During the pilot study, initial findings ranged from 0.50 to 0.86 with an average score of 0.70. The knowledge assessment had a Cronbach's alpha of 0.86 and the 4 self-care sections values ranged from 0.50 to 0.65. According to the formula of Cronbach's alpha calculation, the coefficient alpha depends on average inter-item correlation among the items and total number of items.[196,197] Three aspects of heterogeneity of the underlying contrasts that lowered the inter-item correlation were identified. These were previous diabetes education received in all sections, (b) the four responses in the physical activity section that were frequently recorded as 'non-applicable' and (c) medication adherence rate. After removal of these items for separate analysis, the Cronbach's alpha values of medication intake self-care and physical activity self-care improved from 0.53 to 0.69 and 0.50 to 0.71 respectively as shown in Table 2.

To further improve the Cronbach's coefficient of the questionnaire, three extra items were added to medication self-care and two to SMBG in the final questionnaire of this study as these sections had the lowest number of items. Although the Cronbach's alpha values of medication intake self-care and SMBG improved from 0.69 to 0.70 and 0.70 to 0.71 respectively, the total Cronbach's alpha score of this study improved from 0.71 to 0.73 as compared to the pilot study (Table 3).

Table 2: Cronbach's alpha Results of Diabetes Self-care Activities Questionnaire in Pilot Study (n=19)

Category of Sections	Cronbach's alpha
Diabetes Knowledge	0.86
Dietary self-care	0.76
Medication intake practices	0.69
Physical activity self-care	0.71
Self-monitoring of blood glucose practices	0.70
Total score	0.71

Table 3: Cronbach's alpha Results of Diabetes Self-care Activities Questionnaire in Study 1 (n=126)

Category of Sections	Cronbach's alpha
Diabetes Knowledge	0.80
Dietary self-care	0.65
Medication intake practices	0.70
Physical activity self-care	0.72
Self-monitoring of blood glucose practices	0.71
Total score	0.73

In a meta-analysis of Cronbach's coefficient alpha (n=4,286), the mode of questionnaire administration was found to affect the alpha coefficients readings. Self-administered approach exhibited higher alpha coefficient (alpha =0.77) than interviewed administered scales (alpha coefficient 0.72). The difference was due to the different sample sizes used in the two approaches.[196] Thus the total Cronbach's alpha coefficient of 0.73 in this study was considered satisfactory.

Test-retest was considered but not chosen for the reliability test here as the pilot study was scheduled to last one month. A period of two weeks to one month is recommended between the testing intervals for a questionnaire.[177,198] Furthermore, test-retest findings can only be reliable if the questionnaire remained stable over time. In this study, the questionnaire concerned self-care practices over the preceding seven days. Different times might reflect different self-care practices.

The Flesch-Kincaid reading level of the 'Self-care Activities Questionnaire' was 8th grade. No readability test was done on Mandarin and Bahasa Malaysia for the translated version of the questionnaire as a readability test was not found by the investigator. The final questionnaire consisted of 75 items.

Ethical Issues

The Research Ethics Committee of the University of Adelaide (Appendix 3) and the Malaysian Medical Research and Ethic Committee approved the study (Appendices 4 and 5). The Director-General of Health, Ministry of Health Malaysia and the local Ministry of Health granted permission to do the research at the selected sites. Funding approval was obtained from the institute where the investigator was attached.

To assist the subjects in understanding the reason for the study, both the information sheet and consent form were written in four languages: Bahasa Malaysia, English, Mandarin and Tamil. An information sheet describing the study in the language of the subjects' choice was given to them to read or was read to them by the nurse-in-charge of both the out- and in-patient departments prior to consent taking (Appendix 6). The consent form in the language of the subjects' choice was read by the subjects or read to them by the investigator, if they were illiterate. Written consents which included information to access the subjects' medical records were taken from all participants before the interviews. For those who were illiterate and not able to give their signature, thumbprints were used instead.

The medical records were sourced for two pieces of information. First, the subjects' glycaemic status was attained namely fasting blood glucose levels to assist the investigator in identifying the potential subjects (inclusion criteria). Second, the subjects' current medication(s) were attained since research question three sorts to identify any relationship between medication concordance and poor glycaemic control. No other data was extracted from the medical records. Viewing and extracting information from the subjects' medical records was done solely by the investigator either at the medical in-patient wards or the medical outpatient clinics during official working hours.

Data Collection Procedure

Identification of Subjects

This was done initially by identifying all diabetic subjects. In the general hospital, all patients attending the weekly scheduled diabetes clinic day were people with diabetes. In the out-patient department of the district hospital and healthcare clinics, the investigator worked closely with the nursing staff to identify patients with blood glucose tests done prior to doctors' consultation. For in-patient departments, the ward nurses assisted in identifying diabetic patients. Then identification of patients with poor glycaemic control according to the inclusion criteria was done using nurses in the various departments. There were familiar with their patients with poor glycaemic control or the nurse in- charge identified them via the patients' blood glucose results.

Places of Data Collection

Data collection for out-patient departments was done at the waiting areas outside the doctors' consultation rooms. For in-patient department, data were collected at the subjects' bed sites.

Procedure

Once the potential subjects were identified, the nurse in-charge in both the out- and in-patient departments approached the subjects with the information sheet. If the subjects agreed to participate, the investigator then approached them with the consent form. Data collection commenced following subjects' consent. Then the investigator asked the subjects for their preferred language for interview. After demographic data was collected, each question was read to the subjects. One approach to assist the subjects in choosing their answers was to show the answers in written form prepared in four languages English, Mandarin, Bahasa Malaysia and Tamil (Appendix 7). For responses that deviated from the answers provided, the investigator repeated the particular questions to ensure comprehension to a maximum number of three repeats. The investigator then recorded their answers. Answers that did not conform with the answers provided were deemed as negative or unsure. To allay anxiety, they were constantly assured that there were no right or wrong answers because the interview focused on their daily self-care practices.

In the dietary self-care section the subjects were shown the actual sizes of spoons, bowls, plates, photos of fruits and food servings to choose the quantity of their food intake (Appendix 8). To enhance recall of carbohydrate or sweetened food and drinks consumed over the preceding week, a list of carbohydrate and sweetened food and drinks were read to them. The photos of food items were also shown to them simultaneously. For subjects who took different serving sizes on different days of a particular meals, the investigator totalled the total carbohydrate serving sizes of that particular meal in the preceding seven days and divided them with '7' to get an average meal serving size for that particular meal. Subjects' regular dietary history was recorded at the end of the interview. To ensure consistency in data collection, the investigator converted, totalled and recorded all subjects' food intake quantity to appropriate serving sizes and frequency of consumption after verifying with the subjects.

To ensure consistency of non-leisure physical activity assessment, pictorial representations of sitting, standing and walking on visual analogue scales of 0 to 100 described earlier were shown to all subjects. Studies have shown that the angle at which the subject viewed the VAS could alter the placement of the mark due to perceived variation in the length of the line.[195] The investigator ensured that all subjects viewed the VAS on a sitting position with the VAS at eye level in front of them using a standardised approach.

Many subjects were not familiar with the names of their medications. To assist them in identifying the medications they were prescribed, samples of oral anti-hyperglycaemic medication and insulin were shown to them. Then the subjects were asked on the dosage and frequency of each medication prescribed to check for medication adherence.

Open-ended questions were used to assess comprehension of the previous dietary and exercise education received. To enhance recall the investigator used leading questions on types, frequency and quantity of recommendations. Each interview took about 25 to 30 minutes. Printed educational materials on self-care were given to the subjects after the interview as an appreciation of their time.

Possible Biases

Self-report and recall limitations were the major sources of bias. Based on Cognitive theory of survey response, responses to survey depend on interpretation, information retrieval, judgment formation, and response editing.[189] To minimise interpretation bias, standard household measurements and photos of actual food and fruit servings were shown. Common terms were defined like 'gardening'. To assist in information retrieval, using short recall period of preceding seven days, visual aids in dietary, medication and physical activities enhanced their recall. To assist judgment formation, written answers in the language of their choice were shown. To minimise socially desirable responses due to self-report bias, the investigator assured them of their confidentiality.

To minimise bias caused by translation of the questionnaire from English into Mandarin or English into Bahasa Malaysia, back translations were done by different nurses competent in both languages. To minimise data collection bias, all answers that did not conform to the options given were classified as 'unsure'.

Statistical Analysis

Mean FBG levels and demographic data in sections one and two were analysed using descriptive statistics. Knowledge assessment in section three was measured using an interval scale. To answer research question one, descriptive analysis was used to report the knowledge score. To identify any relationship between knowledge of subjects and their age, duration, mean fasting FBG and the self-care practices, Pearson correlation coefficient and Spearman correlation coefficient were used. Mann-Whitney U, Kruskal-Wallis test and Analysis of Variance (ANOVA) were used to assess any difference between the knowledge of subjects and their gender, types of diabetes, ethnicity, education levels and settings.

For the self-care practices in section four, a combination of nominal, ordinal and interval scales were used to measure self-care practices in diet, medication intake, physical activity and SMBG. To answer research questions two to five on the

self-care practices, descriptive analysis were used to describe each of the above self-care practices. To identify any relationship between these practices and subjects' age, duration and mean FBG levels, Pearson's correlation coefficient and Spearmen's correlation coefficient were used. To identify any difference between self-care practices and subjects' gender, types of diabetes, ethnicity, education levels, settings and treatment mode, for self-care practices recorded in interval scale ANOVA were used. For practices recorded in nominal or ordinal data chi-square, Mann-Whitney U and Kruskal-Wallis test were used.

Perceived importance of each self-care practice was measured using an ordinal scale. Descriptive analysis on frequency and percentage were used to describe its occurrence. To identify any relationship between subjects' perceived importance and their self-care practices, correlation coefficient were used. Previous advice on diabetes education received for diet, exercise and SMBG were measured using a nominal scale. Descriptive analysis on frequency and percentage were used to describe its occurrence. To compare any difference between previous advice received and demographic data of subjects, chi-square was used. Content analysis was undertaken to identify common themes on the advice given regarding dietary and exercise self-care. The Statistical Package for Social Sciences (SPSS) version 13 was used for this analysis. The level of significance was set at 0.05 for all analyses.

Conclusion

This chapter has provided an overview of the research design, construction of the questionnaire as a research tool, piloting of data collection and statistical analysis for the study. It also explained in detail the data collection methods used. The next chapter will provide the results of data analysis.

Chapter 4

RESULTS

Introduction

This chapter presents the results of the study in three sections. In section one, the demographic and glycaemic data are presented. Section two provides results from the analysis of each research question. Section three summarises the major findings of the study.

The demographic and glycaemic data in section one were analysed with descriptive statistics. In section 2, the data of diabetes knowledge and the four self-care practices - diet and medication intake, physical activity and SMBG were collected using a combination of nominal, ordinal and interval scales. The choice of statistical analysis depended on the measurement used, number of groups and normality of distribution. Analysis started with descriptive statistics. Then results from each of the research questions on knowledge and self-care practices were analysed to identify any relationship with age, duration of diabetes and mean fasting blood glucose (mean FBG) of the subjects using Pearson's *r* correlation coefficient and Spearman's rho correlation coefficient. To compare any difference between knowledge or the four self-care practices and age, gender, types of diabetes, education levels and settings, Fisher' Exact Test, Chi-square, Mann-Whitney U, Kruskal-Wallis test and Analysis of Variance (ANOVA), were used. For all results, the levels of significance was set at $p<0.05$. Statistical analysis was done using SPSS version 13.0.

Section 1

Demographic and Glycaemic Information

A total of 147 subjects were approached and 21 subjects (7 males, 14 females) declined to participate due to lack of interest and time. The final convenience

sample consisted of 126 subjects: 60 subjects from one urban general hospital, 30 subjects from one district hospital and 18 subjects from each of the two rural healthcare clinics between June and September 2006. A convenience sample was defined as subjects who attended the out-patient clinics or were inpatients in wards during the data collection days.

Age - The mean age of the subjects was 54.7 years (SD ±11.06) with a range from 21 to 79 years. The mean age of Type 1 subjects was 38.7 years (SD ±15.88) and for Type 2 subjects was 55.5 years (SD±10.21).

Ethnicity - Eight-nine subjects (71%) were Malays with 19 Chinese subjects (15%) and 18 Indian subjects (15%). In all settings, Malays dominated the study subjects. However, 79% of Chinese subjects were recruited from the urban general hospital. Indian subjects were unevenly distributed across the settings.

Gender – There were 82 female subjects (65%) and 44 (35%) male subjects. The ratio of female to male subjects was almost similar in all settings at 2:1.

Types of diabetes – One hundred and twenty subjects (95%) had Type 2 diabetes. Six subjects (5%) from the general hospital had Type 1 diabetes.

Duration of diabetes - The mean duration of diabetes was 10.92 years (SD ±8.39) and ranging from 1 to 33 years.

Marital status - The majority of the subjects were married (82%).

Education level – Eighty-five subjects (67%) had six years or less of formal school education: 67 subjects (53%) attended primary education and 18 subjects (14%) had never attended school. Six subjects (5%) had college education and 4 subjects (3%) had tertiary education and they were recruited mainly from the hospital settings. Thirty-one subjects (25%) had secondary education of which 24 were recruited from the hospital settings.

Social background - 121 subjects (96%) lived with their families.

Mean fasting blood glucose - The mean fasting blood glucose of the subjects was 10.39 mmol/L (SD ± 1.78) and ranged from 7.26-14.78 mmol/L.

Glycated haemoglobin level (HbA1c) – Twenty subjects (16%) had their HbA1c assessed. The mean HbA1c was 10.11% (SD ± 2.52).

Table 4 presents an overview of the demographic data according to settings. At baseline there was no significant differences between the settings in regard to demographic and clinical characteristics of subjects except for racial mix

Table 4: Demographic and Clinical Characteristics of Subjects by Settings

Demographic Variables	General Hospital Mean and SD)/ Percentage		District Hospital Mean and (SD)/ Percentage		Healthcare Clinic 1 Mean and (SD)/ Percentage		Healthcare Clinic 2 Mean and (SD)/ Percentage		Total Mean and (SD)/ Percentage		X^2	P value
No of subjects	60		30		18		18		126			
Age (yrs)	53.0 (12.24)		55.3 (9.23)		55.7 (9.35)		58.4 (10.97)		54.7 (11.06)		6.18	0.40
Gender											0.55	0.91
Male	22	(18%)	9	(7%)	7	(5%)	6	(5%)	44	(35%)		
Female	38	(30%)	21	(16%)	11	(9%)	12	(10%)	82	(65%)		
Race											15.37	0.02*
Malay	39	(31%)	25	(20%)	10	(8%)	15	(12%)	89	(71%)		
Chinese	15	(12%)	1	(1%)	2	(1%)	1	(1%)	19	(15%)		
Indian	6	(5%)	4	(3%)	6	(5%)	2	(1%)	18	(14%)		
Others	0	(0%)	0	0(%)	0	0(%)	0	(0%)	0	(0%)		
Types of diabetes											6.93	0.07
Type 1	6	(5%)	0	0(%)	0	0(%)	0	0(%)	6	(5%)		
Type 2	43	(43%)	30	(24%)	18	(14%)	18	(14%)	120	(95%)		
Education level											7.86	0.79
Nil	7	(6%)	6	(5%)	3	(2%)	2	(1%)	18	(14%)		
Primary	28	(22%)	16	(13%)	11	(9%)	12	(9%)	67	(53%)		
Secondary	19	(16%)	5	(4%)	3	(2%)	4	(3%)	31	(25%)		
College	3	(2%)	2	(1%)	1	(1%)	0	(0%)	6	(5%)		
Tertiary	3	(2%)	1	(1%)	0	(0%)	0	(0%)	4	(3%)		

Table 4: Demographic and Clinical Characteristics of Subjects by Settings (continued)

Demographic Variables	General Hospital		District Hospital		Healthcare Clinic 1		Healthcare Clinic 2		Total		X^2	P value
	Mean and SD)/ Percentage		Mean and (SD)/ Percentage		Mean and (SD)/ Percentage		Mean and (SD)/ Percentage		Mean and (SD)/ Percentage			
Duration of diabetes (yrs)											10.15	0.12
Mean	12.95 (8.86)		10.67 (8.07)		6.06 (5.76)		9.44 (7.66)		10.92 (8.39)			
Median	10.5		9.5		4.5		8.00		10.00			
Range	1-33		1-31		1-20		1-25		1-33			
Marital status											13.79	0.31
Married	48	(38%)	27	(21%)	12	(19%)	16	(16%)	103	(82%)		
Divorced	1	(1%)	0	(0%)	0	(0%)	0	(0%)	1	(1%)		
Widowed	6	(5%)	2	(1%)	5	(4%)	2	(1%)	15	(11%)		
Separated	0	(0%)	1	(1%)	0	(0%)	0	(0%)	1	(1%)		
Single	5	(4%)	0	(0%)	1	(1%)	0	(0%)	6	(5%)		
Living status											4.46	0.88
Family members	56	(44%)	30	(24%)	17	(14%)	18	(14%)	121	(96%)		
Friends	1	(1%)	0	(0%)	0	(0%)	0	(0%)	1	(1%)		
Alone	2	(1%)	0	(0%)	1	(1%)	0	(0%)	3	(2%)		
Others	1	(1%)	0	(0%)	0	(0%)	0	(0%)	1	(1%)		
Mean fasting blood glucose (mmol/L)	10.22 (1.63)		10.59 (1.83)		9.78 (1.79)		11.19 (1.95)		10.39 (1.78)		9.01	0.17

* $p<0.05$; all analysis by Chi-square

Section 2

Section 2 presents the results for each research question.

Research question one: Diabetes-related Knowledge

Is there knowledge deficit in self-management of diabetes among adults with poor glycaemic control?

To answer this question, analysis was done in three steps. First, diabetes self-management knowledge was assessed with descriptive analysis. Step 2 identified the relationship between diabetes knowledge and the four self-care practices. Step 3 considered any relationship between diabetes knowledge with demographic and glycaemic data of the subjects.

Diabetes Knowledge Assessment

The mean score on knowledge assessment of the subjects was 8.56 (SD ± 3.61) and ranged from 0-18 points. The maximum possible score was 20. Fifty-nine subjects (47%) scored 10 points and above with only 2 subjects (2%) scoring 15 points and above. Four subjects scored 0 point. Sub-analysis of the knowledge assessment was done on dietary knowledge (9 questions) and diabetes complication (5 questions).

Sub-analysis of Diabetes Knowledge

The maximum possible score for dietary knowledge assessment was 9 points. The mean score for dietary knowledge assessment was 2.15 (SD ±1.59) with only 8 subjects (6%) scoring more than 4 points or >50% of correct answers. In contrast the mean score for diabetes complications (maximum possible score 5) was 3.29 (SD ± 1.25), with 100 subjects (79%) scoring more than 2 points or >50% of correct answers. Dietary and complications knowledge was further analysed for the 59 subjects who scored 10 points and above in diabetes knowledge assessment. The mean dietary score for these subjects was 3.32 (SD ± 1.28) and complication score was 3.9 (SD ± 0.61). Seventy-three percent of the

subjects who scored more than 10 points in their diabetes knowledge assessment were from the hospital settings. Table 5 presents diabetes knowledge results.

Table 5: Diabetes Knowledge Assessment (n=126)

		Number of subjects	Mean (SD)	Median	Range	Percentage of subjects scored more than 50% of the maximum scores
Diabetes Knowledge score	20	126	8.56 (3.61)	9	0-18	47%
Sub-analysis						
Dietary knowledge Score	9	126	2.15 (1.59)	2	0-8	6%
Diabetes complication knowledge score	5	126	3.29 (1.25)	4	0-5	79%

Relationship between Diabetes Knowledge and Self-care Practices

There was no significant relationship between diabetes knowledge of subjects and physical activity (rho=+0.12, p=0.20), medication intake (rho=+0.04, p=0.64), dietary intake (rho=-0.11, p=0.42) and SMBG (rho=+0.11, p=0.24).

Relationship between Diabetes Knowledge with Demographic and Glycaemic Data

There was a medium inverse relationship between the age of subjects and their level of diabetes knowledge (rho= -0.43, p=<0.01) indicating younger subjects knew more about diabetes than older subjects. It was necessary to further explore the impact of age on level of diabetes knowledge, so the Kruskal-Wallis test was used to analyse the data and it showed a statistically significant difference (x^2=

19.44,df=2, p=<0.01). Subjects at 40 years of age and younger had a mean score of 10.64 (SD ± 1.86) when compared to subjects more than 60 years old with a mean score of 6.31 (SD±3.70). There was also a statistically significant relationship between the level of education and diabetes knowledge of subject (x^2=38.81,df=4, p=<0.01). Subjects with a tertiary education had the highest knowledge scores and those who never attended formal school reported the lowest scores.

Although not statistically significant, there was a trend for higher diabetes knowledge score for males compared to female subjects (Mann-Whitney U= 1637.5, p=0.40); Type 1 diabetic subjects to Type 2 diabetic subjects (Mann-Whitney U=193.5, p=0.06)); insulin users to subjects on oral anti-hyperglycaemic medication (OAM) (x^2 =1.52, df=2, p=0.47) as shown in Table 6. No significant relationship was observed between knowledge of subjects and mean FBG level or other demographic data.

Table 6: Demographic Characteristics and Diabetes Knowledge of Subjects (n=126)

Demographic variables	Number of subjects	Mean Knowledge Score	SD	P value
Age cohort				<0.01**†
<=40 years old	11	10.64	1.86	
41-60 years old	79	9.29	3.28	
> 60 years old	36	6.31	3.70	
Education levels				<0.01**†
No education	18	4.28	3.38	
Primary	67	8.36	10.72	
Secondary	31	10.29	1.90	
College	6	12.17	3.31	
Tertiary	4	12.25	0.96	
Type of diabetes				0.06#
Type 1 diabetes	6	11.17	1.94	
Type 2 Diabetes	120	8.43	3.62	
Gender				0.40#
Male	44	9.20	2.93	
Female	82	8.21	3.89	
Treatment mode				0.47†
Diet control	0	0		
§OAM	65	8.26	3.58	
Insulin injection	33	8.88	3.39	
Combination of §OAM and insulin injection	28	8.86	3.97	

**† p<0.01 analysis by Kruskal-Wallis test
# analysis by Mann-Whitney U
Note: The maximum score for diabetes knowledge assessment was 20
§OAM means Oral Anti-hyperglycaemic Medication

Research Question Two: Dietary Self-care

What are the dietary self-care practices of adults with poor glycaemic control?

To understand the subjects' dietary practices, the study explored their meal patterns, carbohydrate intake in terms of quantity and frequency, relationship of their dietary behaviour with glycaemic control and how they rated the importance of dietary management and advice received.

Meal Pattern

Frequency of Meals Per Day

Overall 101 subjects (80%) consumed four or more meals each day. Subjects who consumed more meals a day had significant higher mean FBG (rho= +0.22, p=0.02). Type 1 diabetes subjects consumed more meals than Type 2 subjects (Mann-Whitney U=185, p=0.03). Chinese subjects consumed more meals per day compared to Malays and Indians (x^2=9.43, df=2 p=0.01) There is also a linear increase in number of meals taken per day with duration of diabetes (x^2=7.21 df=2, p=0.03) as shown in Table 7. No significant difference between meal frequency and other demographic data emerged.

Table 7: Type and Duration of Diabetes, Ethnicity and Frequency of Meals (n=126)

Variables	Number of subjects	Mean no of meals per day	SD	P value
Type of diabetes				0.03*#
Type 1 diabetes	6	4.83	0.75	
Type 2 Diabetes	120	4.13	0.82	
Duration of diabetes				0.03*†
<= 5 years	46	3.91	0.73	
6 – 15 years	46	4.30	0.92	
> 15 years	34	4.29	0.76	
Ethnicity				0.01*†
Malay	89	4.15	0.83	
Chinese	19	4.53	0.84	
Indian	18	3.83	0.62	

*p<0.05
† analysis by Kruskal Wallis test
# analysis by Mann-Whitney U

Daily Meal Interval

Sixty-nine subjects (55%) had minimum four hours interval between their meals. Seventeen subjects (14%) ate every 2-3 hourly during their waking hours. Nine of these 17 subjects were on OAM and eight of them on insulin

treatment. Chinese subject ate more frequently than Malay and Indian (x^2=10.05, p=0.01) which support the above findings that Chinese ate more meals each day. No significant relationship was observed with other demographic data (p>0.05).

Carbohydrate Intake

Carbohydrate intake includes carbohydrate food taken during the main meals, drinks with carbohydrate contents, fruit intake, sweetened food and drinks. Although 96% of subjects consumed 3-5 carbohydrate portions during the three main meals, this intake did not include snacks, fruits or episodic intakes for the day.

Ninety-three subjects (74%) consumed sweetened food or drinks during breakfast or as snacks or as episodic intakes more than five days during the preceding week. Malay subjects consumed the most frequent sweet intake (mean frequency 6.33 ±2.04) and the Indian subjects consumed least frequently (mean frequency 4.84±2.61; x^2=7.33 df=2, p=0.03). This finding was supported by the significant difference between sweet intake and settings. Subjects in the district hospital (mean frequency 6.10±1.92) and the Healthcare clinic 2 (mean frequency 5.78±1.93) most frequently consumed sweetened foods because Malay subjects dominated in both settings. Most Indian subjects were recruited from Healthcare clinic 1. Subjects attending this clinic significantly consumed less frequent sweet intake (mean frequency 4.78±2.57; x^2=8.32 df=3, p=0.04) (see Table 8). No significant difference was observed in frequency of sweet intake and other demographic data.

Table 8: Ethnicity, Setting and Frequency of Sweet Intake (n=126)

Demographic Variables	Number of subjects	Mean no of days last week consuming sweet intake	SD	P value
Ethnicity				0.03*†
Malay	89	6.33	2.04	
Chinese	19	5.67	2.19	
Indian	18	4.84	2.61	
Settings				0.04*†
General hospital	60	5.75	2.30	
District hospital	30	6.10	1.92	
Health clinic 1	18	4.78	2.57	
Health clinic 2	18	5.78	1.93	

*p<0.05
†analysis by Kruskal -Wallis test

Relationship between Dietary behaviour and glycaemic control

As discussed earlier, higher frequency of meals correlated with higher mean FBG. There was also a positive correlation between frequency of sweet intake in the preceding week with mean FBG (rho= +0.23, p=0.01). One hundred and one subjects (80%) self-reported that they did not include their sweetened intake in the daily meal plan (Figure 1). These subjects also had higher mean FBG (rho= +0.19, p=0.04) (see Table 9).

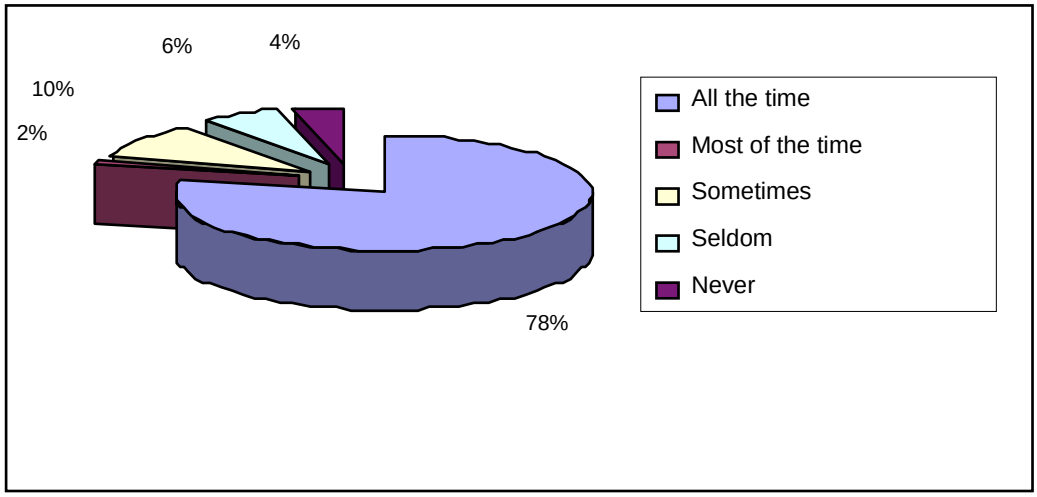

Figure 1: Frequency of NOT INCLUDING sweet intake in daily meal plan (n=126)

Table 9: Dietary Intake Behaviour and Mean Fasting Blood Glucose Levels

Variables	Mean Fasting blood glucose rho	P value
Frequency of meal	+ 0.22	0.02*
Meal interval	-0.16	0.07
Frequency of sweetened intake	+0.23	0.01*
Frequency of NOT including sweetened intake in meal plan	+0.19	0.04*

*p<0.05
rho analysis by Spearmen's Correlation

Fruit Intake

Eighty-two subjects (65%) ate fruit for less than 4 days during the preceding week. Only 28 subjects (22%) consumed fruit daily. Eighty-eight percent of the subjects consumed 1-2 portions of fruit per serving.

Snack intake

One hundred and seventeen subjects (93%) had regular snacks. Sixty percent of these subjects consumed more than 2 carbohydrate exchanges per snack meal. These were curry puff, traditional cakes (sweet kueh), sweetened buns/biscuits/ pau, goring pisang (banana fitters) and sweetened beverages.

Perceived Importance of Diet in Diabetes Management

One hundred and twenty-one subjects (96%) agreed or strongly agreed that diet played an important role in management of diabetes. Five subjects (4%) were unsure. Subjects who perceived the importance of dietary self-care in diabetes management were younger (x^2=19.04, df=2 p=<0.01), had higher education (x^2=15.83, df=4 p=<0.01), more knowledgeable in diabetes self-care (x^2=4.78, df=2 p=0.04) and from the hospital setting (x^2=17.61, df=3 p=,0.01). Malay subjects perceived that dietary management is more important than Indian and

Chinese subjects (x^2=8.3, df=2 p=0.02) (see Table 10).There was no significant relationship between perceived importance of diet in diabetes management and mean FBG or other demographic data.

Table 10: Demographic Factors and Perceived Importance of Dietary Self-care (n=126)

Demographic Variables	Number of subjects	Mean Likert Scale Score	SD	P value
Age cohort				<0.01**†
<=40 years old	11	4.64	0.51	
41-60 years old	79	4.37	0.54	
> 60 years old	36	4.04	0.47	
Education levels				<0.01**†
No education	18	4.15	0.68	
Primary	67	4.23	0.50	
Secondary	31	4.47	0.51	
College	6	4.67	0.52	
Tertiary	4	4.75	0.50	
Settings				0.01*†
General hospital	60	4.40	0.51	
District hospital	30	4.64	0.49	
Health clinic 1	18	4.13	0.51	
Health clinic 2	18	4.22	0.53	
Ethnicity				0.02*†
Malay	89	4.41	0.55	
Chinese	19	4.06	0.44	
Indian	18	4.20	0.56	
Knowledge score				0.04*†
<=5	13	4.08	0.49	
6-10	59	4.31	0.56	
>10	37	4.46	0.51	

**p<0.01; *p<0.05
†analysis by Kruskal-Wallis test
Note: Perceived importance of dietary self-care was assessed with 5-point Likert scale ranging from '1' indicating 'Strongly Disagree' and '5' indicating 'Strongly Agree'.

Dietary Advice Received

Only 4 subjects (3%) indicated that they HAD NOT received any dietary advice and one subject was unsure of the advice received. Subjects in the rural healthcare clinics received less dietary advice compared to subjects in hospital settings (x^2 =8.99,df=3, p=0.03) Female subjects receive dietary advice more

than male subjects did (Mann-Whitney U=1661.5, p=0.03). No other significant relationship or differences were noted between dietary advice received and other demographic data.

Content Analysis of Dietary Advice Provided by the Healthcare Providers

Sixty-eight subjects (54%) had forgotten their dietary advice.

Sweet Intake

Fifty-two subjects (41%) said that they believed they could consume sweet foods but in lesser quantities. Four subjects on OAM said that it was important to consume sweet daily. In contrast, 6 subjects believed that people with diabetes should not consume any sweet food or drinks in their daily meal. No subject mentioned inclusion of sweet intake in their daily meal plan.

Fruit Intake

Thirty-three subjects (26%) had been advised on fruit intake. Thirteen subjects mentioned they had been told to avoid sweet fruits like banana, ciku, durian or grapes. Yet they were allowed to consume less sweet fruits such as apples and guava. No subject mentioned the allowable quantity for fruit intake.

Rice Intake

Fifty-two subjects (41%) said that they had been advised to eat less rice and another two subjects though that rice could only be consumed once a day.

Fat and Vegetable Intake

Thirty-eight subjects (30%) mentioned they had been told to consume less fatty or oily food and 19 subjects (15%) were advised to eat more vegetables.

Research Question Three: Medication Adherence Self-care

What are the medication intake practices of adults with poor glycaemic control?

To understand the medication self-care practices of the subjects, assessment started with descriptive analysis. Then medication adherence percentage was calculated based on the subjects' description of prescribed medication dosage and frequency intake during the preceding week which was compared with the physician's prescription for concordance. Medication adherence rate was then categorised under two groups as 'less than 90% adherence' and 'adherence at 90% or more'. Lastly the relationship and differences between the medication adherence rate and demographic data of subjects were analysed.

Descriptive Analysis

Sixty-five subjects (52%) were prescribed with oral anti-hyperglycaemic medication (OAM), 33 subjects (26%) received insulin treatment and 28 subjects (22%) were on combination of insulin and OAM as shown in Figures 3 and 4. A statistically significant relationship was noted between treatment mode and settings with most insulin users from the general hospital (49 subjects) and the district hospital (9 subjects) compared to 5 subjects from the 2 rural healthcare clinics (Fisher's Exact Test= 54.78, p=<0.01).

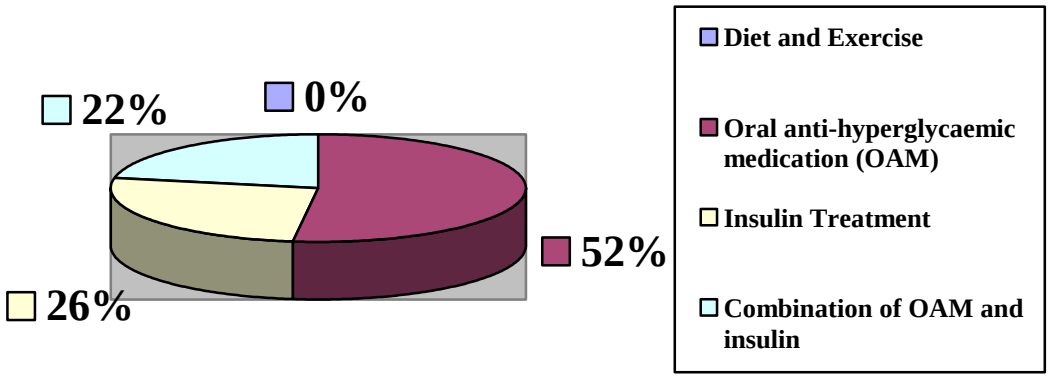

Figure 2: Treatment Mode of Subjects

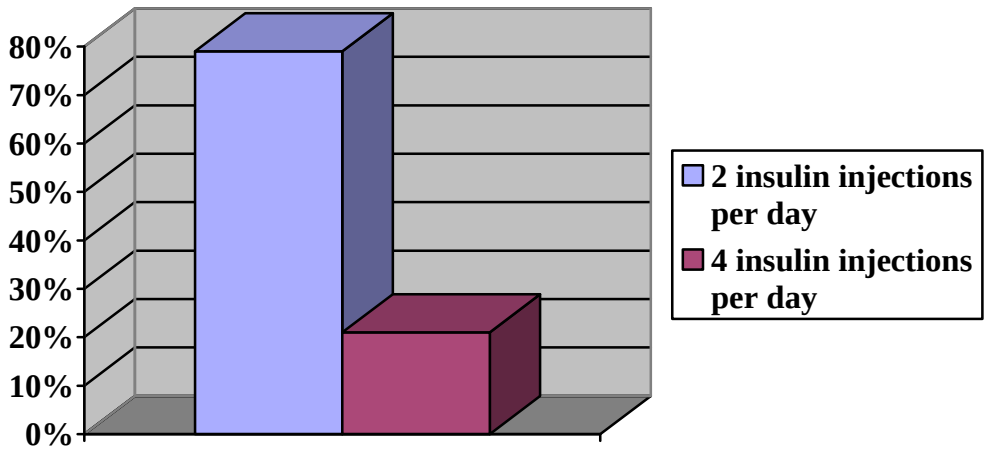

Figure 3: Insulin Regimen of Subjects Prescribed with Insulin Treatment (n=61)

Although 125 subjects (99%) agreed or strongly agreed with the contention that medication adherence was important in diabetes management, no significant relationship emerged between perceived importance of medication intake and medication adherence behaviour (rho=-0.64, p=0.48).

Medication Adherence Analysis

The subjects' overall medication adherence rate stood at 85% (SD ± 17.6) and the median was 91% ranging from 17%-100%. Sixty-eight subjects (54%) achieved more than 90% adherence rate. The mean adherence rate for insulin users was 92% (SD ±13.34) with the median at 99% and ranging from 44%-100%. Eighty-two percent of the insulin users achieved more than 90% adherence rate. In contrast, the mean adherence rate of subjects on OAM was 81% (SD ±19.9) with a median of 86% and ranging from 17%-100%. Only 44% of subjects on OAM achieved more than 90% adherence rate as shown in Table 11 below.

Table 11: Medication Adherence Rate and Treatment Mode

Treatment mode	Number of subjects	Mean medication adherence rate ± S.D. (%)	Range (%)	Percentage of subjects adherence rate >90%
[§]**OAM**	65	81 (19.9)	17-100	44
Insulin treatment only	33	92 (13.34)	44-100	82
[§]**OAM and insulin**	28	82 (17.9)	41-100	43
Overall treatment mode	126	85 (17.60)	17-100	54

[§]oral anti-hyperglycaemia medication

Relationship of medication adherence rate with demographic data of subjects

Based on the findings in Table 11, there was a statistically significant relationship between medication adherence and treatment mode (x^2 =13.26, df=2, p=<0.01). Subjects with tertiary education maintained their medication intake compared to those who had never attended formal school (x^2 21.79,df=4, p=<0.01).

Type 1 diabetic subjects were more likely to adhere than Type 2 diabetic subjects (Mann-Whitney U=236.5, p=0.15); subjects from the lowest FBG group (<9mmo/L) persevered with their medication intake more so than those with the highest FBG group (>11mmol/L) (χ^2=1.17,df=2, p=0.56). The last two findings, however, were statistically not significant (see Tables 12). There was no significant relationship between medication adherence rate and knowledge of diabetes or other demographic data.

Table 12: Demographic Factors and Medication Adherence Rate (n=126)

Demographic Variables	Number of subjects	Mean Medication adherence rate %	SD	P value
Treatment mode				<0.01**†
§OAM	65	81	17.70	
Insulin	33	92	13.34	
Combination of §OAM and Insulin	28	82	17.90	
Education levels				<0.01**†
No education	18	77	22.04	
Primary	67	87	14.59	
Secondary	31	86	17.01	
College	6	88	17.93	
Tertiary	4	96	2.19	
Types of diabetes				0.15#
Type 1 diabetes	6	95	5.00	
Type 2 diabetes	120	85	17.84	
Mean fasting blood glucose				0.56†
<=9 mmol/L	28	88	11.89	
9.1- 11 mmol/L	52	85	19.46	
> 11 mmol/L	46	82	18.29	

**p<0.01
†analysis by Kruskal-Wallis test
analysis by Mann-Whitney U
§oral anti-hyperglycaemic medication

Research Question Four: Physical Activity Self-care Practices

What are the physical activity self-care practices of adult with poor glycaemic control?

To better understand subjects' physical activity practices, assessment included non-leisure activities such as occupational and household activities, transportation mode to the above activity, leisure activities which included a regular exercise program and then totalling both leisure and non-leisure activities as total daily activity. The perceived influence of exercise in diabetes

management and advice received from the healthcare providers regarding subjects' physical activity behaviour was also explored.

Perceived Importance of Physical Activity

Seven subjects (6%) strongly agreed and 111 subjects (88%) agreed that being physically active was important in management of diabetes. There was a correlation between perceived importance of exercise and leisure physical activity (rho =+0.32 p=<0.001) and total daily activity (rho=+0.4 p<0.001).

Physical Activity Assessment

All the activity groups were classified into 3 categories: 'least active', 'moderately active' and 'most active' according to the points scored.

Non-leisure Physical Activity

Descriptive Analysis

Non-leisure activity scores ranged between 6-29 points. The mean score of non-leisure activity was 13.51 (SD ± 3.77) and the median score stood at 13 with a score range from 6-26 points. Sixty-six subjects (53%) were least active during their non-leisure hours. Only 2 % of the subjects were most active (Table 13).

Characteristic of Subjects

Younger subjects were more active than older subjects during non-leisure hours (x^2 =8.61, df=2 p=0.02). Subjects with shorter duration of diabetes were more active than those with longer duration of diabetes during the non-leisure hours (x^2 =5.82, df=2 p=0.04) This finding was supported by a significant relationship between non-leisure activity and treatment mode of subjects (x^2 =15.75, df=3 p=<0.01). Subjects with Type 2 diabetes were prescribed with OAM in the initial years of their diagnosis were more active than those on insulin treatment.

Table 13: Description of Non-leisure Activity

Category of non-leisure activity	Definition of activity	Activity score	Number of subjects	Percentage of subjects
Least active	Almost all the time sitting, almost never standing or walking, seldom carry heavy thing and travel by car or motorbike	6-13	66	53%
Moderately active	Sat, stand and walk about half of the time. Sometimes carry heavy things and use public transport during non-leisure hours	14-21	57	45%
Most active	Almost none of the time sitting, almost always standing or walking, most of the time carry heavy thing, using public transport or cycle or walking between home and other activities	22-29	3	2%

Linear relationship showed that male subjects were more active than female subjects (Mann-Whitney U=1544, p=0.18). Type 1 diabetic subjects were more active than Type 2 subjects (Mann-Whitney U=292, p=0.43). Subjects with higher education compared to no formal schooling were more active (x^2 =4.08, df=4 p=0.04). These differences were not statistically significant (Table 14). No significant correlation was observed between non-leisure activity and other demographic data.

Table 14: Demographic Factors and Non-leisure Physical Activity Levels (n=126)

Demographic Variables	Number of subjects	Mean score of non-leisure physical activity levels	SD	P value
Treatment modes				<0.01**†
§OAM	65	14.46	3.35	
Insulin	33	11.48	3.56	
Combination of §OAM And Insulin	28	13.68	4.19	
Duration of diabetes(yrs)				0.04*†
<= 5	46	14.54	3.54	
6-15	46	13.00	3.90	
>15	34	12.79	3.74	
Age (yrs)				0.02*†
<=40	11	15.64	2.87	
41-60	79	13.76	4.04	
>60	36	12.31	3.05	
Gender				0.18#
Male	44	14.16	4.02	
Female	82	13.16	3.68	
Types of diabetes				0.43#
Type 1 diabetes	6	14.67	4.06	
Type 2 diabetes	120	13.45	3.48	
Education level				0.40†
Never	18	12.17	2.55	
Primary	67	13.84	4.27	
Secondary	31	13.23	3.48	
College	6	14.50	3.33	
Tertiary	4	14.75	1.50	

**p<0.01; *p<0.05
† analysis by Kruskal-Wallis test;
# analysis by Mann-Whitney U
Note: Non-leisure physical activity score ranges from 6-29. The higher the score, the more active the subjects. Refer to Table 12; §oral anti-hyperglycaemia medication

Leisure Physical Activities

The range of leisure activity scores was 4-24 points with a mean score of 9.81 (SD ± 4.98) and median of 8 which was in the 'least active' category. Although 42 subjects (33%) reported that they exercised regularly during their leisure hours, only 6 (5%) achieved the level of exercise recommended for diabetic patients.

This was exercise 5 and more days during the preceding week, minimum of 30 minutes each day with moderate intensity. (Table 15)

Table 15: Description of Leisure Activity

Category of activity For Leisure activity	Description of activity	Activity score	Number of subjects	Percentage of Subjects
Least active	Never or seldom walk around the house and perform gardening, sometimes sat down. Do not have a regular exercise program	3-9	78	62%
Moderately active	Sometimes do gardening, walk around the house, sat down to watch TV May have a infrequent regular exercise program with minimum intensity	10-20	42	33%
Most active	Most of the time walk around the house and perform gardening, seldom sat down in the house, Have a regular exercise program with minimum of moderate intensity with 5 or more days in the preceding week and more than 30 minutes each day	21-31	6	5%

Characteristics of Subjects

Subjects with lower mean FBG levels were more active during leisure activity compared to those with higher mean FBG (rho= -0.2, p= 0.04) Since the data was continuous with a normal distribution, further analysis utilised ANOVA which indicated a significant difference [F(2, 99.95)=4.24, p=0.02] with median effect

size (eta squared =0.6). Subjects with lowest mean FBG = <=9mmol/L in group 1, was significantly different from group 3 with highest FBG = 11.1 or > mmol/L. In contrast group 2 with FBG = 9.1-11 mmol/L did not differ significantly from either group 1 or group 3.

Like non-leisure activity, male subjects were more active when compared to female subjects (Mann-Whitney U=1530, p=0.16). Type 1 diabetics were more active than Type 2 diabetics (Mann-Whitney U=320, p=0.65). However, these findings were not statistically significant (see Table 16). No statistically significant relationship was noted between leisure activities with other demographic data.

Table 16: Types of Diabetes, Gender, Mean Fasting Blood Glucose and Leisure Physical Activity

Demographic Variables	Number of subjects	Mean Score of leisure physical activity levels	SD	P value
Mean fasting blood glucose				0.02*‡
< =9 mmol/L	28	11.54	5.41	
9.1-11mmol/L	52	10.23	5.41	
>11 mmol/L	46	8.23	3.71	
Types of diabetes				0.65#
Type 1 diabetes	6	11.33	7.12	
Type 2 diabetes	120	9.73	4.88	
Gender				0.16#
Male	44	10.48	5.27	
Female	82	9.45	4.81	

*p<0.05; ‡ analysis by ANOVA; # analysis by Mann-Whitney U
Note: Leisure physical activity score ranges from 3-31. The higher the score, the more active the subjects. Refer to Table 14

Daily Total Physical Activity

The mean score of daily total activity was 23.32 (SD ± 6.97), median = 22.5 with a score range of 10-50 points. Sixty-eight subjects (54%) lived a sedentary lifestyle and the rest were moderately active in their daily lives (Table 17)

Table 17: Total Physical Activity Levels

Category of activity for Total activity	Description of Activity	Activity score	Number of subjects	Percentage of subjects
Least active	least active in both non-leisure and leisure activities as defined	9-23	68	54%
Moderately active	moderately active in both non-leisure and leisure activities as defined	24-42	57	45%
Most active	moderately active in both non-leisure and leisure activities as defined	43-60	1	1%

Characteristics of Subjects

In daily activity, younger subjects were more active than older subjects (x^2 =3.70, df=2 p=0.04). Similar to subjects in the leisure activity analysis, less active subjects had higher mean FBG (rho=-0.21, p=0.02). Further analysis was done with ANOVA which indicated a statistically significant difference [F(2,153)=3.28, p=0.04] with small effect size (eta squared =0.05).

Similarly, in daily life, male subjects were more active compared to female subjects (Mann-Whitney U=1585, p=0.26). Type 1 diabetics were more active compared with Type 2 diabetics (Mann-Whitney U=295, p=0.46). Subjects with higher education were more active than those who had no formal education (x^2 =1.41, df=4 p=0.84). However, these findings were again not statistically significant. No significant correlation or relationship was observed between daily total activity level and other demographic variables (see Table 18).

Table 18: Demographic Data and Total Physical Activity (n=126)

Demographic Variables	Number of subjects	Mean total physical activity level score	SD	P value
Mean fasting blood glucose				0.04*‡
< =9 mmol/L	28	25.57	5.88	
9.1-11mmol/L	52	23.73	7.76	
>11 mmol/L	46	21.48	6.24	
Age (yrs)				0.04*†
<=40	11	26.18	2.96	
41-60	79	24.05	7.59	
>60	36	21.44	6.11	
Types of diabetes				0.46#
Type 1 diabetes	6	26.00	9.21	
Type 2 diabetes	120	23.18	6.85	
Gender				0.26#
Male	44	24.55	7.50	
Female	82	22.66	5.61	
Level of education				0.84†
Never	18	21.72	5.38	
Primary	67	23.43	7.87	
Secondary	31	23.65	6.25	
College	6	24.00	5.55	
Tertiary	4	25.00	5.48	

*p<0.05
† analysis by Kruskal-Wallis test
# analysis by Mann-Whitney U
‡analysis by ANOVA
Note: Total physical activity score ranges from 9-60. The higher the score, the more active the subjects. Refer Table 17

Figure 4 compares the three categories of physical activity of non-leisure, leisure and daily total physical activity of the subjects.

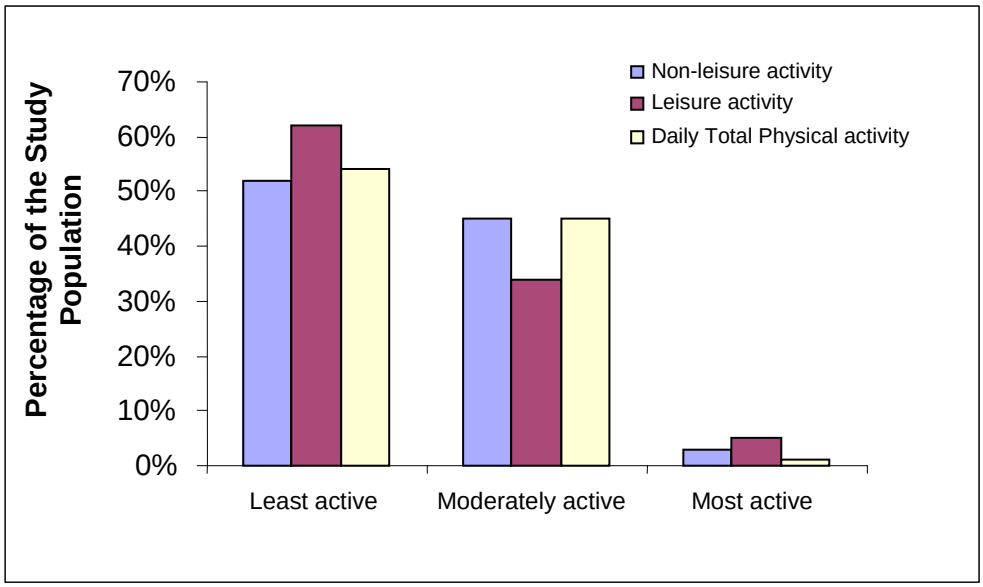

Figure 4: Comparison of Different Categories of Physical Activity Levels of Subjects

Advice on Physical activity provided by Healthcare Providers

One hundred and nine subjects (86.5%) reported having received advice on exercise in diabetes management. No significant relationship was noted between advice received on exercise with all demographic data of subjects based on Chi-square analysis. Furthermore, Content analysis showed that the most common advice given on exercise was walking followed by jogging. Some subjects reported being advised to do housework. Thirty percent of subjects reported being advised to exercise for 30 minutes or more a day. However 40% of subjects could not remember the advice given on duration of exercise. Advice on frequency of exercise varied. Twenty-three subjects (22%) reported being advised to exercise on 5 or more days per week. Thirty-five subjects (28%) said they were advised to exercise 3 or fewer days per week. Others were not sure of advice received.

Table 19 summarises the characteristics of the subjects in terms of the three different categories of physical activities.

Table 19: Demographic Characteristics of Subjects and Categories of Physical Activity Levels

Demographic Variables	Comparison variables			Total physical activity level	Non-leisure Physical activity level	Leisure physical activity level
Age	<=40 yrs	versus	>60 yrs	More active*	More active*	NS
Mean §FBG	<= 9 mmol/L	versus	>11 mmol/L	More active*	NS	More active*
Diabetes duration	<5yr	versus	>15 yr	NS	More active*	NS
Treatment mode	OAM	versus	insulin treatment	NS	More active*	NS
Type of Diabetes	Type 1	versus	Type 2	NS≠	NS≠	NS≠
Gender	Male	versus	Female	NS≠	NS≠	NS≠
Education level	Higher education	versus	lower education	NS≠	NS≠	NS≠

*p<0.05
≠linear relationship observed but not significant; NS means not significant
§ Fasting blood glucose

Research question five: Self-monitoring of Blood Glucose Practices

What is the self-monitoring of Blood Glucose practices of adult with poor glycaemic control?

Due to the small number of subjects who performed SMBG, four different approaches were used to analyse subjects' SMBG practices: descriptive analysis, subjects who performed SMBG, perceived importance of SMBG and being advised to perform SMBG with demographic data of subjects.

Descriptive Analysis

Although 24 subjects (19%) reported practicing SMBG, only 19 subjects (15%) tested their blood glucose during the preceding weeks, Of those tested, five (4%) tested four or more times during the preceding week. Six of 19 subjects (32%) who performed SMBG modified their diet but none modified their medication treatment or physical activity level based on the blood glucose readings. Due to small sample of SMBG data, all continuous variables such as age, duration of diabetes, mean FBG were re-categorised to nominal scale for analysis using Chi-square.

Characteristics of Subjects Who Perform SMBG

Fifteen subjects (68%) on insulin treatment performed SMBG compared to only four subjects (32%) on OAM (Fisher's Exact Test=8.76, p=0.01). Eighteen subjects from the hospital setting compared to one from the rural healthcare clinic practiced SMBG (x^2=8.98, p=0.03). More subjects who had a higher education practiced SMBG compared to those less educated. However, this was not statistically significant (x^2=6.81, p=0.15) (Table 20).There was no statistically significant relationship between subjects who performed SMBG and other demographic data.

Perceived Importance of Performing SMBG in Diabetes Management

Eighty-seven subjects (69%) stated that it was important to perform SMBG in management of diabetes. Thirty-five subjects (28%) were not sure and 4 subjects (3%) disagreed.

Younger subjects were more likely to recognise the importance of SMBG more than older subjects (rho=-2.7, p=<0.01). Subjects with a higher education qualification were also more likely to recognise the importance of SMBG more than those who did not (x^2= 14.83, p=<0.01). As shown in earlier findings, there was a correlation between age and education level of subject (rho=-0.47, p= <0.01). A positive correlation was observed between subjects who perceived the importance of SMBG and practice (rho=+0.27, p=<0.01). There was no

significant relationship between perceived importance and other demographic data.

Table 20: Demographic Factors and Practice of Self-monitoring of Blood Glucose (n=19)

Variables	Number of subjects (%)		P value
Treatment mode			0.01*[b]
[§]OAM	4	(21%)	
Insulin	9	(47%)	
Combination of [§]OAM And Insulin	6	(32%)	
Setting			0.03*[a]
General hospital	14	(74%)	
District hospital	4	(21%)	
Healthcare centre 1	0	(0%)	
Healthcare centre 2	1	(5%)	
Received advice on SMBG			0.04*[b]
Yes	16	(84%)	
No	3	(16%)	
Education			0.15[a]
Never	0	(0%)	
Primary	4	(21%)	
Secondary	9	(47%)	
College	3	(16%)	
Tertiary	3	(16%)	

*p<0.05; [a] Chi-square; [b] analysis by Fisher's Exact test
[§]oral anti-hyperglycaemia medication

Advice Provided by Healthcare Providers to Perform SMBG.

Seventy-four subjects (59%) reported being advised to practice SMBG. Fifty subjects (41%) said they had not received any advice on SMBG. Two subjects were unsure.

Sixty subjects (67%) from the hospital setting compared to 14 subjects (38%) from the rural healthcare clinics reported being advised on SMBG (x^2=8.46, p=0.04). This finding was supported by 47 subjects (64%) on insulin treatment reported being advised on SMBG compared to 27 subjects (36%) on OAM (Fisher's Exact Test=18.31, p=<0.01). This finding was also supported by all

subjects with Type 1 diabetes reported being advised to perform SMBG when compared to only 56% of all subjects with Type 2 diabetes. (Fisher's Exact test=4.26 p=0.08). Even though it was not statistically significant the finding was supported by younger subjects reporting being advised more frequently than older subjects (x^2=6.38, p=0.04). Type 1 subjects were younger than Type 2 subjects (Table 21).

Sixteen (84%) of the 19 subjects who practiced SMBG reported being advised to do so (Fisher's Exact Test= 5.95, p=0.04). Three subjects performed SMBG despite not reported being advised to do so. No significant difference was found regarding performing SMBG, perception of importance of SMBG or being advised to practice SMBG when compared to gender, ethnicity, duration of diabetes and mean FBG.

Table 21: Demographic Characteristics Associated and Advice Received on Self-monitoring of Blood Glucose (n=74)

Demographic factors	Number of subjects (%)		P value
Treatment mode			<0.01**[a]
[§]OAM	27	(36%)	
Insulin	25	(34%)	
Combination of [§]OAM And Insulin	22	(30%)	
Setting			0.04*[b]
General hospital	41	(55%)	
District hospital	19	(26%)	
Healthcare centre 1	8	(11%)	
Healthcare centre 2	6	(8%)	
Age			0.04*[b]
<= 40	8	(11%)	
41-60	51	(69%)	
> =60	15	(20%)	
Type of diabetes			0.08[a]
Type 1	6	(8%)	
Type 2	68	(92%)	

*p<0.05; **p<0.01
[a] analysis by Chi-square; [b] analysis by Fisher's Exact test
[§]oral anti-hyperglycaemia medication

Section 3

Summary of Findings

The mean age of the subjects with poor glycaemic control was 54.7 years. Two-thirds had six or less years of education. The majority of subjects perceived the importance of the four self-care practices. Most subjects reported being advised on dietary and exercise but less than 60% of them reported being advised on SMBG. More than half of the subjects had knowledge deficits in diabetes self-care management especially concerning dietary knowledge. However most were aware of diabetes complications.

In dietary self-care, more than two-thirds of the subjects had 4 or more meals a day, consuming sweet regularly and did not including their sweetened food in their meal plan ($p<0.05$).The overall medication adherence rate was low (85%). Subjects on insulin treatment adhered better to their treatment regiment than those on OAM. More subjects from the hospital setting were prescribed with insulin treatment, reported receiving advice on diet and SMBG in comparison to subjects from the rural healthcare clinics ($p<0.05$).

The majority of subjects lived a sedentary life style. Although one-third of the subjects reported exercising during leisure hours, only 5% of the subjects achieved the level of exercise recommended for diabetes management. Regarding SMBG, only 19% subjects practiced it with 4% practicing at the recommended frequency. Subjects on insulin treatment, from hospital settings, and being advised on SMBG, perceived the importance of SMBG were significantly more likely to practice it.

Various demographic factors appear to influence different self-care practices. Overall, younger subjects compared with older subjects were statistically significantly more knowledgeable on diabetes knowledge, physically active, practiced SMBG, perceived the importance of diet and SMBG self-care and reported receiving advice on SMBG. Subjects with higher education level were

statistically significantly more knowledgeable on diabetes knowledge, adhered better to medication intake, perceived the importance of diet and SMBG self-care.

Finally, subjects with higher mean FBG had statistically significantly more meals per day, consumed more sweet intake and did not include them in their meal plans and were physically less active

Conclusion

Analysis of the findings in this study have shown that Malaysian with poorly controlled diabetes have significant knowledge deficits Furthermore a high prevalence of inadequate self-care practices was observed in these subjects from the four self-cares investigated here. Factors related to the poor self-care practices were explored. In the next chapter, the major findings will be discussed as well as their significance to and implications for clinical practice.

Chapter 5

DISCUSSION OF FINDINGS AND CONCLUSION

Introduction

In this chapter the research problem is restated. The major findings, their significance to clinical practice and study limitations are also discussed. Conclusions are then drawn and further investigations are recommended.

Restatement of the Research Problem

Poor glycaemic control increases the incidence and prevalence of complications resulting in increased morbidity, mortality and global healthcare cost in people with diabetes. Although there are other complex pathological and psychosocial factors that contribute to poor glycaemic control, people's ability to understand and carry out their individual treatment regimen remains critical in the management and control of the disease. Lack of adherence to self-care practices has been reported as a major contributor to poor glycaemic control.[7,199]

Previous researchers reported high incidence and prevalence of complications among Malaysians with diabetes.[200-202] Most studies on diabetes self-care reports have been in Western countries and only a few have been undertaken in Malaysia. Since cultural and psychosocial factors influence the practice of self-care, generalising the findings of another culture and nation to Malaysia may not be appropriate due to cultural and social sensitivities. This study investigated the self-care practices of Malaysian adults with poorly controlled diabetes. Our findings are important and can be used to improve the quality of diabetes care for Malaysians with diabetes.

Major Findings and Their Significance in Clinical Practice

Self-care practices are lacking among adults with poorly controlled diabetes in this study. To understand factors related to poor self-care practices, four themes were discussed: diabetes knowledge deficit; self-care practice; subjects' perceived importance of self-care in diabetes management and advice from healthcare providers.

Diabetes Knowledge

Diabetes Knowledge Assessment

In this study, diabetes knowledge was low among study subjects with poorly controlled diabetes. Two-third of this study subjects had six or less years of education. Age of the subjects also played a significant role in diabetes knowledge deficit. Subjects who were younger or had Type 1 diabetes were more knowledgeable about diabetes care. Also, subjects on insulin treatment had better diabetes knowledge because they were younger with a high demand treatment regimen that required them to know more. The Type 2 diabetic subjects on oral anti-hyperglycaemic medications (OAM) in this study were older with less education. Since OAM regimen was less demanding, this might have contributed to their lack of interest in wanting diabetes related knowledge. Previous studies had consistently reported the relationship between low education levels and older subjects with inferior diabetes knowledge.[203-206] The investigator recognises that both age and type of diabetes influence this observation in addition to other confounding factors. For instance, like follow-up diabetes education and reinforcement of learned behaviours can be confounding factors.

In this study, the subjects also appeared to have problems with comprehension and application of the education received. Ninety-six percent of the subjects reported having received dietary advice. However, only 6% of the subjects achieved more than 50% of the dietary knowledge assessment score. In addition 54% of the subjects reported having forgotten the dietary advice received. This

possible problem with comprehension and application was not influenced by duration of diabetes or ethnicity. Although comprehension of the questionnaire could also compromised by other confounding issues like questionnaire design, readability level and language used, most subjects in this study scored high marks on diabetes complications, which indicated they comprehended the questions asked. Hence it is likely that the poor diabetes-related knowledge among study subjects reflected a true assessment which warrants further analysis. The possible lack of comprehension of the previous education received could be due to low functional health literacy because of their age group and less education. Previous studies had found that being old, low education level and ethnicity were the three most common demographic factors associated with low functional health literacy.[207-210]

Diabetes Knowledge and Glycaemic Control

There were conflicting findings between diabetes knowledge and glycaemic control. The negative finding was consistent with many studies reporting no relationship between diabetes knowledge and clinical outcome.[211-213] Chan *et al* (1999) found no association between diabetes knowledge and self-reported behaviour with direct observation on their foot care practices and glycaemic control in Type 2 diabetes patients. They concluded that acquiring diabetes-related knowledge was not enough to increase compliance in management. [203]

This finding contradicts the assumption in this study which hypothesises that knowledge deficit is related to poor glycaemic control. Despite the strong correlation between lower level of education and poor diabetes knowledge, this study did not find a significant relationship between level of education and higher fasting blood glucose levels. This finding needs to be interpreted within the study limitations. This study involved a small group (n=126) of homogenous subjects with poor glycaemic control. The standard deviation of the mean fasting blood glucose was narrow (mean FBG 10.39 ±1.78) which indicated a narrow variation of FBG among subjects. The small standard deviation may be the outcome of most of the subjects having poor glycaemic control. The non-significant finding could be limited by not examining the influence of other confounders such as

post-prandial glycaemia, health belief, emotional well-being, family support or patient-physician communication which had been shown to influence treatment adherence and disease outcomes.[13,41,99,125] Future studies should be done with larger sample sizes and take into consideration postprandial and overall glycaemic control..

Self-care Practices

Dietary Self-care

This study assessed subjects' carbohydrate intake in regard to poor glycaemic control. However due to lack of information on subjects' height, weight, and body mass index (BMI), it was not possible to calculate the carbohydrate recommendation for comparison with carbohydrate consumption. Instead assessment of carbohydrate consumption was done subjectively using their meal frequency, dietary knowledge, quantity and frequency of sweetened food intake. Hence the results of dietary self-care have to be interpreted within this limitation. Most subjects appeared to take more than their daily carbohydrate requirement for managing their diabetes.

Meal Pattern

Besides the three main meals, 93% of subjects had regular snacks which is consistent with local dietary habits.[79,214] The recommended number of meals per day for people with diabetes depends on treatment regimen, body weight and individual dietary habits.[193,215] For subjects on two daily insulin regimen, carbohydrate snacks are required in between meals to prevent hypoglycaemic episodes.[193,215] The allowable carbohydrate exchange for snacks is usually between 1-2 carbohydrate exchanges which has to be included within the daily allowance.[216] In this study, 60% of subjects consumed more than two carbohydrate exchanges per snack meal. The total carbohydrate intake is usually the primary determinant of postprandial response though the type of carbohydrate also affects the response due to factors like added protein and fat

compositions and food preparation.[217,218] Hence if the carbohydrate content of the meal consumed is larger than the required portion, this could increase the total carbohydrate consumption resulting in post-prandial hyperglycaemia. In this study, there was a significant difference between the number of meals consumed and the mean FBG among subjects (p=0.04).

Content of Food Intake

'Sweet intake' referred to for the extra intake of carbohydrate in this study for two reasons. First, previous dietary studies conducted in Malaysia have shown dietary patterns among the general population have changed over the last three decades from complex to simple carbohydrate. Secondly the findings of previous local dietary studies reveal sugar and sweetened food were common daily food items in Malaysian society.[75,219,220]

Most subjects frequently consumed sweetened intakes in the preceding week. Although interventional studies since the 1980s had shown that free sugars or sucrose are allowed to 10% of total calories intake or 50gm per day in context of a healthy diet and distributed throughout the day,[193,221] it needs to replace other carbohydrate food in total daily calorie.[193,222,223] However, 80% of the subjects who consumed regular sweets did not include sweetened food in their meal plan. This could have resulted in increased total carbohydrate consumption than they required. This findings was supported by the statistically significant finding between the number of sweetened food intakes that were not included in the main meals with higher mean FBG (p=0.01).

The argument that higher carbohydrate intake leads to poor glycaemic control is reported by a European multi-national centres study of people with Type 1 diabetes. It assessed the relationship between HbA1c levels and the source and amount of dietary carbohydrate consumed. It found a link between increased intake of total carbohydrate and a higher consumption of potatoes carbohydrate with higher level of HbA1c. This association was more pronounced in patients with twice daily insulin regimen.[224] Although the findings of this study are not necessarily relevant to Malaysia, it does throw some light on the association of

the possibility of higher carbohydrate intake being associated with higher HbA1c. Another study on the dietary habits of 288 Africans with poorly controlled Type 2 diabetes reported their total carbohydrate intake as 67% of total daily energy intake. This is above the recommended 55% of energy intake for people with diabetes.[58]

Knowledge of glycaemic index was not assessed here because the study subjects did not have the basic dietary knowledge as shown in the dietary assessment. The common snack items like traditional cakes (sweet kueh), goreng pisang, sweetened biscuits/buns/pau and sweetened beverages were food items with medium to high glycaemic index. They may have contributed to the poor glycaemic status of subjects in this study

The Malaysian Clinical Practice Guidelines recommend 55%-60% of total daily calories should be carbohydrate intake for people with diabetes.[215] Two observations can be made about the subjects in this study. First, the majority of the subjects consumed more carbohydrate intake than their daily requirement as suggested by the content of the foods they ate. Second, the extra carbohydrate consumption could have contributed to the high FBG levels. A possible explanation for the extra carbohydrate consumption among study subjects could be dietary knowledge deficit and low functional health literacy.[210,225] Another possible explanations is revealed by a nutritional anthropology report in Malaysia where cooked rice was defined as a 'meal'. All food eaten without cooked rice such as the non-sweetened carbohydrate food items was not considered to be 'real foods' and consequently could be taken in any quantity.[226] Food beliefs can play a role. At the time of this study, regular dietician services were only available in the general hospital and monthly at the district hospital. There was no dietician service available at the rural health care clinics. Hence lack of access to dietary education became a statistical difference between settings. Availability of dietician services was associated with glycaemic control of subjects with diabetes.[58,227,228] Due to the limitations of the assessment tool, there was no clinically significant association between subjects' demographic data and their dietary self-care.

Medication Self-care

Fifty-four percent of subjects adhered to their medication intake which was lower than prior self-reported medication adherence rate.[110,116,125] A possible difference could be due to the definition being 90% concordance and above instead of 80% as stated in the previous studies. In addition, we assessed both OAM and insulin adherence rate. Previous studies mainly assessed patients' OAM adherence rate rather than insulin which usually reported higher adherence rate with OAM.

In contrast to other studies, subjects on insulin treatment in this study adhered better to treatment than subjects on OAM (82% versus 44%, p=0.001). This discrepancy was difficult to ascertain due to only a few studies comparing the two treatment modes.[110,112,116,131] Most studies that compared insulin and OAM treatment adherence used pharmacy databases with older subjects reporting higher adherence rate with OAM when compared to insulin users. Although pharmacy database records are reported as being more accurate than self-report, previous researchers could not assume accuracy for adherence to insulin treatment. This was due to the complexity of insulin treatment which resulted in wastage during preparation, and self-adjustment of dosage. In addition, information was lacking on educational levels, family support or insulin regimens in previous studies. These are important factors associated with better adherence to insulin treatment in this study.

The level of education appears to play a significant role in medication compliance in this study (p=<0.01). More highly educated subjects were found in the hospital settings where insulin users dominated, whereas the majority of subjects with less education derived from rural settings and were prescribed with OAM. The link between better education leading to higher functional health literacy is an important contributor to better medication adherence as reported earlier.[114,204,209]

In this study, only subjects on insulin treatment adhered better to medication than subjects on a combination of insulin and OAM (82% versus 44% and 43%). Brown *et al* (1999) in a large cohort study reported similar findings with fewer

patients in the insulin only groups discontinuing their treatment as compared to combination therapy during two years follow-up.[229] Another study that included only Type 1 diabetes subjects found that subjects on two-injection regimen were more compliant than 4-injections regimen.[230] However, Cramer (2005) found no such relationship. In that study the author excluded patients with multiple daily insulin regimen which may have biased the findings.[112] Most of the subjects in this study were prescribed with two-injection regimen rather than multiple injections which could have further contributed to their adherence behaviour. The difference in adherence rate between the insulin regimen only and combination therapy could be influenced by factors associated with poly-pharmacy.[112,133] However, poly-pharmacy could not totally explain the better adherence rate of insulin users because 10 of the subjects on OAM in this study were also prescribed with one type of oral medication. Hence there have to be other contributing factors.

Type 2 diabetes subjects on insulin treatment usually have had diabetes for a long time and a history of secondary medication failure. They were usually older subjects with possible vision and dexterity problems which could hinder medication non-adherence. This problem was not, however, observed in this study. One possible explanation was 96% of study subjects lived with their family. Family support in insulin injection was assessed wherein almost all subjects who had problems with self-injection were able to receive assistance from family members. This observation was supported by previous studies that examined the effect of family intervention on medication adherence for people with Type 1 and Type 2 diabetes. Those studies findings showed that better family support increased compliance with therapeutic regimen, quality of life and metabolic control.[231-233]

Since the majority of subjects on insulin treatment were from the hospital rather than rural health care settings ($p=<0.01$), better healthcare support and resources with access to diabetes education might have contributed to better adherence rate among the insulin users. It is a practice in this study setting that all insulin users are referred for diabetes education, whereas subjects on OAM were not referred for diabetes education. Cramer (2005) reported better medication compliance of

their patients who received more intense management, for example, better instruction led to better compliance in medication adherence.[112]

With the revolution in diabetes management in the last decade, the finding of better medication adherence among insulin users has important clinical implication. More Type 2 diabetes subjects may be prescribed insulin treatment at an earlier stage of their disease pathway in order to improve glycaemic and metabolic control and reduce morbidity and mortality.[234,235]

The literature review reported conflicting findings in the relationship between age and medication adherence.[113,114,132,236] Although it was generally observed that older persons with financial concerns are typically non-adherent,[114,120,237] this was not found in this study. Cost should not be a barrier to medication adherence since all subjects' medication supplies are heavily subsidised by the Malaysian government. Hence it could have contributed to the findings

Medication Adherence and Glycaemic Control

Earlier studies that used small sample size, self-report and shorter duration reported no association between medication adherence and glycaemic control.[118,238] Studies using large sample size and longer intervention periods in recent years found better adherence with glycaemic control and diabetes complication reduction.[112,120-122,230] In this study, subjects with the lowest FBG appeared to be more adherent to medication intake than those with the highest FBG group. The non-statistical significant difference in this study with a linear relationship warrant further investigation.

Physical Activity Self-care

This study revealed that 54% of the subjects live a sedentary life style with only 5% of subjects exercising sufficiently to achieve the benefits of glycaemic control. This finding was consistent with prior reports that 60% of adults in Malaysia are inactive.[3,219,239,240] There are several possible causes of this behaviour.

Female subjects who constituted two-thirds of the present study population were noted to be less active than the males in all daily activities. Gender difference was observed in earlier studies regardless of age group or among both diabetic and general population.[57,87,89,96,100,241] The explanation for the gender difference is unclear. However, it may reflect cultural expectations or norm and differences in family responsibilities between genders.

In addition, Malay women constitute 48% of the total population. Culturally, Malay women are socially conditioned to act in groups or are frequently chaperoned by family members at social events. This would contribute to poor exercise opportunities if the exercise is individualistic or if there are few family members and friends who want to participate.[240] This finding is also reported by another local survey on the physical activity level of 498 middle-aged Malay women in an urban setting. In that study, 80% of the women did not exercise regularly.[240]

Most subjects in this study agreed that 'being active' was important in diabetes management. Content analysis of physical activity in this study revealed that many of these study subjects considered their daily schedules in housework or work outside their home as physical activity or 'being active'. Because of this local perception, the subjects perceived their daily lives as being already full of physical activities and also perceived that they had done adequate physical activities in their daily living. This perception had highlighted two observations. First, it explained the underlying reason for only 38% of the subjects participating in regular physical activities during leisure hours. Second, it is possible the majority of the study subjects could not achieve the benefits of exercise to improve their glycaemic control. A similar perception about physical activities was reported among Asian people in Western societies.[107,109,242]

Since age is a factor related to physical activity in this study, it is not surprising to find that two-thirds of the subjects were older and less active. Even though the younger subjects were more active during non-leisure and total daily activities, this was not observed with the leisure activity ($p=0.04$). As these younger

subjects constituted the workforce in Malaysia, employment and family responsibilities might limit time available for leisure activities, particularly among subjects with less education and poorer economic circumstances. Similar findings were reported earlier.[62,108]

The most common regular exercise reported in this study was walking outdoors followed by jogging. No subject exercised at the gymnasium. Environmental factors such as the equatorial climate in Malaysia may indirectly influence the activity level because walking and jogging are usually done either in the morning or evening hours during non-rainy days. In assessment of transportation to and from non-leisure activity in this study, most subjects reported using motorised transportation. Only 6 subjects reported walking or cycling as their transportation mode. This reflected the indirect influence of modernisation and mechanisation on Malaysian society. Similar observations were reported by previous studies on the escalating problems of obesity in Malaysia.[219,240] The issue of 'being active' and lacking a regular exercise program could be due to lack of knowledge about exercise among subjects which is indicated in their low diabetes knowledge assessment scores.

Physical Activity and Glycaemic Control

The less active subjects in both leisure and total activities assessment in this study were found to have higher mean FBG than those who are active (p=0.02). This observation is consistent with the empirical findings that showed the benefits of aerobic exercise to improve metabolic control and reduce cardio-vascular complications.[83,108,243] However, there was no significant finding between non-leisure activity and mean fasting blood glucose. Due to lack of occupational information of the study subjects, one possible explanation was their non-leisure activity levels and their perception of 'being active' had not led to increased energy expenditure and reduced glycaemic control.[21] This finding is supported by subjects who exercised at suboptimal intensities did not improve their glycaemic control as compared to the non-exercise subjects (mean FBG 9.98 mmol/L versus 10.68 mmol/L p=0.34). The findings of this study and the

widespread inactivity among Malaysians are important public health concerns and require further research to improve the current situation.

Self-monitoring of Blood Glucose

Only 15% of this study subjects practiced SMBG which was consistent with previous studies done in Malaysia.[5,244] Studies done in the West found the prevalence of SMBG between 40% - 80%.[41,142,147,149,165,245] One study in Hong Kong reported 25% prevalence of SMBG.[119] The low prevalence of SMBG in this study reflected the possible influence of psychosocial issues and the healthcare system.

In this study, the household incomes of subjects were not explored due to data being collected using face-to-face interviews. This study was done in the government healthcare settings where most patients were from the middle to lower socio-economic background.[176,200] As most of the subjects who perform SMBG lived in the urban areas, were younger and better educated, it was assumed that cost could be an important factor of low prevalence of SMBG. Financial barriers have been consistently reported by prior studies as an important barrier to SMBG.[145,159,246] In Malaysia the government heavily subsidises on medications but not the cost of SMBG supplies. This could be a financial burden especially for patients from the poorer background [176]

Previous studies have also reported the low prevalence of SMBG despite free blood glucose meters and test strips were offered in other nations.[148,160] Hence subjects' attitude towards SMBG could be another contributing factor towards low prevalence of SMBG. In this study, most subjects perceived diet, medication intake and physical activities were more important self-care methods than SMBG. Zgibor (2002) examined factors associated with SMBG in a multiethnic community in New Zealand and reported health beliefs as a significant barrier to performance of SMBG twice weekly.[165] Based on the theory of Health Belief Model (HBM) which states that if a person perceives the benefits of a treatment, he/she is more likely to follow the treatment mode.[247] The lack of perceived

importance of SMBG in this study's subjects might contribute to the low prevalence of SMBG and warrants further investigation. In addition more than half of the subjects could be financially dependent because of their age group Perception of the family members on the importance of SMBG in diabetes management might contribute to the low prevalence of SMBG although such data were not gathered for this study. Future research should consider investigating the effect of family support as possible correlating to prevalence of SMBG.

Forty percent of the study subjects reported not having received advice on SMBG as compared to most of them reporting being advised on diet and physical activity. Furthermore, more subjects on insulin treatment and Type 1 diabetes than Type 2 diabetes subjects on oral treatment reported being advised on SMBG. (68% versus 36%, p=<0.01). Since 95% of the subjects had Type 2 diabetes and 52% of these were prescribed with oral therapy and 22% were on combined therapy, it explained the low prevalence of subjects receiving advice on SMBG. The practice of healthcare providers in this study might have indirectly contributed to the low prevalence of SMBG among study subjects. Skelly (2005) reported that 77% of the African-American subjects with Type 2 diabetes performed SMBG in the previous week despite their poorer economic circumstances In that study, 67% of the subjects were advised on SMBG.[146] Similar findings were reported by other studies.[104,248] This finding leads us to question the factors that influence healthcare providers' advisory decisions and warrants further research.

Lack of functional health literacy leading to wrong health beliefs could be another reason for low prevalence of SMBG. Almost all the subjects who performed SMBG lived in urban areas, were younger, and with higher education and more knowledgeable on diabetes care (p=0.005). The non-testers of SMBG in this study were older with less well educated, and may have had problems understanding instruction in SMBG resulting in their dependence on family members to assist with testing. Vincze *et al* (2004) reported that SMBG testers in their study that required assistance performed less frequent SMBG.[145]

SMBG Practice and Glycaemic Control

Frequency of SMBG and treatment modification based on the results of SMBG are important for better treatment efficacy.[147,155,160,249] Only 15% of subjects performed SMBG. Less than 30% of those practicing SMBG monitored according to the recommended frequencies or modified their treatment mode accordingly. This indicated minimum preventive self-care practices. Hence a non-statistically significant finding between SMBG and glycaemic control in this study is to be expected

Perceived Importance of Self-care and Actual Self-care Practices

The majority of the subjects perceived the importance of self-care in diet, medication intake and physical activity but less in regards to SMBG. One possible explanation for the difference of perception within the same study population could be lack of advice provided by healthcare providers. In a multinational survey, 59% of physicians indicated that they preferred to delay insulin and OAM therapy until they were necessary. Fifty-seven percent of these physicians had conveyed their opinions to their patients and this resulted in many patients who had been surveyed simultaneously having a poor opinion on insulin treatment.[114]

The study subjects who perceived the importance of physical activity and SMBG were more likely to practice the particular self-care ($p=<0.01$). This is an encouraging observation as physical activity self-care has been reported to be not very well adhered to as it involves much lifestyle change.[57,106,203] This observation also concurs with the assumption that people with diabetes are inclined to perform self-care. The finding was consistent with a previous study that reported a negative association between perceived importance of exercise in diabetes with the number of barriers endorsed.[97] The relationship between perceived importance and actual self-care behaviour may be explained using the Health Belief Model and Theory of Reasoned Action. The Theory of Reasoned Action states that the best predictor of a patient's behaviour is his/her intention to

behave in a certain way. For example the theory suggests that the best predictor of whether a patient will carry out SMBG to obtain tight blood glucose control would be the patient's expressed intention to do so. This intention is then coupled by the Health Belief Model which suggests that a given health behaviour is most likely to occur when a person perceives a health threat and believes that the behaviour in question is instrumental in averting this threat.[99,250]

However, perceived importance of dietary and medication self-care did not lead to its actual behaviour which indicates that there are other contributing factors. Previous studies showed that adherence to a prescribed diet requires that individuals with diabetes to learn specific dietary principles, alter previous eating patterns and reorganise dietary activities into new daily patterns. Each of these capabilities requires specific knowledge and skill. Less education, aging, low functional health literacy, lack of self-efficacy and lack of dietetic consultation have been documented as problems in dietary adherence.[227,228,251,252] Thus it was not surprising that even with the correct perception of diet, many elderly subjects in this study with dietary knowledge deficits, low levels of education and lack of access to dietetic facilities at the district hospital and rural healthcare settings had problems with adhering to dietary self-care.

Low medication adherence in this study could have been magnified by our definition of adherence rate, low functional health literacy with wrong health belief and treatment complexity.[209,253] In addition many Malaysians generally like to use alternate medicines, and non-pharmacological treatments to supplement their 'regular' medicine which was not investigated in this study but reported by prior literature.[62,130,254] This behaviour could have contributed to medication non-adherence practices.

Other studies had also reported psychosocial factors such as social support, depression, restrictive regimen and physician-patient communication which were not examined here. These could have confounded dietary and medication adherence.[199,251] The difficult in preserving with dietary and medication self-care agrees with the assumption of this study where individuals with diabetes intend to

practice self-care but were unable to do so due to the complexity of diabetes management.

Previous Health Education

The majority of the subjects self-reported having received dietary advice. However half of them had forgotten the content of their dietary advice. There are several possible reasons for this. Firstly, more subjects from the general hospital setting received dietary advice when compared to subjects from the rural settings due to the availability of dietary services at the general hospital. This finding raised the issue for possible differences of dietary education provided by dieticians or other healthcare providers at the different settings. On the other hand, even if there was a difference in the education provided by the dieticians, it could not have contributed totally to the lack of dietary comprehension among the subjects because general hospital subjects only contributed to 47% of the total study subjects. While 54% of subjects had forgotten the content of their dietary advice. Secondly, subjects' characteristics such as age and level of education could have affected the comprehension of education. Previous studies have shown that older subjects and low literacy levels influence the comprehension of education intervention.[109,255] Thirdly, this may also suggest that people may forget what they are taught unless reinforcement of learning is provided. Due to the shortage of dieticians, the general practicing nurses and doctors at the out- and in-patient departments have to deliver health education. Previous studies revealed low prevalence of exercise and high fat intake among the diabetic population despite most being advised on self-care by their physicians. The possible reasons cited were time constraint, and the brief and non-specific information given.[256-258] An audit on diabetes management was done in five government out-patient settings in Malaysia. The doctors spent an average of 4.2 minutes per patient.[259] Similar problems were reported in the nursing literature including time constraints, limited resources and staff being inadequately prepared to assume the role of diabetes educator.[260-262] These point to the need for healthcare providers to be knowledgeable in diabetes instruction. Lastly 85% of the nurses working in the government healthcare system are Malays and most

health education is delivered in Bahasa Malaysia – the national language.[263] Language could be another problem of comprehension for non-Malay elderly subjects. Previous researchers had frequently reported linguistic barriers to diabetes knowledge and glycaemic control.[264-266] All the above possible reasons highlight the need to examine the current educational approach which was not explored here.

Most subjects in this study reported being advised on exercise. However, content analysis showed it is possible that only 30% of subjects were advised according to clinical practice guidelines. This finding raises the concern on the possibility of knowledge deficits among the healthcare providers and would require further research. In the same audit discussed earlier in Malaysia, half of the doctors who participated were found to have inadequate diabetes knowledge.[259] Other studies done in Malaysia reported most physicians' practices did not follow clinical practice guidelines.[267,268]

It was reported that there was less advice provided by the healthcare providers on SMBG compared to other self-cares. Subjects on insulin treatment and Type 1 diabetes subjects more frequently reported being advised on the practice SMBG in contrast to subjects on OAM and Type 2 subjects. Previous studies reported the same observation without establishing cause and effect due to the limitation of study designs. Karter (1999) reported the practice of SMBG improved clinical outcomes of all individuals with diabetes regardless of treatment modes.[147] The disparity of advice given may reflect the different expectations and recommendations of healthcare providers on best methods of diabetes control. One study reported only 31% of physicians agreed with having tight control of blood glucose for people with Type 1 diabetes. In that study it was also noted that the physician management practices such as frequency of HbA1c tests, treatment intensity and use of dietician/educator services were in proportion to their perception of tight control of blood glucose.[269] Another study reported that doctors continued to adopt the extreme heterogeneous target of fasting blood glucose (FBG) levels in patients with Type 2 diabetes. In the same study, there was statistical correlation with patients' HbA1c levels >7.9% with their physicians' FBG targets. The conclusion was reached that doctors' attitudes

towards tight glycaemic control was an independent predictor of patients' metabolic control.[270]

Furthermore more than 90% of the subjects who performed SMBG were from the hospital settings. This raises the question concerning any difference in advice provided between settings. Findings from the nursing literature reported that due to heavy workload, some nurses from the general wards perceived that it was the job of diabetes nurses to educate patients.[262,271] In this study, two of the three diabetes educators were attached to the general hospital which may have contributed to the high rate of subjects receiving advice there.

In summary, adherence to different self-care practices varies among the study subjects. Similar findings were reported by previous studies.[42,167] This may be due to each aspect of the regimen requiring different knowledge and skills as well as different levels of patients' motivation. In this study medication intake was the most adhered-to self-care practice among the study subjects followed by exercise while the least was diet and SMBG.

Limitations of the Study

In order for the results and conclusions of this research to be better understood, it is imperative that the constraints of the study are articulated.

[1] Self-report

The answers to the questions were self-reported. Using self-report instead of direct observation of the self-care practices is the main limitation of this study. There was a possibility of under-reporting among the study subjects because of the inclusion criteria of adults with poorly controlled diabetes only. Previous studies have shown that intentional under-reporting was more common among the non-compliant or obese subjects to avoid confrontation with healthcare providers.[272,273] The areas that were most probably affected by under-reporting were dietary and physical activity self-report due to its complex regimen rather than medication or SMBG. However, some of the under-reporting in this study

occurred for subconscious reasons due to forgetfulness: the majority of subjects were elderly and not well educated. There was less likelihood of under-reporting due to systematic bias caused by language or cultural problems, as the questionnaire was designed according to local practice and the questionnaire was read to the subjects in their choices of language.[95,272]

[2] Questionnaire Designs

The measuring tool for the self-care practices was a new one for which the reliability and validity was tested. Although reliability test using Cronbach's alpha was acceptable for a new tool, several limitations of the questionnaires designs were noted. The questionnaire was not validated in each language as has been traditionally done. The closed questionnaire denied the opportunity to explore factors relating to it. Then there was lack of information about subjects' height, weight, BMI and occupation hindering analysis of any possible association between variables.

[3] Confounding Factors

The relationship between self-care and glycaemic control of people with diabetes is complex. In this study, we only assessed the four self-care practices that directly affect glycaemic control: diet and medication intakes, physical activity and SMBG. However, factors such as psychosocial and socio-economic factors like family support, low income, development of diabetes complication, depression, healthcare provider-patient relationship and self-efficacy can also influence the acquisition of knowledge and self-care practices.[13,41,101,274-276] These confounding factors were not included in the assessment and analysis phases.

[4] Generalistion

The use of convenience sampling and cross-sectional design limit the generalisation of findings to the entire Malaysian population. Other similar studies using much larger sample sizes are needed

Implication for Practice

This study revealed that poor levels of education are common among patients with poorly controlled diabetes and highlighted two major findings: knowledge deficit and poor comprehension of education provided. Most subjects perceived the importance of all the self-care practices but had problems following them. One possible reason is diabetes knowledge deficit. Clinical trials and systematic reviews had shown that diabetes self-management education improve clinical outcomes.[18,277,278] All individuals with diabetes regardless of age and treatment mode should be provided with the opportunity for diabetes education to enhance their self-care practices.

This finding also suggested the possibility of not comprehending previous advice given and this affected the subjects' daily self-care practices. Healthcare providers involved in the treatment of people with diabetes should actively assess for potential poor comprehension in education during clinic visits and education sessions. This is especially important when the patients are elderly Type 2 diabetics with low education background. This finding also suggests that healthcare providers may need to develop better methods of promoting effective health education. Healthcare providers may need to spend more time and provide specific rather than general information and also use appropriate education tools for patients who have not had much education.

Finally one component of effective education is the updated knowledge of the healthcare providers who deliver the education. This study identified possible lack of this knowledge among the healthcare providers. This finding has important implication for healthcare policy makers to provide continuous diabetes education to those who are responsible for the care of people with diabetes.

Conclusion

This study explored the four cornerstones of diabetes self-care management: diet and medication intakes; physical activity and self-monitoring of blood glucose practices of adults with poorly controlled diabetes. In so doing it attempts to define the magnitude of the problem. The results showed that there was lack of self-care practices among study subjects in all the self-care themes explored. Most subjects had problems understanding their meal plan and half of them were inactive in daily life or non-adhering to their medication intake. Few self-monitored their blood glucose.

Several common characteristics of the study subjects that predicted poor self-care were identified. There were low level of education, poor diabetes-related knowledge, older subjects and Type 2 diabetes subjects who were prescribed with OAM. However, it was also observed that there were different demographic predictors for each self-care practice which reflected the complexity of diabetes self-care and the need to analyse each practice separately. The results indicated poor glycaemic control was associated with poor dietary habits and living a sedentary lifestyle. However no statistically significant association was observed between poor glycaemic control with medication non-adherence, poor diabetes knowledge and lack of practice of SMBG.

The findings of this descriptive study have significant nursing and education implications. Despite the majority of subjects perceiving the importance of self-care and reported being 'advised' on the self-care practice, their glycaemic control was still poor. Several possible factors were identified such as poor diabetes knowledge, problems with comprehending of the 'advice' received that might be added to by patients, healthcare providers and healthcare system factors. This again suggested the complexity of self-care processes in achieving good glycaemic control outcomes. The results also suggested that the current education strategy does not improve the current status of poor diabetes control among the study subjects. Previous interventional studies had shown that improving self-care practices enhance clinical outcomes, quality of life and nations' economies.[279,280] Hence, these findings form an important basis for

future interventional studies to improve current diabetes education approaches and diabetes management.

Recommendation for Further Investigation

Based on the insight gained in this study, the following recommendations are worth considering:

[1] Educational Approach

The majority of study subjects said that they were advised on the different self-care practices. However, diabetes knowledge assessment, content analysis of dietary and physical activity as well as the different self-care practices reflected poor comprehension of the education received. Hence future research should explore on the different educational methodologies and theories, duration of education and ways that would enhance comprehension and reinforcement of such education should be researched.

[2] Perceived Importance of Self-care and Actual Self-care Behaviours

The majority of subjects perceived the importance of the four self-care practices but their actual self-care behaviours were not consistent with their beliefs. Several possibilities such as lack of knowledge and skills, cost factors and health beliefs were observed. The cross-sectional design could not determine cause and effect of the variables. Future studies should not only aim to identify cause and effects of low adherence to the four self-care practices, but also barriers and facilitators including psychosocial, economic and cultural factors in order to improve clinical outcomes.

[3] Advice from Healthcare Providers

It appears that inconsistent advice on the different self-care practices may have been provided by the healthcare providers. It appears that some of the advice given was not based on evidence-based medicine. Hence, it is vital to explore other factors like knowledge deficiency, beliefs and attitudes of healthcare

providers which could influence educational outcomes. A standardised diabetes education curriculum should be introduced.

[4] Study Population

The findings of this study could not be generalised to all diabetic people in Malaysia. Bearing in mind of the high prevalence of diabetes complications among the local diabetic population, this type of study should be expanded so that it can be generalised to the whole of Malaysia. A public health approach is needed.

[5] Study Design

Further investigation on the same topic should be done using a triangulated research methodology with questionnaire and focus groups and/or qualitative research interviews. Interpretive research methods encourage exploration and lead to a better understanding of people and their behaviour.

[6] Healthcare System

Limited availability of dietician service, diabetes nurse educator service and cost of SMBG may have contributed to study subjects' poor glycaemic control. Hence future studies could aim to identify factors in the healthcare system that could contribute to improving of diabetes self-care. A health policy with sound strategies, plans and resources for good diabetes care can improve the lives of Malaysians who have diabetes and thereby reduce the burden of this disease to the nation.

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APPENDIX 1 : DIABETES SELF-CARE ACTIVITIES QUESTIONNAIRE

Date:_____

A **Glycaemic data in the last year (From patient's record)**

1.Item/Date						Mean
Fasting blood glucose level mmol/L						

Baseline HbA1c: _____% (*if available, date taken:_____)

B. Demographic Data

ID No:_____ Centre: _____

Age: _____ years

Gender: □$_1$ Male □$_2$ Female

Race: □$_1$ Malay □$_2$ Chinese □$_3$ Indian □$_4$ Others

Type of diabetes: □1 □ 2

Duration of diabetes: _____years _____ Not sure

Marital status: □$_1$ Single □$_2$ Married □$_3$ Divorced □$_4$ Separated □$_5$ Widowed

Education : □$_1$ Never □$_2$ Primary □$_3$ Secondary □$_4$ College □ $_5$ Tertiary

Living with: □$_1$ Family member □$_2$ Friends □$_3$ Alone □$_4$ Others

C. Diabetes Knowledge Assessment:

	Increase	Decrease	No effect	Not sure
1. What is the effect of oats on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$
2. What is the effect of corns on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$
3. What is the effect of unsweetened fruit juice on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$
4. What is the effect of chicken on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$
5. What is the effect of potato on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$
6. What is the effect of wholemeal bread on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$
7. What is the effect of guava on blood glucose?	□$_1$	□$_2$	□$_3$	□$_4$

8. Eating foods lower in fat reduces your risk of developing:

□$_1$ Nerve disease
□$_2$ Kidney disease
□$_3$ Heart disease
□$_4$ Eye disease
□$_5$ Not sure

9. What is the effect of exercise on blood glucose?

□1 Lowers it
□2 Raises it
□3 Has no effect
□4 Not sure

10. If you take your morning diabetes tablets/insulin injection but skip breakfast, your blood glucose level will usually:

□1 Increase
□2 Decrease
□3 Remain the same
□4 Not sure

11. If you **DO NOT** take your diabetes medicine prescribed by your doctor, your blood glucose level will usually:

□1 Increase
□2 Decrease
□3 Remain the same
□4 Not sure

12. Which is the better method for monitoring your diabetes control?

□1 Urine testing
□2 Blood testing
□3 Both are equally good
□4 Not sure

13. Infections such as a cold or influenza are likely to cause:

□1 An increase in blood glucose
□2 A decrease in blood glucose
□3 No change in blood glucose
□4 Not sure

	Yes	No	Not Sure
14. High blood glucose can be caused by regular exercise	□1	□2	□3
15. High blood glucose can be caused by taking too much fruit	□1	□2	□3

Which of the following is a complication of diabetes?

	Yes	No	Not Sure
16. Eye problems	□1	□2	□3
17. Kidney problems	□1	□2	□3
18. Nerve problems	□1	□2	□3
19. Lung problems	□1	□2	□3
20. Stroke	□1	□2	□3

D. Self-care activities

I) Diet

1. Indicate your level of agreement with the following statement.

‘Following your meal plan or controlling your diet is important in your diabetes care.’

□$_1$ Strongly disagree □$_2$ Disagree □$_3$ Not sure □$_4$ Agree □$_5$ Strongly agree

2. Has any of your healthcare provider (doctor, nurse, dietician) advised you to control your diet?

□$_1$ Not Sure □$_2$ No □$_3$ Yes

If yes, what was the advice?

_____

3. Last week, how many meals did you eat each day including snacks?

□1 □2 □3 □4 □5 □6 □7 or more □$_8$ Inconsistent

The investigator will convert carbohydrate quantity to serving portion for questions 4 to 10

4. Last week, on average, what did you take for breakfast?
(Assessment is based on carbohydrate serving(s) only)

□1 □2 □3 □4 □5 □6 □7 or more □$_8$ Inconsistent

5. Last week, on average, what did you take for lunch?
(Assessment is based on carbohydrate serving(s) only)

□1 □2 □3 □4 □5 □6 □7 or more □$_8$ Inconsistent

6. Last week, on average, what did you take for dinner?
(Assessment is based on carbohydrate serving(s) only)

□1 □2 □3 □4 □5 □6 □7 or more □$_8$Inconsistent

7. Last week, on average, how many of carbohydrate drink(s) did you consume each day?
(Example of carbohydrate drinks are soft drinks/Ribena/ syrup/ honey/ Milo/ Horlick/ Ovaltine/coffee or tea with sugar/Vitagen/ milk powder/ condensed milk/ fruit juice /cereal/soya bean /bean powder/red or green pea soup/coconut water/sugar cane water)

□0 □1 □2 □3 □4 □5 □6 or more □$_7$ Inconsistent

8. What was the average carbohydrate serve(s) in each of the carbohydrate drink(s) you consumed last week?

□1 □2 □3 □4 □5 □6 □7 or more □$_8$ Inconsistent

9. How many days did you eat fruit last week?

□0 □1 □2 □3 □4 □5 □6 □7

10. Each time, how much fruit did you eat?

□1 □2 □3 □4 □5 □6 □7 or more □$_8$ Inconsistent

11. How many days did you have sweetened food or drinks last week?
(Example of sweetened food are sweets/ chocolate/ ice cream/ cakes/ honey/ syrup/condensed milk/ kaya/ jam/ sweetened biscuits or buns or pau or kueh or pancake or sweetened drinks)

□0 □1 □2 □3 □4 □5 □6 □7

12. Last week, each time when you ate your sweetened food or drinks, did you reduce your intake of carbohydrate food during meals?

□$_1$ Never □$_2$ Seldom □$_3$ Sometimes □$_4$ Most of the time □$_5$ All the time

13. How often did you eat during your waking hours last week?

□$_1$ Inconsistent □$_2$ <2 hourly □$_3$ 2-3 hourly □$_4$ 4-5 hourly □$_5$>5 hours

14. Did your eating habits last week resemble the way you ate in the last 3 months?

□$_1$ Never □$_2$ Seldom □$_3$ Sometimes □$_4$ Most of the time □$_5$ All the time

II) Medication

1. How do you control your diabetes?

□$_1$ Diet control
□$_2$ Diabetes tablets
□$_3$ Insulin injections
□$_4$ Combination of oral drug and insulin injection

What current medication(s) do you take for your diabetes?

No	Medicine	Prescribed dose	Actual dose	Prescribed frequency	Actual frequency	Not sure
2						
3						
4						
5						
6						
7						

Questions 2/4/6 assess for actual dosage taken
Questions 3/5/7 assess for actual frequency taken

8. Indicate how much you agree with the following statement.

'It is important to take all the medication(s) as prescribed by the doctor.'

□$_1$ Strongly disagree □$_2$ Disagree □$_3$ Not sure □$_4$ Agree □$_5$ Strongly agree

9. Last week, how many times did you miss taking your diabetes medicine(s)?

□0 □1 □2 □3 □4 □5 □6 □7 or more

10. Last week, how many times did you need help in taking your medicine(s)?

□0 □1 □2 □3 □4 □5 □6 □7 or more

11. Compliance rate: OAM _____%; Insulin _____ % Total: _____%

III. Physical activity

1. Indicate how much you agree with the following statement.

‘Regular exercise or being physically active helps to control my diabetes.’

□1 Strongly disagree □2 Disagree □3 Not sure □4 Agree □5 Strongly agree

2. Has your doctor or nurse or dietician advised you to exercise regularly or be physically active daily?

□1 Not Sure □2 No □3 Yes

If yes, what did they recommend?
Type_____
Frequency_____
Quantity_____

A) Non-leisure physical activity

When you are at work or doing housework or in college, on an average:

3. How much time do you spend sitting?

□1 Almost none of the time
□2 Less than ½ the time
□3 About ½ the time
□4 More than ½ time
□5 Almost all the time

4. How much time do you spend standing?

□1 Almost none of the time
□2 Less than ½ the time
□3 About ½ the time
□4 More than ½ time
□5 Almost all the time

5. How much time do you spend walking?

□1 Almost none of the time
□2 Less than ½ the time
□3 About ½ the time
□4 More than ½ time
□5 Almost all the time

6. Do you have to lift or carry heavy things?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

7. How do you travel to and from work or marketing or shopping or college?

□1 Others
□2 Car and/or Motorbike
□3 Bus and/or Train
□4 Cycle and/or walk

8. If you cycle to and from work or marketing or shopping or college, how many minutes do you cycle?

□1 0-5 mins
□2 6-15 mins
□3 16-30 mins
□4 31-45 mins
□5 >45 mins

9. If you walk to and from work or marketing or shopping or college, how many minutes do you walk?

□1 0-5 mins
□2 6-15 mins
□3 16-30 mins
□4 31-45 mins
□5 >45 mins

B) Leisure physical activities

10. How often do you walk around your house or apartment during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

11. How often do you do gardening like mowing or digging but not watering pot plants during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

12. How often do you read book/magazine/newspaper, watch TV, play or work on a computer during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

13. Do you have a regular exercise program?

□1 No (go to part IV) □2 Yes

14. If yes, what exercise do you do?

□1 Mild exercise (minimal effort)
(Examples are yoga, golf, easy walking, Tai chi, Chinese martial art, fishing from river bend, archery)

□2 Moderate exercise (mild increased in heart beats or breathing)
(Examples are brisk walking, easy bicycling, volleyball, badminton, table tennis, leisure swimming, popular and folk dancing, bowling)

□3 Strenuous exercise (heart beats rapidly and increase breathing)
(Examples are running, jogging, football, soccer, squash, basketball vigorous swimming, long distance bicycling, tennis)

15. Last week, how many days did you exercise?

□0 □1 □2 □3 □4 □5 □6 □7

16. If you exercised regularly last week, on average, how many minutes did you exercise each session?

□1 0-5 mins
□2 6-15 mins
□3 16-30 mins
□4 31-45 mins
□5 >45 mins

IV) Self-monitoring

1. Indicate how much you agree with the following statement.

'It is important to test my blood glucose level at home and in between clinic visits.'

□1 Strongly disagree □2 Disagree □3 Not sure □4 Agree □5 Strongly agree

2. Has your doctor or nurse or dietician advised you to monitor your blood glucose at home and in between clinic visits?

□1 Not Sure □2 No □3 Yes

If yes, how often did he/she advise you to test?

_____

3. Do you test your blood glucose at home or in between clinic visits?

□1 No □2 Yes (go to Q4-5)

4. Last week, how many times did you test your blood glucose level?

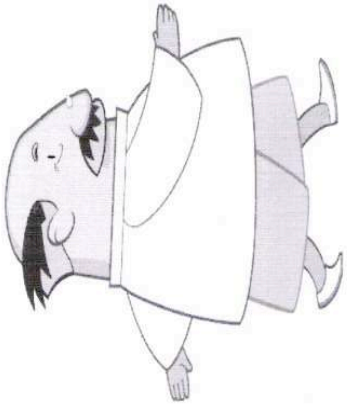
□0 □1 □2 □3 □4 □5 □6 □7 or more

5. Last week, how many times did you change your treatment plan like modify your diet intake or physical activity or medicine based on your blood glucose reading(s)?

□0 □1 □2 □3 □4 □5 □6 □7 or more

Thank you for your participation

APPENDIX 2 : SAMPLE VISUAL ANALOGUE SCALE



0	25	50	75	100
Almost none Of the time	**Less than ½ of the time**	**About ½ of the time**	**More than ½ of the time**	**Almost all the time**
Hampir tidak Sepanjang masa	**Kurang dari ½ masa**	**Lebih kurang ½ masa**	**Lebih dari ½ masa**	**Hampir sepanjang masa**
很少的时间	少过一半的时间	大约一半的时间	多过一半的时间	大部份的时间
கிட்டத்தட்ட எந்தநேரமும் இல்லை	பாதிக்கும் குறைவான நேரம்	அதேகமாக பாதிநேரம்	பாதிக்கும் அதிகமான நேரம்	கிட்டத்தட்ட எல்லா நேரமும்

Sample Visual Analogue Scale on Standing

APPENDIX 3 : UNIVERSITY OF ADELAIDE LETTER OF ETHICS APPROVAL

THE UNIVERSITY OF ADELAIDE AUSTRALIA

OFFICE OF THE DEPUTY VICE-CHANCELLOR (RESEARCH)

SABINE SCHREIBER
SECRETARY
HUMAN RESEARCH ETHICS COMMITTEE
THE UNIVERSITY OF ADELAIDE
SA 5005
AUSTRALIA
TELEPHONE +61 8 8303 6028
FACSIMILE +61 8 8303 7325
email: sabine.schreiber@adelaide.edu.au
CRICOS Provider Number 00123M

Applicant: Ms JM Magarey

Department: Clinical Nursing

Project Title: *Self-care practices of adults with poorly control diabetes*

THE UNIVERSITY OF ADELAIDE HUMAN RESEARCH ETHICS COMMITTEE

Project No: **H-146-2005** RM No: 0000006702

APPROVED for the period *until*: 31 December 2006

subject to approval from the Ministry of Health Malaysia and the Malaysia Medical Research Ethics Committee. Thank you for the supplementary information and revised participant information and consent documents. It is noted that this study is being conducted by Ms Ming Yeong Tan, Doctor of Nursing student.

Refer also to the accompanying letter setting out requirements applying to approval.

Associate Professor Garrett Cullity
Convenor
Human Research Ethics Committee

Date: 21 DEC 2005

Page 1 of 1

APPENDIX 4 : MALAYSIAN RESEARCH AND ETHICS APPROVAL LETTER (BAHASA MALAYSIA VERSION)

PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN MALAYSIA
(PENYELIDIKAN & SOKONGAN TEKNIKAL)
KEMENTERIAN KESIHATAN MALAYSIA

OFFICE OF THE DEPUTY DIRECTOR GENERAL OF HEALTH MALAYSIA
(RESEARCH & TECHNICAL SUPPORT)
MINISTRY OF HEALTH MALAYSIA

Alamat (Address)
d/a Institut Penyelidikan Perubatan
(c/o Institute for Medical Research)
Jalan Pahang, 50588 Kuala Lumpur, Malaysia
Tel: 03-26989820 Fax: 03-26920675
Kawat (Cable): RESEARCH KUALA LUMPUR
E-mail: ismail@imr.gov.my

MEDICAL RESEARCH & ETHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
C/o Institute for Medical Research
Jalan Pahang
50588 Kuala Lumpur

Ruj. Tuan :

Ruj. Kami : KKM/JEPP/ 02 Jld.2 (121)

Tarikh : 23 Januari 2006

Cik Tan Ming Yeong
Damai Medical and Heart Clinic
49 N, Jalan Ong Kim Wee
75300 Melaka

Puan,

Self-care practices of adults with poorly controlled diabetes

Dengan hormatnya permohonan kajian bertajuk seperti di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia mengambil maklum bahawa protokol projek tersebut telah diluluskan oleh Jawatankuasa Etika, Universiti Adelaide.

3. Oleh demikian dan memandangkan kajian ini tidak melibatkan intervensi, Jawatankuasa Etika dan Penyelidikan Perubatan, Kementerian Kesihatan Malaysia tiada halangan, dari segi etika, di atas pelaksanaan projek tersebut dengan syarat-syarat berikut:

i. Data peribadi subjek kajian adalah dianggap sulit,
ii. Borang Maklumat dan Persetujuan Pesakit hendaklah juga disediakan dalam Bahasa Malaysia dan Bahasa Cina
ii. Kebenaran untuk menjalankan projek diperolehi terlebih dahulu daripada Pengarah Hospital yang terlibat

3. Puan adalah dikehendaki mengemukakan laporan tamat kajian kepada Jawatankuasa Etika & Penyelidikan Perubatan selepas tamatnya projek ini.

Sekian terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(DATO' DR ZAKI MORAD MOHD ZAHER)
Pengarah Rangkaian Pusat Penyelidikan Klinikal
Institut Kesihatan Negara (NIH)
Kementerian Kesihatan Malaysia
&
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia
s.k. Urusetia Jawatankuasa Tetap Penyelidikan, KKM

(Sila catatkan rujukan surat ini apabila menjawab)

APPENDIX 5 : MALAYSIAN RESEARCH AND ETHICS APPROVAL LETTER (ENGLISH TRANSLATED VERSION)

TRANSLATION

OFFICE OF THE DEPUTY DIRECTOR GENERAL OF HEALTH MALAYSIA
(RESEARCH & TECHNICAL SUPPORT)
MINISTRY OF HEALTH MALAYSIA

Address
c/o Institute for Medical Research
Jalan Pahang, 50588 Kuala Lumpur , Malaysia
Tel: 03-26989820 Fax: 03-26920675
Cable: RESEARCH KUALA LUMPUR
E-mail: ismail@imr.gov.my

MEDICAL RESEARCH & EITHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
C/o Institute for Medical Research
Jalan Pahang
50588 Kuala Lumpur

Your Ref:
Our Ref: KKM/JEPP/02 Jld.2 (121)
Date : 23 January 2006

Miss Tan Ming Yeong
Damai Medical and Heart Clinic
49 N, Jalan Ong Kim Wee
75300 Melaka

Madam,

Self-care practices of adults with poorly controlled diabetes
With respect the application of the research titled as above is referred.

2. The Medical Research & Ethics Committee (JEPP), Ministry of Health Malaysia has taken note that the protocol of the said project has been approved by the Ethics Committee of the University of Adelaide.

3. Therefore since this research does not involve intervention, the Medical Research & Ethics Committee, Ministry of Health Malaysia has no objection from the ethical point of view in the implementation of the said project with the following conditions:

i. The personal data of the researched subject is considered confidential,
ii. The Information and Patient's Consent Form must be prepared in the National Language of Malaysia and the Chinese Language
iii. The permission to carry out the project must first be obtained from the Director of the hospital concerned.

3. You are required to submit the report on completion of the research to the Medical Research & Ethics Committee after completion of this project.

That's much. Thank you.
" TO SERVE FOR THE SAKE OF THE COUNTRY "

Yours truly,

…… Signed ……
(DATO' DR ZAKI MORAD MOHD ZAHER)
Director Clinical Research Centre
National Institute of Health (NIH)
Ministry of Health Malaysia

Appendix 5 (continued)

&
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia

c.c. Secretariat Permanent Committee of Research, Ministry of Health Malaysia

STATUTORY DECLARATION	AFFIRMATION
I, TAN MING YEONG, Identity Card No: 531225-05-5380 is the holder of this document in the National Language of Malaysia (Bahasa Malaysia) and declare that this is the true English translation and I make this solemn declaration believing the same to be true and by virtue of the provisions of the Statutory Declarations Act, 1960.	I, ONG SAN KEE, a Commissioner For Oaths practising at 47-B (First Floor), Ong Kim Wee Road, 75300 Malacca, Malaysia have sighted the original of this document in the National Language of Malaysia (Bahasa Malaysia) and having satisfied myself of its authenticity of this document and its English translation, I hereby affix my stamp of office.
Signed by the above-named:	Signed by the above named :

ONG SAN KEE
PESURUHJAYA SUMPAH
COMMISSIONER FOR OATHS
47-B, (TINGKAT SATU)
JALAN ONG KIM WEE,
75300 MELAKA.

21 FEB 2006

COMMISSIONER FOR OATHS
No. M 015
ONG SAN KEE
MALAYSIA

APPENDIX 6 : INFORMATION SHEET

THE UNIVERSITY
OF ADELAIDE
AUSTRALIA

DISCIPLINE OF NURSING
SCHOOL OF POPULATION HEALTH AND CLINICAL PRACTICE
FACULTY OF HEALTH SCIENCES

LEVEL 3, ELEANOR HARRALD BLDG
THE UNIVERSITY OF ADELAIDE
SA 5005
AUSTRALIA

TELEPHONE +61 8 8303 3595
FACSIMILE +61 8 8303 3594

CRICOS Provider Number 00123M

Information Sheet

Dear Sir/Madam,

The following information is to explain a proposed study titled:

'A study to understand self-care behaviour of adults with poor diabetes control'

About 9% of the people in Malaysia have diabetes mellitus. Many of the people with diabetes in Malaysia suffer from diabetes complications. One of the reasons is because their blood glucose levels are frequently above the normal range. Thus the purpose of this study is to find out how does people with frequent high blood glucose levels manage their diabetes daily.

You are invited to participate in this study because your blood glucose levels are frequently above the normal range. The investigator will interview you regarding how you manage your diabetes daily like your diet habits, activities, medication intake and self-monitoring practices. The interview will take about 20-30 minutes. Prior to your interview, the investigator will need to access your medical record for information of your blood glucose results in the last year and also the name of the medication you are currently taking.

No drug will be administered in this study. Your medical care will not be affected.

You may not benefit directly from the study. However, the result of this study will help the health care personnel to understand and assist in managing your diabetes better in the future.

Your identity will be kept confidential while the study is being conducted or when the study is reported or published.

This study is done as a research project by the investigator for her course in Doctor of Nursing with the University of Adelaide, Australia.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

If you have any question at any time, you can contact the investigator, Ms Tan, at +60-6-2841204.

If you wish to discuss aspects of the study with someone not directly involved, you may also contact either:

1. the investigator's employers, Dr. Boon Leong Lee or Dr. Ramesh Kumar, Damai Medical and Heart Clinic, Melaka at +60-6-2841204 0r
2. the investigator's supervisor, Dr. Judy Magarey at +61-8-8303 6055 or
3. the Human Research Ethics Committee's secretary at +61-8-8303 6028. The Human Research Ethics Committee's independent complaint form is attached.

Thank you.

APPENDIX 7 : SAMPLE QUESTIONNAIRE ANSWER AIDS

Never	Seldom	Sometimes	Most Times	All the times
Tidak	**Jarnag**	**Kadang-kadang**	**Selalu**	**Sepangjang Masa**
从来没有	很少	有时	时常	常常
எப்பொழுதும் இல்லை	எப்பொழுதாவது	சில சமயங்களில்	பல சமயங்களில்	எல்லா சமயங்களிலும்

Questionnaire Answer Aid

APPENDIX 8 : DIETARY VISUAL AIDS

Standard Household Measurement

Section 3

Research Study 2

Enhancing Self-care Practices of Adults with Poorly Controlled Diabetes Using a Self-efficacy Education Approach

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ABSTRACT

Purpose: The purpose of this study was to assess the effectiveness of a self-efficacy diabetes education program.

Background: Previous researchers in Malaysia have reported a high prevalence of diabetes complications among local people. Diabetes self-management education has been shown to improve self-care practices and clinical outcomes.

Research design and methods: A longitudinal quasi-experimental design was used and 164 adults with poorly controlled diabetes were recruited from two settings. Subjects were randomised to control and intervention groups. All subjects' glycated haemoglobin, diabetes knowledge and self-care practices which included dietary and medication intakes, physical activity levels and self-monitoring of blood glucose (SMBG) practices were assessed at baseline and 12th week. The intervention group received three monthly self-efficacy education sessions which included two face-to-face individual sessions and one telephone follow-up. Self-care practices and diabetes knowledge were assessed using a pre- and post-questionnaire administered using a one-to-one interviewing approach.

Results: Between group comparison showed at week 12 follow-up the intervention group had shown significant improvement in diabetes knowledge (p=0.001), HbA1c levels (p=0.01), SMBG practices (p=<0.001) and a small increment in physical activity levels (p=0.002) when compared to the control group**.** However, the improvement in dietary and medication self-care between the two groups was not significant.

Within group comparison showed at follow-up, there was statistically significant improvement in diabetes knowledge (p=<0.001), HbA1c level (p=0.001), SMBG

practices (p=<0.001) and medication self-care (p=0.03) but not physical activity levels (p=0.47) and dietary intake (p=0.20) within the intervention group. In contrast, the control group had only a slight improvement in diabetes knowledge (p=<0.001) and HbA1c levels (p=0.75) but no change in all self-care practices.

Seventy-seven percent of the intervention subjects received all three education sessions. There were significant relationships between total education time but not the number of education interventions and SMBG practices (r=+0.38 p=0.001), medication adherence behaviour (r=+0.22, p=0.04) and diabetes knowledge (r= +0.34, p=0.02). Factors related to limited education opportunities included transportation (rho=-0.31, p=0.006) and telephone access (rho=-0.28, p=0.01) problems.

Medication adherence (B=-0.23, p=0.009) and SMBG practices (B=-0.21, p=0.007) predicted the HbA1c levels at 12th week

Conclusion: The self-efficacy diabetes education program was effective in improving diabetes knowledge, glycaemic control and self-care practices such as SMBG and medication intake but not dietary intake or physical activity. Social factors such as telephone access and transportation problems appear to reduce education opportunities. The long term effect of the education program was not been determined.

Key words: Adults, Poorly controlled diabetes, self-care, self-efficacy education

Chapter 1

INTRODUCTION

Context of the Study

Landmark studies have clearly demonstrated that improving glycaemic control can prevent the onset or delay the progression of microvascular complications in diabetes.[1,2] However this requires individuals with diabetes to undertake and maintain active self-care behaviours that include following meal-plan and prescribed medication, being physically active and monitoring blood glucose levels daily and adjusting regimens accordingly. Diabetes self-management education assists people with diabetes to acquire self-care knowledge and skills.

It appears that there is a discrepancy between being educated about how to improve glycaemic control and the practice of self-care to achieve better glycaemic control. Researchers have reported that improvement in self-care practices and improvement in glycaemic control is inconsistent. One possible explanation is that the relationship between diabetes self-management education and self-care practices or glycaemic outcome is not straightforward. Many factors influence outcomes of diabetes self-management education such as the methodology, duration, number of interventions, participants' characteristics, and factors related to interventional staff.[3-5] Furthermore, in a critical review of 28 studies from 1993 to 2004, it was found that many of the interventions tested were not designed to be compatible with the realities of current practice or to be delivered in the settings in which most diabetes care was provided. This was because the interventions were complex, required multiple delivery modes and contacts that involved multidisciplinary healthcare providers.[6]

In view of the increase in the prevalence of diabetes globally, it is a challenge for healthcare providers to find effective and appropriate approaches to diabetes education which will promote positive self-care practices and reduce the prevalence

of chronic complications. Studies have shown that diabetes education programs based on the concept of self-efficacy improve diabetes self-management.[7,8]

The prevalence of diabetes in Malaysia increased dramatically from 0.6% in the 1960s to 11% in 2006.[9] Prior studies found that exacerbating this situation was poor glycaemic control among Malaysians with diabetes and prevalent chronic diabetes complications.[10-12] Findings from the previous study of this portfolio indicated that despite recognising the importance of self-care and having received 'advice' on diabetes care, most subjects appeared to have problems acting on the 'advice' received. This may have been due to poor comprehension of the advice received. As a result, this appeared to have contributed to their lack of self-care practices. Since few studies were found on diabetes education in Malaysia, there was an urgent need to re-evaluate the current approach to diabetes education.

Although previous studies found self-efficacy interventions let to improved self-care practices, the majority of these study subjects were Caucasians with education beyond high school and from high socio-economic backgrounds.[7,13-15] Findings from the preliminary study of this portfolio reported 67% of its subjects had six and less years of education. Hence it was expected that the majority of subjects in this study would also have limited formal education. Thus whether self-efficacy has similar effects in enhancing self-care and glycaemic control among subjects with low education qualifications was not known and therefore assessed by this study.

Purpose of the Study

The purpose of this study was to examine the effectiveness of a structured self-efficacy education program to enhance diabetes knowledge and thus self-care practices to improve glycaemic control of adults with poorly controlled diabetes over a 12-week follow-up period. The self-care practices targeted in this study were diet, medication adherence, physical activity and self-monitoring of blood glucose (SMBG).

Hypotheses

As reported in previous research presented in this portfolio, adherence to different self-care practices varies. In addition, patients with diabetes who adhere to one aspect of the regimen do not necessarily stay with another. Hence this study addressed the self-care practices in four separate hypotheses in addition to diabetes knowledge and glycated haemoglobin. There were a total of six hypotheses.

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.

$H_1$1: There will be a difference in the medication adherence self-care practices of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

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.

$H_1$2: There will be a difference in the SMBG self-care practices of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

Ho3: There will be no difference in physical activity self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

$H_1$3: There will be a difference in physical activity self-care practices of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

Ho4: There will be no difference in dietary self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

$H_1$4: There will be a difference in dietary self-care practices of adults with poorly controlled diabetes who receive a structured self-efficacy education when compared to those who receive standard education.

Ho5: There will be no difference in the levels of knowledge about diabetes between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

$H_1$5: There will be a difference in the knowledge about diabetes of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

Ho6: 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.

$H_1$6: There will be a 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.

Significance of the Study

The findings of this study may provide alternative approaches to education in Malaysia that aim to improve management and clinical outcomes for Malaysians with diabetes. In addition, it will assist in identifying specific characteristics, facilitators and barriers to enhancing diabetes education in Malaysia. It is hoped that results from this study will contribute to developing diabetes education in Malaysia

and other developing countries with limited resources, in particular those in the Asian region.

Assumptions

Three principal assumptions underpin the design of the education program for this study.

Self-monitoring of Blood Glucose Practices

Findings from the previous study of this portfolio indicated that subjects who were advised on SMBG were more likely to perform them. Previous studies have also found a higher prevalence of SMBG practices when financial aid is evident.[16,17] Hence the investigator hypothesised the provision of free blood glucose test strips to the intervention subjects and educating them about diabetes would encourage regular practice of SMBG. Self-monitoring of blood glucose would enhance their understanding of the effects of diet, medication and physical activity on glycaemic control. This would act as an incentive to improve self-care practices.

Self-monitoring of Blood Glucose Benefits All Individuals with Diabetes

Empirical studies have shown the benefits of SMBG for individuals with Type 1 diabetes.[18,19] However, there is controversy as to whether SMBG is beneficial for those with Type 2 diabetes especially those not on insulin but on oral anti-hyperglycaemic medication (OAM) or diet control.[20-22] The investigator hypothesised that one of the reasons for previous negative findings was lack of frequency and treatment modification based on the findings of the SMBG practices. As discussed in the first assumption of this study, encouraging treatment modification based on the SMBG results could enhance understanding of self-care practices. Hence practice of SMBG would benefit all individuals with diabetes regardless of type of diabetes and treatment modes.

Brief Structured Diabetes Education that includes Behaviour Science and Cultural Sensitivity would Enhance Self-care and Clinical Outcomes

Although there is controversy regarding the effectiveness of short-term education for individuals with diabetes, the features of a successful approach have been identified as being culturally sensitive and incorporating behaviour science and problem-solving skills.[23-25] Hence it is hypothesised that a brief diabetes self-management education program incorporating these characteristics would enhance diabetes self-management and clinical outcomes. This could be done by incorporating self-efficacy concept (behavioural science). The previous study in this portfolio indicated that 80% of the subjects did not replace their regular refined carbohydrate intakes with other daily carbohydrate consumption. This could have resulted in increased total carbohydrate intake leading to higher fasting blood glucose levels. Studies on Malaysian dietary habits revealed frequent consumption of sweet intake.[26-28] Incorporating knowledge and skills in carbohydrate exchange could enhance dietary adherence (cultural sensitivity). Lastly, discussing the causes and treatment of hyperglycaemia (problem-solving) could further enhance diabetes self-care.

Definition of Terms

Certain terms that are used extensively in this study are defined below.

Self-care or self-management

Diabetes self-care or self-management behaviour is an active, cognitive process in which individuals with diabetes perform tasks as part of their daily regimen to manage their diabetes including appropriate diet and medication intake, exercise and monitoring.[29]

Self-efficacy

Self-efficacy is defined as one's perceived confidence in his or her ability to perform behaviour in a prospective situation.[30]

Glycoslated Haemoglobin (HbA1c)

Glycoslated haemoglobin results from linkage of glucose to erythrocyte haemoglobin. It is used as an index of long-term glycaemic control (2-3 months) and has been associated with decreased incidence of microvascular diabetes complications. The recommended goal of HbA1c is ≤6.5%.[31]

Diabetes Self-management Education

Diabetes self-management education is a planned learning experience using a combination of methods such as teaching, counselling and behaviour modification techniques that influence a patient's knowledge and health behaviour.[32]

Structured Self-efficacy Education

This is a planned educational program or learning activities based on the four principles of self-efficacy - performance accomplishment, vicarious experience, verbal persuasion and emotional arousal. It consists of a structured process and outcomes assessment.

Standard Education

The education programs or activities that are currently used at the study settings.

Brief Education Program

An education program of less than six hours' duration.

Poor Diabetes Control

The reference interval of glycated haemoglobin (HbA1c) is 4-5.9% in people without diabetes. The recommended treatment targets of HbA1c for individuals with diabetes and coronary artery disease is ≤ 6.5%. HbA1c of >7% is associated with increased incidence of micro- and macro-vascular complications.[33] Therefore poor diabetes control in this study is defined as HbA1c of > 7%.

Summary

Education on self-managing diabetes plays a vital role in the overall control because it helps individuals to learn the necessary knowledge and skills of self-care to manage their day-to-day regimens. However, for it to be effective, education on self-management of diabetes needs to incorporate behavioural science and the program should apply across practice settings and aim to improve clinical outcomes. This chapter presents a proposal for a structured self-efficacy diabetes education program aiming to enhance self-care practices, improve knowledge and glycaemic control for adult individuals with poorly controlled diabetes. Six research hypotheses were identified and their underlying assumptions discussed. The next chapter will review the relevant literature and Chapter 3 will discuss in detail the methods and choice of statistical analysis used in this study. The results of the data analysis are reported in Chapter 4. In Chapter 5, the major findings of this study and their significance in nursing practice are presented and discussed.

Chapter 2

LITERATURE REVIEW

Introduction

The previous chapter and the first study of this portfolio have demonstrated the importance of self-care in managing diabetes. Providing diabetes education is one approach to facilitate self-care practices. In this chapter, the literature review focuses on diabetes education in relation to management, self-care and self-efficacy. The review begins with a discussion on the effectiveness of diabetes education followed by the application of self-efficacy theory in self-management and education.

The literature review was undertaken using the following databases: Cumulative Index of Nursing and Allied Health Literature (CINAHL), MEDLINE, Educational Resource Information Centre (ERIC), PsycINFO and Cochrane Library. It also looked at dissertations and the web pages of the American Association of Diabetes Educators. The medical subject headings (MeSH) searched were 'health education', 'patient education' combined with 'Diabetes Mellitus' and/or 'self-efficacy'. Key words used were diabetes, diabetes mellitus, education, health education, self-care, self-management, self-efficacy, self-efficacy education, diet or nutrition, medication intake or adherence, exercise or physical activity and self-monitoring of blood glucose (SMBG). A manual search was done by reviewing articles published in the *Journal of the Australian Diabetes Educators Association*. The search was limited to English language studies published from 1980 to 2007 because the majority of diabetes education studies began to be published during the1980s.[3,34]

Effectiveness of Diabetes Education

Diabetes Education and Knowledge

A meta-analysis based on 47 studies included all study designs from 1966-1986 analysed the effects of patient teaching on knowledge, self-care behaviour and metabolic control in adults with diabetes. It reported that the greatest effect was knowledge improvement with small effects on self-care behaviour, metabolic control and psychological well-being.[34] 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.[35,36] Recent systematic reviews that examined the effectiveness of self-management training of Type 2 diabetes based on randomised controlled trials also found significant findings on knowledge improvement regardless of the educational strategies used.[4,32,37] With regular reinforcement, knowledge level can be sustained for 24 months.[36-39]

Patient education appears more effective in younger patients particularly for knowledge outcomes.[36] No other demographic variable is reported in relation to knowledge improvement in the meta-analyses. 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 subjects often benefit less from education interventions.[40-42] The positive effects of knowledge outcomes via diabetes education must be interpreted within the methodological limitations like possible contamination due to infeasibility of participant blinding, lack of uniform measures of knowledge and the validity of the tools used.[4,32,34,35,37] Hence the next question is to investigate whether the beneficial effects of education go beyond knowledge.

Diabetes Education and Glycaemic Control

Most researchers reported moderate reduction in glycated haemoglobin with educational interventions regardless of age groups.[4,43-45] The glycated haemoglobin

levels improve between one to six months post-intervention and the levels frequently returned to baseline after six months.[32,36,37] Studies with follow-up periods longer than one year showed mixed effects on glycaemic control[37,46-50] 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 favourable results particularly if the interventions are repetitive and ongoing.[3,51-54] 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.[55] Studies with significant findings usually used intensive education interventions.[38,46,48,56,57] A meta-analysis reported that it required 23.6 hours of education to reduce 1% of HbA1c.[58]

Other studies that included treatment modification concurrently improved glycaemic control.[1,2,51,59] Some studies found that physicians yielded better educational outcomes than nurses and dieticians as they were able to adjust the medication timely together with education interventions.[44,51] In contrast, other researchers have argued that physicians had poor knowledge on education methodology and that the positive outcomes were due to medication adjustment rather than the effects of education.[60,61] Some studies found no significant effects despite regular follow-ups[47,62,63] One possible explanation is that Type 2 diabetes is a progressive disease and further deterioration of beta-cell function could have masked the effect of education if it is not accompanied by medication adjustment.[51]

Some researchers have reported improvement of glycaemic control in both the control and study groups. In these studies, the education interventions were usually unblinded.[37] In addition, lack of standardised measurements of glycated haemoglobin such as shorter than 12 week duration might not have documented the full effect of the interventions.[4,37]

Diabetes Education and Self-care

Earlier studies found that diabetes education had small effects on self-care management.[34-36] One possible reason was lack of theoretical framework is frequently observed in these studies. In one meta-analysis, only 3 of the 18 studies based their study framework on theoretical concepts.[64] In another review, only two of the eight studies used behavioural theory to explain cognitive and psychosocial processes.[65] Such behavioural theories and models are important as they provide an understanding of the cognitive and psychosocial processes that influence health decision-making and behaviour.[66] During the 1990s the educational effects on self-care improved when behavioural science was incorporated into the education components.[8,54,67-70]

The effects of self-care via education are inconsistent and vary according to the self-care measured. Improvement in dietary and medication self-care after education interventions were frequently reported.[37,49,62,71-73] However, the effects on SMBG practices were inconclusive due to confounding factors like socio-economic and treatment modalities.[19,49,58,74] The effects of education on physical activity were variable.[37,39,75,76] Similar to the effect of education on glycaemic control, the majority of the interventions reported six months short-term effects. Mixed results were found with intervention of longer duration.[32,36,37]

Significant findings with educational self-care programs frequently involve intensive interventions. In one study, participants attended 24 weekly educational interventions.[77] Other researchers reported using 10-37 contact hours.[53,78,79] Few studies that involve brief education intervention achieved positive results. A pretest-post-test study that compared the effectiveness of self-care practices between standard care and a 6-hour group education on Type 2 diabetic subjects (n=243) found diet, SMBG, physical exercise and foot care practices increased in both groups at three months. In that study only the interventional group was able to sustain the self-care practices over 12 months. However, the validity of that finding was limited by the study design and 32% attrition rate in a year.[39] Another study used three brief

behavioural measures via an interactive CD-ROM program to enhance diet and physical activities over six months (n=422). The majority of these subjects (>85%) were Caucasian from higher socio-economic backgrounds which could limit generalisation.[80]

The number of self-care measured influences the study outcomes. Most studies measured one to three self-care practices in a study.[49,70,73,79] One study assessed the effect of education on SMBG, exercise, insulin adherence and insulin adjustment among Type 1 and Type 2 diabetic subjects (n=82) found that none of the subjects improved in all self-care behaviours. In that study, an inverse improvement of self-care practices was observed with the number of self-care measured.[81]

The measurements of skill performance and behaviour outcomes are frequently subject to methodological limitations. More objective measurements like weight loss yield smaller effect size than self-reported measures in dietary self-care which questions the validity of the self-report tools.[34,35,37,82] It is difficult to blind patients in educational interventions. Thus performance bias is always present. Limited information on psychometric properties of the measuring tools also undermines the validity of the study findings.

Two systematic reviews explored the evolution of education approaches in the last two decades and their effectiveness in health outcomes.[3,51] These indicated that simply improving a person's level of knowledge rarely, if ever leads to behaviour changes necessary for managing the disease effectively. To cope effectively with the complex demands of a diabetes regimen, behaviour change was essential in day-to-day management to maintain long-term clinical outcomes. One such behaviour was having a sufficient sense of self-efficacy.

Self-efficacy and Diabetes Education

Self-efficacy

The concept of self-efficacy which was the key construct of social cognitive theory was first introduced by the American psychologist, Albert Bandura in 1977. Social Cognitive Theory represents a triadic reciprocal causation model in which the behaviour of a person, the characteristics of that person, and the environment within which the behaviour is performed are constantly interacting.[83] For example, if an individual with diabetes has lost his/her job during an economic recession, lack of money will influence that person's self-management behaviour. Self-efficacy is defined as 'people's judgments of their capabilities to organize and execute courses of action required attaining designated types of performances. It is concerned not with the skills one possesses but with judgments of what one can do with whatever skills one possesses' (Bandura 1986, p391).[84] Self-efficacy beliefs are influenced by four sources of information: performance accomplishments, vicarious experience, verbal persuasion, and physiological information.[84] Performance accomplishment refers to the individual's performance of the particular behaviour as an indicator of the ability to do it. Successful accomplishment of a task increases the expectation of mastery. Vicarious experience refers to individuals learning by observing others as models and comparing themselves with the observed experience. Verbal persuasion refers to the process of giving praise and coaching. Lastly, when people identify their state of arousal on the basis of somatic symptoms, physiological state can alter the level of self-efficacy.[85,86]

Self-efficacy and Diabetes Self-care

Self-efficacy has been identified as a key psychosocial variable related to diabetes self-care. In adults, Crabtree (1986) first studied self-efficacy as it related to social support. Social support as a whole was not found to be a predictor of self-care but the self-efficacy subscales were predictors of general self-care, diet, exercise but not medication-taking behaviour.[87] Hurley and Shea (1992) developed the Insulin

Management Diabetes Self-efficacy Scale based on the Crabtree scale and reported self-efficacy was associated with diabetes self-care behaviour particularly for individuals with complex insulin requirement.[7] When the same scale was translated into a Spanish version to assess 97 insulin-requiring Hispanic adults from a lower social-economic background, the subjects reported low to average self-efficacy in their daily self-care especially on coping with problem situations like insulin adjustment.[85] The controversial findings between the two studies using the same scale could be due to 90% of earlier subjects having high school education and previous diabetes education. However, 77% of the Hispanic subjects from the later study had poorer education and only 47% had experienced diabetes education. However another study did not find any link between self-efficacy and self-management with ethnicity and health literacy. In this study, diabetes self-efficacy was significantly associated with four of the five self-management domains: diet, exercise, SMBG, foot care but not medication adherence. The lack of significance in findings between self-efficacy and ethnicity and health literacy could be biased due to unequal distribution of subjects according to ethnicity (15% Caucasian versus 85% of Minority). Furthermore, 52% of the subjects had limited health literacy.[88]

Studies on Type 2 diabetic adults found that greater self-efficacy predicted better dietary and medication intakes, more frequent blood glucose monitoring, but not exercise or hypoglycaemia management.[14,53,86,89,90] Although the above studies on Type 2 diabetes reported a correlation between self-efficacy and medication as part of the assessment, it was unclear on the types of medication studied. Studies with Type 1 diabetics also found self-efficacy predicted diet, exercise and SMBG.[13,91,92] However due to cross-sectional study designs and self-report limitations of the above studies, the reasons regarding the effects of self-efficacy with different self-care practices are unclear. Hence the search was extended to identify the efficacy of self-efficacy in longitudinal study design.

Self-efficacy and Longitudinal Effect

Hurley and Shea (1992) reported that self-efficacy accounted for 33% of the variance in self-care scores one month after the self-efficacy measure was taken (n=142**).**[7] Kavanagh and colleagues (1993) measured self-efficacy and treatment adherence twice, two months apart. Self-efficacy predicted diet and exercise adherence but not SMBG.[93] One study on Type 1 diabetes (n= 88) showed greater self-efficacy was a significant longitudinal predictor of better self-care in diet, SMBG, exercise and HbA1c with nine months follow-up.[13] However, the validity of the above study was limited by 20% attrition rate at nine month follow-ups. In contrast, Skelly *et al* (1995) found that self-efficacy accounted for 24% of variance in diet adherence and 53% of the variance in exercise adherence at pre-test. These figures fell to 0% and 29% respectively four months later (n=118)**.**[15] In one literature review, self-efficacy was found to be a predictor for exercise behaviour but the predictability of self-efficacy over time was inconclusive. The reason was the majority of the 13 primary studies were correlation designs with three intervention studies of which only one was a randomised control trial.[94] The same limitations were found for correlation designs, small sample sizes, high attrition rate, making it unclear whether self-efficacy is a reliable predictor of future adherence rather than perhaps merely an index of past adherence achievement. Therefore randomised controlled trials (RCT) to determine the effect of self-efficacy with better self-care are examined.

Self-efficacy and Randomised Controlled Trials

Two studies using 10 weeks of self-management and empowerment programs to enhance self-efficacy of dietary knowledge and SMBG practices with elderly Type 2 diabetic reported improvement in dietary knowledge, SMBG self-care, glycaemic control, self-efficacy and weight reduction at three months follow-up when compared to the controlled subjects.[95,96] In contrast, a 2-day empowerment group education with elderly Type 2 subjects (n= 88) found better knowledge gain without improvement in self-efficacy and glycaemic control 1 year post-intervention.[46] Though the subjects in the earlier two studies were randomised to intervention and

controlled groups, it used a pretest-post-test study design rather than true randomisation.

A randomised controlled trial assessing dietary adherence of 88 Type 1 diabetes adolescents in problematic situations during two summer camps noted that subjects with higher self-efficacy persevered with their dietary meal plans. Limited information on the education program was reported.[97] Another RCT program (n=50) that used self-determination guided by diabetes nurses over 8 weekly 2 hourly sessions to enhance self-efficacy in SMBG and increased autonomy in daily self-care practices among poorly controlled Type 1 diabetic subjects, also reported increased frequency in SMBG, fewer diabetes related problems and improved glycaemic control.[50] However, the validity of these studies was limited by the new tool and small sample sizes.

Fifty-eight adults with Type 2 diabetes were randomly assigned to either intervention group that kept daily exercise records or control group for 6 weeks. Although the intervention resulted in enhanced self-efficacy among the interventional group, physical activity improved in both groups. Small sample size, single setting and using one intervention with daily activity record which only applied one of the four constructs of self-efficacy could have resulted in the lack of significant findings. Furthermore, as explained by the author, the subjects who agreed to participate in the study were probably motivated to exercise.[24] This assumption was supported by a study that investigated the factors associated with exercise behaviour among adults with diabetes from a randomised population. Self-efficacy and behavioural process of change were significantly higher for those in the action and pre-action stage of exercise readiness.[76]

A study on gestational diabetes (n=58) that randomised subjects to 4 daily SMBG monitoring or usual care for 1 month reported insignificant findings with regard to feelings of self-efficacy, maternal and foetal outcomes. The differences between the findings of this study and earlier research that reported positive correlation between

self-efficacy and SMBG or dietary intake could be the study population. Women with gestation diabetes were generally highly motivated in comparison to non-pregnant adults with diabetes.[98]

Few meta-analyses report the effect of self-efficacy on self-care. This may be because few randomised controlled trials were done with small sample sizes. A meta-analysis of controlled studies that assessed the educational and psychosocial interventions on persons with diabetes concluded that diet instruction and social learning interventions showed the strongest effects while relaxation had the weakest effects.[99] In evaluating the barriers to psychosocial factors that enhance self-care, Glasgow and colleagues (2001) reported the two strongest general psychosocial barriers were low self-efficacy and low levels of family/social support.[100] Hence finding ways to improve a person's self-efficacy should be a primary goal of education intervention.

Use of Self-efficacy Concept in Diabetes Education

Self-efficacy has been used in chronic disease education programs and it has resulted in enhanced self-care, for example : reducing inter-dialysis weight gain[101]; improving dietary adherence among dialysis patients;[102] reducing breathing difficulties in chronic obstructive airway diseases;[103,104] and reducing post-hospitalisation after coronary artery bypass in elderly patients.[105]

In diabetes literature, a multidisciplinary intensive education program (37 hours) using coping skills to enhance self-efficacy, self-esteem and self-care with 12 months follow-up, reported improvement in self-esteem, reduce anxiety, and better self-efficacy and knowledge. However, small samples (n=91) with 70% Caucasians and 59% having some college education and a 33% attrition rate reduced its generalisability.[81] Another study found that after a 5-day intensive education therapy used by a multidisciplinary team, knowledge and self-efficacy were maintained up to 12 months in 91 adults with Type 1 and 2 diabetes[81] The above study also included multifaceted components in its education programs. Hence which aspects of the

intervention(s) influence the positive findings were unclear. Furthermore the validity of that study was limited by 45% attrition rate at 12 month follow-up. Other studies showed similar findings with intensive education intervention between 10-24 hours.[96,106-108] In contrast, two RCTs using brief-tailored interventions for elderly Type 2 diabetics to reduce dietary fat intake and enhance physical activity resulted in improved self-care and glycaemic control at 3 to 12 months follow-up. However, there was no significant improvement in self-efficacy.[47,109] This raises the question is there any relationship between education duration and enhanced self-efficacy.

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Few studies address the mechanism that improved self-efficacy in diabetes education programs. Wilson and Prait (1987) demonstrated that elderly Type 2 diabetics had significantly greater weight loss after participating in an education program supplemented with peer social support (vicarious experience) compared to those who participated only in an education program.[110] Peer advisor intervention has shown to be successful in a variety of other settings, capitalising on the commonalities and benefits of shared life experience.[7,111]

Another study (n=261) used postal survey and direct observation to examine the application of the four sources of Bandura self-efficacy among Dutch diabetes educators in their educational practices. Although using performance accomplishments and verbal persuasion were often cited in the survey, direct observation revealed that only verbal persuasion was applied in daily practices. However, the validity of the direct observation was limited by the small number of observations (n=4) compared to postal responses (n=261).[112]

Self-efficacy and Glycaemic Control

Incorporating self-efficacy in education programs appears to achieve glycaemic improvement for both Type 1 and Type 2 Caucasian diabetics at cross-sectional and longitudinal studies.[13,50,113] However, this relationship is inconsistent among minority groups. One pilot study that examined the effectiveness of a community-

based culturally sensitive education program to enhance self-efficacy in daily diabetes management on five Mexican Americans reported improvement in diabetes knowledge and glycaemic control after eight weekly intensive 20 hours education session.[114] Other studies, however, did not find a correlation between glycaemic control with self-efficacy and self-management among adult African-American women with Type 2 diabetes.[115,116] Due to small sample size and study limitations, the findings of previous studies comparing the Caucasians and ethnic minorities are unclear.

Limitations of Literature Reviews

There were several limitations identified in the literature that needed further research into diabetes education and self-efficacy. First, although some studies support the efficacy of diabetes education in relation to enhanced knowledge, glycaemic control and self-care practices, these are frequently hampered by inadequate descriptions of the education interventions being investigated. An example concerns interventions that are usually reported in frequency or duration with content described as being either didactic, structured and /or self-directed with no further details given.[36,68,74] Hence it was unsure which component of the education program was effective in improving the outcomes.

Second, diabetes education efforts have to date focused predominantly on patients who are sufficiently motivated and able to attend a series of intensive diabetes education classes. While such comprehensive diabetes self-management education programs play an important role, brief ongoing self-management interventions that can be integrated into routine practices are also needed to reach a broader patient population. Leemen (2007) argued that a central factor delaying the uptake of current research findings into practice is the disconnection between intervention research and the resources and constraints of real-world practice.[6] An example was a study done in Mexico with 12 months follow-up on 45 subjects. The intervention comprised six 60-90 minutes of education sessions, 20 individual counselling

sessions each lasting 30-90 minutes and two home visits throughout the 50 weeks.[56] Although the above study showed significant improvement in glycaemic control and self-care, the applicability in real-world practice is limited in developing countries that have limited resources.

Third, effect of self-efficacy varies with different self-care practices. The majority of these studies involve Caucasians with higher education and better socio-economic circumstances.[7,14,104] Studies that include ethnic minority adult diabetics with less education frequently report low to average self-efficacy in managing their diabetes.[15,85] Thus the relationship between education level and psychosocial factors with self-efficacy, self-care practice and glycaemic control warrants further research.

Fourth and finally, despite the vast amount of literature on diabetes education and studies related to self-efficacy, few such studies were reported from South-East Asian countries like Malaysia**.** The majority of the studies done in such countries was limited by small sample sizes, diabetes duration of less than 10 years and exclusion of subjects on insulin treatment.[57,79,104,117] Hence there was a need to explore the effectiveness of education intervention based on a theoretical framework such as self-efficacy with shorter duration that can be integrated into real-world practice in Malaysia. It is a country with limited resources and patients who have lower levels of education and psychosocial functioning.

Conclusion

Diabetes education has been shown to enhance knowledge and short-term glycaemic improvement but with variable effects on long-term diabetes control and self-care. Nevertheless it is unclear which component of the educational methodology had the greatest influence. Integrating behavioural science such as self-efficacy in diabetes education appears to enhance the education outcomes. However, there are areas of controversy related to the effectiveness of self-efficacy in improving diabetes self-care. There are also gaps in the application of current research findings in clinical

practice due to its intensity and complexity. Hence this study explores a brief diabetes education program using the theory of self-efficacy to improve self-care management. The method of the study will be discussed in the next chapter.

Chapter 3

METHODS

Introduction

Few researchers have investigated the application of brief diabetes education interventions in outpatient settings. This study aimed to assess the effectiveness of a brief diabetes education program in the outpatient environment. In this chapter the method used to conduct this research is discussed. It begins with a discussion regarding study design, theoretical framework, method used and concludes with the methods proposed for statistical analysis.

Method

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 12-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.[118] A double-blinded randomised study design was considered but was not feasible as the investigator was responsible for implementing the intervention and collecting data on outcomes.[118,119]

Theoretical Framework

The previous study in this portfolio indicated that knowledge and skill deficits appeared to be associated with poor self-care practices among adults with poorly controlled diabetes. Findings from literature reviews have shown the importance of incorporating behavioural theories in Diabetes Self-management Education interventions because they provide an understanding of the cognitive and

psychosocial processes that influence health decision-making and behaviour. Self-efficacy has been shown to act as the mediating link between cognitive preparation (knowledge and skill) and actual task engagement.[7,14,90] 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 behaviour when compared to Health Belief Model, outcome expectancies, autonomous self-regulation and social support in both Type 1 and Type 2 diabetics.[14,90,120] Hence self-efficacy was the choice of theoretical framework for this study.

Subjects

Inclusion Criteria

Subjects were included if they:

- were non-pregnant adults >18 years of age regardless of gender or ethnicity
- had either Type 1 or Type 2 diabetes
- 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- and macro-vascular complications.[1,121,122]

Exclusion Criteria

Subjects were excluded from the study if they:

- were unable to give consent (<18 years)
- were above 18 years of age but unable to answer the questionnaire independently due to mental illness, senility, 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

Sample Size

The required sample size was calculated with a power analysis using the procedure provided by Polit and Hungler.[123] Self-care practice was the primary outcome. The power was set at 0.8 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).[123] 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 63 in each group or a total of 126. 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 164 subjects with 82 subjects in each group.

Setting

One hundred and sixty-four subjects with poor diabetes control were recruited from the diabetes and general medical outpatient clinics of an urban general hospital and a rural healthcare clinic in the state of Melaka. A general hospital was defined as the

main government hospital in the state offering tertiary care. The rural healthcare clinic was the main health centre operated by the government in the state's rural region. Both settings are typical government health clinics in Malaysia in that they provide continuing medical care to urban and rural people. From the rural healthcare centre, 44 subjects were recruited with equal numbers in the intervention and control groups. Another 120 subjects were recruited from the diabetic and general medical outpatient clinics of the general hospital with 60 subjects for the control and interventional group respectively. Subjects were not recruited from the private clinics and hospitals for reasons of possible demographic and psychosocial differences which could affect the intervention outcomes.

Research Tools

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

[1] Glycated Haemoglobin (HbA1c)

Glycated haemoglobin (HbA1c) was analysed using Bayer DCA 2000 analyzer. Quality assurance of the reagent cartridge was assessed in two steps. First, one in every 10 reagent cartridges was calibrated with the control solution provided. Second, one in every 20 reagent cartridges was also calibrated with a random HbA1c blood sample in the reference laboratory. HbA1c in the reference laboratory was measured using Roche/Hitachi 902 analyser. The method used was standardised according to the International Federation of Clinical Chemist (IFCC) with the results reported based on the Diabetes Control and Complication Trials/National Glycohaemoglobin Standardisation Program (DCCT/NGSP) values using the formula in Table 1.[124,125]

Table 1: Formula for Calculating HbA1c in the Reference Laboratory

NOTE:
This table is included on page 29 of the print copy of the thesis held in the University of Adelaide Library.

Adapted from Jeppsoon et al 2002[124]

The correlation between the quality control of Bayer DCA 2000 and the reference laboratory was r = +0.98, p=0.001 as shown in Figure 1.

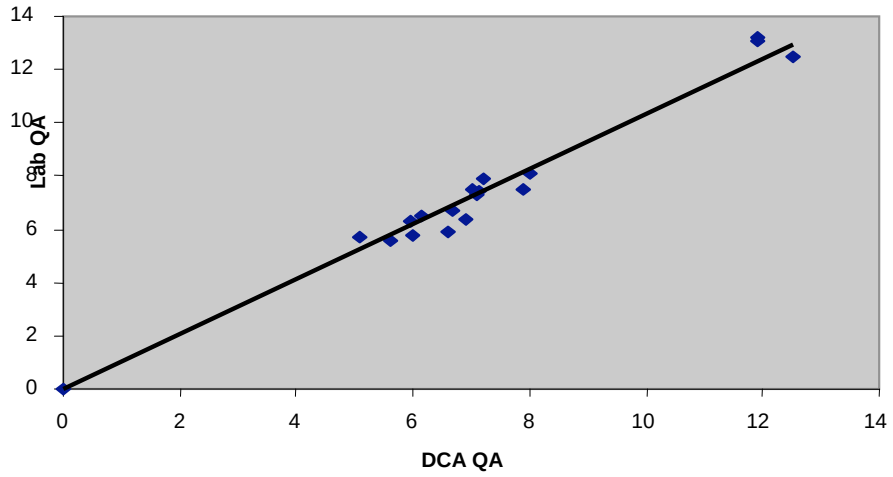


Figure 1: Correlation of HbA1c Tests between Bayer DCA 2000 Analyser and Reference Laboratory

[2] Assessment Tool

Revised Diabetes Self-care Activities Questionnaire

The assessment tool consisted of two sets of Revised Diabetes Self-care Activities Questionnaires (RDSA Questionnaire). The first set, the pre-questionnaire, was administered at baseline and the post-questionnaire, was administered 12 weeks later.

Both questionnaires were administered by the investigator using a one-to-one interview approach. The Revised Diabetes Self-care Activities Questionnaire was modified from the Diabetes Self-care Activities Questionnaire (DSA questionnaire) used during the previous study in this portfolio. The DSA questionnaire was designed by the investigator based on several previously validated self-care questionnaires.[126-132]

Pre-questionnaire

The pre-questionnaire (77 items) had five major components, namely: the demographic data (15 items), previous and current glycaemic control (2 items), diabetes knowledge assessment (20 items) and self-care practices which was sub-divided into four daily self-care practices namely medication intake (20 items), physical activity (11 items) and self-monitoring of blood glucose practice (7 items). Dietary intake was assessed using a Food Frequency Questionnaire (1 item) and two 24-hour dietary recalls (1 item).

Diabetes Knowledge Assessment

Diabetes knowledge was assessed using multiple choice questions (13 items) or Yes/No/Not Sure (7 items). One point was given for each correct answer with a maximum score of 20 points. No point was allocated for wrong or unsure answer. The reliability of the knowledge assessment tool was assessed during the previous study of this portfolio using Cronbach's alpha. The result was 0.86. The content of the assessment was the same as the previous study but the sequence was re-arranged**.** A minimum score of 50% was deemed to represent adequate diabetes-related knowledge.

To assess the subjects' self-care practices, data were collected on medication adherence, levels of physical activity, self-monitoring of blood glucose (SMBG) and regular dietary habits. Previous studies have shown that these different self-care practices do not correlate highly.[25,132,133] Consequently, each self-care practice component was assessed individually.

Medication Intake Practices

Assessment of medication adherence included the subjects' reported medication intake on dosage and frequency which was compared with the physicians' prescription 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 2.[73] 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.

Table 2: Formula for Calculating Medication Adherence Rate

Medication adherence percentage =

$$\frac{\text{Total medication dosage consumed during the last one week}}{\text{Total prescribed medication dosage during the last one week}} \times 100\%$$

Physical Activity Self-care

The assessment of physical activity included items from both non-leisure physical activities like occupational-/housework-/college-related activities (4 items) and leisure activities (7 items). Based on the findings of the previous study, to enhance clarity, the activities level was assessed using a 5-point Likert scale with '1' indicating 'never' and '5' indicating 'all the times' from questions one to seven. (For questions 1 and 7, the score are reversed). Questions 8 to11 assess the frequency, intensity and duration of the leisure activity during the preceding week. The total

score was calculated for both leisure and non-leisure physical activities. In each category, the levels of activities were defined as ‘least active’, ‘moderately active’ and ‘most active’ according to the score achieved (see Table 3).

Table 3: Category of Physical Activity Levels

Types of physical activity	Category of activity	Definition of category of physical activity	Activity score
Non-Leisure activity	Least active	Almost all the time sitting, seldom standing, walking, or carrying heavy things	0-5
	Moderately active	Sometimes sitting, standing, walking or carrying heavy things.	6-11
	Most active	Almost none of the time sitting, almost all the time standing or walking, most of the time carry heavy things,	12-16
Leisure activity	Least active	Never or seldom walk around the house or gardening. Most time sitting down. No regular exercise program	0-6
	Moderately active	Sometimes gardening, walking around the house, sitting down to watch TV. Inconsistent exercise program with minimum intensity	7-16
	Most active	Most of the time walking around the house, gardening and seldom sit down. Exercise regularly with moderate intensity on 5 or more days a week with more than 30 minutes each session	17-28

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 recognised the importance of SMBG in diabetes management, there were discrepancies between the recommended frequency and timing of SMBG.[134-136] Previous researchers reported less than 25% of Malaysians with diabetes practiced SMBG.[137,138] 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.

Dietary Intake

Dietary intake behaviour was assessed at baseline and after the intervention using two methods. First, a two 24-hour dietary recall. Second, a culturally appropriate Food Frequency Questionnaire (FFQ) developed by the investigator.

24-hours Dietary Recall

The first 24-hour dietary recall was recorded during the baseline interview. The second 24-hour dietary recall was done by telephone interview within 7 days of the first interview. At end of study, the first 24-hour dietary recall was recorded the week before their last appointment. The second 24-hour dietary recall was done during the 12th week appointment day.

Food Frequency Questionnaire

The FFQ contained 100 food items commonly consumed in Malaysian diet to identify the daily and episodic carbohydrate consumption during the preceding week. The list of food items was derived from the daily dietary intake of 145 food records collected in the previous study and the pilot study. The portion sizes of the FFQ were

divided into small, medium and large of which small = 0.5 X standard/ medium portion size, medium = 1 X medium portion size and large = 1 X 1.5 standard/medium portion size. The medium portion is the common household measurements converted into food weights in grams based on local food.[139] To enhance precision, the investigator weighted some commonly consumed food items. In addition, the manufacturers' data were also used for some processed foods that were not listed in the local food references.

Dietary Assessment

Adherence to dietary self-care was assessed by the quantity and frequency of carbohydrate intake in relation to subjects' HbA1c results. It also assessed intake of protein, fat and total calories per day. A ratio of reported energy intake to basal metabolic rate (EI: BMR) is used as a guide to assess the accuracy of self-reported food recorded in this study. The formula for calculating of EI: BMR for the study subjects is based on a previous study with Malaysian people (see Table 4).[140]

Table 4: Predictive Equations for Estimation of Basal Metabolic Rate in Malaysian Adults (Male and Female)

NOTE:
This table is included on page 34 of the print copy of the thesis held in the University of Adelaide Library.

Adapted from Ismail et al 1998[140]

Post-questionnaire

The post-questionnaire (59 items) was the same as the pre-questionnaire but excluding demographic data, previous glycaemic control and recommendation for SMBG. The sequence of the 20-item diabetes knowledge assessment session was re-arranged to minimise the effect of learning from the previous questionnaire. All scoring systems remained the same. It was administered to all subjects at the 12 ± 2 weeks during follow-up to identify any difference in knowledge and the four self-care practices between groups and within groups.

The Flesch-Kincard reading level for the Revised Diabetes Self-care Activities Questionnaire was sixth grade.

[3] *Education Program*

The self-efficacy theory provided the theoretical framework for the self-care education intervention program using the four self-efficacy concepts namely performance accomplishment, vicarious experience, verbal persuasion and emotional arousal. Performance accomplishment refers to an individual's successful performance of the particular behaviour. Successful accomplishment of a task increases the expectation of mastery. Vicarious experience refers to learning through observing others as models and verbal persuasion refers to the process of giving praise and coaching. Lastly, the emotional state of a person can alter the level of self-efficacy.[85,86] The education program consisted of three monthly sessions that included two face-to-face individual education sessions and one telephone follow-up. The investigator enhanced her knowledge and skills of self-efficacy education programs by attending a workshop on self-efficacy and via literature reviews..

Pilot Study

As all patients from the medical out-patient department of the private 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'

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 diabetics and 2 Type 1 diabetics.

Content Validity

A panel comprising three diabetologists, three diabetes nurse consultants, two dieticians, one pharmacist, and two adults with Type 2 diabetes reviewed the questionnaire independently for face and content validity prior to the pilot study. All indicated the questionnaire had good face 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.[141-143]

Criterion-related Validity

An instrument such as the Revised Diabetes Self-care Activity Questionnaire has criterion-related validity if the scores gained and those of a separate criterion (HbA1c) correlate.[123] For example, subjects who reported better self-care levels on the Revised Diabetes Self-care Activities Questionnaire should have lower HbA1c levels and vice versa. To assess the criterion-related validity of the instrument, subjects with varying levels of glycaemic control were included in the pilot study (Table 5) Three of the self-care practices correlate with HbA1c (Table 6). In a

multiple regression model, four of the self-care practices were significant independent predictors of HbA1c (Table 7).

Table 5: HbA1c Levels of Pilot Study Subjects (n=50)

HbA1c values	No of subjects
< 7.00%	12
7.00 - 7.50%	11
7.51 - 8.00%	9
8.00 - 8.50%	7
>8.50%	11

Table 6: Correlation between HbA1c Levels and Self-care Practices of Pilot Study Subjects (n=50)

Variable	r	P value
Medication adherence	r^a = -0.45	<0.001**
Dietary adherence	r^b = 0.32	0.02*
Non-leisure activity level	r^b = 0.16	0.63
Leisure activity level	r^b = -0.30	0.04*
SMBG[§]	r^b = 0.22	0.10

*p<0.05
** p<0.01
r^a analysis by Pearson Correlation
r^b analysis by Spearman Correlation
[§] means self-monitoring of blood glucose

Table 7: Self-care Predictors of HbA1c in Pilot Study

Self-care	Beta	P value
Medication adherence	B= -0.036	0.001**
Dietary intake	B= 0.500	0.22
Non-leisure activity level	B= 0.601	-0.03*
Leisure activity level	B= 0.633	0.008**
SMBG[§]	B= 0.561	0.007**

*p<0.05
** p<0.01
[§] means self-monitoring of blood glucose

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. (Table 8)

Table 8: Cronbach's Alpha Results of Revised Diabetes Self-care Activities Questionnaire

Assessment	Cronbach's alpha value
Diabetes knowledge	0.90
Medication intake	0.83
Physical activity level	0.73
Practice of SMBG	0.60
Total	0.80

The low Cronbach alpha value of SMBG could be because it has the least number of items (7) among all sections. According to the formula for Cronbach's alpha calculation, the coefficient alpha depends on the total number of items and the average inter-item correlation among the items.[144,145] Different timing of SMBG has different significance in diabetes management.[134,136] Hence three further questions to assess the timing of SMBG were added.

After the pilot study, three questions were rephrased to improve clarity. The final Pre-RDSA questionnaire (80 items) began with knowledge assessment, medication intake, physical activity, SMBG, diet recall and FFQ. For the final FFQ (122 items), five food items that were consumed less than 10% during the pilot study were removed and 27 commonly consumed ethnic local food items were added. The FFQ was reorganised to include four main sections: fruits, beverages, cereals/tubular/legumes and food and beverages with added sucrose. (Appendix 1) The final Post-RSDA questionnaire consisted of 62 items (Appendix 2). The average interviewing time was 40 minutes.

Ethical Consideration

The Research Ethics Committee of the University of Adelaide (Appendix 3) and the Malaysian Medical Research and Ethic Committee (Appendix 4) approved this study. The Director-General of Health for the Ministry of Health in Malaysia and the state of Melaka as well as the medical superintendents of the General Hospital and the rural healthcare centre granted permission to access the research settings and subjects' medical records.

Recruitment of the subjects was done with the assistance of the nurse-in-charge of the out-patient clinics from the general hospital and the rural healthcare centre. The nurse-in-charge informed potential subjects of the study and gave them an information sheet. Potential subjects with low literacy levels were helped by the nurse-in-charge who read the information sheet to them (Appendix 5). Once an

eligible subject agreed to participate in the study, the investigator approached them to gain written consent. Again if subjects who were unable to read, the consent form was read to them by the investigator. Written consent was gained before the interview, blood sampling and education intervention. All interviews, education interventions and sourcing of the medical records for subject's glycaemic status namely fasting or random blood glucose readings to assist in identifying the potential subjects and the subjects' current medication(s) were done at the above study settings by the investigator alone.

Data Collection

Randomisation

Participants were randomised to intervention or control group using a computer generated number list. The odd number in the list indicated control subjects and even number referred to intervention subjects (Appendix 6).

First Visit

After gaining informed consent, subjects' height in centimetres and weight in kilograms were measured with subjects wearing light clothing without footwear. A Seca 807 electronic scale was used. A wall mounted measuring tape was used to measure height. Body Mass Index was calculated as weight in kilograms divided by height in meters square (kg/m2). Waist circumference was measured in centimetres halfway between the lowest rib and the iliac crest using a Roche waist circumference measuring tape. Baseline HbA1c by finger prick method was analysed on a Bayer DCA 2000 analyser. Then the investigator interviewed all subjects using the language of their choice to assess the baseline knowledge and self-care practices using the Revised Diabetes Self-care Activities pre-questionnaire. To enhance recall,

samples of oral medications and insulin were shown. Subjects on insulin treatment were requested to demonstrate insulin injection technique.

Dietary assessment began with the first 24-hour dietary recall which was the previous day's dietary intake. To enhance accuracy, different sizes of spoons, plates, bowls, cups, commonly used in Malaysian common households, food and fruit photographs and actual food items were used. Match boxes were used to demonstrate the size of protein food portions. For the Food Frequency Questionnaire (FFQ), subjects were required to indicate their portion intake and frequency in terms of daily or during the previous week for each of the food items consumed when a food list was read to them. They could also answer 'never or rarely' if the food items were consumed infrequently. Some prompting questions were used to assist those who had problems with recall (Table 9). After the 24-hour diet recall and FFQ the investigator checked with the subjects for accuracy of food consumption.

The second 24-hour dietary recall was done unannounced within one week of the first interview. Findings from the pilot study reported a number of the subjects had problems with previous day 24-hour dietary recalls. To enhance validity, the investigator used the same day recall by telephoning them after their dinner intake at night followed by whether they had taken any supper during the previous night.

Control Group

After the above procedure, the investigator thanked the subjects and gave them printed educational materials on diet, medication, exercise and SMBG. All the subjects in the control group were requested to return during their next appointments date at 12 ± 2 weeks.

Table 9: Recall Cues and Dietary Formula Used to Enhance Food Frequency Questionnaire Dietary Recall

Recall Cues	
Meals/food	**Description**
Fruits	Do you eat fruit daily?
Beverage	What are the drinks that you take daily?
Main meals	How many meals do you usually eat in a day?
Dietary Formula Used for Calculating the Meals Consumed during the Previous Week	
Dietary formula e.g. breakfast	What do you usually eat for breakfast (usual food)?
	What 'other food' do you eat for breakfast?
	How many times did you eat 'other food' for breakfast last week by listing one food at a time from the list in the FFQ?
	Total the frequency that 'other food' was eaten
	No of times 'usual food' was eaten in the preceding week = 7 days – (frequency of 'other food' + number of meal(s) skipped during breakfast)
	The same formula is used for lunch, dinner, afternoon snack and supper

Intervention Group

A structured individualised education program based on the principle of self-efficacy was provided to subjects in the interventional group via three monthly sessions. These include two face-to-face individual education sessions and one telephone follow-up during the 12 week period

First Education Intervention Using a Face-to Face Approach

The aim of the first education session was to identify and enhance areas of low self-efficacy in knowledge, diet and medication intake, physical activity and SMBG based on the findings of the Revised Diabetes Self-care Activity Pre-Questionnaire.

Using the subjects' past experience in self-care, the investigator discussed with them the approaches to overcome self-care deficits by improving knowledge and skills on dietary and medication intake, SMBG and physical activity. They were also given time to practice SMBG (performance accomplishment). To further enhance self-care, evidence-based studies like DCCT and UKPDS were discussed with the subjects (vicarious experience and verbal persuasion). Table 10 outlines the first education intervention.

Table 10: First Education Intervention

Aims	• To provide subjects with an understanding of the importance of self-care in the management of diabetes • To identify area(s) of low self-efficacy in daily self-care practices • To enhance self-efficacy by providing the subjects with the knowledge and skills of self-care			
Assess areas for low-self-efficacy	**Questions used for assessments**	**Encouraged Self-efficacy by:**	**Concept of Self-efficacy used**	**Tool used**
Diabetes related knowledge	• What was the subjects' level of knowledge on diet, medication, exercise, SMBG and complications?	• Providing information on the importance of diet and medication adherence, physical activity and SMBG in relationship to diabetes control	• Verbal persuasion	• Revised Diabetes Self-care Activity questionnaire.
Diet	• Could the subjects identify CHO food items from their daily intakes? • Were the subjects familiar with CHO exchanges?	• Showing subjects the list of CHO food items in our daily life. • Explaining the importance of consistent quantity of CHO intake in each meal • Facilitating the subjects with the skills of CHO exchanges when consuming food and beverages with added sucrose • Explaining the problems regarding irregular mealtime with glycaemic control	• Verbal persuasion • Performance accomplish-ment	• A Food Chart with a list of local food items that contains CHO

Table 10: First Education Intervention (continued)

Assess areas for low-self-efficacy	Questions used for assessments	Encouraged Self-efficacy by:	Concept of Self-efficacy used	Tool used
Diet	• Did the subjects apply the concept of CHO exchanges when consuming food and beverages with added sucrose?	• Encouraging the subjects to reduce the CHO intake if required and consumed more vegetables and fruits. • Providing examples of what others had achieved	• Verbal persuasion • Vicarious experience	
Medication	• What was the current medication adherence rate? • Was timing of medication intake correct? • Was there any problem with insulin injection technique?	• Emphasising the importance of medication adherence • Identifying barriers to medication non-adherence • Demonstrating insulin injection if required • Explaining the action of each of their prescribed medications and the importance of correct medication timing • Discussing what others had done like using medicine box, putting the medicine on the dinning tables, on their wallets with their IDs	• Verbal persuasion • Performance accomplish-ment • Vicarious experience	• Samples of OAM • Insulin action charts • Novo pens • Insulin syringes • Samples of various insulin

Table 10: First Education Intervention (continued)

Assess areas of low-self-efficacy	Questions used for assessments	Encouraged Self-efficacy by:	Concept of Self-efficacy used	Tool used
SMBG	• Did the subjects practice SMBG? • If yes, assessed frequency and timing? • What were the results of previous SMBG? • Was there any treatment modification done previously?	• Emphasising the importance of SMBG in relation to diabetes control • Showing subjects SMBG techniques • Discussing the frequency and timing of SMBG and its rationale. • Discussing the rationale for treatment modification based on their SMBG findings • Discussing what others had done	• Performance accomplish-ment • Verbal persuasion • Vicarious experience	• SMBG chart • 'Living with diabetes' • SMBG records of other patients
Exercise	• What was the current level of physical activity? • If exercise program already present, to assess frequency, duration, intensity?	• Discussing the importance of exercise in diabetes management. • Explaining findings from the preliminary results that there was a correlation with improved glycaemic control and leisure exercise	• Performance accomplish-ment • Verbal persuasion	• Used toy car as sample • The more frequent and further the car traveled, the more petrol was used.

Table 10: First Education Intervention (continued)

Assess areas of low-self-efficacy	Questions used for assessments	Encouraged Self-efficacy by:	Concept of Self-efficacy used	Tool used
Exercise	• If subjects had not started exercise, what were the barriers?	• Discussing what others had done like taking the baby for walk, taking short walks within the house compound several times a day, arm chair exercise, exercise on their treadmill while watching their favourite TV programs	• Vicarious experience	• 'Petrol' represented blood glucose level in the blood. • Car was used as an example as all subjects were familiar with it.
Evaluation of learning	Adherence to self-care would be done during the second education session.			

Note: CHO means carbohydrate

SMBG means self-monitoring of blood glucose

OAM means oral anti-hyperglycaemic medication

If they had not done it previously, subjects were taught SMBG skills using a Roche Advantage 2 blood glucose meter. If the subjects already practiced SMBG, they were requested to use the Roche Advantage meters during the intervention period. One bottle of blood glucose test strip was supplied during the first visit. The subjects were requested to monitor and record their blood glucose levels using the algorithm in Table 11 to identify causes related to hyperglycaemia. The data would provide them with information to enhance glycaemic control.

The education process took about 30-45 minutes excluding assessment. Printed materials on the four self-care practices were provided to reinforce the discussion. Together with the subjects, two realistic and achievable short-term goals were set.

Table 11: Algorithm for Self-Monitoring of Blood Glucose (SMBG) Self-care Practices

No of week	SMBG regimen		Interpretation of SMBG results	Topics of discussion
	Frequency of monitoring	**Timing of monitoring:**		
1st week	**3 days per week**	• **Fasting blood glucose (FBG)**	**[A] If FBG persistently >10 mmol/L, possible reasons were:** • Medication-related problems e.g. ❖ medication non-adherence [146,147] ❖ wrong timing of medication ❖ medication inertia.[148] ❖ medication induced hyperglycaemia e.g. steroid intake [149-151] • Rebounced hypoglycaemia, dawn phenomenon[148] **[B] In cases of variable FBG levels between 4 to >10 mmol/L, it could be due to:** • Food-related factors like excessive or inconsistent quantity of CHO intake during the previous night [152-155]	• Explored the underlying causes of medication related problems • Explained patho-physiology of rebounced hypoglycaemia, dawn phenomenon. • Explored food items that could contribute to increase blood glucose levels • Discussed relationship of food intake and glycaemic control

Table 11: Algorithm for Self-Monitoring of Blood Glucose Self-care Practices (continued)

No of week	SMBG regimen		Interpretation of SMBG results	Topics of discussion
	Frequency of monitoring	**Timing of monitoring:**		
			• Inconsistent evening medication intake • Acute illness for example fever **[C] If subjects live a sedentary lifestyle, activity level was unlikely as a contributing factor of hyperglycaemia**	• Explained importance of medication adherence • Discussed relationship of acute illness and glycaemic control • Discussed benefits of exercise in lowering blood glucose level
2nd and 3rd week	**3 days per week :**	• **Each day choose a meal, either breakfast, lunch or dinner** • **Monitor pre- and 2 hours post-meal**	To identify **[A] Meal-related hyperglycaemia which was shown as a difference between post- and pre-meal blood glucose level of more than 4 mmol/L.**	• Identified CHO sources that could contribute to meal-related hyperglycaemia • Reduced quantity of CHO intake if the difference between post- and pre meal results was more than 4 mmol/L

Table 11: Algorithm for Self-Monitoring of Blood Glucose Self-care Practices (continued)

No of week	SMBG regimen		Interpretation of SMBG results	Topics of discussion
	Frequency of monitoring	**Timing of monitoring:**		
			[B] Medication and meal related problems such as: • Medication non-adherence • Wrong timing of medication intake	• Discussed importance of correct timing of medication intake especially when Acarbose or sulphoneureas or insulin was prescribed
4th week	**2 days per week**	• **Fasting blood glucose (FBG)**	**[A] Allowed comparison of the FBG readings after enhancing self-care practices like lifestyle adjustment**	

Second Follow-up

Second Education Intervention Using Face-to-face Approach

The second education session was scheduled a month later. The investigator praised the subjects' achievement and discussed their SMBG results to identify the effect of dietary intake, physical activities and medication on the blood glucose levels (performance accomplishment). The investigator and the subjects together explored problems encountered and identified solutions to modify diet, medication intake, physical activity to set another two accomplishable short-term goals (verbal persuasion). Other subjects who had improved their glycaemic control via enhanced self-care were used as examples (vicarious experience). For subjects who encountered hypoglycaemia because of self-care modification or were unwell during the intervention period, hypoglycaemia prevention and sick day management were discussed. The investigator also explored with the subjects any emotional problems involving their daily care (emotional arousal). The intervention took about 15-30 minutes as shown in Table 12. Two bottles of blood glucose reagents were supplied to the subjects. They were requested to follow the same monitoring regimen and return their SMBG diary via a self-addressed envelope. No medication dosage was adjusted by the investigator.

Table 12: Second Education Intervention

Aims	• To reassess areas of low self-efficacy in self-care practices • To facilitate interpretation of SMBG results in relationship to medication and diet intake, physical activities • To facilitate modification of self-care practices based on SMBG results • To discuss hypoglycaemia prevention and sick day management • To discuss psychosocial problems.		
Self-care	**Assessment and Discussion**	**Concept of Self-efficacy used**	**Tool used**
Medication	• Did the subjects achieve >90% medication adherence if it was not achieved at baseline? • Was the medication timing correct? • Identified problems concerning medication non-adherence if present	• Performance accomplishment • Verbal persuasion	• Samples of OAM • Insulin charts • Novo pens • Insulin syringes • Samples of various insulin
Dietary intake	• Discussed the meal-related SMBG results. Encouraged subjects to identify their CHO food intake when the difference between post- and pre-meal results were more than 4 mmol/L • Discussed CHO exchanges when consuming food and beverages with added sucrose with other CHO food items	• Performance accomplishment • Verbal persuasion	• A list of CHO food items

Table 12: Second Education Intervention (continued)

Self-care	Assessment and Discussion	Concept of Self-efficacy used	Tool used
Diet intake	• Emphasized the importance of consistent CHO intake throughout the day. • Encouraged consumption of vegetable intake between half to one cup (200mls) (1-2 exchanges) with lunch and dinner • Identified areas of excessive CHO intake • Provided examples of what others had achieved	• Verbal persuasion • Performance accomplishment • Vicarious experience	
Physical activity	• Assessed whether physical activity had been started and its frequency and duration. • If no, identified barriers. • Discussed what others had achieved	• Performance accomplishment • Vicarious experience	• Used toy car as sample
SMBG	• Discussed problems related to SMBG and their perception of SMBG • To provide individuals' glycaemic target values • Subjects were requested to continue monitoring using the same regimen as described earlier • Then the subjects were able to compare the FBG results during the first and second month to identify the effect of lifestyle changes on glycaemic control. • They were also instructed to monitor whenever they experienced hypoglycaemia symptoms or during sick day	• Performance accomplishment • Verbal persuasion	• Subjects' SMBG records

Table 12: Second Education Intervention (continued)

Self-care	Assessment and Discussion	Concept of Self-efficacy used	Tool used
SMBG	• Subjects were provided with a self-addressed envelope for purpose of sending their SMBG results to the investigator • Set 2 accomplishable short-term goals to enhance positive self-care	• Verbal persuasion	
Psychosocial	• Discussed any emotional problem with their daily care	• Emotional arousal	
Hypoglycaemia	• Discussed signs and symptoms of hypoglycaemia • Discussed on causes of hypoglycaemia • Discussed on prevention of hypoglycaemia	• Verbal persuasion	• Subjects' SMBG records • Hypoglycaemia chart
Sick day management	• Did the subjects report unwell or signs and symptoms of infection like URTI or fever during the intervention period? • Discussed sick day management	• Verbal persuasion	• 'Living with diabetes chart
Evaluation of learning	Adherence to self-care would be done during the third education session		

Note: CHO means carbohydrate
SMBG means self-monitoring of blood glucose
OAM means oral anti-hyperglycaemic medication

Third Follow-up

Third Education Intervention Using Telephone Approach

The telephone follow-up was provided between the 7th and 9th weeks after the investigator received the subjects' SMBG results. The aim of the third intervention was to reinforce the aims of the second intervention. The investigator discussed with the subjects their SMBG results to re-identify the effects of food intake and physical activity on blood glucose levels and to increase their self-efficacy in dietary, physical activity and medication self-care practices (performance accomplishment and verbal persuasion). Subjects who did not achieve improvement in SMBG, the investigator re-assessed their food intake, physical activity level, medication adherence and other barriers to self-care. Subjects who had achieved reduction in their HbA1c via enhanced self-care were used as role models. The phone calls also provided personalised problem-solving training based on the problems concerning self-care activities. This session took about 10 to 15 minutes.

12th Week Follow-up

All subjects had their body weight and HbA1c reassessed. Diabetes knowledge and self-care practices were assessed by interview with the investigator using the Revised Diabetes Self-care Activities post questionnaire. One week before the final follow-up, the investigator reminded the subjects of their follow-up appointments via telephone and recorded their first 24-hour diet recall. The second 24-hour diet recall was recorded on the day of follow-up. No educational intervention was delivered during the 12th week. Subjects from the control group were given a small present to thank them for their time.

Data collection process is summarised on Table 13.

Table 13: Summary of Data Collection Process

Intervention group	**Control group**
• General Hospital • Rural healthcare centre	• General Hospital • Rural healthcare centre •
First visit	**First visit**
• Consent • Height, weight, BMI[§], waist circumference • Blood sample for HbA1c • Pre-questionnaire • First 24-hour dietary recall • First education intervention -Face to face individual -Demonstrate technique of blood glucose monitoring and supply one bottle of blood glucose test strip and meter • Written education materials on diet, medicine, exercise and self-monitoring of blood glucose provided • Second 24-hour dietary recall by telephone within a week of the interview	• Consent • Height, weight, BMI[§], waist circumference • Blood sample for HbA1c • Pre-questionnaire • First 24-hour dietary recall • Written education materials on diet, medicine, exercise and self-monitoring of blood glucose provided • Second 24-hour dietary recall by telephone within a week of the interview
Second visit (4th week)	
• Face to face individual education • Two bottles of blood glucose test strip supplied	
Third visit (7th -9th weeks)	
• Telephone intervention	
12th week	**12th week**
• First 24-hour dietary recall by telephone a week prior to the interview • Post-questionnaire • Blood sample for HbA1c • No education intervention • Second 24-hour dietary recall	• First 24-hour dietary recall by telephone a week prior to the interview • Post-questionnaire • Blood sample for HbA1c • Second 24-hour dietary recall

Note: § BMI means body mass index

Statistical Analysis

Demographic data was analysed using descriptive statistics. A 2-tailed t-test was used to analyse any difference between the intervention and control groups and within groups for ratio data such as medication adherence rate. For ordinal data such as exercise, analysis was done with the Kruskal-Wallis test. Nutrient and total dietary calories were analysed using the Nutritionist Pro version 2.0. Chi-square was used to analyse the relationships between nominal data such as gender. Multiple regressions 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 13.00. The level of significance was set at 0.05.

Conclusion

This chapter has provided an overview of the research methodology and piloted the data collection tool. It also explained in detail the interventions. The result of the pilot study demonstrated that both the reliability and validity of RSCQ were acceptable in the population studied. Due to time and other feasibility constraints, more stringent testing of the validity assessment such as convergence was not done. The next chapter reports the results of the study.

Chapter 4

RESULTS

Introduction

This chapter presents the findings in four sections. Section one describes the subjects' demographic data. Section two presents the findings of research hypotheses in relation to self-care, knowledge and HbA1c levels between and within the intervention and control groups. Section three presents the results of the six hypotheses then the results are summarised in Section four.

Statistical Analysis

The demographic data were reported using descriptive statistics. To assess for any significant differences and relationship between groups, chi-square and unpaired t-test were used. While within groups, paired t-test was used. To assess for any significant difference between demographic or clinical data and different self-care practices, HbA1c and knowledge levels, unpaired t-test, Kruskal-Wallis test and Mann-Whitney U were used. To establish whether there was a relationship between the above variables, Pearson r or Spearman rho correlations were used. Multiple regressions were used to identify the predictors for glycaemic control and two-way between groups ANOVA was used to explore the effect of medication change on HbA1c levels. To assess the agreement between Food Frequency Questionnaire (FFQ) and 24-hour diet recall, Wilcoxon Signed Rank Test was used. Dietary data was analysed using Nutritionist Pro program. All data other than dietary information was analysed using SPSS program version 13. A $p=<0.05$ was considered to be statistically significant.

Section 1

Baseline Characteristics of Participants

Of the 201 subjects who met the study-entry criteria, 37 subjects declined to participate due to lack of time and interest. One hundred and sixty-four subjects were randomised to either control or intervention group with 82 subjects in each group. Thirteen subjects withdrew from the study for reasons of lack of interest (n= 9), transferred to other healthcare centres (n=2), severe anaemia and hence were unable to read the post-HbA1c (n=1) and one died. The primary results of this study were based on data from the 151 subjects who completed the 12-week follow-up (intervention=78, control=73) (see Figure 2 below).

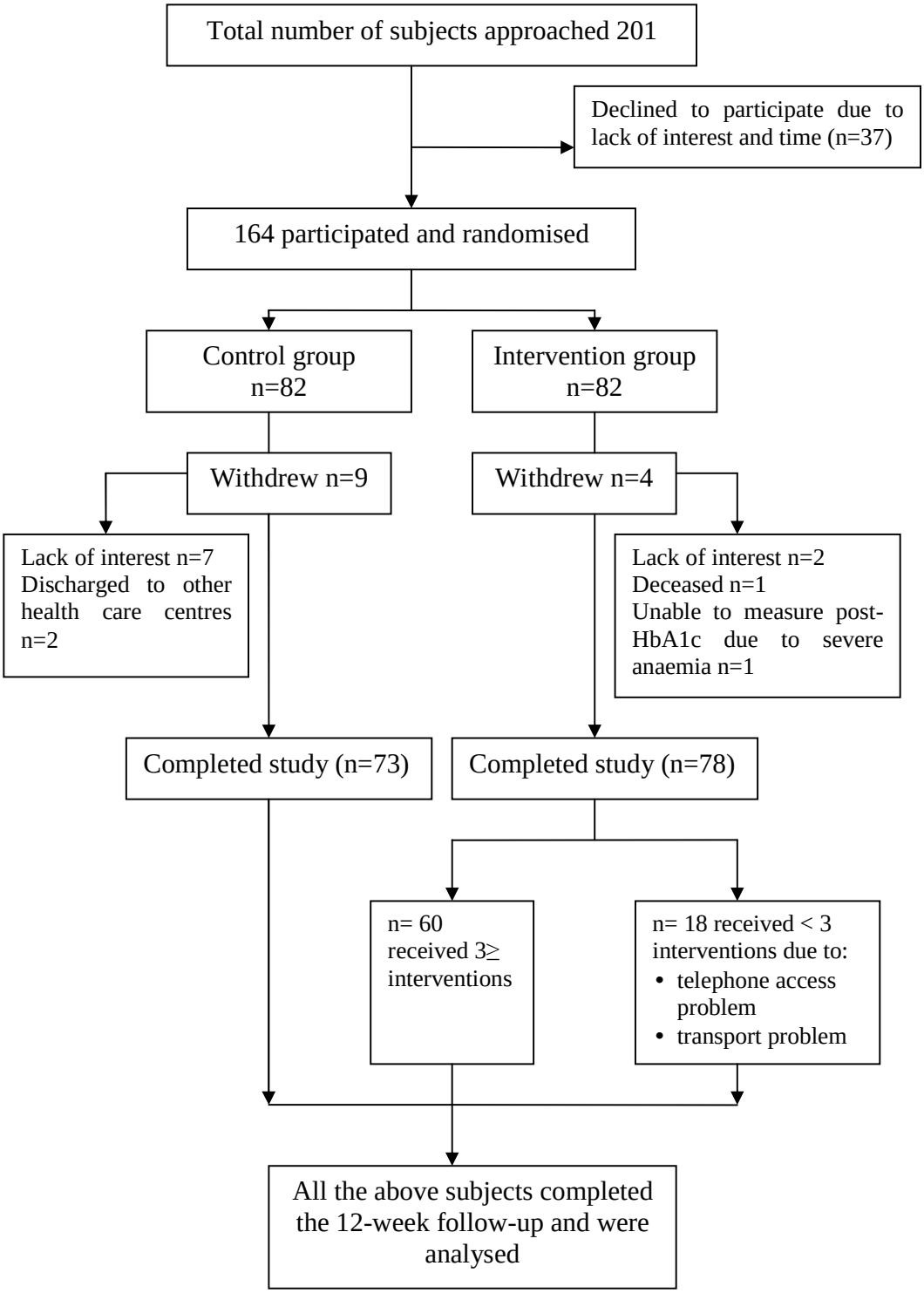


Figure 2: Flow Chart of the Phases of Randomisation

There was no significant relationship between the demographic and clinical characteristics of participants who completed the study and those who did not (Table 14).

Table 14: Comparison between Demographic Data of Subjects Who Had and Had Not Completed the Study at Baseline (n=164)

Subjects	Participants=151 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					0.05	0.82‡
-male	60	40%	4	36%		
-female	91	60%	7	64%		
Education level					0.81	0.93‡
-Never	8	5%	1	9%		
-Primary	83	55%	6	55%		
-Secondary	49	32%	3	27%		
-College	9	5%	1	9%		
-Tertiary	4	3%	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					0.75	0.38‡
-Type 1	7	5%	0	0%		
-Type 2	144	95%	11	100%		

≠ analysis by t-test
‡analysis by Chi-square

At baseline there was no significant relationship between the intervention and control groups who completed the study in demographic, clinical and psychosocial contexts (Table 15).

Table 15: Baseline Characteristics of Subjects Who Completed the Study (n=151)

Variables	Intervention(n=78) mean (SD)/percent		Control (n = 73) mean (SD)/percent		X^2 /*t*	P value
A. Demographic						
Age (years)	54	(9.81)	54	(10.29)	0.03	0.98[≠]
Gender					0.05	0.10[‡]
Male	31	40%	29	40%		
Female	47	60%	44	60%		
Race					4.35	0.23[‡]
Malay	44	56%	48	65%		
Chinese	18	23%	18	25%		
Indian	14	18%	9	10%		
Others	2	3%	0	0%		
Education					-1.55	0.12[‡]
Never	4	5%	4	6%		
Primary	38	49%	45	62%		
Secondary	29	37%	20	27%		
College	4	5%	3	4%		
Tertiary	3	4%	1	1%		
Marital status					3.96	0.41[‡]
Single	5	6%	3	4%		
Married	64	82%	58	80%		
Divorced	1	1%	0	0%		
Separated	1	1%	0	0%		
Windowed	7	10%	12	16%		
B.Clinical Variables						
Types of Diabetes					1.61	0.26[‡]
Type 1	2	3%	5	7%		
Type 2	76	97%	68	93%		
Duration of Diabetes (yrs)	12.09	(8.61)	10.62	(8.82)	1.03	0.30[≠]
Treatment mode					1.09	0.58[‡]
OAM[§]	33	51%	37	42%		
Insulin	17	22%	13	18%		
OAM[§] and insulin	28	37%	23	32%		
HbA1c (%)	9.84	(1.75)	9.60	(1.78)	-0.81	0.41[≠]
BMI[§] (kg/m2)	28	(5.41)	28	(5.79)	0.55	0.58[≠]
Male	27	(4.05)	27	(5.70)	-1.19	0.24[≠]
Female	29	(6.03)	29	(5.79)	3.07	0.38[≠]
Waist circumference (cm)	94	(10.01)	95	(12.44)	0.55	0.58[≠]
Male	95	(10.01)	97	(12.80)	1.64	0.25[≠]
Female	93	(11.00)	94	(12.18)	0.66	0.49[≠]

Table 15: Baseline Characteristics of Subjects Who Completed the Study (continued)

Variables	Intervention(n=78) mean (SD)/percent		Control (n = 73) mean (SD)/percent		X^2 /*t*	P value
C. Psychosocial						
Setting					0.60	0.81‡
Hospital	58	74%	53	73 %		
Healthcare centre	20	26%	20	27%		
Social status					1.47	0.48‡
Living with family members	74	95%	68	93%		
Living with friends	0	0 %	1	2 %		
Living alone	4	5 %	4	5 %		
Occupation					3.13	0.66‡
Office	6	7 %	5	7 %		
Factory	18	23%	14	19%		
Fieldwork	3	4 %	5	7 %		
Housewife	34	44%	29	40%		
Professional	1	1 %	4	5 %		
Retired	16	21%	16	22%		

≠ analysis by t-test
‡ analysis by Chi-square
§ OAM means Oral anti-hyperglycaemic medication
BMI means body mass index

Likewise there was no significant difference with diabetes knowledge and self-care practices except for carbohydrate intake in FFQ assessment (Table 16).

Table 16: Baseline Knowledge and Self-care practices of Subjects Who Completed the Study (n=151)

Variables	Intervention (n=78) mean (SD)	Control (n = 73) mean (SD)	X^2 /*t*	P value
Knowledge score	9.38 (3.38)	8.51 (3.08)	-1.67	0.97≠
Medication Adherence rate	85.21 (17.26)	84.52 (20.79)	-0.22	0.82≠
Total physical level	15.01 (6.44)	13.49 (5.24)	-1.58	0.12≠
SMBG Practices per week	0.50 (1.40)	0.6 (1.34)	0.46	0.65≠
Dietary intake				
FFQ- CHO	217 (51)	238 (65)	2.14	0.03*≠
24-hr dietary intake				
Total calories (Kcal)	1732 (455)	1731 (464)	-0.01	0.99≠
CHO (gram)	246 (64)	259 (71)	1.12	0.27≠
Protein (gram)	67 (25)	66 (25)	-0.40	0.69≠
Fat (gram)	52 (22)	47 (18)	-1.45	0.15≠
Sugar (gram)	24 (16)	27 (17)	1.13	0.26≠

* $p<0.05$; ≠ analysis by t-test;
Note: CHO means Carbohydrate; FFQ means Food Frequency Questionnaire

Section 2

Self-care Activities

Medication Adherence Self-care

Between Groups

There was no statistically significant difference in the medication adherence rate between the intervention (M=89.50, SD=17.98) and control groups [M=84.60, SD=17.16; t(149)=-1.7, p=0.06] at follow-up.

Within Groups

Within the intervention group, however, there was a significant difference in medication adherence rate from baseline (M=85.21, 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). The control group did not show any significant difference in medication adherence practices (M=84.52, SD=20.79) to follow-up [M=84.60, SD=17.16, t(72)=-0.04, p=0.97].

Factors Influencing Medication Adherence Self-care

Hypoglycaemia Episodes

During the study, 11 subjects (14%) 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. Subjects with no previous hypoglycaemic episodes had higher medication adherence rate (M=91.10, SD=15.71) when compared to those with history of hypoglycaemic episodes [M=82.45, SD=18.48; t(76)=1.65, p=0.10]. The finding was not statistically significant.

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 least to medication intake (mean adherence rate 83% ± 21.9, X^2= 2.22, df=2, p=0.04). Post-knowledge assessment, other demographic data and self-care practices were not related to medication adherent practices (p=>0.05).

Medication Self-care and HbA1c levels

Wrong Timing of Medication Intake

Of the 57 subjects (73%) from the intervention group who reported adherent to their daily medication intake after the education intervention, 21 subjects (37%) 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.[156-158] Short acting and premix insulin are injected at 30 to 45 minutes before food. [159] Injection Glargine is not time-specific. Subjects 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; t(26.18),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 did not (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=52; X^2=3.38, df=4, p=0.41). These findings were not statistically significant.

Self-monitoring of Blood Glucose Self-care

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 moderate effect size (eta squared= 0.06).

Within Groups

Within the intervention group, not all the subjects monitored their SMBG four times a week as instructed. During the 12 weeks the mean number of times this was done was 2.94 (SD=2.25) ranging between 0-8 tests per week. Despite the inconsistent practice, there was a statistically significant difference in SMBG practices from baseline (M=0.50, SD=1.40) to follow-up [M=2.94, SD=2.25, t(77)=-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 results (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 practice with demographic data or post-knowledge assessment or levels of physical activity.

As for the control group, there was no significant difference in SMBG practices from baseline (M=0.60, SD=1.34) to follow-up [M=0.47, SD=1.36, t(72)=0.97, p=0.34] and no relationship was also found between the number of blood glucose tests done with demographic or clinical variables.

Physical Activity Self-care

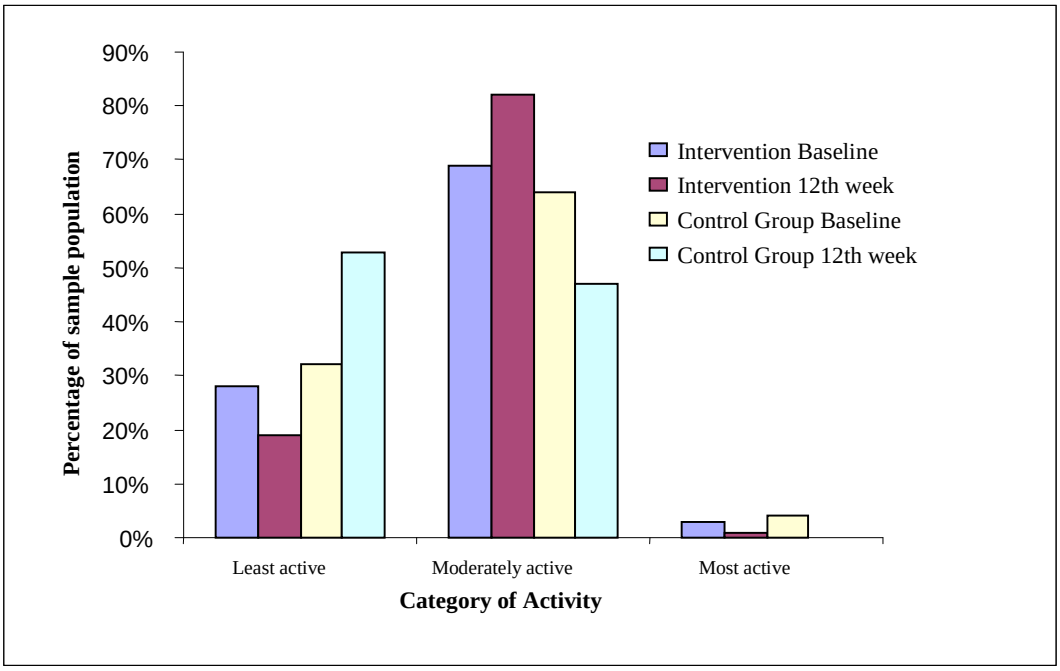
Total physical activity was defined as the combination of non-leisure and leisure activities.

Between Groups

There was a statistically significant difference in total physical activity levels between the intervention (M=15.45, SD=5.64) and control groups [M=12.75, SD=4.86; t(148.04)=-3.15, p=0.002] at follow-up with small effect size (eta squared= 0.04). Sub-analysis showed that the significant difference was in leisure activity levels between the intervention (M=8.71, SD=5.18) and control groups [M=6.22, SD=4.42; t(147.75)=-3.18, p=0.002] with no difference in the non-leisure activity (p=0.43).

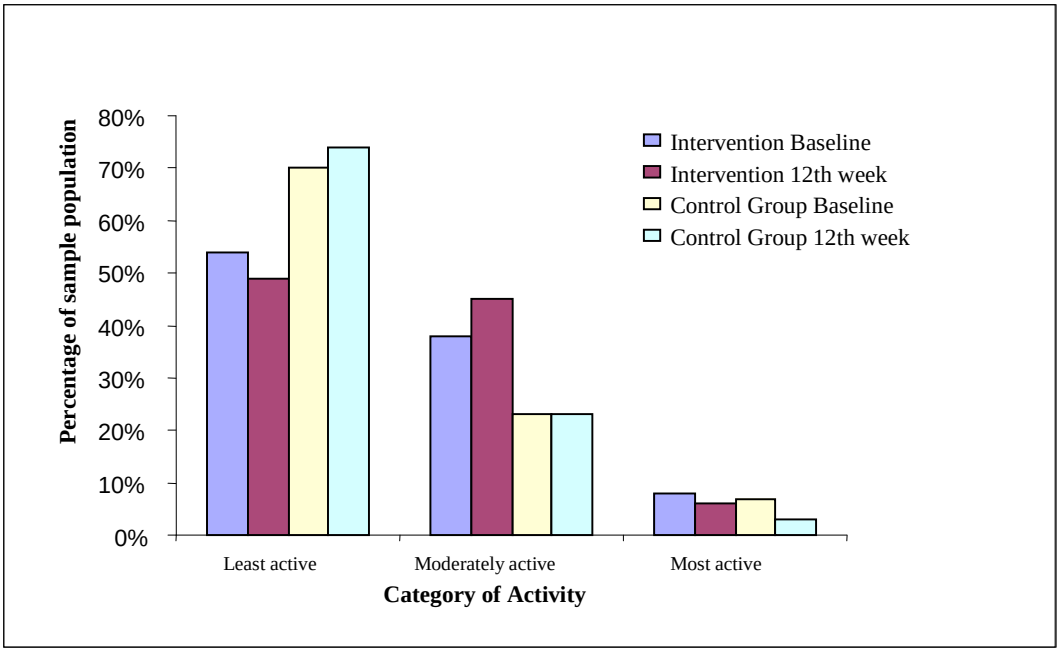
Within Groups

After education, the intervention group showed slight improvement in total, non-leisure and leisure activity but this was not significant. As for the control group there was no difference in all levels of physical activities with deterioration in total activity level from baseline. Figures 3, 4 and 5 compared the frequency of all activity levels of the intervention and control groups at baselines and 12th week. No significant relationship was found between demographic or clinical variables, post-knowledge assessment and post-HbA1c levels with subjects' physical activity levels.



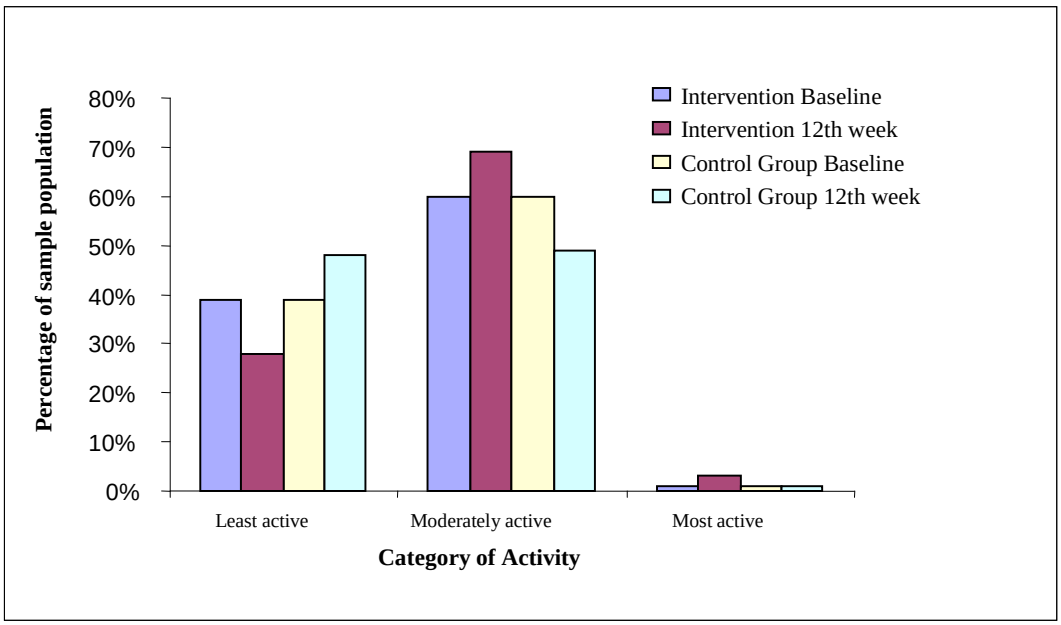
Note: There was no significance between the frequency of non-leisure activity levels from baseline and 12th week for both the intervention and control groups

Figure 3: Frequency of Non-leisure Activity Levels at Baseline and 12th Week



Note: There was a significant difference in frequency of leisure activity between the intervention and control group at 12th week. However, within both the intervention and control groups, there was no significant difference regarding the frequency of leisure activity levels from baseline and 12th week .

Figure 4: Frequency of Leisure Activity Levels at Baseline and 12th Week



Note: There was a statistically significant difference in frequency of total physical activity levels between the intervention and control groups at 12th week. However, within both the intervention and control groups, there was no significant difference regarding frequency of total physical activity levels from baseline and 12th week

Figure 5: Frequency of Total Physical Activity Levels at Baseline and 12th week

Dietary Self-care

Total daily carbohydrate intake in grams was assessed using the FFQ and two 24-hour dietary recalls. Twenty-four-hour dietary intake was analysed using the Nutritionist Pro version 2.0, First Databank, USA. Based on the Wilcoxon Signed Rank Test, there was significant difference between the agreement of the two assessment tools ($Z=-4.18$, $p=<0.001$). Due to significant differences in the FFQ results and those of the 24-hour dietary recall, the investigator chose to analyse the dietary result with only the 24-hour diet recall data for several reasons. First, 24-hour diet recall documented the subjects' actual previous day's intake. The FFQ provided an overview of habitual food intake over the previous week which might not necessarily had been actually taken by the subjects in reality. In addition the FFQ was developed based on the dietary history of subjects from the previous study of this portfolio and not from the current study subjects. It might have overestimated the intake especially when a large number of foods were listed. Furthermore the consistency with assessment of total daily calories, protein, fat and sugar intake which were derived from the 24-hour diet recall data was taken into account.

Between Groups

At week 12, there was no difference in the 24-hour dietary recall between the intervention and control groups in total daily calorie, carbohydrate, protein, fat and sugar intake (Table 17).

Table 17: Comparison of 24-hour Dietary Intake between the Intervention and the Control Groups at 12th week (n=151)

Food composition	Intervention Group (n=78) Mean (SD)	Control group (n-73) Mean (SD)	t	P value
Total daily calorie (kilocalories)	1579 (376)	1663 (418)	1.28	0.20
Carbohydrate (gram)	236 (60)	252 (63)	1.58	0.18
Protein (gram)	59 (18)	61 (18)	0.56	0.57
Fat (gram)	45 (15)	47 (21)	0.60	0.55
Sugar (gram)	23 (18)	29 (22)	1.79	0.74

Within Groups

In the intervention group there was statistically significant reduction in daily total caloric intake from baseline (M=1732, SD=455) to follow-up (M=1579, SD=376; t(2.66) df=77, p=0.009); protein intake from baseline (M=68, SD=25) to follow-up (M=59, SD=18; t(2.55, df=77, p=0.01) and fat intake from baseline (M=53 SD=22) to follow-up (M=45, SD=15; t(2.77) df=77, p=0.01). There was slight reduction in carbohydrate and sugar intake but this was not statistically significant (Table 18)

For the control group, in contrast there was no significant difference in daily total calories, carbohydrate, protein, fat and sugar intake between baseline and follow-up.

Table 18: Comparison of 24-hour Dietary Intake of the Intervention Group from Baseline to 12th week (n=78)

Food composition	Intervention Group		t	P value
	Baseline Mean (SD)	Week 12 Mean (SD)		
Total daily calorie (kilocalories)	1732 (455)	1579 (376)	2.66	0.009*
Carbohydrate (gram)	247 (64)	236 (60)	1.26	0.18
Protein (gram)	68 (25)	59 (18)	2.55	0.01*
Fat (gram)	53 (22)	45 (15)	2.77	0.01*
Sugar (gram)	25 (16)	23 (18)	0.57	0.57

*p<0.05

Demographic Data and Dietary Self-care

Male subjects (mean 1850 ± 512 kilocalories) consumed more calories daily than female subjects (mean 1550 ± 421 kilocalorie; Mann-Whitney U=1759, p=<0.001). The fieldworkers consumed the highest daily calories (mean 1930 ± 322 kilocalorie) with the least being consumed by housewives (mean 1593 ± 383 kilocalorie; x^2= 13.96, df=5, p=0.02).

Both male and female Malay subjects had the highest sugar intake (mean 29 ±19 gram) with the Chinese consuming the least (mean 21 ± 20 gram, x^2= 9.18, df=3, p=0.03). These findings were supported by the Malay subjects having the heaviest body weights (p=0.004), highest BMI (p=<0.001) and largest waist circumferences (p=0.01). No relationship was found between carbohydrate and total daily calorie intakes with other demographic or clinical variables.

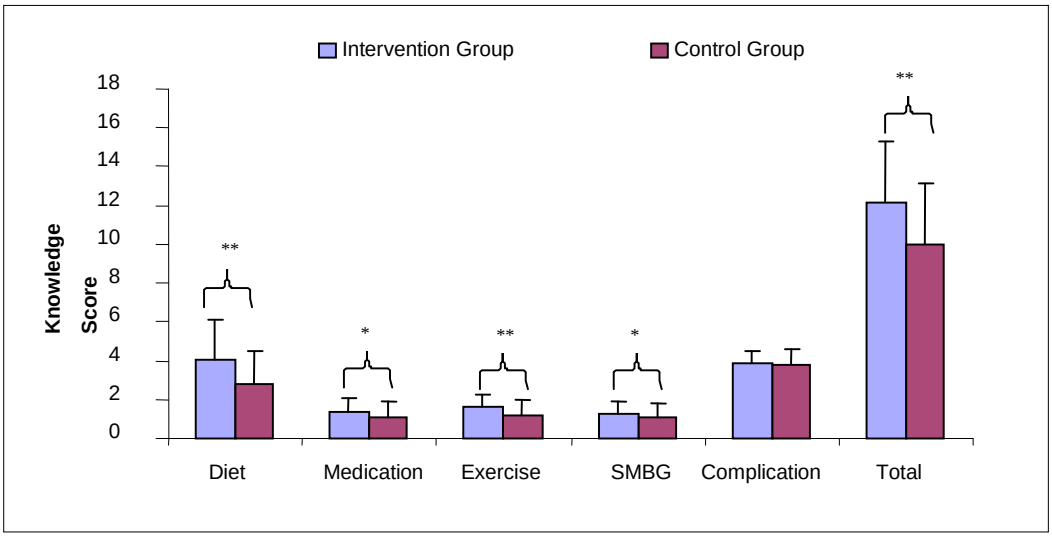
Goldberg et al (1991) and Black (2000) reported a ratio of basal metabolic rate (EI:BMR) below 1.2 is usually regarded as an energy intake too low for the

maintenance of body weight.[160,161] In this study, 57% of intervention subjects and 54% of control subjects had an EI:BMR ration below 1.2 which might indicate possible under-reporting of their 24-hour dietary intake.

Diabetes Knowledge Assessment

Between Groups

The possible score for knowledge assessment ranged from 0-20 points. After the education session the intervention group (M=12.17, SD=3.16) showed greater improvement in knowledge when compared to the control group [M=9.97, SD=3.18; t(149)=0.10, p=0.001] with large effect size (eta squared =0.14) as shown in Figure 6 below.



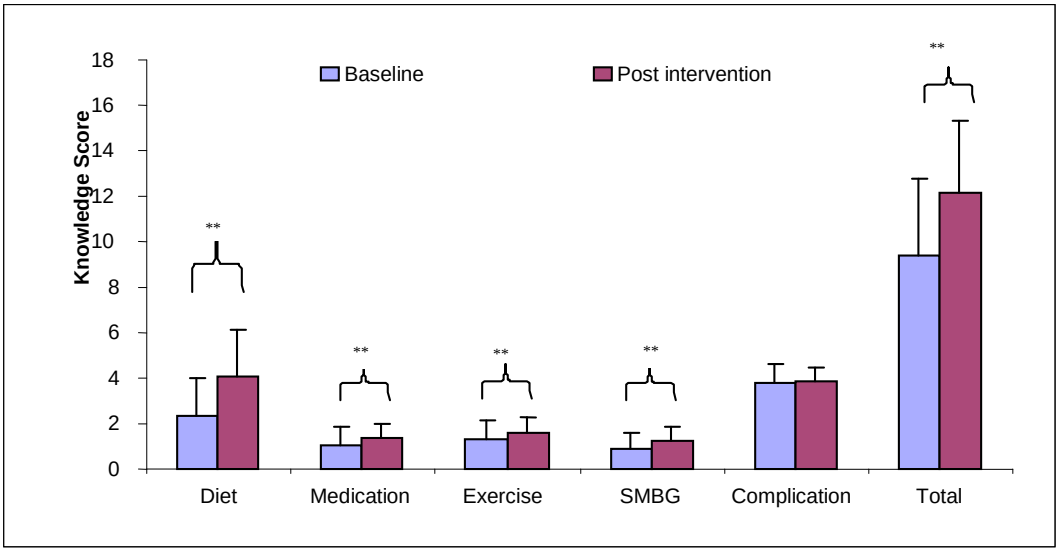
*p<0.05; ** p<0.01

Figure 6: Comparison of the Knowledge Score between the Intervention and the Control Groups at 12th week (n=151)

Within Groups

Analysis within groups showed that the intervention group had improved their diabetes-related knowledge from baseline (M=9.38, SD=3.39) to 12th week [M=12.17, SD=3.16, t(77)=-9.54, p=<0.001]. Although the control group also increased their knowledge from baseline (M=8.51, SD=3.04) to 12th week [M=9.97,

SD=3.18 t(72)=-5.31, p=<0.001], the improvement was smaller (M=1.47 SD=2.36) compared to the intervention group (M=2.78, SD=2.58). For both groups, the greatest knowledge gained concerned diet and self-monitoring with no significant change in diabetes complications. Figure 7 and 8 present changes of knowledge score within groups.



** p<0.01

Figure 7: Comparison of the Knowledge Score of the Intervention Subjects from Baseline and 12th week (n=78)

**p<0.01

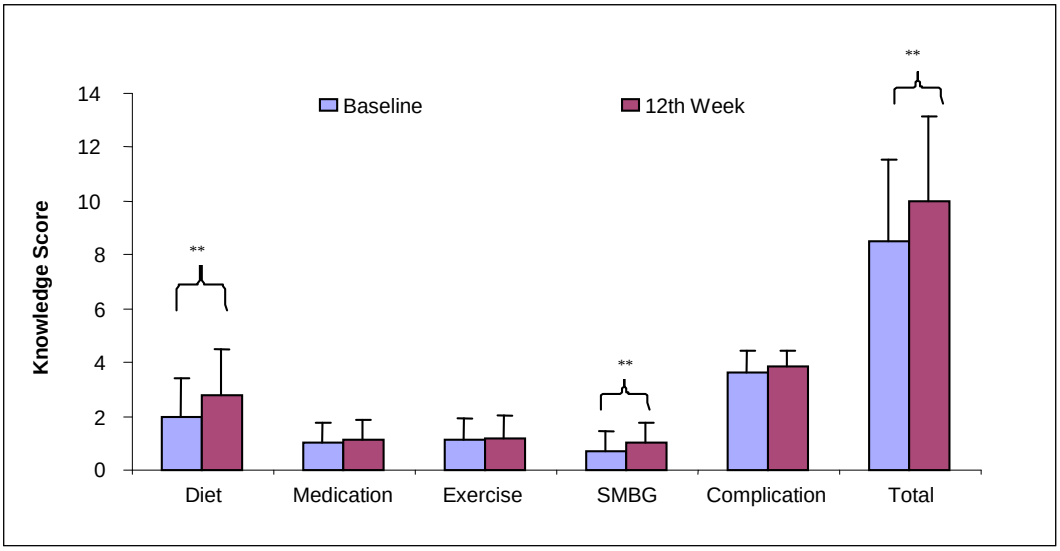


Figure 8: Comparison of the Knowledge Score of Control Subjects from Baseline and 12th week (n=73)

The Relationship between Diabetes Knowledge and Demographic Data

At baseline, subjects <40 years old when compared to subjects >60 years old (X^2= 9.41, df=2, p=0.009); subjects with college and tertiary education versus those with six and less years of formal school (X^2= 21.18, df=4, p=<0.001); Type 1 diabetic subjects compared with Type 2 diabetic subjects (Mann-Whitney U= 183.500, p=0.004) had higher diabetes-related knowledge. After the education intervention, the same results were observed except that the difference in levels of knowledge between Type 1 and Type 2 diabetics became non-significant. No other significant relationship was found between improved diabetes related knowledge and other demographic data (p>0.05).

Glycated Haemoglobin

Between Groups

The intervention group reported greater reduction in HbA1c (M=8.74, SD=1.78) than the control group (M=9.54, SD=2.07). This difference was significant, [M=9.54, SD =2.07, t(149)=2.57, p =0.01] as shown in Figure 9.

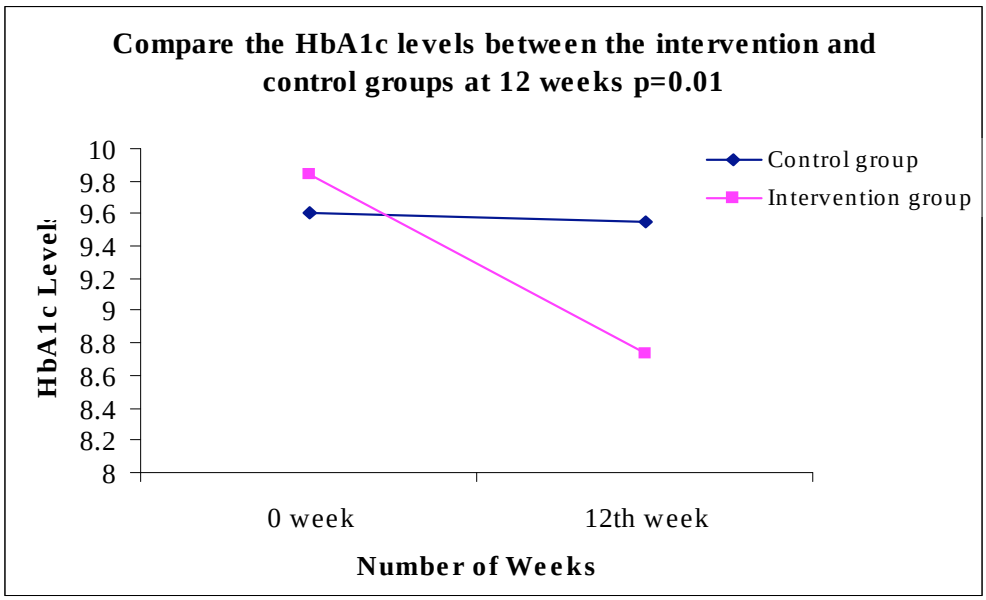


Figure 9: Comparison of the HbA1c Levels between the Intervention and the Control Groups at 12th Weeks

Within Groups

Similar to knowledge gained, both groups had reduced their HbA1c levels. However the control group decreased its HbA1c by 0.06% from baseline (M=9.60, SD=1.78) to 12th week [M=9.55, SD=2.07, t(72)=0.32, p=0.75] with no statistically significant difference. In contrast the intervention group reduced its HbA1c by 1.1% from baseline (M=9.84, SD=1.75) to 12th week [M=8.74, SD=1.78; t(77)=6.08, p=0.00] with large effect size (eta squared =0.32).

Variation of HbA1c Levels in Both Groups

Although both groups generally displayed a mean reduction in their HbA1c levels, for individuals the result varied. For the intervention group, 60 subjects (77%) improved their HbA1c levels while 16 (20%) subjects' HbA1c levels deteriorated by 0.1% to 2.6% despite having been educated. Within the control group 29 subjects' HbA1c levels (40%) deteriorated by 0.1% to 6.6% from baseline. Another 12 subjects (16%) had no change in their HbA1c levels. Thirty-two subjects (43%) improved their glycaemic control with standard education as shown in Table 19.

Table 19: Variation in HbA1c levels of the Intervention and Control Groups from Baseline to 12th week (n=151)

Category of glycaemic status	Definition	Intervention Group (n=78)		Control Group (n=73)	
		Number of subjects (percent)	HbA1c (range	Number of subjects (percent)	HbA1c (range)
Improved	Reduction in HbA1c by ≥ 0.1% from baseline to 12th week follow-up	60 (77%)	0.1% to 3.4%	32 (43%)	0.1% to 3.3%
Remained the same	No change in HbA1c levels during 12 weeks	3 (3%)		12 (17%)	
Deteriorated	Increase in HbA1c by ≥0.1% between baseline and 12 weeks follow-up	16 (20%)	0.1% to 2.6%	29 (40%)	0.1% to 6.6%

Factors that Influence HbA1c Levels

To determine the factors that could possibly influence the change in glycaemic status, the data were analysed using: t-test, Mann-Whitney U, Kruskal-Wallis test, multiple regressions and two-way between groups ANOVA.

Demographic Predictors of HbA1c Levels

Subjects who were divorced, separated or widowed had higher mean HbA1c than those who were married (X^2=12.10, df=4, p=0.02). Type 2 diabetic subjects at both baseline (Mann-Whitney U=259.000, p=0.03) and after intervention had lower HbA1c levels than Type 1 subjects (Mann-Whitney U= 8.500, p=0.17). No other

relationships were observed between other demographic or clinical characteristics and HbA1c levels.

Self-care Predictors of HbA1c Levels

Based on multiple a regression model, medication adherence (B=-0.23, p=0.009) and SMBG practices (B=-0.21, p=0.007) accounted for 10.7% of the total variance in HbA1c levels at 12th week. The effect of total physical activity level (B=-0.06, p=0.49) and total carbohydrate intake (B=-0.21,p=0.24) was not statistically significant.

Medication Change

Since the intervention in this study was to introduce an education program, change of prescribed medications either by increasing the existing dosage or addition of new oral anti-hyperglycaemic medication(s) or insulin could have been a possible confounding factor that influenced the reduction of HbA1c levels in both groups. To ascertain this effect, a two-way between-groups ANOVA was used for analysis. At 12 weeks, the difference in HbA1c levels between the intervention and control groups was the same regardless of whether or not the subjects had changed their medication dosage [f(1, 147)=0.32,p=0.57].

Diabetes Education

Effect of education intervention on self-care practices, diabetes-related knowledge and HbA1c level were assessed.

Self-care Practices

There was a significant relationship between total education time with SMBG practices (r=+0.38 p=0.001) and better medication adherence behaviour (r= +0.22,

p=0.04) but not physical activity level (rho=+0.09, p=0.41) and total dietary intake (rho =+0.10 p=0.39).

Knowledge

The total education time (r=+0.34, p=0.02) but not number of education sessions (rho=-0.20, p=0.06) was related to knowledge improvement at 12 week

HbA1c level

There was no significant correlation between education and HbA1c levels (r=-0.03, p=0.78)

Factors Influencing Education Duration and Frequency

This study proposed the implementation of three education interventions. However, not all subjects in the intervention group received the three sessions with a range between one to six education interventions. Eighteen subjects (23%) received less than three stipulated education interventions. Several barriers were identified and found to be significantly related to the duration and frequency of education received by the subjects. One such barrier was telephone access which was defined as inability to contact subjects by telephone for data collection or education intervention on three consecutive occasions over three days. There was a negative correlation with the number of education sessions (rho=-0.27, p=0.02) and the total education time (rho=-0.28, p=0.01) received with problems regarding telephone access. In addition, subjects who had problems with transportation (23%) to attend the education session received less education (rho=-0.31, p=0.006). Problem with transportation was defined as self-reported lack of transport facility to attend education sessions. These subjects were female (Mann-Whitney U= 332.500, p=<0.001), older age group (rho=-0.26, p=0.02) and those with low education level (X^2=7.52, df=4, p=0.04). Subjects with transportation problem also had higher HbA1c at follow-up (rho= +0.24, p=0.03). Another 16 subjects (21%) received more than the three stipulated education sessions due to the presence of hypoglycaemia or

febrile illness. There was a positive correlation between number of subjects who reported hypoglycaemia or febrile illness with the total number of education interventions (r= +0.22, p=0.05) and education time (r=+0.23, p=0.04).

Section 3

Findings of Hypothesis Testing

In the following section, findings are summarised for each hypothesis.

Hypothesis 1

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.

$H_1$1 : There will be a difference in the **medication adherence self-care practices** of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education

Since the difference in the **medication adherence** rate between the intervention group (M=89.50, SD=17.98) and control group [M=84.60, SD=17.16; t(149)=-1.7, p=0.06] was not statistically significant, the null hypothesis one was accepted and the alternative hypothesis rejected. Thus there was no difference in **medication adherence self-care practices** between adults with poorly controlled diabetes who had received a structured self-efficacy education as compared to those who received standard education.

Hypothesis 2

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.

$H_1$2: There will be a difference in the **SMBG self-care practices** of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education

The result of the t-test had shown a statistical difference in the number of SMBG practices between intervention group (M=2.94, SD=2.25) versus control group (M=0.47, SD=1.36; p=<0.001). This leads the investigator to reject the null hypothesis and accept alternative hypothesis two. Thus, after receiving a structured self-efficacy education, adults with poorly controlled diabetes had improved in their **SMBG practices** as compared to those with standard education.

Hypothesis 3

Ho3: There will be no difference in **physical activity self-care practices** between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

$H_1$3: There will be a difference in the **physical activity self-care practices** of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education

There was a statistically significant difference in mean total physical activity levels between the intervention (M=15.45, SD=5.64) and control groups (M=12.75, SD=4.86; p=0.002). Therefore null hypothesis three was rejected and the alternative hypothesis accepted. Using a structured self-efficacy education program had improved the **physical activity self-care practices** of adults with poorly controlled diabetes compared to those who received standard education.

Hypothesis 4

Ho4: There will be no difference in **dietary self-care practices** between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

H_A4: There will be a difference in **dietary self-care practices** of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

The results indicate that the null hypothesis four should be accepted and the alternate hypothesis should be rejected. There was no statistical significance in the results for the t-test of the mean carbohydrate intake between the intervention group (M=235.73, S=59.14) compared to the control group (M=261.52, SD=63.49; t(149)=1.58, p=0.18). Thus there was no difference in **dietary self-care practices** between adults with poorly controlled diabetes who had received a structured self-efficacy education when compared to those who received standard education.

Hypothesis 5

Ho5: There will be no difference in the levels of **knowledge about diabetes** between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

$H_1$5: There will be a difference in the **knowledge about diabetes** of adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education

The statistically significant improvement in diabetes knowledge of the intervention group (M= 12.17, SD=3.16) when compared to the control group (M=9.97, SD=3.18; p=0.001) leads the investigator to reject null hypothesis five and accept the alternative hypothesis five. Thus there was an improvement in **knowledge about diabetes** of adults with poorly controlled diabetes who received a structured self-efficacy education compared to those who received standard education.

Hypothesis 6

Ho6: 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.

$H_1$6: There will be a 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.

There was a statistically greater reduction in HbA1c of 1.1% for the intervention group compared to the control group with 0.06% (p=0.01). Therefore the null hypothesis six was rejected and the alternative hypothesis six accepted. After receiving a structured self-efficacy education, adults with poorly controlled diabetes had improved their **glycaemic control** measured by glycated haemoglobin (HbA1c) compared to those who received standard education.

Section 4

Summary of Findings

At baseline, there was no difference in demographic and clinical characteristics, knowledge, glycaemic levels and self-care practices between the intervention and control groups. At the end of the study, the intervention group showed statistically significant improvement in knowledge, HbA1c levels and SMBG practice in comparison to the control group. Although it was statistically significant, any improvement between the groups regarding physical activity was small. However, the improvement in dietary and medication self-care between the two groups was not significant.

At follow-up, within the intervention group there was a statistically significant improvement in diabetes-related knowledge, HbA1c level, SMBG practices and medication self-care. Although there was also slight improvement in dietary intake and physical activity levels, the findings were not statistically significant. The control group had small improvement in diabetes-related knowledge and HbA1c, but none of the self-care practices.

Due to the complexity of diabetes management, the only direct impact of education was on improvement of diabetes-related knowledge, enhanced medication intake and SMBG practices. Both medication adherence and SMBG practices predicted the HbA1c levels at follow-up. Seventy-seven percent of the intervention subjects received all three education sessions. There was a positive significant relationship between total education time but not the number of education interventions with SMBG practices (r=+0.38 p=0.001), medication adherence behaviour (r=+0.22 p=0.04) and improve diabetes knowledge (r=+0.34, p=0.02). Factors related to reduced education opportunity included transportation (rho=-0.31, p=0.006) and telephone access problems (rho=-0.28, p=0.01)

Conclusion

The introduction of a brief out-patient diabetes education program based on the self-efficacy theory used in this study had different effects regarding comparisons between and within groups. Between groups comparison showed the intervention group had a statistically significant improvement in diabetes-related knowledge, HbA1c levels, SMBG practices and a small increment in physical activity levels compared to the control group. The intervention group also improved but their dietary and medication self-care practices did not do so significantly. Within groups comparison showed in the intervention group a statistically significant improvement in diabetes-related knowledge, HbA1c level, SMBG and medication self-care practices. There was also slight improvement, although not significantly in dietary and physical activity self-care. In the control group there was small improvement in diabetes-related knowledge and HbA1c levels but none of the self-care practices. Factors relating to facilitators and barriers to education were explored. In the next chapter, the major findings will be discussed regarding their significance to clinical practice.

Chapter 5

DISCUSSION OF FINDINGS

Introduction

This chapter begins by reviewing the purpose and aims of the study. Then the findings of this study are discussed in relation to each of the hypotheses within the context of the available literature, taking into the account the method used. The chapter also highlights implications for clinical practice, presents limitations of the study and the investigator's suggestions for further research

Restatement of the Problems

Concomitant with the increasing global prevalence of diabetes is the increase in medical costs for this population.[162,163] One explanation for the heavy economic burden is that a substantial proportion of the cost of diabetes treatment is spent on treating complications.[65,164] 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 hyperglycaemia 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 Malaysian with diabetes,[165-167] 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.

Major Findings and Their Significance in Clinical Practices

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

Comparison between groups

The intervention group showed a statistically significant improvement in diabetes-related knowledge, HbA1c levels, self-monitoring blood glucose (SMBG) practices and a small increment in physical activity levels when compared to the control group. Even though not statistically significant, the intervention group had also improved their dietary and medication self-care practices.

Analysis within groups

At follow-up, within the intervention group, there was a statistically significant improvement in diabetes-related knowledge, HbA1c level, SMBG practices and medication self-care. Although there was also slight improvement in dietary and physical activity self-care, this was not statistically significant. The control group had small improvement in diabetes-related knowledge and HbA1c levels but none of the self-care practices.

Effects of diabetes education

Diabetes education intervention was shown to improve diabetes-related knowledge, enhanced SMBG and medication adherence practices. Likewise medication adherence and SMBG practices predicted the HbA1c levels at follow-up. The education provided did not change self-care practices that require lifestyle changes like dietary intake and physical activity nor improved glycaemic control. The total education time rather than the number of intervention was associated with the above positive outcomes.

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

Self-care Practices

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 12. 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.[1,168] 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 defined 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.[156] In this study all subjects were prescribed with conventional insulin like Actrapid or Premix 30/70. Previous studies found that most insulin-treated diabetic patients regardless of the types of diabetes did not follow the recommended pre-meal injection time for conventional insulin injection but administered it at an interval shorter than advised.[159,169,170] This could have resulted in insufficient time to raise serum insulin levels to correspond with the effect of meals which could contribute to post-prandial hyperglycaemia and higher HbA1c levels.[159,169,171] 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 behaviour as it could result not only in post-prandial hyperglycaemia but also possible hypoglycaemia that could endanger life.[172] 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.[146,156,173] 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.[156,174,175]

The detailed investigation of the subjects' medication intake behaviour 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 further 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.[137,176,177]

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.[18] Instead all the intervention subjects were advised to practice SMBG between 3-6 times per week according to the algorithm discussed in Chapter 3. 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 monitoring occurred for other reasons. Previous studies had cited these being: attitude towards SMBG, lifestyle interference, inconvenience, pain, old age and cost.[178-180] 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.[137] As explained earlier, Malaysians engage in social medicine where the government heavily subsides the cost of medication for patients attending government-run healthcare facilities.[181] The government, however, does not finance the cost of SMBG. This could act as a financial barrier to SMBG self-care especially for patients from lower socio-economic backgrounds.

Although it was not the purpose of this study to encourage SMBG self-care, at the end of the study the intervention subjects were given this incentive by the Roche (Malaysia) pharmaceutical company to purchase a new Roche blood glucose monitoring meter at 50% discount price. Sixty-four percent of the intervention subjects regardless of age, level of education and types of diabetes continued to practice SMBG after the study. This is an important observation which reflected the acceptance of SMBG practices and treatment satisfaction by individuals in the intervention group.

Earlier researchers have reported conflicting findings on the efficacy of SMBG among Type 2 diabetic subjects, especially those prescribed with OAM.[20,182,183] In this study the intervention group comprised 95% of Type 2 diabetics 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 subjects' medication adherence. In addition, there was also a significant relationship between total number of SMBG performed and HbA1c results ($p=0.03$) 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.[19,184] The increased frequency of SMBG had enhanced the self-care practices of the intervention group in dietary and medication intakes.

Previous studies found improved HbA1c levels with self-adjustment of insulin dosage.[185,186] 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 for 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 hours 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 16mmo/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 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.[187,188] 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.

Physical Activity Self-care

Ho3: There will be no difference in physical activity 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 in physical activity self-care practices between the intervention and control groups and therefore the null hypothesis was rejected. However this finding has to be interpreted with caution The small difference in physical activity levels between the groups and absence of significant improvement in within group comparison may be due to several reasons in Malaysia.

Twenty-seven percent of the subjects were either factory or field workers. These subjects frequently reported lack of time as a problem in engaging in regular exercise. In addition, they also perceived they had done enough activity during their working hours (between 8 to 12 hours per day for six to seven days a week). Previous researchers have reported similar results among Asian people of lower social economic status.[189,190] Females comprised 60% of the intervention group of which 84% were housewives. Previous studies frequently reported that females were less active than males especially in regular exercise programs due to cultural expectations that they do household and childcare activities.[191-193] This might explain the finding of the small difference in non-leisure physical activity between the groups.

Thirty-six percent of this study subjects were Malay females. One previous study done in Malaysia reported that in general, Malay Muslim women were socially conditioned to act in groups.[189] If there was lack of family support, this could act as a barrier to exercise which has been reported.[189,193-195] In addition, exercise facilities such as parks or sports centres are not easily accessible as some form of transportation is often necessary to reach such community establishments. In this study, females constituted one group that had problems with transportation (p=0.04).

The incidence of 'snatch theft' in Malaysia has increased during the last few years and contributed to an unsafe environment especially for females exercising alone outdoors.[196,197] Due to lack of local sport facilities, walking around the house compound was frequently encouraged. However, walking for obese subjects involved a high degree of effort and pain.[198] This might explain the low exercise adherence since 40% of the study population had BMI of more than 30.

According to Bandura's theory of self-efficacy, performance expectations predict whether an individual will choose to engage in a behaviour.[30] In this study, to encourage achievable goal and behaviour change, the goals were usually set by the subjects. Despite providing an explanation and encouragement to exercise, most of the subjects chose to set their immediate goals related to diet and SMBG rather than exercise. The outcome of this was improvement in their dietary knowledge compared to knowledge regarding exercise.

Only five percent of the intervention subjects increased their leisure physical activity levels from baseline after the intervention. These results were consistent with the Malaysian Non-communicable Disease Surveillance done in 2006, which reported 60% of Malaysian adults between 25-64 years were physically inactive.[9] Barriers to exercise and the underlining reasons for not setting exercise goals during the education sessions were not explored in this study. Importantly, further research on this theme is necessary to overcome the problem of inactivity in Malaysia.

There are two possible explanations for the lack of change in HbA1c levels despite increased physical activity of the intervention group. First, there was only a small increment in overall physical activities among intervention subjects. Second, those subjects with regular exercise programs or during their non-leisure physical activities did not achieve the duration and intensity of physical activity levels as recommended for people with diabetes. To benefit from physical activity, people with diabetes need to perform a minimum of 150 minutes per week of moderately intense aerobic physical activity which is equivalent to achieving 50%-70% of maximum heart

rate.[199] Hence although the alternate hypothesis of physical activity was supported, it had little clinical implication**.**

Diet Self-care

Ho4: There will be no difference in dietary self-care practices between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

This result showed no difference in dietary self-care practices between the intervention and control groups which supports the null hypothesis. However for the within group comparison the intervention group showed significant reduction from baseline to week 12 in daily total calorie, protein and fat intakes. The lack of significant difference between groups may have several explanations. Firstly, due to lack of data on variance, a medium size effect was arbitrarily chosen which could have resulted in the sample size not being big enough. Secondly, the instrument was not sensitive enough to detect any difference. Thirdly, factors other than or in addition to diabetes education are needed to make a bigger difference in order to demonstrate a difference between groups. Lastly, the Malaysian setting can be an influencing factor. This is explained in more detail below.

Underreporting of food intake is a well known phenomenon and the prevalence varies with the method used, ranging from 22.2% to 66.7%.[200-202] In this study, the self-reported low energy intake was compared to the subjects' basal metabolic rate and appeared to suggest this had occurred. One previous study assessing the nutrient intakes of adult Pakistani, European and African-Caribbean communities of an inner city in Britain reported that the European participants were least likely to underreport their dietary intake. The author explained that cultural influence, food habits and missing data from the food composition tables were potential factors for the Pakistanis who had the highest underreporting rate.[202] In Asian cultures, foods are usually served in common dishes rather than individual servings. Hence assessing portion sizes can be difficult. Obtaining accurate reports for foods eaten in mixed

dishes was problematic. Although the food composition analysis software, Nutritionist Pro, has included a Malaysian food composition table, the information available on specific local ethnic foods is limited. This could be due to the fact that the last edition of the Malaysian food composition table was updated in 1997.[203] All the above factors could have contributed to the possible underreporting in this study. Similar to previous studies, it was also observed that subjects with higher BMI and waist circumference in this study more often self-reported as taking less dietary intake.[204-207]

Despite increased dietary knowledge and setting dietary goals during the education sessions, reduction of carbohydrate and sugar intake was not significant among the subjects in the intervention group. There could be several possible explanations for this finding. Even though it was planned, few intervention subjects were taught about carbohydrate counting because of their low dietary knowledge. Only 11% of the intervention subjects could identify sources of common daily carbohydrate food items at baseline. Hence the objective of the dietary education was changed to enhance the subjects' dietary knowledge on sources of carbohydrate food. Reducing carbohydrate portion sizes was done subjectively rather than objectively.

Dietary self-care is constantly influenced by social, cultural, religious and environmental contexts that can make changing eating habits more difficult when compared with other self-care practices.[194,198,208,209] It is a local practice especially among families of a lower social economic status to prepare family beverages and food in common servings rather than individual servings. If there was a lack of family support or understanding about the importance of dietary self-care in diabetes management, individual dietary behaviour would become a problem due to family members' dietary preferences and food preparation. This was illustrated in a qualitative study of older Hispanic adults with Type 2 diabetes (n=138) which reported the most difficult issue was '*being around with people who are eating or drinking things that they should not take*'.[210] Although family support related to dietary intake was not explored in this study, 82% of subjects in this study were

married and lived with family members. This could have contributed to a minimal reduction in carbohydrate intake quantities compared to baseline.
Furthermore in this study 40% of the subjects were males and 82% were married. The family members who prepared the family meals did not accompany subjects to education sessions despite being encouraged to do so. This could act as a barrier to dietary self-care for the male subjects as reported in previous studies.[198,208] Further research should be conducted to see if including families in clinic visits does, in fact, improve dietary adherence.

Dietary modifications often require individuals with diabetes to alter the behaviour of a lifetime which are based upon strong and entrenched preference. In this study, Malays consumed the most sugar (p=0.03). This finding is supported by previous studies that explored dietary habits of the Malay population in Malaysia.[26-28] In one study, 72% of subjects had morning or afternoon snacks every day or almost every day besides their main meals. The subjects in that same study regularly consumed biscuits, traditional sweet cakes, condensed milk or sugar in their daily beverages. Although sugar or sucrose is allowed in a daily diet to a maximum of 10% of total calories, it needs to replace other carbohydrates.[152,211,212] It was uncertain whether the subjects in the intervention group had understood or underestimated their replacement of sucrose intake with their staple diet - rice or noodles.

Sixty percent of the subjects in this study were Malays. This factor may contribute to the findings regarding insignificant reduction of carbohydrate intake. This finding has important public health implications as the Malay subjects with habitual sugar intake were also more likely to have higher BMI and waist circumference (p=0.001). Malays constitute 65% of the Malaysian population.[213] Obesity and metabolic syndromes are major risk factors for developing diabetes mellitus and contribute to poor glycaemic control among the diabetics.[214,215] Previous studies that found positive dietary interventions usually involved more than six hours of dietary intervention with continuous reinforcement.[216-218] In this study, the mean education

intervention lasted 97 minutes to address all four self-care practices. This could have contributed to the insignificant findings.

As reported earlier, meal-related SMBG was shown to reduce carbohydrate intake. The frequency of SMBG among the intervention subjects, however, was inconsistent which could have contributed to the small reduction in carbohydrate intake. Nevertheless, in the intervention group, there was reduction in total daily caloric consumption after the education as compared to the control group. The reduction in daily total caloric intake was contributed to by a reduction in fat and protein intake. (p=0.01) A reduced fat intake may reduce serum lipids and modify a major risk factor for cardiovascular complications in diabetes.[219-221] Hence a reduction in fat intake reflects good self-care practices**.**

Diabetes-related Knowledge

Ho5: There will be no difference in the levels of knowledge about diabetes between adults with poorly controlled diabetes who receive a structured self-efficacy education compared to those who receive standard education.

Although both groups had improved in diabetes knowledge, improvement in the intervention group was significantly greater than the control group which led to a rejection of the null hypothesis. This finding is consistent with previous research.[34,37,222,223] The small knowledge improvement in the control group could be explained by the advice received during routine follow-ups, written materials provided at baseline, mass media such as television and possible contamination during the data collection process as it was done in the common waiting areas [49,137,224]

Similar to previous studies, subjects younger than 40 years of age, having Type 1 diabetes, with college education achieved higher diabetes-related knowledge scores than older and less educated subjects.[225,226] This is an important finding which possibly indicates the proposed education program in this study did not fully benefit

the older subjects and those with less education. Since almost 90% of the study subjects were 40 years old and more with less than college education, the proposed education program needs further modification to incorporate special low literacy approaches with longer education intervention to achieve better outcomes in the future. Also the effect of such education programs in elderly people with diabetes should be studied.

Within the intervention group, the statistically significant difference of knowledge scores between Type 1 and Type 2 diabetes subjects at baseline was reduced to non-significance after the intervention. This could be explained by Type 2 diabetes subjects from the intervention group having improved their diabetes-related knowledge through education. Previous trials on diabetes education interventions improved diabetes knowledge and clinical outcomes among Type 2 diabetics regardless of treatment mode.[37,48,109,227] This observation has important clinical implications. In the current healthcare system, people with Type 1 diabetes are regularly referred for diabetes education but not people with Type 2 diabetes on oral anti-hyperglycaemic medication (OAM).

Supporting the results of previous studies, improvement in knowledge among the control subjects did not translate to better self-care practices and clinical outcomes.[35,49,228] This suggests interventions other than diabetes-related knowledge may be needed. It could probably be due to the didactic education approach used for the control group. Since the 1990s, it has been widely advocated that diabetes education was more effective when behaviour science strategies were used.[3,48,51,55] The first study in this portfolio found low diabetes-related knowledge and skills among the study subjects. Since this study was done in the same settings, it was decided to use a diabetes education program that incorporated self-efficacy as the behavioural science for the intervention. The self-efficacy education program aimed to enhance the subjects' diabetes-related knowledge, skills and perceived confidence in his or her ability to perform daily self-care. The findings of this study have supported previous research that indicates self-efficacy education programs enhance

diabetes-related knowledge, self-care practices and clinical outcomes.[81,107] This also supports the assumption of this study that a structured education program that incorporates behaviour science could enhance diabetes self-cares in medication adherence, SMBG practices and clinical outcomes.

Glycated Haemoglobin

Ho6: 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.

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%.[2] 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 the study, this had 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 (p=0.002) and dietary intakes. These are the cornerstones of diabetes management. Previous researchers have reported similar findings.[16,147,229-233] However, whether the improved self-care practices were due to subjects' 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 subjects who were older, female and with less education had

problems attending education sessions 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 subjects.[234,235] Other studies have revealed the importance of social support to subjects' glycaemic controls.[210,236,237] 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 phones 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-thirds 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 RM10). 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.[238-240] 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 and thus were excluded from the study. In the third study, 25% of the phone calls 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 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 salient question is what could

have contributed to the 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.[241] Another possible reason could be the use of complementary therapy. Previous studies done in Malaysia reported the popular use of complementary therapy.[242-245] Some complementary therapies may contain anti-diabetic effects[246-248] This could result in over-medication if the subjects also consumed the doctors' prescription at the same time without informing their attending doctors. Due to the limitations of this study, use of complementary medication by both the study groups was not investigated Due to limitation of self-report, the control subjects might have improved in dietary habit, medication adherence and physical activity without reporting them.

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.[62,148,249]

With the minimal improvement in physical activity level and dietary self-care behaviour, it was no surprise that the predictors of HbA1c in this study were SMBG and improved medication adherence practices. The difficulty in making lifestyle changes has been reported in other studies.[250-253]

Education Intervention

Overall there was no significant correlation between diabetes education and HbA1c suggesting other factors account for improved glycaemic control. Instead diabetes education time was correlated with diabetes-related knowledge, SMBG self-care and medication adherence self-care.

Self-monitoring of blood glucose practices predicted HbA1c. By improving SMBG practices (a self-care practice) in the intervention group, it could have partially accounted for the lowering of HbA1c at the end of the study. In the control group, there was no improvement in SMBG and this could partially explain the small lowering in HbA1c. Medication adherence (another self-care practice) also predicted HbA1c. There was improvement in medication adherence in the within intervention group comparison and this was associated with a lowering of HbA1c. In the between group comparison there was no significant improvement in medication adherence although HbA1c declined when comparing the two groups. Why this is so is not clear. It is possible that the improvement in SMBG was sufficient to account for the improvement in HbA1c.

The education provided did not alter self-care practices that require lifestyle changes like dietary intake and physical activity. Several explanations are possible. First, education intervention is a complex process constantly influenced by factors related to patients, healthcare providers, health care system and psychosocial environment.[250,254-256] Second, other interventions besides education are needed to improve dietary intake and physical activity. It could also be that sample size was not large enough and the self-efficacy education program was not effective in changing lifestyle self-practice. All these indicate the need for more research in this area.

Several characteristics were observed in previous clinical trials that reported positive outcomes with a brief education approach.[109,222,257] One such characteristic was the pre-assessment that allowed the education to be tailored to individual needs. For example, if the self-care deficit was wrong timing of medication despite adherence to medication intake, education that targets the mechanism of medication action could enhance correct timing of medication and improve clinical outcomes. Hence in this study, even though the mean education time was 57 minutes, the investigator would argue that absolute education time should include the pre-assessment time of 40 minutes giving a total of 97 minutes.

Other than the telephone and transportation barriers, another possible explanation for limited improvement in self-care and HbA1c among the intervention subjects was readiness to change was not assessed prior to intervention. Previous clinical trials have shown positive outcomes with brief interventions, frequently assessed for readiness to change based on the 'Transtheorectical model' or 'Stages of change'.[257,258] According to this theory, those who are ready to make lifestyle changes are more likely to do so. This change-readiness is depicted as stages: pre-contemplation, when no lifestyle change is considered; contemplation, when change is desirable but there is no committed effort; preparation, when there is a definite intention to change; action when there is some change; and maintenance when the changed behaviour is sustained for six months. Behaviour change would be successful if a person is in the action and maintenance stage.[259] It is possible that most intervention subjects were not ready to change their physical activity levels. Hence even by enhancing self-efficacy education intervention, there was a negative clinical outcome.

The positive relation of total education time ($p=<0.05$) rather than number of education intervention episodes ($p=0.06$) with enhanced knowledge, SMBG and medication self-care practices was an important finding. In view of the problems of transportation among the study subjects to attend the education sessions, future intervention should emphasise the total education duration provided rather than the number of education intervention.

In sum, the effect of self-efficacy varies with different diabetes self-care practices as shown in Table 20 and reported in previous studies.[7,13,14,24,90,91] The overall findings of this study only partially supported the assumption that structured diabetes education incorporating behavioural science and cultural sensitivity would enhance diabetes self-care and clinical outcomes. It appears that medication and SMBG self-care had improved but not physical activity or dietary self-care. This reflects the

complex interaction between diabetes self-management education, self-care practices and glycaemic control.

Table 20: Comparison of the Effects of a Self-efficacy Education Program between and within Intervention and Control Groups on Diabetes Knowledge, Glycaemic Control and Self-care Practices

Variable	Between groups comparison Intervention versus Control	Within group Intervention	Within group Control	Effect of Education
Diabetes Knowledge	Improved in Intervention group*	Improved*	Small improvement*	Improved*
HbA1c	Improved in Intervention group*	Improved*	Small improvement	None
SMBG	Improved in Intervention group*	Improved*	None	Improved*
Medication adherence	None	Improved*	None	Improved*
Physical activity	Small improvement in Intervention group*	None	None	None
Dietary adherence	None	None	None	None

* statistical significant

Limitations of the Study

This study had a number of limitations which must be considered in interpreting the aforementioned results.

Self-report

Self-report instead of direct observation of self-care practice is a major limitation of this study. Self-report has several limitations such as under-reporting due to the subjects' ability to recall events especially among elderly subjects. The subjects could also over-report due to individual interpretations or social desirability particularly after receiving the intervention.[204,260] Of the four self-care practices, under- or over-reporting was possible in dietary and medication intake and physical activity. Self-monitoring of blood glucose practices had the minimum self-report bias as all data from the blood glucose meters were downloaded via computer software.

Study Design

The use of two 24-hour diet recalls instead of the three 24-hour diet recall could have reduced the validity of the dietary data. In addition, the longitudinal study design in this study invariably spread dietary data collection over cultural and religious celebrations like Ramadan, Hari Raya and the moon cake festival. To minimise contamination of food habits, no dietary recalls were collected at least three days before and after the festivals. However, dietary data collection for the Malay Muslim subjects was unavoidable during Ramadan. Furthermore, although the subjects were randomised there was only one investigator. Hence blinding was not possible during the data collection and intervention process.

The duration of the education intervention may not be long enough. The education program was designed to take into account the shortage of trained diabetes educators and dieticians balanced with the number of Malaysian with diabetes to be educated. Duration also affected the 12 weeks of this short study and the reasons for this were logistical. A one year study will be needed to determine the long-term effects of such an education program.

Finally, different sample sizes may be needed for different components of the

variables studies. When the sample size for this study was estimated, there was no data on the variances for each variable in the Malaysian setting.

Confounding Factors

As observed in this study, many factors could enhance or inhibit the learning process. Some of these factors were highlighted during the data collection process such as telephone access and transportation problems influencing subjects' learning opportunities and worsening their glycaemic control. Other factors like family support,[261-263] lower socio-economic status,[190,264] depression,[265,266] readiness to change,[258,267] healthcare system[137,268,269] and practices of healthcare providers[270-272] can influence the acquisition of knowledge and self-care practices. These factors were not investigated in this study.

Generalisation

Although this was a longitudinal study design with two study settings, all data were collected in one state in Malaysia, The generalisation of education efficacy is limited to the population from which the sample was drawn.

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 individualised 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 with 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 session, medication intake in relation to meal-timing should be emphasised 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 a unique position to assist dieticians in enhancing dietary knowledge and self-care. This could be done by emphasising 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 intervention 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. Since finance has been reported to be the major problem regarding the practice of SMBG by people with diabetes,[19,273,274] if resources could be provided to encourage individuals with diabetes to practice regular SMBG, it may lead to reducing both acute and chronic diabetes complications and healthcare costs.

Conclusion

This research has shown a brief structured education program that incorporated behaviour science specifically self-efficacy was effective in enhancing knowledge, some of the self-care practices (SMBG and medication adherence) and improving glycaemic control in the intervention group. Improvement of self-care practices that require lifestyle changes such as diet and increased in physical activities are problematic. This could be due to the complexity of these self-care practices that are socially and culturally constructed and often lifetime habits when compared to medication intake and SMBG. Previous studies reported that positive effects of self-care and clinical outcomes usually involved lengthy education and intensive interventions.[58,79] The brief education implemented in this study appeared to enhance self-efficacy in self-care practices leading to behavioural change and better clinical outcomes.

This study also highlights the complexity of the process of education for diabetes self-management. As demonstrated by the control group, although knowledge gain is essential to build skills in self-management of diabetes, this alone is unlikely to change behaviour. In the intervention group, integration of behaviour theory with education appeared to promote self-efficacy, resulting in improved self-management and subsequently improvement in glycaemic control.

This research also showed that a subset of intervention subjects despite having received education did not improve their self-care practices and glycaemic control. Social factors like telephone access and transportation problems appeared to reduce their education opportunities. Although not investigated in this study, other psychosocial factors such as lack of family support, depression, lower socio-economic status, healthcare providers and healthcare system could also have influenced the outcomes.

Understanding these multifaceted causalities would help in the future development of a more effective and efficient education intervention. The potential translation of this study's findings into nursing and primary care practices could serve as a foundation for development of future diabetes education program in Malaysia.

Recommendations for Further Investigation

This study has raised questions that need to be answered by future research. Although there were encouraging results at 12-week duration, the long-term impact of this structured self-efficacy education on self-care and glycaemic outcomes was not investigated. Several meta-analyses reported deterioration of educational efficacy when intervention lasted longer than six months.[36,37] Hence the same education approach should be repeated in the future with longer duration of follow-up.

Due to limitations of self-report in this study, the validity of the findings in future studies could be enhanced with objective measurements. For example, these could include pedometers to measure physical activity levels, validation of medication adherence with pill counting and weighing of food items or provision of subjects with standard measurement tools like bowls, cups, plates and spoons to enhance accuracy of dietary intake.

Education about diabetes was delivered using an individualised approach. With diabetes increasing in Malaysia, group education may be a more efficient way to provide diabetes education. Group learning has other benefits such as providing peer support. Future research could explore the impact of group education based on the same intervention on glycaemic control and self-care practices.

In this study, the impact of self-efficacy on self-care practices of the intervention group was not assessed. Hence no conclusion could be made regarding whether changes of self-care practices were due to improved self-efficacy. Using the same

education intervention, future clinical trials could evaluate the impact of self-efficacy on changes to self-care practice.

Several psychosocial barriers such as depression, lack of social, family or peer support may have inhibited the subjects' learning process. Future research could triangulate methodology to explore the impact of these barriers and assist in the development of targeted interventions.

The current education intervention did not improve dietary self-care. One possible reason identified was inadequate time spent on dietary education. Future research could increase the time allocated for dietary education. Dietary habits are frequently influenced by cultural habits and customs. Future research could also assess the efficacy of cultural intervention like recipes devised to enhance dietary self-care.

Despite the provision of free test strips, some subjects in the intervention group did not practice SMBG as was recommended. A previous epidemiological study reported similar findings.[275] In view of the significant impact of SMBG on glycaemic control, future studies should explore the barriers associated with SMBG practices among the local population. To broaden generalisability, the same intervention should be investigated for the whole of Malaysia and for more diverse population groups.

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APPENDIX 1: REVISED DIABETES SELF-CARE ACTIVITIES PRE-QUESTIONNAIRE

Date:_____

A **Glycaemic data in the last year (From patient's notes)**

1.Item/Date						Mean
Fasting blood glucose level mmol/L						
Random blood glucose level mmol/L						

B. Baseline HbA1c : _____ % (Date taken: _____)

C Demographic Data

ID No:_____ Centre: _____

Age: _____ years

Gender: □$_1$ Male □$_2$ Female

Height: ____cm Weight: ____ kg BMI: _____ kg/m^2

Waist circumference:___ cm

Race: □$_1$ Malay □$_2$ Chinese □$_3$ Indian □$_4$ Other

Occupation: _____

Type of diabetes: □1 □ 2

Duration of diabetes: _____years _____ Not sure

Current treatment mode: □$_1$ Diet control □$_2$ Diabetes tablet □$_3$ Insulin injection
□$_4$ Combination of diabetes tablet and insulin injection

Marital status: □$_1$ Single □$_2$ Married □$_3$ Divorced □$_4$ Separated □$_5$ Widowed

Education : □$_1$ Never □$_2$ Primary □$_3$ Secondary □$_4$ College □ $_5$ Tertiary

Living with: □$_1$ Family member □$_2$ Friends □$_3$ Alone □$_4$ Others

D Diabetes Knowledge Assessment:

	Increase	Decrease	No effect	Not sure
1. What is the effect of oats on blood glucose?	□1	□2	□3	□4
2. What is the effect of corns on blood glucose?	□1	□2	□3	□4
3. What is the effect of unsweetened fruit juice on blood glucose?	□1	□2	□3	□4
4. What is the effect of chicken on blood glucose?	□1	□2	□3	□4
5. What is the effect of potato on blood glucose?	□1	□2	□3	□4
6. What is the effect of wholemeal bread on blood glucose?	□1	□2	□3	□4
7. What is the effect of guava on blood glucose?	□1	□2	□3	□4

8. If you take your morning diabetes tablets/insulin injection but skip breakfast, your blood glucose level will usually:

□1 Increase
□2 Decrease
□3 Remain the same
□5 Not sure

9. If you **DO NOT** take your diabetes medicine as prescribed by your doctor, your blood glucose level will usually:

□1 Increase
□2 Decrease
□3 Remain the same
□5 Not sure

10. What is the effect of regular exercise on blood glucose?

□1 Lower it
□2 Raises it
□3 Has no effect
□5 Not sure

11. Which is the better method for monitoring your diabetes control?

□1 Urine testing
□2 Blood testing
□3 Both are equally good
□5 Not sure

12. Infections such as a cold or influenza are likely to cause:

□1 An increase in blood glucose
□2 A decrease in blood glucose
□3 No change in blood glucose
□5 Not sure

13. Taking a low fat diet is more likely to reduce your risk in developing:

□1 Nerve disease
□2 Kidney disease
□3 Heart disease
□4 Eye disease
□5 Not sure

	Yes	No	Not Sure
14. High blood glucose can be caused by regular exercise	□1	□2	□3
15. High blood glucose can be caused by eating too much fruit	□1	□2	□3

Which of the following are complications of diabetes?

	Yes	No	Not Sure
16. Eye problems	□1	□2	□3
17. Kidney problems	□1	□2	□3
18. Nerve problems	□1	□2	□3
19. Lung problems	□1	□2	□3
20. Stroke	□1	□2	□3

D. Self-care activities

I) Medication

What current medication(s) do you take for your diabetes?

No	Medicine	Doctor's Prescription			Participant's description			
		dose	frequency	time	dose	frequency	time	Not sure
1/2								
3/4								
5/6								
7/8								

Questions 1/3/5/7 assess for actual dosage taken
Questions 2/4/6/8 assess for actual frequency taken

9. Last week, how many times did you miss taking your MORNING diabetes medicine(s)(oral and insulin)?

□0 □1 □2 □3 □4 □5 □6 □7

10. Last week, how many times did you miss taking your NOON diabetes medicine(s) (oral and insulin)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7

11. Last week, how many times did you miss taking your EVENING diabetes medicine(s) (oral and insulin)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7

12. Last week, how many times did you miss taking your NIGHT diabetes medicine(s) (insulin)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7

13. Last week, what time did you take your MORNING diabetes medicine?

□1 >60 mins before food
□2 30 to 60 mins before food
□3 <30 mins before food
□4 with food
□5 < 30 mins after food
□6 30 to 60 mins after food
□7 >60 mins after food

14. Last week, what time did you take your NOON diabetes medicine?

□1 >60 mins before food
□2 30 to 60 mins before food
□3 <30 mins before food
□4 with food
□5 < 30 mins after food
□6 30 to 60 mins after food
□7 >60 mins after food

15. Last week, what time did you take your EVENING diabetes medicine?

□1 >60 mins before food
□2 30 to 60 mins before food
□3 <30 mins before food
□4 with food
□5 < 30 mins after food
□6 30 to 60 mins after food
□7 >60 mins after food

16. Compliance Rate: OAM _____% Insulin _____% Total: _____%

<u>For Insulin user only</u>

17. Last week, how many times did you need help with your insulin injection(s)?

□0 □1 □2 □3 □4 □5 □6 □7

18. Last week, how many times did you take a different insulin dosage from your doctor's prescription? (participant to demonstrate drawing of insulin dosage)

□0 □1 □2 □3 □4 □5 □6 □7

19. Last week, where did you usually inject your insulin injection?

□1Not specific □2 Buttock □3Legs □4 Arms □5 Abdomen

20. Last week, how often did you rotate your insulin injection site?

□1 Never □2 Seldom □3 Sometimes □4 Most of the time □5 All the time

II) Physical activity

A) Non-leisure physical activity

When you are at work or doing housework or in college, on an average:

1. How much time do you spend sitting?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

2. How much time do you spend standing?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

3. How much time do you spend walking?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

4. Do you have to lift or carry heavy things?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

B) Leisure physical activities

5. How often do you walk around your house or apartment during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

6. How often do you do gardening such as trimming the shrubs, digging, mowing the lawn but not watering pot plants or pottering around during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

7. How often do you sit down to relax, read books/magazines/newspapers, watch TV, play or work on a computer during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

8. Do you have a regular exercise program?

□0 No (go to part IV) □1 Yes

9. If yes, what exercise do you do?

□1 Mild exercise (minimal effort)
(Examples are yoga, golf, slow walking, Tai chi, Chinese martial art, calisthenics, fishing fom river bend)

□2 Moderate exercise (mild increased in heart beats or breathing) (Examples are brisk walking, easy bicycling, volleyball, badminton, table tennis, leisure swimming, popular and folk dancing, bowling

□3 Strenuous exercise (heart beats rapidly and increase breathing) (Examples are running, jogging, football, soccer, squash, basketball, vigorous swimming, long distance bicycling, tennis)

10. Last week, how many days did you exercise?

□0 □1 □2 □3 □4 □5 □6 □7

11. On average, how many minutes did each session last?

□1 0 -15 mins
□2 16-30 mins
□3 31-45 mins
□4 46-60 mins
□5 >60 mins

III) Self-monitoring

1. Has your doctor , nurse or dietician advised you to monitor your blood glucose at home and in between clinic visits?

□0 Not Sure □1 No □2 Yes

2. If yes, how often did he/she advise you to test your blood glucose level per week?
□$_0$ N/A □1 □2 □3 □4 □5 □6 □7 □ more than 7

3. Do you test your blood glucose at home or in between clinic visits?

□$_0$ No □$_1$ Yes (go to Q4-7)

4. Last week, how many times did you test your blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

5. Last week, how many times did you test your fasting blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7

6. Last week, how many times did you test your pre-meal blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7

7. Last week, how many times did you test your 2 hours post-meal blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7

8. Last week, how many times did you change your food intake based on the results of your blood glucose reading(s)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

9. Last week, how many times did you change your physical activity based on the results of your blood glucose reading(s)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

10. Last week, how many times did you change your medication dosage based on the results of your blood glucose reading(s)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

IV) Diet

For consistency, the investigator will record all the answers on the two 24-hour dietary records and Food Frequency questionnaire.

24-hour Dietary Recall

First 24-hour dietary recall (record during the interview)

Meal	Timing of meal	Food taken	Portion size	Method of cooking	Wt ref	Ref Source

Date: _____

2. Second 24-hour dietary recall (To be recorded within one week from the interview by telephone)

Meal	Timing of meal	Food taken	Portion size	Method of cooking	Wt ref	Ref Sources

FOOD FREQUENCY QUESTIONNAIRE

Write in the column how many times per day/week you would have eaten the food the past one week

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
A. Fruit			**S**	**M**	**L**	**Per day**	**Per wk**		
Apple	**1 medium**	**115**							
Orange	**1 medium**	**165**							
Pear	**1 medium**	**167**							
Star fruit	**1 medium**	**235**							
Banana	**1 small**	**62**							
Mango	**½ small**	**106**							
Nanga	**4 pieces**	**205**							
Cempadak	**4 pieces**	**60**							
Papaya	**1 slice**	**211**							
Pineapple	**1 slice**	**142**							
Watermelon	**1 slice**	**250**							
Honeydew	**1 slice**	**215**							
Grapes	**8 pieces**	**92**							
Guava	**½ fruit**	**150**							
ciku	**1 medium**	**54**							
Lychee	**5 pieces**	**77**							
Plum	**1 small**	**70**							
Kiwi	**1 medium**	**156**							
Dates (kurma)	**3 pieces**	**21**							
Strawberry	**5 whole**	**47**							
Duku langsat	**8 pieces**	**93**							
Langsat	**8 pieces**	**73**							
Durian	**4 medium seeds**	**150**							
Rambutan	**5 whole**	**170**							
Mangosteen	**4 small (30g)**	**96**							
Mata Kuching	**10 whole medium**	**52**							
Fruit juice	**1 cup (240ml)**								
B. Beverages									
Milk powder (full cream)	**4 rounded tbsp**	**29**							
Milk powder (skim)	**4 rounded tbsp**	**32**							
Packet milk drinks	**1 cup (240 ml)**	**256**							
Evaporated milk	**½ cup (120ml)**	**130**							
Milo	**3 rounded tbsp**	**19**							
Holick	**2 rounded tbsp**	**21**							
Ovaltine	**3 rounded tbsp**	**20**							
Nestum	**3 rounded tbsp**	**25**							
Oats(uncooked)	**3 rounded tbsp**	**18**							
Oats (cooked)	**½ cup**	**126**							
Coconut water	**1 glass (240ml)**	**240**							

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
B. Beverages			**S**	**M**	**L**	**Per day**	**Per week**		
Soya milk (unsweetened)	**1 glass (240ml)**								
Soya milk (sweetened)	**1 glass (240ml)**								
Barley water (unsweetened)	**1 glass (240ml)**								
Tau-hoo-fah (unsweetened)	**1 cup (250ml)**	**368**							
Yogurt plain	**1 cup**	**150**							
Yogurt (sweetened)	**1 cup**	**150**							
C. Cereal Tubular/ legumes									
Common Food									
Rice	**1 Chinese bowl**	**150**							
Rice porridge	**2 Chinese bowl**	**498**							
Kueh teow/Mee hoon (fried)	**1 plate**	**170**							
Kueh teow/Mee hoon (soup)	**1 bowl**	**500**							
Kueh teow/Mee hoon (Bandung style)	**1 bowl**	**450**							
Mee (fried)	**1 plate**	**170**							
Mee (soup)	**1 bowl**	**563**							
Mee (Bandung style)	**1 bowl**	**450**							
Wan tan mee noodle dry/soup	**1 plate** **1 bowl**	**330** **408**							
Loo See Fun	**1 Chinese bowl**	**212**							
Mee Hon Kueh	**1 bowl**	**450**							
Bread (white/ wholemeal)	**1 slice**	**30**							
Bun (plain)	**1 bun**	**34**							
Corn flake (unsweetened)	**1 cup**	**28**							
Roti canai	**1 piece**	**84**							
Pisang goreng	**1 piece**	**80**							
Kelidek goreng	**1 piece**	**80**							
Curry puff	**1 piece**	**48**							
Rojak	**1 plate**	**330**							
Biscuit (unsweetened)	**3 pieces**	**21**							
Spring roll (popiah)	**1 piece**	**51**							
Yong Tau Foo	**1 piece**	**80**							

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
C. Cereal Tubular/ legumes			S	M	L	Per day	Per wk		
Pau Ayam	1 piece	96							
Indian Food									
Chappati 20cm diameter	1 piece	100							
Dosai, 30 cm diameter	1 piece	180							
Idli	1 piece	82							
Putu mayam	1 piece	40							
Vadai	1 piece	60							
Malay Food									
Cekodok pisang	3 pieces	30							
Cucur bedak	1 piece	40							
Cucur udang	1 piece	90							
Soto ayam	1 bowl	493							
Murtabak	1 piece	320							
Tapai	1 piece	80							
Chinese Food									
Yau-car-kue	1 piece	70							
Ham-chin-pan	1 piece	75							
Yam cake	1 piece	140							
Chee cheong Fan	1 roll	179							
Lor-mai-kai	1 piece	285							
Western Fast food									
Pizza	1/8 piece	68							
Hot dog	1	68							
Beef burger	1	100							
Tubers									
Potato	1 small	84							
Corn on the cob	1small (6cm)	145							
Corn in cup	1 cup	120							
Sweet potato	½ cup	48							
Tapioca	½ cup	45							
Yam	½ cup	45							
Breadfruit (Sukum)	1 slice	75							
Pumpkin	1 cup	143							
Legume									
Dal kuning (cooked)	½ cup	100							
Baked beans, canned	1/2 cup	118							

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
D. Food and beverages with added sucrose			**S**	**M**	**L**	**Per day**	**Per wk**		
Sweets/ cough sweet	**1 piece**	**5**							
Chocolate	**1 medium bar**	**27**							
Chocolate	**3 pieces**	**17**							
Cakes	**1 piece**	**23**							
Cake with icing	**1 piece**	**66**							
Sweetened biscuit	**3 piece**	**94**							
Sweetened biscuit with cream	**3 piece**	**25**							
Sweetened kueh	**1 piece**	**100**							
Sweetened Pau	**1 Pau**	**80**							
Sweetened bun e.g. coconut	**1 bun**	**83**							
Dognuts	**1 piece**	**75**							
Jam	**1 tbsp**	**26**							
Kaya	**1 tbsp**	**26**							
Sweetened beverages									
Packet drinks	**(250ml)**								
Carbonated drink	**(240ml)**								
Drinks with added sugar	**1 tbsp**	**15**							
Drinks with added condensed milk	**1 tbsp**	**21**							
Orange squash/ syrup/ Ribena	**2 tbsp**	**36**							
Honey	**1tbsp**	**19**							
Sugar cane water	**(240ml)**								
Sweetened desserts									
Pulut hitam/ Bubur kacang hijau/ merah + 1tbsp sugar	**1 bowl**	**374**							
Cendaol	**1 bowl**	**716**							
Ice cream	**1 scoop**	**63 ml**							
Sweetened jelly crystal	**1 cup (250 ml)**								
Fruit cocktail in syrup, canned	**½ cup (125ml)**								
ABC	**1 bowl**	**506**							

Total FFG = _____ gm CHO No of CHO exchanges = _____

APPENDIX 2: REVISED DIABETES SELF-CARE ACTIVITIES POST-QUESTIONNAIRE

Date:_____

A. Post HbA1c : _____ % (Date taken: _____)

B. Height: ____cm Weight: ____ kg BMI: ____ kg/m^2 Waist circumference:___ cm

C. Diabetes Knowledge Assessment:

1. Which is the better method for monitoring your diabetes control?

□$_1$ Urine testing
□$_2$ Blood testing
□$_3$ Both are equally good
□$_4$ Not sure

2. Infections such as a cold or influenza are likely to cause:

□$_1$ An increase in blood glucose
□$_2$ A decrease in blood glucose
□$_3$ No change in blood glucose
□$_4$ Not sure

3. If you take your morning diabetes tablets/insulin injection but skip breakfast, your blood glucose level will usually:

□$_1$ Increase
□$_2$ Decrease
□$_3$ Remain the same
□$_4$ Not sure

4. If you DO NOT take your diabetes medicine as prescribed by your doctor, your blood glucose level will usually:

□$_1$ Increase
□$_2$ Decrease
□$_3$ Remain the same
□$_4$ Not sure

5. What is the effect of regular exercise on blood glucose?

□$_1$ Lower it
□$_2$ Raises it
□$_3$ Has no effect
□$_4$ Not sure

6. Taking a low fat diet is more likely to reduce your risk in developing:

□1 Nerve disease
□2 Kidney disease
□3 Heart disease
□4 Eye disease
□5 Not sure

	Yes	No	Not Sure
7. High blood glucose can be caused by regular exercise	□1	□2	□3
8. High blood glucose can be caused by taking too much fruit	□1	□2	□3

	Increase	Decrease	No effect	Not sure
9. What is the effect of oats on blood glucose?	□1	□2	□3	□4
10. What is the effect of corns on blood glucose?	□1	□2	□3	□4
11. What is the effect of unsweetened fruit juice on blood glucose?	□1	□2	□3	□4
12 What is the effect of chicken on blood glucose?	□1	□2	□3	□4
13. What is the effect of potato on blood glucose?	□1	□2	□3	□4
14. What is the effect of wholemeal bread on blood glucose?	□1	□2	□3	□4
15. What is the effect of guava on blood glucose?	□1	□2	□3	□4

Which of the following are complications of diabetes?

	Yes	No	Not Sure
16. Eye problems	□1	□2	□3
17. Kidney problems	□1	□2	□3
18. Nerve problems	□1	□2	□3
19. Lung problems	□1	□2	□3
20. Stroke	□1	□2	□3

D. Self-care activities

I) Medication

What current medication(s) do you take for your diabetes?

No	Medicine	Doctor's Prescription			Participant's description			
		dose	frequency	time	dose	frequency	time	Not sure
1/2								
3/4								
5/6								
7/8								

Questions 1/3/5/7 assess for actual dosage taken
Questions 2/4/6/8 assess for actual frequency taken

9. Last week, how many times did you miss taking your MORNING diabetes medicine(s) (oral and insulin)?

□0 □1 □2 □3 □4 □5 □6 □7

10. Last week, how many times did you miss taking your NOON diabetes medicine(s) (oral and insulin)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7

11. Last week, how many times did you miss taking your EVENING diabetes medicine(s) (oral and insulin)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7

12. Last week, how many times did you miss taking your NIGHT diabetes medicine(s) (insulin)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7

13. Last week, what time did you take your MORNING diabetes medicine?

□1 >60 mins before food
□2 30 to 60 mins before food
□3 <30 mins before food
□4 with food
□5 < 30 mins after food
□6 30 to 60 mins after food
□7 >60 mins after food

14. Last week, what time did you take your NOON diabetes medicine?

□1 >60 mins before food
□2 30 to 60 mins before food
□3 <30 mins before food
□4 with food
□5 < 30 mins after food
□6 30 to 60 mins after food
□7 >60 mins after food

15. Last week, what time did you take your EVENING diabetes medicine?

□1 >60 mins before food
□2 30 to 60 mins before food
□3 <30 mins before food
□4 with food
□5 < 30 mins after food
□6 30 to 60 mins after food
□7 >60 mins after food

16. Compliance Rate: OAM _____% Insulin _____% Total: _____%

For Insulin user only

17. Last week, how many times did you need help to give your insulin injection(s)?

□0 □1 □2 □3 □4 □5 □6 □7

18. Last week, how many times did you take a different insulin dosage from your doctor's prescription? (participant to demonstrate drawing of insulin dosage)

□0 □1 □2 □3 □4 □5 □6 □7

19. Last week, where did you usually inject your insulin injection?

□1Not specific □2 Buttock □3Legs □4 Arms □5 Abdomen

20. Last week, how often did you rotate your insulin injection site?

$□_1$ Never $□_2$ Seldom $□_3$ Sometimes $□_4$ Most of the time $□_5$ All the time

II) Physical activity

A) Non-leisure physical activity

When you are at work or doing housework or in college, on an average:

1. How much time do you spend sitting?

$□_1$ Never
$□_2$ Seldom
$□_3$ Sometimes
$□_4$ Most of the time
$□_5$ All the time

2. How much time do you spend standing?

$□_1$ Never
$□_2$ Seldom
$□_3$ Sometimes
$□_4$ Most of the time
$□_5$ All the time

3. How much time do you spend walking?

$□_1$ Never
$□_2$ Seldom
$□_3$ Sometimes
$□_4$ Most of the time
$□_5$ All the time

4. Do you have to lift or carry heavy things?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

B) Leisure physical activities

5. How often do you walk around your house or apartment during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

6. How often do you do gardening such as trimming the shrubs, digging, mowing the lawn but not watering pot plants or pottering around during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

7. How often do you sit down to relax, read books/magazines/newspapers, watch TV, play or work on a computer during your leisure hours?

□1 Never
□2 Seldom
□3 Sometimes
□4 Most of the time
□5 All the time

8. Do you have a regular exercise program?

□0 No (go to part IV) □1 Yes

9. If yes, what exercise do you do?

□1 Mild exercise (minimal effort)
(Examples are yoga, golf, slow walking, Tai chi, Chinese martial art,calisthenics, fishing fom river bend)

□2 Moderate exercise (mild increased in heart beats or breathing) (Examples are brisk walking, easy bicycling, volleyball, badminton, table tennis, leisure swimming, popular and folk dancing, bowling

□3 Strenuous exercise (heart beats rapidly and increase breathing) (Examples are running, jogging, football, soccer, squash, basketball, vigorous swimming, long distance bicycling, tennis)

10. Last week, how many days did you exercise?

□0 □1 □2 □3 □4 □5 □6 □7

11. On average, how many minutes did each session last?

□1 0 -15 mins
□2 16-30 mins
□3 31-45 mins
□4 46-60 mins
□5 >60 mins

III) Self-monitoring

1. Last week, how many times did you test your blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

2. Last week, how many times did you test your fasting blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7

3. Last week, how many times did you test your pre-meal blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7

4. Last week, how many times did you test your 2 hours post-meals blood glucose level?

□0 □1 □2 □3 □4 □5 □6 □7

5. Last week, how many times did you change your food intake based on the results of your blood glucose reading(s)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

6. Last week, how many times did you change your physical activity based on the results of your blood glucose reading(s)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

7. Last week, how many times did you change your medication dosage based on the results of your blood glucose reading(s)?

□N/A □0 □1 □2 □3 □4 □5 □6 □7 □ more than 7

IV) Diet

For consistency, the investigator will record all the answers on the two 24-hour dietary records and Food Frequency questionnaire.

24-hour Dietary Recall

First 24-hour dietary recall (record during the interview)

Meal	Timing of meal	Food taken	Portion size	Method of cooking	Wt ref	Ref Source

Date: _____

2. Second 24-hour dietary recall (To be recorded within one week from the interview by telephone)

Meal	Timing of meal	Food taken	Portion size	Method of cooking	Wt ref	Ref Sources

FOOD FREQUENCY QUESTIONNAIRE

Write in the column how many times per day/week you would have eaten the food the past one week

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
A. Fruit			**S**	**M**	**L**	**Per day**	**Per wk**		
Apple	**1 medium**	**115**							
Orange	**1 medium**	**165**							
Pear	**1 medium**	**167**							
Star fruit	**1 medium**	**235**							
Banana	**1 small**	**62**							
Mango	**½ small**	**106**							
Nanga	**4 pieces**	**205**							
Cempadak	**4 pieces**	**60**							
Papaya	**1 slice**	**211**							
Pineapple	**1 slice**	**142**							
Watermelon	**1 slice**	**250**							
Honeydew	**1 slice**	**215**							
Grapes	**8 pieces**	**92**							
Guava	**½ fruit**	**150**							
ciku	**1 medium**	**54**							
Lychee	**5 pieces**	**77**							
Plum	**1 small**	**70**							
Kiwi	**1 medium**	**156**							
Dates (kurma)	**3 pieces**	**21**							
Strawberry	**5 whole**	**47**							
Duku langsat	**8 pieces**	**93**							
Langsat	**8 pieces**	**73**							
Durian	**4 medium seeds**	**150**							
Rambutan	**5 whole**	**170**							
Mangosteen	**4 small (30g)**	**96**							
Mata Kuching	**10 whole medium**	**52**							
Fruit juice	**1 cup (240ml)**								
B. Beverages									
Milk powder (full cream)	**4 rounded tbsp**	**29**							
Milk powder (skim)	**4 rounded tbsp**	**32**							
Packet milk drinks	**1 cup (240 ml)**	**256**							
Evaporated milk	**½ cup (120ml)**	**130**							
Milo	**3 rounded tbsp**	**19**							
Holick	**2 rounded tbsp**	**21**							
Ovaltine	**3 rounded tbsp**	**20**							
Nestum	**3 rounded tbsp**	**25**							
Oats(uncooked)	**3 rounded tbsp**	**18**							
Oats (cooked)	**½ cup**	**126**							
Coconut water	**1 glass (240ml)**	**240**							

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
B. Beverages			**S**	**M**	**L**	**Per day**	**Per week**		
Soya milk (unsweetened)	1 glass (240ml)								
Soya milk (sweetened)	1 glass (240ml)								
Barley water (unsweetened)	1 glass (240ml)								
Tau-hoo-fah (unsweetened)	1 cup (250ml)	368							
Yogurt plain	1 cup	150							
Yogurt (sweetened)	1 cup	150							
C. Cereal Tubular/ legumes									
Common Food									
Rice	1 Chinese bowl	150							
Rice porridge	2 Chinese bowl	498							
Kueh teow/Mee hoon (fried)	1 plate	170							
Kueh teow/Mee hoon (soup)	1 bowl	500							
Kueh teow/Mee hoon (Bandung style)	1 bowl	450							
Mee (fried)	1 plate	170							
Mee (soup)	1 bowl	563							
Mee (Bandung style)	1 bowl	450							
Wan tan mee noodle dry/soup	1 plate 1 bowl	330 408							
Loo See Fun	1 Chinese bowl	212							
Mee Hon Kueh	1 bowl	450							
Bread (white/ wholemeal)	1 slice	30							
Bun (plain)	1 bun	34							
Corn flake (unsweetened)	1 cup	28							
Roti canai	1 piece	84							
Pisang goreng	1 piece	80							
Kelidek goreng	1 piece	80							
Curry puff	1 piece	48							
Rojak	1 plate	330							
Biscuit (unsweetened)	3 pieces	21							
Spring roll (popiah)	1 piece	51							
Yong Tau Foo	1 piece	80							

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
C. Cereal Tubular/ legumes			S	M	L	Per day	Per wk		
Pau Ayam	1 piece	96							
Indian Food									
Chappati 20cm diameter	1 piece	100							
Dosai, 30 cm diameter	1 piece	180							
Idli	1 piece	82							
Putu mayam	1 piece	40							
Vadai	1 piece	60							
Malay Food									
Cekodok pisang	3 pieces	30							
Cucur bedak	1 piece	40							
Cucur udang	1 piece	90							
Soto ayam	1 bowl	493							
Murtabak	1 piece	320							
Tapai	1 piece	80							
Chinese Food									
Yau-car-kue	1 piece	70							
Ham-chin-pan	1 piece	75							
Yam cake	1 piece	140							
Chee cheong Fan	1 roll	179							
Lor-mai-kai	1 piece	285							
Western Fast food									
Pizza	1/8 piece	68							
Hot dog	1	68							
Beef burger	1	100							
Tubers									
Potato	1 small	84							
Corn on the cob	1small (6cm)	145							
Corn in cup	1 cup	120							
Sweet potato	½ cup	48							
Tapioca	½ cup	45							
Yam	½ cup	45							
Breadfruit (Sukum)	1 slice	75							
Pumpkin	1 cup	143							
Legume									
Dal kuning (cooked)	½ cup	100							
Baked beans, canned	1/2 cup	118							

Food Item	Reference Portion	Wt (g)	Your Serve			Number of times eaten		Total amount of food eaten in a week	Rarely or Never
D. Food and beverages with added sucrose			**S**	**M**	**L**	**Per day**	**Per wk**		
Sweets/ cough sweet	**1 piece**	**5**							
Chocolate	**1 medium bar**	**27**							
Chocolate	**3 pieces**	**17**							
Cakes	**1 piece**	**23**							
Cake with icing	**1 piece**	**66**							
Sweetened biscuit	**3 piece**	**94**							
Sweetened biscuit with cream	**3 piece**	**25**							
Sweetened kueh	**1 piece**	**100**							
Sweetened Pau	**1 Pau**	**80**							
Sweetened bun e.g. coconut	**1 bun**	**83**							
Dognuts	**1 piece**	**75**							
Jam	**1 tbsp**	**26**							
Kaya	**1 tbsp**	**26**							
Sweetened beverages									
Packet drinks	**(250ml)**								
Carbonated drink	**(240ml)**								
Drinks with added sugar	**1 tbsp**	**15**							
Drinks with added condensed milk	**1 tbsp**	**21**							
Orange squash/ syrup/ Ribena	**2 tbsp**	**36**							
Honey	**1tbsp**	**19**							
Sugar cane water	**(240ml)**								
Sweetened desserts									
Pulut hitam/ Bubur kacang hijau/ merah + 1tbsp sugar	**1 bowl**	**374**							
Cendaol	**1 bowl**	**716**							
Ice cream	**1 scoop**	**63 ml**							
Sweetened jelly crystal	**1 cup (250 ml)**								
Fruit cocktail in syrup, canned	**½ cup (125ml)**								
ABC	**1 bowl**	**506**							

Total FFG = _____ gm CHO No of CHO exchanges = _____

APPENDIX 3: UNIVERSITY OF ADELAIDE LETTER OF ETHICS APPROVAL

THE UNIVERSITY OF ADELAIDE
AUSTRALIA

RESEARCH BRANCH
RESEARCH ETHICS AND COMPLIANCE UNIT

SABINE SCHREIBER
SECRETARY
HUMAN RESEARCH ETHICS COMMITTEE
THE UNIVERSITY OF ADELAIDE
SA 5005
AUSTRALIA
TELEPHONE +61 8 8303 6028
FACSIMILE +61 8 8303 7325

8 March 2007

Ms JM Magarey
Discipline of Nursing

Dear Ms Magarey

PROJECT NO: H-001-2007 *Enhancing self-care practices of adults with poorly controlled diabetes using self-efficacy education approach*

I write to advise you that the Human Research Ethics Committee has approved the above project. Please refer to the enclosed endorsement sheet for further details and conditions that may be applicable to this approval.

Approval is current for one year. The expiry date for this project is: 31 March 2008

Where possible, participants taking part in the study should be given a copy of the Information Sheet and the signed Consent Form to retain.

Please note that any changes to the project which might affect its continued ethical acceptability will invalidate the project's approval. In such cases an amended protocol must be submitted to the Committee for further approval. It is a condition of approval that you immediately report anything which might warrant review of ethical approval including (a) serious or unexpected adverse effects on participants (b) proposed changes in the protocol; and (c) unforeseen events that might affect continued ethical acceptability of the project. It is also a condition of approval that you inform the Committee, giving reasons, if the project is discontinued before the expected date of completion.

A reporting form is available from the Committee's website. This may be used to renew ethical approval or report on project status including completion.

Yours sincerely

S. Schreiber

Professor Garrett Cullity
Convenor
Human Research Ethics Committee

APPENDIX 4: MALAYSIAN RESEARCH AND ETHICS APPROVAL LETTER

PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
(PENYELIDIKAN & SOKONGAN TEKNIKAL)
(RESEARCH & TECHNICAL SUPPORT)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Aras 12, Blok E7, Parsel E, Presint 1
Level 12, Block E7, Parcel E, Precinct 1
Pusat Pentadbiran Kerajaan Persekutuan
Federal Government Administrative Centre
62590 PUTRAJAYA

Tel : 03 88832543
Faks : 03 88895184

MEDICAL RESEARCH & ETHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
d/a Institut Penyelidikan Perubatan
Jalan Pahang
50588 Kuala Lumpur

Ruj. Kami : (5) dlm.KKM/NIHSEC/08/0804
Tarikh : 13 December 2006

Ms Tan Ming Yeong
Damai Medical & Heart Clinic
Melaka

Dear Ms Tan,

Enhancing Self-care practices of adults with poorly controlled diabetes using a self-efficacy educational approach.
Project Sites : Hospital Seremban / Hospital Melaka / Masjid Tanah Health Clinic/ Durian Tunggal Health Clinic

With reference to the above, we are pleased to inform that your application to conduct the above study as per requirement to your PhD programme in the Discipline of Nursing, the University Of Adelaide has been approved by the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

You would be required to submit a copy of the project report or thesis to the Committee after completion of your project.

Thank you.

Yours sincerely,

(DR ZAKIAH ISMAIL)
Acting Director, Institute for Medical Research
for the Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia

c.c. NIH Secretariat, MOH

APPENDIX 5: INFORMATION SHEET

THE UNIVERSITY
OF ADELAIDE
AUSTRALIA

DISCIPLINE OF NURSING
SCHOOL OF POPULATION HEALTH AND CLINICAL PRACTICE
FACULTY OF HEALTH SCIENCES

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CRICOS Provider Number 00123M

Information Sheet

Dear Sir/Madam,

The following information is to explain a proposed study titled:

'Using diabetes education program to enhance self-care practices of adults with poor diabetes control'

About 9% of the people in Malaysia have diabetes mellitus. Many of these will suffer from complications of their diabetes. One of the reasons is because their blood glucose levels are frequently above the normal range. Thus the purpose of this study is to introduce a diabetes program to help people with frequent high blood glucose levels to manage their diabetes daily.

You are invited to participate in this study because your blood glucose levels were frequently above the normal range. This study will involve a period of 12 weeks or 3 months. At the beginning of the study, the investigator will interview you regarding how you manage your diabetes daily like your diet habits, activities, medication intake and self-monitoring practices. Prior to interview, the investigator will need to access your medical record for information of your blood glucose result in the last year and also the name of the medications you are currently taking. The investigator will also need to take your blood sample to assess your diabetes control. After the first interview and blood test, the investigator will discuss with you on how to improve your diabetes control. At the end of the 12 week, the investigator will interview you again on how to manage your diabetes daily and the second sample of your blood will be taken. Each interview will take about 20-30 minutes. The purpose of these blood tests and the two interviews is to assess how much you have benefited from the education program.

No drug will be administered in this study. Your medical care will not be affected.

Your many not benefit directly from the study. However, the result of this study will help the health care personnel to understand and assist in managing your diabetes better in the future.

This is a research project and you don not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

Your identity will be kept confidential while the study is being conducted or when the study is reported or published.

This study is done as a research project by the investigator for her course in Doctor of Nursing with the University of Adelaide, Australia.

Appendix 5: Information Sheet (continued)

If you have any question at any time, you can contact the investigator, Ms Tan, at +60-6-2841204.

If you wish to discuss aspects of the study with someone not directly involved. You may contact the investigators' employer, Dr. Lee Boon Leong or Dr. Ramesh Kumar at Damai Medical and Heart Clinic, Melaka or phone number +60-6-2841204.

If you have questions or problems associated with the practical aspects of your participation in the project or wish to raise a concern or complaint about the project, you may contact either:

The investigator's supervisor at University of Adelaide, Dr. Judy Magarey on phone number +61-8-8303 6028

The Human Research Ethics Committee's secretary of the University of Adelaide on phone number +61-8-8303 6028

The Human Research Ethics Committee's independent complain form is attached.

Thank you

APPENDIX 6: RANDOMISATION LIST

Even numbers represent intervention subjects and odd numbers represent control subjects

Random List	Subject ID	Allocated Treatment
30	001	Intervention subject
12	002	Intervention subject
144	003	Intervention subject
90	004	Intervention subject
68	005	Intervention subject
13	006	Control subject
162	007	Intervention subject
55	008	Control subject
66	009	Intervention subject
61	010	Control subject
122	011	Intervention subject
62	012	Intervention subject
96	013	Intervention subject
63	014	Control subject
71	015	Control subject
142	016	Intervention subject
47	017	Control subject
121	018	Control subject
133	019	Control subject
119	020	Control subject
9	021	Control subject
8	022	Intervention subject
28	023	Intervention subject

Full list ranges from random number 1 to 164

Accessed from: http://www.random.org/sequences/

Portfolio Conclusion

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CONCLUSION OF PORTFOLIO

Introduction

As outlined in Section one of this portfolio, diabetes is a common, growing, serious and costly health problem for many nations including Malaysia. Landmark studies have provided convincing evidence that improving glycaemic control can prevent the onset and delay the progression of microvascular complications. For macrovascular complications, the Diabetes Control and Complication Trial/Epidemiology of Diabetes Interventions and Complications Study (DCCT/EDIC) has observed that early intensive insulin therapy leads to better glycaemic control and decreased coronary heart disease morbidity and mortality. People with diabetes manage their disease on their own for more than 95% of their life. Having the appropriate diabetes-related knowledge and skills is a prerequisite for successful self-care. Of the many self-care practices needed, four have been identified as important: dietary self-care, physical activity self-care, medication adherence self-care and self-monitoring of blood glucose self-care. The aims of the research presented in this portfolio were to define these four self-care practices in Malaysian subjects with poorly controlled diabetes and to study the effect of a short diabetes education program that incorporated self-efficacy on these four self-care practices. This section briefly summarises the findings of both studies. The issues central to both studies are discussed and their implications for practice especially nursing practice. Conclusions are drawn and recommendations made for further research.

Summary of the Portfolio

The results of the first study indicated that the majority of the subjects with poor control of their diabetes had deficits in diabetes-related knowledge and lack of self-care practices in their diet, medication intake, physical activity and self-monitoring

of blood glucose (SMBG). Although the subjects recognised the importance of the self-care practices in diabetes management, they did not practice them. Lack of diabetes knowledge and self-care practices among the study subjects were related to patient factors such as increased age and limited education. It appeared that factors such as the possibility of health professionals providing inadequate health education and lack of access to structured education and dietician services in healthcare system also contributed to a lack of self-care practices by the subjects

There was a gap between perception of the importance of self-care and implementation. The majority of subjects in the first study reported having received advice on diet, physical activity and SMBG. However it may be possible that they had problems understanding the advice provided. Hence a structured education program based on self-efficacy theory was introduced to compare with the standard care in the second study of the portfolio using a quasi-experimental approach.

In the second study, both groups had knowledge deficits and poor self-care practices at baseline. Although both groups had increased their diabetes knowledge at the end of study, the control subjects had small non-significant improvement in HbA1c but none of the self-care practices. Most subjects in the intervention group had significant glycaemic improvement at 12th week duration regardless of treatment mode. These subjects also improved significantly in their medication adherence and SMBG practices. However, their physical activity levels and dietary intakes only improved slightly.

A sub-group of the intervention subjects deteriorated in their glycaemic control and this correlated with increased age, less education and psychosocial factors such as problems with transportation and phone access.

Implications to Practices

The results of the two studies highlighted several factors that have implications for clinical practice. These factors are discussed in relation to patient, diabetes self-management education, healthcare providers, healthcare system and other confounders.

Patient Factors

Increased Age and Less Education

The findings of both studies in this portfolio showed that increased age and having six or less years of education may be a significant barrier to the effectiveness of diabetes education and self-care. This has important implications for clinical practice. In the first study of this portfolio, despite reporting having received advice, most subjects scored low on diabetes-related knowledge assessment and almost half did not remember the advice received on diet and exercise. Thus it appears that these subjects might have problems understanding the education they received. In the second study, although older subjects and those with less education improved their diabetes knowledge after the structured education intervention, these subjects achieved lower scores in the post-knowledge assessment when compared with the younger better educated subjects. This again may indicate inadequate comprehension of the principles being taught by this group.

Although knowledge of diabetes does not necessarily correlate with clinical outcomes,[1-3] it is a prerequisite for self-care practices.[4-6] This was observed in the studies presented in this portfolio. In the first study, subjects with lower education levels appeared to persevere less with their medication intake. Although adherence to medication improved after the education intervention in the second study, many subjects with less education still do not follow instructions regarding their prescribed medication. This may be due to difficulty in comprehension.

Although in this study low health literacy was not assessed with a validated tool, older subjects with less education appeared to have problems related to low literacy which Schillinger (2002) defined as 'inability to read, write, speak, understand and follow medical instruction to effectively participate in self-care'.[7] Other researchers reported similar findings of the association between low health literacy with older subjects, lower education level, ethnicity and poorer clinical outcomes.[8-11] Greenberg (2001) asks an important question. 'Does health literacy automatically imply better medical compliance?' If so, why do many highly educated individuals continue to live an unhealthy lifestyle?[12] The pertinent question to ask is 'Other than possible low health literacy, what other factors could be associated with the problems of comprehension of the education received among the present study subjects?' Could it be related to the education methodology used in the current healthcare system or the education intervention? The following discussion explored this matter.

Diabetes Self-management Education

Education and Patient Factors

There are reports of positive outcomes with education intervention provided to people with diabetes who are elderly and less educated.[12-16] These interventions usually involved individualised, culturally sensitive, behaviour-related tasks, frequent assessment and feedback, use of low literacy materials and high intensity with more than 10 contacts and longer than six months' duration. On the other hand didactic teaching and interventions that solely focused on diabetes knowledge reported more negative outcomes.[15-18]

The education intervention used in the second study of this portfolio featured most of the above positive criteria. However, again the approach benefited the younger subjects with higher education more than the older and less educated people. The lack of efficacy of the proposed educational approach for the older and less

education subjects could be related to lack of intensity and duration of the education. The mean duration of the proposed educational approach was 97 minutes with three interventions to facilitate the four daily self-care management skills. A previous meta-analysis found that it required 23.6 hours of education contact hours to reduce 1% of HbA1c.[19] In planning and delivering diabetes education, nurses need to consider these two demographic factors by individualising the education approach. For older subjects and those with less formal education, besides using materials suited for low health literacy, higher intensity of education approach is necessary to enhance their understanding and application in daily self-care. This is important in all settings especially in Malaysia's current healthcare system. There is a similarity of the study population in this portfolio with the diabetic population in Malaysia. Without a national registry of Malaysians with diabetes, it is difficult to obtain accurate population demographics for this group. Thirteen studies that investigated diabetes-related status from 1996-2008 in Malaysia reported the mean age of their study subjects between 53-62 years old which was similar to the mean age of the current study subjects. (54.7 years old).[20-32] Only three of the above 13 studies reported the education level of their study subjects and indicated that 44% to 77% of their subjects had 6 years or less of formal education. This again mirrored the education levels of subjects in this study. The efficacy of the proposed higher intensity education approach requires further research.

Education on Self-care

Introducing diabetes self-management education in the second study of this portfolio improved medication adherence and SMBG practices in the intervention group. However, the proposed education approach did not achieve significant findings with self-care practices that required lifestyle changes, dietary intake and physical activity level.

Dietary Self-care

This study did not explore the factors related to dietary non-adherence. A recent systematic review did not find any obvious characteristics of dietary interventions such as comparing group versus individual or computer approach, duration of study or total number of intervention that distinguished the significant and non-significant dietary studies.[33] Although the duration of education interventions was not reported in that systematic review, it was observed that interventions that improved HbA1c had longer contact hours (mean = 11.3 hours versus mean = 7.3 hours). This might partially explain the non-significant finding of the educational intervention in this study due to its shorter intervention duration of 1.5 hours.

The dietary diaries of the subjects in this research indicating their dietary intake reflect the local culture.[34-36] Rice, noodles and wheat products represented the staple diet. There was also frequent consumption of food high in calories like sweetened beverages, local sweet cakes, food prepared with coconut milk, deep fried food with infrequent intake of fruits and vegetables. In addition, being a multiracial society, Malaysia has many festival and religious celebrations where families get together. According to the Family Health Model,[37] people with diabetes have to adopt new dietary routines to decrease consumption of sweetened foods and fats and increase intake of fruits and vegetables. This needs to occur at diagnosis and continue for life.[38] Since cultural food patterns in families motivate eating practices, the suggested healthy dietary standards by the healthcare professionals often conflict with typical Malaysian eating patterns. This situation can be exacerbated by lack of social and family support or family members' poorer dietary knowledge.[37] One study exploring the self-care practices of Malay diabetic patients in Malaysia noted that '*sometimes my husband will buy whatever food he wants to eat and ask me to eat it……my children too*'[39]

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Furthermore several studies have highlighted gender differences in dietary care. Women may cook special meals for a chronically ill husband but less likely to alter cooking habits if they suffer from a disease themselves. This is because it may place

them in conflict with maternal and domestic roles that emphasise others' needs over their own.[40,41]

Understanding the above factors that can lead to non-adherence in dietary self-care, nurses and other healthcare professionals have to look beyond providing standard dietary education that targets people with diabetes. Instead nurses can take the lead to change the traditional education approach by working together with dieticians, nutritional anthropologists, clinical psychologists, people with diabetes and their family members or carers to develop individualised plans that people with diabetes are able and willing to do within their support system. Family members who prepare family meals should be invited to attend the education sessions with the persons with diabetes to enhance their understanding of the concept of diabetes care and dietary knowledge. Other scholars have reported better family support and using culturally sensitive dietary approach improved dietary self-care and metabolic outcomes.[42-45] Since there is scanty evidence reported from Malaysia, future research could explore whether education programs that incorporate family members and culturally appropriate approaches can enhance dietary adherence among local people.

Physical Activity Self-care

Many subjects in this research lived a sedentary lifestyle. Although there was a significant improvement when comparing the physical activity between intervention and control group in the second study of this portfolio, the 2.7 unit difference was not clinically significant. Furthermore, there was only slight and insignificant improvement in the physical activity of the intervention group after the education.

Another recent systematic review assessing the evidence regarding interventions to enhance physical activity among people with diabetes did not identify any specific characteristics for positive behaviour outcomes. There was a suggestion that using structured exercise regimens had more significant impact on behaviour outcomes.[46] Although not reported, it was observed that 76% of the primary studies with positive outcomes in that systematic review had included exercise classes and longer duration

in their interventions. In this study, only verbal persuasion based on self-efficacy was used. Another systematic review that assessed the effectiveness of advice given on physical activity in routine primary care settings reported minimal efficacy in sustaining increased physical activity levels in the long term.[47] These two systematic reviews emphasise the importance of leisure activities in daily life to reduce glycaemic and cardiovascular risks. Similar findings were observed in the first study of this portfolio. Subjects who reported having regular leisure activities had significant lower mean fasting blood glucose level than those who did not.

Although subjects in this research perceived the importance of physical activity in diabetes management, common barriers to engage in regular exercise were lack of time due to long working hours and gender role with family commitments. Similar findings were found in previous studies done in Malaysia.[39,48] The concept of self-management in exercise is to allow people with diabetes to manage their condition in their own in daily lives. Most well-conducted exercise studies take place in controlled, artificial settings rather than in the reality of a person's daily life. Hence translation of these positive interventions into practice is a challenge for nurses and other healthcare professionals. Previous studies revealed that the work environment can be a mainstay in a comprehensive healthcare system since worksites involved the largest number of people for many years of their adult lives.[49-51] However, the 1992 National Survey of Worksite Health Promotion Activities in the United States reported that only one-third of worksites employing 50-99 people offered any physical activity programs.[52] From the public health prospective, it would be appropriate to suggest strategies to increase daily physical activity levels such as incorporating three 30-minute exercise sessions per week during working hours besides encouraging walking and using stairs. There were mixed outcomes in previous studies on worksite exercise programs and also paucity of information on worksite programs in Malaysia.[48-50,53] Future research could explore whether such a program could enhance physical activity levels. Implementing a worksite program to increase physical activity would need to include a top-down approach with

environmental and policy interventions to reduce obstacles that discourage exercise and ensure safety, availability, accessibility and convenience.[54,55]

Previous surveys done in Malaysia reported 60% of adults are inactive and there was 280% increase in obesity from 1996 to 2007.[56,57] Malay and Indian women in rural Malaysia had the highest prevalence of obesity which is defined as more than 30 kg/m^2 body mass index. Similar findings were observed in this study. The Malaysian government and other non-government organisations have initiated free exercise programs in some urban regions. These programs should be extended nationally to include rural areas in order to be accessible and benefit the rural female population who are the highest risk group. Based on a systematic review, diabetes self-management education conducted at community levels yield better outcomes when the interventions are carried out in community halls or religious institutions compared to schools or worksites.[58]

Within the healthcare system, nurses should incorporate exercise classes into the standard diabetes education sessions. One small study undertaken in Malaysia has shown this to be feasible with improvement in glycaemic and metabolic control when monthly exercise classes were incorporated in the 6-month intervention program.[59] In planning a future education program, extra hours should be allocated for education regarding diet and physical activity. All the proposed strategies would need further research to assess its efficacy in Malaysia.

Diabetes Education and Psychosocial Barriers

To be effective in health promotion, it is important for nurses to understand the problems associated with local situations. A quarter of the elderly and female subjects in the intervention group in the second study of this portfolio reported having problems with transport and could not attend education classes due to their dependency on other family members. The same subjects also had problems receiving the third education intervention via phone access. Mobile phones are

common in Malaysia and the reason for this barrier was not investigated here. It is possible that with lower socio-economic status, one mobile phone is shared by family members. Since the elderly and female family members are frequently housebound, the mobile phone is usually used by the younger and male family members who are in the workforce. Telephone interventions have been reported as a feasible approach for education including research done in one Asian country.[60-62] Further research is, therefore, required to explore this issue in Malaysia.

Inaccessibility to diabetes education is a global problem. According to a report released by the United States Department of Health and Human Services in 2000, 40% of people with diabetes had attended formal diabetes education classes.[63] Due to scarcity of trained diabetes educators in Malaysia, the diabetes resource centres are located in hospitals in urban areas and rural health care clinics in the suburbs. The healthcare system in Malaysia is comprised of state and district hospitals, rural health care clinics, health clinics and health mobile teams where the later three are situated at the rural regions.[64] In 2005, 44% of the Malaysian population resided in the rural regions.[65] As reported in the first study of this portfolio, these rural folk usually have problems with accessibility to diabetes education and dietician services. Furthermore it is evident that nurse-led clinics improve patient outcomes in multiple chronic medical conditions including diabetes.[66-68] Currently there are midwife-led clinics for maternal and child care at the rural regions in Malaysia, but no diabetes nurse-led clinic. Hence one proposal is to integrate diabetes nurse-led clinics into the current rural healthcare system by utilising the present primary healthcare staff nurses who could be supervised by their local physicians and diabetes nurse educators from the nearest diabetes resource centres. The objectives of the diabetes nurse-led clinics would include providing structured diabetes education, monitoring patients' diabetes status and facilitate care delivery including liaison with physicians on titration of medication. To overcome the problem of human resource shortage, it is proposed to initiate the program with once weekly diabetes nurse-led clinics at the health clinics.

Literature reviews have also shown that television and videotapes are effective in providing structured, standardised health information which when compared to written materials is more likely to increase retention.[69,70] Since televisions, videos and radios are common items in Malaysian households, these media may be used to overcome elderly people's lack of transportation. Two surveys have shown that rural folk in Malaysia have reported receiving knowledge on SARS and dengue fever via television and radio.[71,72] Research is required to assess any improvement in accessibility to diabetes health promotion using nurse-led clinics or mass media like structured television programs. Future research should also assess the efficacy of structured diabetes television programs to improve diabetes knowledge and self-care as diabetes management is more complex than SARS and dengue fever.

Healthcare Providers

In the first study of this portfolio, only two-thirds of the subjects reported receiving advice on SMBG and 28% of the subjects reported that they were advised to exercise three times per week instead of a minimum of five days a week as in congruent with present standard of care. These findings might imply inadequate advice provided by healthcare professionals. However while this portfolio explored the self-care practices of adults with poorly controlled diabetes, factors concerning the healthcare providers were not investigated. Due to limited trained personnel at the primary care settings as discussed earlier, most diabetes education is provided by generalist nurses, physicians and other healthcare providers who may lack educational preparedness for this role. A previous study undertaken in Malaysia that assessed the diabetes knowledge of 33 doctors, reported only 55% of them had adequate knowledge of diabetes.[32] No study in Malaysia has assessed the general nurses' knowledge of diabetes. Although previous literature has shown that general nurses perceive the importance of diabetes education in its management, there were multiple barriers that they experience when educating patients with diabetes, for example, inadequate knowledge and skills and limited time and resources.[73,74] Further research is required to develop this nursing role in diabetes education in the general hospital

setting. In addition it is important to have a long-term strategy on continuous diabetes education and management programs for healthcare professionals involved in diabetes management. Such programs should not only aim to enhance knowledge and skills but also emphasise the importance of multidisciplinary team approach in diabetes management.

Healthcare System

What became apparent during this research was factors related to the current healthcare system might have contributed indirectly to the poor clinical outcomes of the subjects. An example was the instructions on medication intake. There are only two instructions on the medication bags which were: 'before meal' and 'after meal' with no specific timing related to meal being mentioned. In addition, there was no instruction on 'with meal' that is required for the administration of Acarbose. The administration of pre-meal insulin injection and the sulphonylurea group of oral anti-hyperglycaemia medication are time-specific. The findings in the second study indicated a significant relationship between wrong timing of medication intake with higher glycaemic control despite adherence to medication. During diabetes education sessions, besides emphasising the importance of medication adherence, nurses should assist patients, especially the elderly and those with less education to understand the instructions on their medication prescriptions, especially dosage, frequency and timing. Adding a simple instruction like "To be taken___min before meals" on the medication bag could enhance proper timing of medication intake.

Fifteen percent of the subjects in the first study practiced SMBG. Similar findings were reported by previous studies in Malaysia.[23,28] Subjects who were older, on oral anti-hyperglycaemic medication and lived in the country were less likely to report having received advice on SMBG compared to advice given on diet and exercise. The reasons underlying the possible behaviour of the healthcare providers were not explored and require further research. Previous studies have shown that knowledge, attitude and beliefs of the healthcare providers correlated with the glycaemic control

of their subjects.[75-77] Another important observation from the first study of this portfolio was that those subjects who had received advice on SMBG were more likely to practice it. This observation was confirmed by the findings of the second study. With encouragement and free supply of blood glucose monitoring equipment, the intervention subjects regardless of treatment mode, age and settings showed an improvement in self-care practices and glycaemic control. With financial subsidies from the blood glucose monitoring device companies to purchase their equipment, 60% of the intervention subjects continued to practice SMBG after the study. Nurses constitute the largest group of healthcare professionals and they also have lengthy contact with diabetic patients and are thus in a unique position to encourage them to practice SMBG and also to get family members to assist in achieving this goal.

Two aspects of diabetes education need to be considered**.** One is its accessibility and the second, its efficacy. As shown in the first study of this portfolio, despite having received advice on diet, exercise and SMBG, their glycaemic control was suboptimal. The current diabetes education program provided with the standard care in the second study of this portfolio did not improve the self-care practices and clinical outcomes of the subjects. Similar results were found by a recent Malaysian National Audit on treatment adequacy of Type 2 diabetes in government primary care settings (n=973). In that audit, almost half of the subjects had received advice or education provided either by the healthcare providers or dedicated diabetes centers. However, the mean HbA1c was 10.4% with no difference in the status of control between settings with or without diabetes services.[25] Having received ‘advice’ or ‘education’ or ‘structured education’ could produce different outcomes because it depends on the content, intensity and methodology used, besides factors related to patients and the educators. The introduction of the proposed education in the second study enhanced self-care practices of SMBG and medication adherence leading to improve glycaemic control. Since there was no information on the education methodology used in standard care making a comparison is not possible. Other than providing knowledge on diabetes management, the education strategy used in this study involved self-efficacy theory via an individualised approach. The literature has not

demonstrated improved outcomes comparing individual versus group education.[78] However, other researchers have reported better educational outcomes with inclusion of behavioural science in the education program in comparison to the didactic approach.[79,80] When providing medical education on management of diabetes for healthcare providers, it is vital for diabetes nurse educators to include education methodology, behavioural science, and communication skills.

Other Confounders

As observed in this portfolio, self-care and learning about diabetes self-management is a complex process. In this portfolio, the investigator only explored and introduced interventions to enhance the four self-care practices that had directly influenced glycaemic control, namely dietary and medication intake, physical activity and SMBG. Besides factors discussed earlier, other psychosocial and biological factors also influence the acquisition of knowledge and self-care practices. These factors include low income, development of diabetes complications, depression,[81,82] previous personal and family experiences, health beliefs, locus of control,[83,84] healthcare provider-patient relationship[85,86] and cultural influence.[87-89] These were not included in the assessment and analysis. Hence the findings of this portfolio will need to be interpreted within the limitations of the studies.

Feasibility of the Education Program

Any attempt to improve the standard of care provided needs to be cost-effective, congruent with the current healthcare system and reaching the target population. To assess the feasibility of the proposed self-efficacy education program in the contemporary healthcare system, the investigation used the criteria for feasibility described by Vincent *et al* (2007).[90] The intervention program was well accepted by the intervention group with a low attrition rate of 0.48%. The 12th week education intervention was well suited to the current follow-up system as most of the patients

with diabetes were followed-up every three months following monthly collection of their medication supply. Furthermore this program could involve just one discipline, the diabetes nurse educator who usually has most contact with the individuals with diabetes or it could involve more disciplines if resources were available. Although only 75% of the intervention subjects completed the three interventions with 84% completing two interventions, the findings from the second study indicated that the total education time rather than number of education intervention were significantly associated with enhancing four self-care practices and diabetes knowledge. Hence the number of interventions could be individualised. Importantly, the interventions enhanced self-care practices and improve clinical outcomes in short term. However, some modifications are necessary to further enhance outcomes. The duration of future program should increase to accommodate better comprehension in diet and exercise components especially for older patients and those less well educated. Education sessions should also include family members and incorporate exercise classes. Diabetes education should be accessible to all individuals with diabetes and their family members through the urban and rural healthcare centres' network. Education sessions should be delivered using a face-to-face approach rather than telephone due to accessibility problems as discussed earlier.

Although this research has illustrated the benefits of the proposed diabetes education program for adults with poorly controlled diabetes, implementing such a program would not be a simple process. It would involve a significant cost in training healthcare staff, an increase in diabetes resources and subsidised SMBG equipment. However, the high cost involved in treating current diabetes complications discussed in the introduction of this portfolio would probably outweigh the cost of training and implementing the program.

Conclusion

This portfolio presented the reports of two separate research studies on the nursing care of Malaysian adults with poorly controlled diabetes. The findings have

illustrated that self-care practices of individuals with diabetes play a significant role in managing their disease. Poor self-care contributes to poor glycaemic control. Subjects in this study who improved their self-care practices in medication adherence and SMBG practices improved their glycaemic control. The challenge for both the individuals with diabetes and nurses is that the process of self-care is not a straight forward process but is constantly influenced by ability, psychosocial, cultural, environmental and behavioural factors An example was despite receiving education and recognising the importance of diet and exercise in the management of diabetes, the study subjects still had difficulty changing their self-care practices.

Because of this complexity, providing diabetes self-management education to people with diabetes is a challenge for nurses and all healthcare providers. Nurses should use a holistic approach instead of viewing diabetes self-management education as a routine activity. When exploring barriers to self-care, nurses should look beyond patient-related factors and explore factors related to healthcare providers and the healthcare system. When delivering education, it needs to be tailored to individual needs such as use of low literacy materials for older people and for those with less education. In addition, different education approaches for self-care practices like the inclusion of family members or carers are vital in dietary interventions.

The findings in the second study showed that increasing diabetes-related knowledge, medication adherence self-care and SMBG self-care in Malaysians with poor glycaemic control led to better glycaemic control. Further research is needed to find ways to improve dietary and physical activity self-care.

Lastly, in section one the journey begins with the true story of Mr. Chong in Malaysia. Section four ends the journey by re-examination of the case study. The problems of living with diabetes as experienced by Mr. Chong highlighted the findings of this portfolio that the process of diabetes self-care and education was indeed a complex endeavour. Diabetes management has to be approached holistically

by addressing a list of psychosocial problems**.** Mr. Chong's case is by no means an isolated case. This is shown by the facts and figures on diabetes globally (Table 1).[91]

Table 1: Prevalence of Diabetes and Diabetes Complications Globally

Every 10 seconds two people develop diabetes
Each year a further 7 million people develop diabetes
Every 30 seconds a leg is lost to diabetes somewhere in the world
More than 2.5 million people worldwide are affected by diabetic retinopathy
Cardiovascular disease contributes to 50% of all diabetes fatalities
10% to 20% of people with diabetes die of renal failure
Every 10 seconds a person dies from diabetes-related causes
Diabetes is the 4th leading cause of global death by disease

Adapted from International Diabetes Federation: Facts and Figures[91]

While we do not have similar facts and figures for Malaysia, diabetes is indeed a serious and costly health problem in this nation and it must catch-up with advances in diabetes education and self-care. In the early 2000s, the United States and the International Diabetes Federation implemented standard diabetes self-management education programs to improve the care of diabetes.[92,93] To avoid tragic outcomes as in Mr. Chong's case, it is a challenge for nurses and healthcare providers in Malaysia to work towards meeting the global standard of care for people with diabetes. This includes improving Malaysian national diabetes self-management education programs. Hence it is hoped that the findings reported in this portfolio may contribute to improving the care of individuals with poorly controlled diabetes and assist in reducing the prevalence of complications that lead to increased morbidity and mortality in Malaysia.

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Section 5

Publication

Publication

Ming Yeong Tan, Judy Magarey. Self-care Practices of Malaysian Adults withDiabetes and sub-optimal glycaemic control.Patient Education and Counseling 2008; 72: 252-267

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