MONASH University

Malay**s**ian **D**iabetes **a**nd **R**esearch on **L**ifestyle **In**tervention **G**roup **(MY DARLING)** Study:

The impact of diabetes education on knowledge, metabolic control, self-care skills and self-efficacy in Type 2 Diabetes patients in ambulatory settings.

BADARIAH BINTI AHMAD

MBBS (Ireland), MSc Physiology (Ireland).

A thesis submitted for the degree of Doctor of Philosophy at

Monash University in 2018

Jeffrey Cheah School of Medicine & Health Sciences

Monash University Malaysia

Supervisors:

Professor Dato' Dr Anuar Zaini Md Zain (Principal Supervisor)

Jeffrey Cheah School of Medicine and Health Sciences,
Monash University Malaysia
Jalan Lagoon Selatan, 47500 Bandar Sunway,
Selangor Darul Ehsan, Malaysia.

Associate Professor Dr Quek Kia Fatt (Co-Supervisor)

Jeffrey Cheah School of Medicine and Health Sciences,
Monash University Malaysia
Jalan Lagoon Selatan, 47500 Bandar Sunway,
Selangor Darul Ehsan, Malaysia.

Professor Dato' Dr Khalid Abdul Kadir (Co-Supervisor)

Jeffrey Cheah School of Medicine and Health Sciences,
Monash University Malaysia
Jalan Lagoon Selatan, 47500 Bandar Sunway,
Selangor Darul Ehsan, Malaysia.

Copyright notice

Notice 1

Notice 2

List of Figures

List of Tables

List of Abbreviations

AADE	American Association of Diabetes Educators
ACCORD	Action to Control Cardiovasular Risk in Diabetes
ACG	Action Control Group
ADA	American Diabetes Association
BQ	Behavioural Questionnaire
DAFNE	Dose Adjustment For Normal Eating
DESMOND	Diabetes Education of Self-Management for On-going and Newly Diagnosed
DKQ	Diabetes Knowledge Questionnaire
DKS	Diabetes Knowledge Score
HbA1C	Haemoglobin A1C
HAPA	Health Action Process Approach
HBM	Health Belief Model
IDF	International Diabetes Federation
KK	Klinik Kesihatan
LAY	Look After Yourself
MOH	Ministry of Health
MDKT	Michigan Diabetes Knowledge Test
MY DARLING	Malaysian Diabetes And Research on Lifestyle Intervention Group
MY DEMO	Malaysian Diabetes Education Module
ROMEO	Rethink Organisation to Improve Education and Outcomes
ROSES	Role of Self-monitoring of blood glucose and intensive education in Type 2 Diabetes
SMBG	Self-monitoring blood glucose

STeP	Structured Testing Program
STG	Structured Testing Group
TC	Telephone Contact
X-PERT	Expert Patient Education Versus Routine Treatment

Acknowledgement

- *First and foremost, I am grateful to Allah the Almighty for blessing me with the full faculty of mind, body and soul to embark on this journey of knowledge. Without His Blessings, I will not be here to successfully complete this thesis.*
- *My special appreciation and deepest gratitude to my supervisors who had given me the support, guidance, motivation and valuable advice throughout this endeavour. To Professor Dato' Dr Anuar Zaini Md Zain who has encouraged me to explore and experiment with my ideas yet was always there to give me sound, wise and practical "real world" advice. To Associate Professor Dr Quek Kia Fatt for his endless patience which taught me the importance of being throrough, methodical and exact in research. To Professor Dato' Dr Khalid Abdul Kadir who was pivotal in the development and conception of MY DARLING. Each one of you have been a source of inspiration to me.*
- *I will be forever grateful to Puan Mageswari for her dedication, enthusiasm and hardwork during the long period of recruiment – without your determination, it would have been impossible to achieve the "magic" number I needed.*
- *I would also like to record my thanks to Ministry of Higher Education, Malaysia for funding this PhD project. Through the Exploratory Reserarch Grant Scheme (ERGS), I was able to fund, conduct and implement one of the core components of my research which was self-care.*
- *I have been truly blessed to be surrounded with my close-knit family and friends during this challenging yet enriching period. To my inspirational parents Tuan Haji Ahmad Berek and Puan Aishah Muda and my beloved husband, Fikri Abu Bakar who have been my mountains of support, only Allah swt can repay you for all that you have done for me. To my siblings and aunts, thank you for always being there for me. To my daughter, Sara – I hope to entrust you with a knowledge legacy. To all my wonderful friends, the Med Hatters and Rabata Sisters who have been my network of support, strength and friendship - thank you from the bottom of my heart.*
- *Finally to all my patients (past, present and future), thank you for sharing and teaching me so many things. Your perspective and experience of your condition was an important lens for me to view from in the process of development and implementation of this programme.*
- *25th April 2018*

Abstract

Background

Given the "tsunami" of Type 2 Diabetes in the 21st Century, something drastic needs to be done to delay the onset of diabetes and its debilitating complications in order to minimise the escalating burden of disease. Thus, one of the important aspects to tackle in the face of a diabetes epidemic is diabetes education and self-care management. The current literature on structured diabetes education programmes in Malaysia is quite limited indicating several possibilities; a knowledge gap among diabetes patients, a gap in the diabetes education delivery in the health care system or gaps in both areas. Indeed, Malaysia is quite wanting of a systematic diabetes education programme, both from the aspects of resources and content material as well from an implementation framework point of view.

Hypothesis and Aims

The study hypothesis states "Poorly-controlled Type 2 Diabetes patients who are SMBG-naive, when intervened with diabetes education and self-care monitoring skills (i.e. self-monitoring blood glucose) will improve their metabolic outcome, diabetes-related knowledge and self-care behaviour and these improvements will be sustained for at least one year to 18 months". Hence, the aim of the current study is to develop a contextualised and structured diabetes education module and consequently evaluate the programme by measuring several indicators such as patient's glycaemic control, knowledge retention, adoption and self-efficacy of a self-care practice (i.e. self-monitoring blood glucose) throughout the intervention period.

Methods

MY DARLING was a prospective intervention study divided into three phases; developmental, recruitment and implementation. The developmental phase involved development and validation of the education module (MY DEMO) and its measurement

tools; Diabetes Knowledge Questionnaires (DKQs) and Behavioural Questionnaires (BQs). The DKQs and BQs were used to measure patients' knowledge and self-efficacy for self-monitoring blood glucose (i.e. SMBG) respectively. The recuitment and implementation phase were conducted simultaneously and staggered over 3.5 years to achieve adequate sample size (n=286). Study subjects were suboptimally controlled Type 2 Diabetes with none or limited experience with SMBG. All patients who fulfilled the inclusion and exclusion criteria of the study, attended the education module (MY DEMO) and subsequently divided into two groups (Group 1 and Group 2). The two groups attended the second education module (i.e. SMBG video) and started their SMBG, 6 months apart from one another (i.e. Group 1 started first). All patients were followed-up with Telephone Contact for 18 months and return for a final visit and to get their HbA1C blood test and collection of SMBG logbook.

Results

The positive impact of the education intervention programme was reflected by the global improvements in patients' ***glycaemic control***, ***SMBG Compliance***, ***psychological determinants*** (i.e. action planning and maintenance and recovery self-efficacy) and diabetes knowledge. ***Glycaemic control*** There was a significant within group improvement of patients' glycaemic control, with a reduction of HbA1C of greater than 1.0% (p=0.0001). The only significant predictor for glycaemic control in this study was short duration of disease (p=0.001). ***SMBG*** In addition, 66.2% of patients had Compliance Index score of ≥ 80.0% during the six months of SMBG intervention. Majority of patients (75.0%) were strongly compliant, compliant and moderately compliant to the modified SMBG protocol at 6 months. ***Psychological determinants*** There were high level of total action planning (i.e. baseline, 3 months and 6 months) and SMBG self-efficacy scores (i.e. maintenance and recovery) among patients. These results indicated study patients were encouraged to perform action planning

and had increased self-efficacy to continue with SMBG even if they had stopped monitoring for 3 to 6 months. Correlation between action planning and SMBG frequency were statistically significant ($p=0.001$) and moderately correlated ($0.20<r< 0.30$) indicating the potential role of action planning in SMBG. However, only a small correlation between Diabetes Knowledge and SMBG frequency ($r<0.20$) and not statistically significant ($p<0.05$) were found. ***Diabetes knowledge and Telephone follow-up*** Majority of patients scored Very Good (72.6%) or Excellent (7.8%) in their Diabetes Knowledge Score at the end of the 18 months follow-up. All the ten diabetes topics tested from the education module performed very well with mean performane scores of $\geq$ 70.0%. There was a high retention rate of almost seventy percent (69.6%) for telephone contact follow-up at 18 months.

Conclusion & Recommendations

The research hypothesis had been affirmatively answered by the significant reduction of HbA1C achieved among the poorly-control SMBG-naive Type 2 Diabetes patients who successfully completed the intervention module. In addition, majority of the patients also achieved high level of diabetes knowledge score, adopted the SMBG behaviour successfully with high level of Compliance Index and self-efficacy. Majority of patients also remained engaged throughout the telephone contact follow-up and the intervention period.

As part of a *solution* to address the lack of resources in diabetes education programmes in this country, I would recommend MY DEMO be utilised as a stand-alone education tool or as part of a larger diabetes education toolkit. One of the strengths of diabetes care management in Malaysia is the annual screening programme. I am proposing to combine the delivery of a contextualised diabetes education together with the annual screening programme through an existing delivery care system. This is to ensure each diabetes patients will receive the appropriate education to help them manage their condition better. To date, Malaysia does not have any reimbursement policies on SMBG. I recommend for the government to consider a

full or partial reimbursement policy on SMBG. With full or partial financial support on SMBG-related tools (i.e. glucose strips), more patients can perform SMBG to improve their diabetes metabolic control. Ultimately, an improvement in patients' glycaemic control will delay or minimise diabetes-related complications and reduce the escalating cost and burden of the disease in the country.

Declaration

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

Signature: 

Print Name: BADARIAH BINTI AHMAD

Date: 25th April 2018

Thesis including published works declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes 2 original papers published in peer reviewed journals. The core theme of the thesis is to develop a suitable structured diabetes education module and determine measures to evaluate the effectiveness of the education module. The ideas, development and writing up of both papers in the thesis were the principal responsibility of myself, the student, working within the Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia, under the supervision of Professor Anuar Zaini Md Zain, Associate Professor Quek Kia Fatt and Professor Khalid Kadir.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

My contribution to the publications involved the following:

List	Publication Title	Status	Nature and % of student contribution	Co-author name(s) Nature and % of Co-author's contribution*	Co-author(s), Monash student Y/N*
1	A pilot study: The development of a culturally tailored Malaysian Diabetes Education Module (MY-DEMO) based on the Health Belief Model.	Published	Study concept and conduct, sample and data collection, data analysis, statistical analysis, drafting of the manuscript (85%).	Amutha Ramadas; statistical analysis (5%), Anuar Zaini Md Zain; study concept and design (5%), Quek Kia Fatt; statistical analysis, drafting of manuscript (5%)	No – for all co-authors

2	Type 2 Diabetes patients are more amenable to change following a contextualised diabetes education programme in Malaysia.	Published	Study concept and conduct, sample and data collection, data analysis, statistical analysis, drafting of the manuscript (90%)	Anuar Zaini Md Zain; study concept and design, drafting manuscript (5%) Quek Kia Fatt (5%); statistical analysis, drafting of manuscript	No – for all co-authors

Student signature: [redacted]

Date: 25th April 2018

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author I have consulted with the responsible author to agree on the respective contributions of the authors.

Main Supervisor signature [redacted]

Date: 25th April 2018

PhD-related presentations during the PhD period

Dates	Conferences/Venues	Topic	Delivery
Aug 2012	International Diabetes Asia Conference in Kuala Lumpur, **Malaysia.**	"The Development and Evaluation of a Culturally Tailored Malaysian Diabetes Education Module (MY-DEMO): A Pilot Study".	Oral (2^{nd} prize)
Jan 2013	1^{st} Dubai International Conference in Higher Education: Succeeding in the Pursuit of Quality, Dubai, **U.A.E.**	"The Development and Evaluation of a Malaysian Diabetes Education Module".	Poster (1^{st} prize)
Feb 2015	3^{rd} Dubai International Conference in Higher Education Today's Universities: Combining Rigour with relevance, Dubai, **U.A.E.**	The impact of knowledge on diabetes and metabolic control and intervention of self-care skills in diabetes management.	Oral
Aug 2015	International Diabetes Asia Conference in Kuala Lumpur, **Malaysia.**	MY DARLING Study: Telephone Contact Follow-up to Assess Knowledge Amongst Suboptimally controlled Diabetes Patients.	Oral
Dec 2016	International Conference of Behavioral Medicine in Melbourne, **Australia.**	The Impact of Diabetes Education Module and Self-monitoring blood glucose on patients' glycaemic control and self-care behaviour.	Oral
Oct 2017	University of Eastern Finland (UEF), Kuopio, **Finland**.	The impact of diabetes education on knowledge, metabolic control, self-care skills and self-efficacy in Type 2 Diabetes patients in ambulatory settings.	Lecture

1.0 INTRODUCTION

Title

Malaysian **D**iabetes **A**nd **R**esearch on **L**ifestyle **I**ntervention **G**roup (MY DARLING) Study: The impact of diabetes education on knowledge, metabolic control, self-care skills and self-efficacy in Type 2 Diabetes patients in ambulatory settings.

1.1 How and Why I became interested in the Diabetes Education and Behaviour field?

When Jeffrey Cheah School of Medicine and Health Sciences opened in Monash University Malaysia in 2006, one of its fundamental aims was to establish a good working relationship with the Ministry of Health, Malaysia. Following a signing of Memorandum of Understanding (MOU) between Monash University Malaysia and Ministry of Health Malaysia, Monash Specialist Heart and Diabetes Clinic was established in the same year at Tanglin Community Clinic, Kuala Lumpur. I am part of a 4-person team from School of Medicine and Health Sciences that provide specialist care for diabetes and heart patients including referrals to other specialists in tertiary centres in Malaysia. This unique specialist set up within a government primary care centre is the first in Malaysia. Our team collaboratively work with the primary health care doctors and allied health care workers such as nurses, pharmacists and medical assistants to treat patients with chronic diseases including Type 2 Diabetes.

In a recent cross-sectional study conducted by us, we compared the glycaemic control among Type 2 Diabetes patients attending both public versus private clinical settings; general versus specialist care. Our study showed, among the health care settings which were surveyed, the best glycaemic control was achieved by Tanglin Community Clinic where there is a combination of both primary health care practitioners and specialists care working in the same healthcare setting (1).

It was during the time when I was working and seeing patients in the clinic that I noticed some knowledge gaps among diabetes patients about their own condition. Generally, patients were unaware of the symptoms and signs of hyper- and hypo- glycaemia, pathophysiology of the disease, as well as modifiable and non-modifiable risk factors. In addition, most patients struggled to cope with the complex diabetes regimen and suffered from common diabetes complications (i.e. limbs or toes amputations, erectile dysfunction, ischaemic heart disease and stroke) due to their suboptimal glycaemic control. Consequently, I was spending more and more time during each face-to-face consultation, explaining and discussing with patients about their condition. From my observation, I noticed a deficit in patients' knowledge and the difficulty in self-care among my patients which were then reflected in their poor glycaemic control and general well-being. I decided then to explore this problem further and looked into the area of diabetes education in a more systematic manner. This thesis will document my research journey in trying to find some answers to the issues that presented at the primary health care centre in Malaysia.

1.2.1 Problem Statement

Type 2 Diabetes is a huge problem in Malaysia (2) and around the world (3-5). Type 2 Diabetes is a lifelong disease and it's well accepted that education and self-care are the two cornerstones of diabetes management (6, 7). The current literature review on structured diabetes education programmes in Malaysia is quite limited indicating several possibilities; a knowledge gap among diabetes patients, a gap in the diabetes education delivery in the health care system or gaps in both areas.

1.2.1.1 Existing diabetes framework system in Malaysia

To understand the current scenario, it is best to consider the history of diabetes care management in Malaysia. The framework of diabetes management care was established about 3 to 4 decades ago around 1980 to 1990s. One of the infrastructures identified as important to

develop were “Diabetes Resource Centres” or “one-stop-diabetes-centre” in both public hospitals and ambulatory clinics. Over the years, these resource centres have been instrumental in ensuring smooth diabetes care delivery in both clinical settings. The yearly diabetes care screening (i.e. fundal examination, electrocardiogram and diabetes foot-care) became an integral part of diabetes ambulatory clinics (8) and a Malaysian Clinical Practice Guidelines for Type 2 Diabetes mellitus was developed by the local endocrinologists and subsequently these guidelines has been revised and utilised as an overarching national guidelines for diabetes (9).

Cognizant of the surge in national diabetes prevalence from the 1980 to 1990s, there was also an emphasis on capacity building of healthcare personnel especially in the area of chronic diabetes care management (2). A collaborative effort from Ministry of Health (MOH) Malaysia, affiliated government hospitals and non-governmental organisations brought about training programmes which educated many primary care nurses and medical assistants especially in the area chronic diabetes care management. As a consequence of previous capacity building efforts, the number of diabetes nurses and diabetes educators had increased from 600 (8) in 2006 to a total of 900 educators in 2015 (9) to meet the needs of a growing diabetes population in the country.

In contrast, there was a conspicuous lack of emphasis in the development of a structured diabetes education for patients in Malaysia. Perhaps, justifiably, the lack of development and availability of high quality structured diabetes education in Malaysia gave way to the nation’s overall priority to build a solid framework of chronic healthcare delivery including for diabetes care. Nevertheless, the time is now ripe for more researchers to come together and thoughtfully consider the critical process of developing and delivering a high quality structured diabetes education for diabetes patients.

Compared to other countries such as United Kingdom (UK) which in 2005 (i.e. 22 years ago) instigated an effort to finance, regulate and ensure quality of diabetes education (10), Malaysia must make up for lost time and consider how best to bridge the knowledge transfer from healthcare providers to the patients. We must also learn from nations who have had a lead role in diabetes education in the past such as Finland, England, United States and Australia and be aware of their previous successes and current challenges. This type of reflection is necessary so lessons can be learnt and mistakes or oversights can be avoided in the future.

In the recent Malaysian DiabCare 2013 audit, nineteen tertiary hospitals reported very high screening rates especially for urinalysis (97.8%), foot examination (97.1%) and fundal examinations (93.3%), with an impressive 90% of patients going through all three tests within the last one year (11). Unfortunately, the same rigour was not seen for the implementation and evaluation for quality diabetes education.

Despite encouraging reports of high screening take-up rates (11), there were no significant improvements in glycaemic control and prevalence of diabetes complications when compared with the earlier DiabCare 2008 study (8). Of concern, the glycaemic control among Malaysian patients continue to deteriorate with mean HbA1C increasing from 8.0% (2003) to 8.66% (2008) (8). Furthermore, majority of patients (78.0%) remained sub-optimally controlled with HbA1C levels of >7.0% (> 53mmol/mol) (8).

One of the main challenges of diabetes treatment stems from the fact that it is a chronic disease with very little symptoms. In most patients, symptoms only manifest at the onset of its complications. Thus, management of diabetes must involve education strategies that emphasise a high degree of adherence to prescribed diet, regular exercise, medication taking, self-care and self-monitoring throughout the patient's life. By ensuring a smooth pathway of diabetes education, outcomes such as patients' knowledge and understanding, their sense of

self-management and self-determination, their general well-being and quality of life can be measured. Consequently, any issues or setback that rise can be addressed and hopefully this will lead to an improvement in glycaemic control and reduction in diabetes-related complications (12).

MY DARLING study is a prospective intervention study. Because diabetes is such a complex disease with multiple aetiology, treatment strategies and complications (13, 14) it is logical to approach the management of this versatile condition from various aspects. The three aspects of MY DARLING intervention namely knowledge (through contextualised diabetes education), self-care behaviour, motivation and self-efficacy (through blood glucose monitoring) and utilising telephone contact to measure patients' knowledge retention (through tele-health modality for follow-up) will hopefully help pave inroads in the development and delivery of structured diabetes education to patients in Malaysia.

Although it would have been ideal to invite and consult a group of patients during the development process of this MY DARLING intervention, this was not explicitly done and is one of the limitations of the current study. The reasons for the lack of patients' participation in the initial part of program development could be attributed time, resources (i.e. patients' availability, space availability) and costs constraints.

Another important factor to consider was potential researcher's bias. As this was a doctorate project, I was primarily involved in the entire process of developing the interventions and measurement tools, delivering the education module and collecting the data. For this reason, I kept a regular logbook documenting the progress of the research, issues faced during various stages of recruitment and implementation and the resolutions taken. I found the research logbook useful as it allowed me to reflect upon what had happened during the research study, my thought process, the rationalisation and decisions made in response to the event(s). I was

also in regular contact with my supervisors to discussed issues which cropped up throughout the study and ways to minimised bias.

1.3 Significance of Study

I wish to see the positive impact of the structured diabetes education intervention reflected in patients' knowledge, behavioural changes and metabolic control. The findings of my study will be able to inform the research discipline area in several ways. Firstly, I will be able to recommend a suitable theory-based, structured diabetes education programme to help educate diabetes patients in Malaysia. Many studies have supported theory-based education programme in improving patients' diabetes control (15-18). By formalising an education programme pathway for patients to follow post diagnosis, patients' access to diabetes education are more assured.

In addition, I will be able to shed some insight regarding patients' level of knowledge and newly acquired self-care behaviour, and whether the knowledge pattern and self-care skills and efficacy will change and whether education reinforcements are needed in the future. Finally, I may be able to suggest an optimum time-frame for patients to receive their diabetes education.

It is also my aspiration to collaborate with other diabetes educators and researchers within Malaysia, pertaining specific input regarding content, structure and delivery of a contextualised diabetes education and self-care module suitable for diabetes patients in this country. Potentially MY DARLING intervention programme can be implemented (either wholly or partially) at ambulatory diabetes "one-stop-centre" clinics around Malaysia.

1.4 Research Hypothesis

Suboptimal controlled Type 2 Diabetes patients who are SMBG-naive, when intervened with diabetes education and self-care monitoring skills (i.e. self-monitoring blood glucose) will

improve their metabolic outcome, diabetes-related knowledge and self-care behaviour and these improvements will be sustained for at least one year to 18 months.

1.5 Overarching Aims and Research Questions

1.5.1 To develop a suitable structured and tailored diabetes education intervention to support diabetes patients to manage their condition better.

1.5.2 To determine the effectiveness of the newly developed education intervention by measuring patients glycaemic control, diabetes knowledge retention and behavioural changes through a newly adopted self-care skill (e.g. self-monitoring blood glucose) and self-efficacy before and after the intervention.

- *RQ 1. What is the impact of a structured and tailored diabetes education module (MY DEMO) on patients' glycaemic control, knowledge level and behavioural change (i.e. self-monitoring blood glucose compliance and self-efficacy)?*
- *RQ 2. What is the patients' glycaemic control at the end of SMBG intervention?*
- *RQ 3. What is the patients' knowledge level at 18 months of Telephone Contact follow-up?*
- *RQ 4. Will patients adopt a new prescribed/guided self-care behavior (i.e. SMBG)?*
- *RQ 5. What is the SMBG Compliance during the duration of SMBG?*
- *RQ 6. What is patients' motivation and self-efficacy in SMBG?*

1.5.3 To determine the effectiveness of telephone contact (tele-health) intervention as a modality for diabetes education and management.

- *RQ 7. What is the patients' Telephone Contact retention rate at 18 months?*

2.0 LITERATURE REVIEW

2.1 Brief Background of Diabetes Mellitus

Diabetes Mellitus is a group of metabolic disease which is characterised by prolonged hyperglycaemia with abnormalities of carbohydrate, fat and protein metabolism resulting from impairment of insulin secretion, insulin action or both (13, 14). The complications of diabetes mellitus include long term damage, dysfunction and failure of multiple organs. The chronic hyperglycaemia in diabetes mellitus exacerbates endothelial dysfunction and accelerates macro- and micro-vessels disease and results in numerous diabetes complications such as stroke, myocardial infarction, nephropathy, neuropathy, retinopathy and limbs amputations (13, 14). Several pathogenic processes have been identified in the development of diabetes. The processes include destruction of insulin-producing β-cell of the pancreas glands leading to insulin deficiency and others, that result in resistance of target cells (i.e. liver, adipose tissue and skeletal muscles) to insulin action (13, 14).

The more recent classification of Diabetes Mellitus are based on the various degrees of hyperglycaemia in individuals and include any of the disease processes leading to Diabetes Mellitus (14). Briefly the aetiological classification of diabetes are divided into four broad categories (i) Type 1 is due to an autoimmune or idiopathic origin (ii) Type 2 – is predominantly due to insulin resistance defects or insulin secretory defects or a combination of both conditions (iii) other specific types – which include genetic defects, diseases of exocrine pancreas, drug-induced, infections *etc.* (iv) gestational diabetes (13, 14).

Commonly, Type 1 diabetes is due to an autoimmune destruction of the insulin-producing β-cell of the Islets of Langerhans in the pancreas glands leading to absolute insulin hormone depletion. Type 1 diabetes is less common and accounts for only 5-10% of diabetes worldwide and is usually seen in children and young adults (13, 14). On the other hand, Type 2 Diabetes accounts for 90-95% of those with diabetes (13) is associated with modifiable (i.e.

obesity, metabolic syndrome, sedentary lifestyle, poor diet) and non-modifiable (i.e. hereditary, ethnicity and aging) risk factors (13). Insufficient control of these risk factors can lead to sub-optimum control of diabetes, chronic hyperglycaemia and long term organ damage. Gestational diabetes is a carbohydrate intolerance resulting in hyperglycaemia which occurs during pregnancy and can cause foetal deaths and complications if it is not well control during gestational period (19).

2.2 The Scope and Burden of Type 2 Diabetes

2.2.1 Diabetes Prevalence

Globally, the prevalence of Type 2 Diabetes is increasing as a consequence of social, epidemiologic and demographic shifts such as aging and urbanisation and many of these patients live in low and middle income countries including many Asian nations (3). The latest figures from International Diabetes Federation (IDF) had surpassed all previous estimations with the global prevalence of diabetes standing at 8.3%. It was estimated in 2013, there are 382 million adults suffering from diabetes and this will rise to a staggering 592 million in 2035 (4).

According to the latest IDF estimates, Malaysia's prevalence for diabetes when adjusted to the world population is 10.9%. Of concern, Malaysia is among the top ten emerging diabetes hotspots within the Western Pacific zone with one of the highest number of subjects affected by diabetes (5). The surge in diabetes prevalence amongst Malaysian adult population age ≥ 30 years for the past four decades as per reported in the Third National Health Morbidity and Mortality Survey is a sombre warning for the national healthcare system (2). To boot, another large epidemiological study in Malaysia revealed the prevalence of overweight and obesity has reached 33.6% and 19.5% respectively (20) indicating the parallel expansion of both entities in Malaysia.

2.2.2 Costs and Burden of Disease

With the global diabetes epidemic, the cost of treating Type 2 Diabetes and its complications have also increased exponentially. Beulens *et al* estimated the global health expenditure for treatment and prevention of diabetes and its complication will escalate from USD 232 billion in 2007 to more than USD 302 billion by 2025 (21). In the United States, the annual economic cost of diabetes treatment was USD174 billion. The costs included both direct (i.e. diabetes care, diabetes-related complications and general healthcare cost) and indirect (i.e. absenteeism, disease-related unemployment disability and reduced productivity) healthcare expenditures (22). Notably, the cost of care varies immensely between countries; USD13 per patient in Bangladesh; USD11,157 per patient in the United States annually (23).

In Malaysia, patients are still burdened by the high cost of diabetes treatment. The estimated expenditure to treat a patient with diabetes is USD957 or RM3747 per year. Although healthcare is highly subsidised by the government, patients' out-of-pocket and indirect cost expenses remains higher by 0.44 times compared to the amount provided by the healthcare provider (24).

2.3 Diabetes Education

Diabetes education and self-care remains the pillars of diabetes management (6, 7). Remarkably, although numerous diabetes education studies had been conducted in the past, diabetes education had not been well defined (12). In an effort to make sense of the myriad of diabetes education research results, and to establish a systematic way to measure the effectiveness diabetes education programmes, certain terminologies and criteria needed to be outlined. Several international diabetes bodies such as American Association of Diabetes Educators (AADE), Diabetes UK and Diabetes Australia came up with their own guidelines on diabetes education.

About 20 years ago (1997) the American Association of Diabetes Educators (AADE) established a diabetes education taskforce in response to pressure from the National Medicare Service regarding the effectiveness of diabetes self-management education (25, 26). This brought about a comprehensive web-based known as National Diabetes Education Outcome System (NDEOS), a reporting service for diabetes education from an individual, program and national level (27).

The AADE position determined behaviour change as a unique outcome of diabetes self-management education (27). The AADE have included seven self-care behaviours considered essential for an effective diabetes self-management. These behaviours include "healthy eating, being active, monitoring of blood glucose, taking medication, problem solving, healthy coping and reducing risks" and also known as the AADE7^{TM} Self-care Behaviours. (28). In addition, the AADE has identified diabetes patient specific outcomes and indicators through numerous publications including "Standards for Outcomes Measurement of Diabetes Self-Management Education" (29). In this present study, there will be an emphasis on self-monitoring blood glucose. Various aspects of SMBG from patients' skills, self-efficacy, frequency of monitoring and utility of structured SMBG protocol will be explored. Figure 2.1 highlights the seven self-care behaviours of AADE.

Figure 2.1 AADE7 Self-care Behaviours (28).

In between the year 2005 and 2007, both Diabetes UK (10) and Diabetes Australia (12) published their own respective recommendations and reports.

2.3.1 Definitions of Diabetes Education

In 2005, Diabetes UK described what constituted a structured education programme and included five main criteria (10). According to the Patient Education Working Group the key criteria comprise of *"a clear underlying philosophy of the programme, a written structured curriculum which is theory-driven and evidence-based, trained educators who have an understanding of educational theory and familiar with the content of the programme and its*

delivery and a quality assurance system which can be applied to the process, content and delivery of the programme and an audit of the programme including not only biomedical but psychosocial and patient experience" (10, 15, 30, 31) . Figure 2.2 highlights the five main criteria of a structured diabetes education programme.

Figure 2.2 Key Criteria for structured education programme. Adapted from the Patient Working Group, Diabetes UK, 2005 (10).

Consequently, in 2007, Diabetes Australia released a National Consensus Position on "Outcomes and Indicators for Diabetes Education" (12). The report defined diabetes

education as follows: *"Diabetes education is an interactive process that facilitates and supports the individual and/or families, carers or significant social contacts to acquire and apply knowledge; confidence; practical problem-solving and coping skills needed to manage their life with diabetes to achieve the best possible outcomes within their own unique circumstances"* (12).

This national effort was unique and thorough in its approach. A range of stakeholders including people with diabetes (i.e. primary stakeholders), diabetes educators and key opinion leaders were involved in a comprehensive consultation process (i.e. through focus groups, workshops, personal interviews respectively) to recognise what outcomes of diabetes education were considered most important to each of them individually and as a group (12).

2.3.2 Outcomes and Indicators of Diabetes Education

The Australian national consensus was reached and four major outcomes were considered the most directly linked to diabetes education (12). The four outcomes outlined were (i) knowledge and understanding (i.e. diabetes knowledge, knowledge application, problem-solving ability) (ii) self-management (i.e. SMBG, insulin injections, medication taking, physical activity, appropriate eating, risk reduction, appropriate attendance to medical care, carrying diabetes identification, hypoglycaemia management, sick day management and emergency hospital admission) (iii) self-determination (i.e. self-efficacy, empowerment, coping skills, confidence with diabetes self-management, participation in goal-setting and decision-making) (iv) psychological adjustments (i.e. general well-being, quality of life, mental status) (12). Hence, in the process of measuring the effectiveness of a diabetes education programme, the four components highlighted above are the best ones to measure to see the impact of the programme.

In contrast, clinical outcomes (i.e. physical – BMI, weight, blood pressure; biochemical – HbA1C, lipids, kidney function; complications – short-term and long-term; presence or

absence) and cost effectiveness (i.e. individual – out-of-pocket expenses; societal – financial burden of complications, loss of productivity) were not included as direct indicators for the effectiveness of diabetes education programme. This is because it was not possible to measure the impact of diabetes education on both of these indicators independently of the medical treatment received by patients. Hence, although clinical outcomes and cost-effectiveness are salient diabetes outcomes, from the point of view of effectiveness of diabetes education they do not feature as the dominant factors (12).

Summary

Both the guidelines from Diabetes UK and Diabetes Australia had helped informed to a certain degree on how the education intervention been planned and developed for the current study. The 5 key criteria of structured education had been used as guidelines in developing the education module (MY DEMO) and the Diabetes Education and Its Outcome and Indicators report had helped determined the important parameters which was included as measures to evaluate its effectiveness of the current study.

2.3.3 Education Theories in Diabetes Education

In 2008, the International Diabetes Curriculum for Healthcare Professionals (IDF) developed a comprehensive guideline on the structure, content and delivery of a high quality diabetes education curriculum (32). In the report, the importance adult learning theories (i.e. Knowles) and social learning theories (i.e. Health Belief Model and Social Cognitive Theory) were highlighted as the basis of the diabetes education programme, compelling diabetes educators globally to be well-versed with adult learning theories in the process of delivering diabetes education to patients (32).

2.3.3.1 Adult learning theories

Adult learning theories have been used to describe how adults integrate knowledge, skills and attributes. There are 5 main classes of adult learning theories, with the two most prominent

theories (33) being self-directed and experiential learning. The most renowned self-directed learning theory is andragogy (33). Andragogy had its educational roots from the Greek philosopher Plato and had been championed over the past 5 decades by distinguished intellectuals such as Dewey, Anderson and Knowles (33, 34).

Knowles delineated the concept of andragogy by making assumptions that adults; (i) are independent and self-directing in their learning (ii) have various degrees of experience (iii) integrate their learning to the demand of their daily life (iv) are more interested in immediate problem centred approaches and (v) are motivated by internal drives more than external drives (34). However, andragogy had been criticized among other things for excluding self-reflection; deemed as an important process of adult learning (35). In fact, self-reflection was acknowledged as the second step of experiential learning in the Kolb cycle (36, 37). According to Kolb, "experiential learning occurs through a repeated series of four steps; (i) *concrete experience* – where learner is involved in a specific real-life situation and apply their new knowledge to overcome a problem (ii) *reflective observation* – where learner reflects on the concrete experience from different aspects and give the experience some meaning and arrive to an intuitive understanding (iii) *abstract conceptualization* – where the learner integrates the meaning from the experience with those from other personal experience and develop a personal concept (iv) *active experimentation* –where the learners' conclusion is used to guide decision-making, planning and implementation" (37, 38).

As a result of experiential learning, adults tend to have broader experience of experience and more to contribute in the learning of others. However, adults also tend to be less open-minded and have acquired a larger number of fixed habits and patterns when compared to children or young learners (38). This highlights the subtle differences in approach in diabetes education programmes in children, adolescents and adults.

Summary

By being cognizant and understanding the tenets of adult learning theories such as andragogy, had informed me on how to approach teaching my adult patients and how they might learn more effectively. Hence, while designing the education module of the current study, I was more aware of (i) the different styles of learning (ii) the various life experiences patients bring with them when they attend the module (iii) the importance of integrating and applying what they learn in the module with their daily life (iv) their degrees of problem solving capacities and (v) motivation to learn and hopefully make meaningful changes in their health behaviour.

2.3.3.2 Self-Regulation Theory

Self-regulation theory focuses on individual's illness representation and include five core elements namely; "(i) identity (ii) cause (iii) timeline (iv) consequences and (v) treatment effectiveness" which encompasses an individual's illness representation (39). In contrast, many research had consistently shown that patients hold a diverse set of illness beliefs, which may have been influenced by their family or friends and media campaigns. Unfortunately these beliefs may not necessarily be accurate, up-to-date or complete (40). This is pertinent as these beliefs or misconceptions are strongly rooted in the patients' mind and can determine patients' emotional well-being and self-care behaviour (41).

2.3.3.3 Dual Process Theory

Dual process theory is useful in making a distinction between *heuristic* and *systematic processing*. In heuristic processing, patients assumed a passive role and listened to experts giving, usually generic information about their illness (42). One of the limitations with heuristic processing is that behavioural changes that occur, tend to be superficial, and susceptible to further change in light of other contradictory information from other "experts" – which could be from health care professionals, friends, relatives or the media (42). In

contrast, systematic processing emphasised the need to actively involve patients in the learning process. This systematic processing can be achieved through utilising relevant analogies and good quality questions, to strengthened patients' understanding of difficult concepts (42). Importantly, active learning encourages firmer health beliefs which are resilient to contradictory information. This systematic process had been shown to help in knowledge retention in some patients up to a year after their intervention (40).

2.3.3.4 Self-Determination Theory

Self-determination theory distinguishes the difference between controlled and autonomous motivation. While autonomous motivation means doing things for intrinsic reason (i.e. for one self), controlled motivation is the opposite (i.e. doing things to make others happy). Autonomous motivation have been shown to be predictive of successful self-care, weight loss and glycaemic control (43). One of the ways to support autonomous motivation in a diabetes education programme will be to encourage patients to exercise autonomy and make their own decisions about their diabetes management (43).

Summary

By recognising the principles of various other education theories have informed me on how to present and deliver the content material in a more acceptable manner. The reason why I chose to include the above as examples of the education theories was because I found the principles of these theories focused on gaining deeper understanding of the subject matter and addressed difficult issues such as patients' illness belief which may sometimes be inaccurate. In essence, these theories informed me in determining methods to promote better understanding and knowledge retention among diabetes patients.

2.3.4 Health Literacy in Diabetes Education

Health literacy is defined as "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate

health decisions" (44). Health literacy has been posited as one on the non-clinical factor that may lessen the risk of poor outcomes in diabetes (37, 45, 46). Given the high level of complexity required to manage diabetes, patients should ideally possess a group of skills to help them manage their condition. These health literacy skills include cultural and contextual knowledge, aural and oral literacy (i.e. listening and speaking), print literacy (i.e. reading and writing) and numeracy (i.e. ability to understand and use numbers) (44). Health literacy skills specific to diabetes would include reading labels on bottles, following written or verbal instructions and comprehending information on brochures and informed consent forms. On the other hand, numeracy skills would include understanding dose medications, insulin requirements, interpreting food labels and blood tests (44, 47).

Apart from the content material, other factors such as readability, acceptability, design and layout of the materials should also be taken into consideration when developing and implementing diabetes education interventions. Successful methods for teaching patients with low literacy level had been posited by Cowan *et al* (48). These include verbal instruction, repetition of the instructions, demonstration and return demonstrations and teaching in small increments to allow for process and comprehension (48). Key instructions should be made concise and as explicit (i.e. idea/message unpacked into smaller components or segments) as possible and patients' own terminology included whenever possible. Breaks should be provided at the end of segment to allow for review, feedback and questions. Audio-visual presentations can be used to enhance written instructions whenever possible (48).

For readability and layout, written material should; (i) be printed or typed with lowercase and uppercase (ii) use large fonts (iii) utilised subheadings (iv) not be handwritten or in cursive writing (v) avoid the use of all capitalized letters. To ease comprehension, "chunking" of words and ideas into a meaningful context and ensuring only one idea is conveyed in each

sentence or paragraph should be considered. Finally, the use of active voice makes material easier to read and understand and lend a more personal touch to patients (48).

In a recent systematic review on health literacy sensitive interventions a few teaching methods were associated with significant improvements in self-care and diabetes controls (49). These methods included the use of at least one spoken communication strategy such as plain language, limiting teaching items to only 3 to 5 key points and incorporating Teach-Back to ensure patients' comprehension. In a survey done on diabetes educators on preferred method of teaching and communication, Howe *et al* found simple language, written patient education materials and using Teach-Back were most frequently reported techniques while phone calls and drawing pictures were least reported. The authors also found experienced diabetes educators (> 16 years), nurses and those who had formal health literacy during their school or training used more teaching techniques when educating people with diabetes (50). Teach-Back is communication technique to check for patients' comprehension. As the name suggested, Teach-Back requires patients to reiterate in their own words or demonstrate health instructions to in an understandable manner to confirm their understanding of the subject matter (50, 51).

The recent narrative synthesis by Cooper *et al* found mixed results between health literacy and various diabetes-related outcomes. For most parts, studies found strong association between health literacy and diabetes-related knowledge. In contrast, relationship between health literacy with communication, self-efficacy, adherence and glycaemic control were not so clear cut (44). Sarkar *et al* found patients with low health literacy have an increased risk of hypoglycaemia. This serves as a practical reminder to physicians, to be cognizant of patients' health literacy level before commencing on insulin or oral hypoglycaemia agents (52). In another recent systematic review by Al-Sayah *et al*, authors also found positive association between health literacy and diabetes knowledge and self-care activities. In contrast, there

were little evidence to support (or refute) the association between health literacy with clinical indicators and important clinical events (i.e. mortality, cardiovascular disease) (53). Osborne et al found health literacy not directly related to HbA1 reduction, but was indirectly associated through self-efficacy (47). Bailey et al reported a range of health literacy sensitive intervention conducted seemed effective in improving diabetes outcomes including those focusing on patient education, self-care and disease management (44). However, it remains unclear whether these interventions can reduce health literacy-related disparities (44). In addition, question regarding the appropriateness of a screening programme among limited health literacy patients remained unanswered (54). A larger trial combining health literacy sensitive intervention may be required in the future to determine whether screening would be warranted and resource-effective in the future (44). Notably, both authors of systematic reviews highlighted methodological limitations of the studies (i.e. mostly cross-sectionals) and the diverse measurement tools and multiple cut off points used in different studies. In addition majority of studies were conducted in primary care clinics in the United States and only very few conducted elsewhere (i.e. Japan, China, Ireland) (44, 53).

Summary

Health literacy is an important consideration when designing education intervention to ensure all diabetes patients regardless of their literacy and numeracy level will be included, so that they will also gain the benefit of receiving diabetes education. Since methods and content of delivery might differ from a more "standard" diabetes education programme, diabetes educators and programme developers have to be cognizant of these differences. Although, for the current study, specific health-literacy methods of teaching and communication were not done because of study exclusion criteria (i.e. illiteracy and innumeracy), this is an important consideration to include for future research intervention.

2.3.5 Training and Support for Diabetes Educators

Diabetes self-management education and support (DSMES) is an interactive and collaborative process in which people with diabetes gain knowledge and skills and modify their behaviour to self-manage their conditions (55). Although, there were national standards for provision of diabetes self-management education and support (DSMES), there were no standard guidelines for health providers to acquire and refined their core knowledge and skills in order to develop fully as a diabetes educator (55).

Hence, for the past ten years since 2009, the AADE workgroups had developed several guidelines which delineates *practice levels* and *competencies levels* which diabetes educators can adhere to, in order to upscale themselves as professionals who are engaged in diabetes education (56). The purpose of establishing *practice levels* in the guideline were three-fold. Firstly, to delineate the roles and responsibilities of diabetes educators. Second to recommend a career path for diabetes educators and thirdly, to facilitate individual's entry point into the practice of diabetes education and clarify competencies required for the next level. In addition, the guidelines for *competencies levels* provided a "*master list of minimal knowledge and skills required across the continuum care at various levels of practice and provide a basis for education, training and an appraisal process for individuals who are engaged in diabetes education and support*" (56).

Competencies levels had been structured in to five domains; (i) Pathophysiology, Epidemiology and Clinical Practice of Prediabetes and Diabetes (ii) Cultural Competency Across the Lifespan (iii) Teaching and Learning Skills (iv) Self-management Education and (v) Program and Business Management. For each domain, specific competency was defined and specific objectives assigned for diabetes educators to follow. The *practice levels* were subdivided into (i) diabetes paraprofessional level 1 and 2 and (ii) diabetes educator level 1, 2 and 3. The breadth and depth of knowledge and skills required for diabetes educators and

paraprofessional differed according to their level of entry, experience and qualifications and had been clarified in the above guideline (56).

Summary

The advantage of having an across-the-board training programme is obvious. The availability of comprehensive guidelines such as "Competencies for Diabetes Educators and Diabetes Professionals" by AADE is helpful for countries that are looking for a solid framework to train professional and paraprofessionals as diabetes educators. In Malaysia and globally, diabetes education and support services are provided through a wide range of public and private settings. While it is recommended for these guidelines (i.e. competencies and practice levels) to be followed, the training and development programs for diabetes educators in Malaysia should also reflect the local context, regulation, resources and expertise available.

2.3.6 Diabetes Education Studies

2.3.6.1 Diabetes Education Studies in the UK & Europe

Through the past four decades, diabetes education have evolved from primarily didactic or prescriptive interventions to a more collaborative and theoretically base "empowerment" models (57). Despite the emphasis of diabetes education in disease management, there were still some obvious discrepancies in the standard and quality of patient education services in the UK as recent 10 years ago (58).

Over the past 15 years, several educational programmes had been developed in the UK and Europe in an effort to provide better diabetes education and care. In the UK, several structured diabetes education programmes such as **d**iabetes **e**ducation of **s**elf-**m**anagement for **o**n-going and **n**ewly **d**iagnosed (DESMOND) Type 2 Diabetes patients (15) and e**x**pert **p**atient **e**ducation versus **r**outine **t**reatment (X-PERT) (17) and **d**ose **a**djustment for **n**ormal **e**ating (DAFNE) for type 1 diabetes patients (16) and **L**ook **A**fter **Y**ourself (LAY) programme (59) were developed, implemented and rigorously evaluated.

Justification for individual diabetes education studies

In the following sections, I will be outlining some of the salient points of the diabetes education studies mentioned in the above paragraph (15-17, 59). This will facilitate readers gain a clearer overview of some diabetes education studies. The framework of each study was in sync with the recommended key criteria for structured education programme by Diabetes UK 2005 (10). Hence in the following diabetes education sections (2.3.3.1 till 2.3.3.5) key components such as (i) underlying theory or philosophy (ii) diabetes education curriculum (iii) delivery or implementation (iv) training of trainers (v) auditing of programme by different measurements (i.e. biochemical, psychosocial and patient experience) were discussed in varying details. A concluding remark were also posited by respective authors of the studies to improve the overall diabetes education standards and diabetes outcomes (15-18, 59).

2.3.6.1.a The DAFNE study

This programme was established for type 1 diabetes in the UK; **d**ose **a**djustment **f**or **n**ormal **e**ating (DAFNE) randomised-control-trial was conducted in 2002 to evaluate whether flexible insulin treatment in combination with "dietary freedom" and insulin modification can improve diabetes control and quality of life (16). The programme was modified from a five-day structured *inpatient* training on intensive insulin treatment to a five-day structured *outpatient* training using principles of adult learning principles such as goal settings explicit and learning objectives by patients. The results showed DAFNE training significantly improved glycaemic control without any significant increase in hypoglycaemia amongst type 1 diabetes patients at six months and one year. Furthermore, lasting positive effects on general well-being, quality of life and treatment satisfaction were reported despite of an increase in insulin injection requirements.

However, a follow-up study at 44 months showed the glycaemic improvement had deteriorated (0.32%) (60). The authors of UK DAFNE study concluded that the programme offers major long-term advantages for quality of life and treatment satisfaction and modest long-term advantages for glycaemic control and no change in hypoglycaemic episodes. Similarly, the Australian DAFNE study – which utilised the UK DAFNE curriculum also reported an improvement of glycaemic control especially for those with elevated baseline HbA1C level (61). In contrast, the Australian study found a reduction of severe hypoglycaemic episodes incidence among study patients (61) as oppose to no change in the number of hypoglycaemic episodes in the UK study (60). Of note, the Australian DAFNE study is an independent diabetes education study which was replicating the DAFNE curriculum and not part of a larger multicentre study design of DAFNE (61).

Rankin *et al* conducted a qualitative study exploring patients' experiences and views after participating in DAFNE (62). The authors questioned the reasons behind the lack of diabetes knowledge amongst type 1 diabetes patients by specifically asking patients (i) the type of information patients received since diagnosis (ii) their views on education delivery and (iii) how these can be improved (62). The results highlighted overlapping reasons why patients suffered gaps in their knowledge. These gaps were linked with patients' perceptiveness and receptiveness of the programme based on the challenges they faced throughout their own life-course. The authors concluded there is no "best time" to provide diabetes education. Diabetes education should be on-going and become a lasting feature in one's life. However, healthcare professionals should be cognizant about which stage or "starting point" their patients are in, especially in terms of their knowledge acquisition and knowledge gap (62).

2.3.6.1.b The DESMOND study

The DESMOND study was one of the first cluster randomised controlled trial that made a robust effort to evaluate the effectiveness of its programme. The study's philosophy was

grounded on an empowerment model which was based psychological theories of learning (63). The structured curriculum was delivered by two trained healthcare professionals over the duration of six hours either as a single day or an equivalent two half days. The authors of DESMOND looked not only at the HbA1C levels, but also included psychosocial and lifestyle measurement indicators at 1 year and 3 years post intervention. At one year, results showed greater improvements in weight loss, smoking cessation and in illness beliefs. However, HbA1C levels did not show any difference between intervention and control group (15).

The 3-year follow-up study confirmed earlier findings and showed no difference in biomedical and lifestyle outcome measures. However, sustained improvements in illness beliefs such as greater understanding of the disease, ability to affect the course of the disease and better perception of the disease with longer disease duration were demonstrated (64). In addition, the evidences seemed to suggest diabetes education programme should adopt an on-going model rather than delivered as single discrete session. However factors such as optimum interval between education sessions, contact time and duration of follow-up remained unanswered and need to be further explored in the future (64).

2.3.6.1.c The LAY study

The "**L**ook **A**fter **Y**ourself" or LAY programme was another randomised controlled design education study looking at short-term (i.e. 6 months) and long-term (i.e. 12 months) impact of education on patients' self-care behaviour, illness beliefs and glycaemic control. The empowerment-based programme was a structured education for Type 2 Diabetes patients and consisted of several components such as exercise and physical activity, relaxation and health topics like pathogenesis of diabetes, smoking cessation and overview self-management principles. In addition, mixed methods of delivery such as group discussion, goal setting, role-playing, relaxation and skills practice were taught by trained leaders in eight weekly

sessions lasting two hours each. The authors found the structured educational programme was associated with significant educational and psychological benefits but had limited benefits in terms of glycaemic control (59). The authors of the LAY programme reiterated diabetes education programme should be regarded as having more global benefits and its success should not be judged solely on clinical endpoints such as glycaemic control (59, 65).

2.3.6.1.d The X-PERT study

Another landmark diabetes education study, X-PERT was a patient-centred structured group diabetes education programme, based on empowerment theory and discovery learning amongst established Type 2 Diabetes patients (17). This programme included six weekly sessions lasting two hours each. A goal setting session was included at the end of each learning sessions and patients were encouraged to choose an area they would like to modify. Notably, an important aspect of autonomy was to respect patients' decision if they chose not to goal-set. At 14 months, the comprehensive X-PERT results confirmed not only sustained improvements in glycaemic control but also other positive trends such as; increased self-empowerment, psychosocial adjustment to diabetes, increased physical activity, increased knowledge of diabetes and foot-care and reduced requirement in diabetes medication, body weight, waist circumference and BMI. Remarkably, the results showed long term (i.e. 14 months) HbA1C values were better than short term (i.e. 4 months) values. The sustained glycaemic improvements was probably due to patients increase self-care skills, knowledge and confidence that they have in themselves to address any issues regarding their diabetes condition (59).

2.3.6.1.e The ROMEO study

A long term Italian study, **R**ethink **O**rganisation to i**m**prove **E**ducation and **O**utcomes (ROMEO) was a 4 year multicentre randomised study looking at group care model versus individual care of established Type 2 Diabetes patients (18). The curriculum encompassed

major self-care behaviours such as weight control, choosing and planning a meal, exercise, checking and improving metabolic control, smoke cessation, medication taking and preventing complications. The programme was divided into 4 sessions in the first two years, and multiple sessions in the second two years to avoid excessive repetition and facilitate meaningful discussion and learning. The 4 year results demonstrated stabilisation of HbA1C, lowering of BMI and increasing HDL cholesterol in the group care patients. Other positive trends included an improvement in diabetes knowledge, quality of life and health behaviours. In addition, the group care patients also showed a reduction in the dosage of oral hypoglycaemic medications and a delay in retinopathy progression. The authors of ROMEO convincingly argued that a structured systemic group education model is more successful than the traditionally dominated one-to-one care basis. The authors opined that Type 2 Diabetes patients can be managed more effectively using a group education model while simultaneously reserves individual medical attention for specific cases (18).

Summary

The consensus and emphasis from these diabetes education studies strongly posit improvement in glycaemic control alone should *not* be the only benchmark used in assessing whether a diabetes education module is successful or not (59, 60, 65). Other factors such as quality of life, treatment satisfaction, greater understanding of the disease, ability to affect the course of the disease and better perception of the disease with longer duration are also important, and should be included when developing and evaluating how effective the education module had been (12). In addition, earlier studies also suggested that diabetes education should be an on-going process (64) and group education might be more effective in certain situation than one-to-one counselling (18).

2.3.6.2 Diabetes Education Studies in Malaysia and Neighbouring Region

2.3.6.2.a Diabetes Education Studies in Malaysia

One of the salient diabetes education study done in Malaysia was by Ming *et al*. A 2008 study by Ming *et al* concluded there were diabetes-related deficits and inadequate self-care practices amongst diabetes patients in Malaysia (66). The authors reported non-engagement in patients to adhere to healthy meals, medication and physical activities leading to higher fasting blood glucose amongst patients. Although majority of patients acknowledged the four cornerstones of self-care management; diet, physical activity and medication, they did not perceived the importance of SMBG and consequently only 15% of patients practiced self-monitoring blood glucose (SMBG). Consequently, in 2011 Ming *et al* developed a structured education programme based on the self-efficacy concept such as "performance accomplishments, vicarious experience, verbal persuasion and physiological information". The programme consisted of three face-to-face sessions and one telephone follow-up for 12 weeks. Their results showed an increased in physical activity, better medication adherence, an increased in SMBG frequency which was associated with an improvement in diabetes knowledge and a concomitant decrease in HbA1C amongst a cohort of suboptimally controlled diabetes patients (67).

A more recent intervention study by Sazlina *et al* promoted physical activity as part of self-care diabetes management. The study intervention was based on the Social Cognitive Theory to encourage elderly patients to change from sedentary behaviour to being physically active through social support and self-efficacy. Personalised feedback from health care providers and peer support from other diabetes patients were recognised as predictive factors to enhance physical activities quantitatively measured using pedometers (68).

Another small-scale cross-sectional study by Azimah *et al* showed there were knowledge gaps in certain domains such as food proportion, food sources, meal practice, physical

activity and diabetes complications. Although patients who had seen a dietitian showed significantly higher level of knowledge score the frequency of meetings did not increase patients' level of knowledge. The authors posited for diabetes patients to be referred to dietitian at least once, to increase their diabetes knowledge and metabolic control (69). Haddad *et al* compared two diabetes education programmes in Malaysia. The authors reported glycaemic control significantly deteriorated in the *less* structured group, while significantly improved in the structured group indicating a structured programme was more effective (70). Both studies (69, 70) did not elaborate the underlying theory of their structure or content of their education module.

Summary

Based on the current literature review, only a handful of small-size diabetes education studies had been conducted and published in Malaysia. Apart from a diabetes education study module developed and published by Ming et al (67), based on her earlier finding on deficits in diabetes self-care practices (66), the other studies found were small cross-sectional studies looking at specific outcomes of diabetes self-care practices (68, 69). In contrast to the nationwide theory-based diabetes education programme conducted in UK, Europe or Australia (15-18, 59) there has not been similar ones conducted or reported in Malaysia to date except for Ming *et al* (67) and Shariff-Ghazali (68). This gap signals a clarion call for a more robust research in this particular area and was one of the main reason why I had started the current study.

2.3.6.2.a Diabetes Education Studies in the South East Asia Region

Singapore

A cross-sectional study in Singapore showed that an overwhelming majority of the diabetes population have received some form of diabetes education. However, when compared with their non-diabetes counterparts, there were no significant difference between the two group's

diabetes knowledge scores. The result was most likely due to the wide availability of diabetes education in Singapore and highlighted the strength of Singapore's public health education (71).

India

In contrast, a cross-sectional study in Karachi, India reported, only "casual diabetes education" were provided to patients by physicians during their brief consultations, as well as inadequate clinical monitoring. The lack of systemic diabetes monitoring and structured education were also reflected by the high prevalence of diabetes complications such as retinopathy, neuropathy and amputation of limbs (72).

Furthermore, diabetes education studies in different parts of India faced more challenging problems such as gender differences, inaccessibility to education and health literacy. Women patients tend to have lower diabetes knowledge score compared their men counterpart. This is unsurprising as almost 50% of women living in rural India are illiterate, creating an inherent barrier to a diabetes education programme (73).

Patients' lack of knowledge about their condition can also influence their confidence and self-efficacy. Consequently in modern India, many women patients lack the sense of self-efficacy regarding their diabetes. In the recent study, Mehta *et al* delivered theory based diabetes education study to rural women in India and found positive correlation between diabetes knowledge and self-efficacy amongst women. In addition, the authors strongly advocate for future educational programmes to place greater emphasis on educating rural women in India to help increase their knowledge in diabetes (73).

China

A recent systemic review involving 53 studies (48 Chinese; 6 English) on structured diabetes education for Chinese patients, strongly confirmed that on-going, didactic structured diabetes education is associated with large glycaemic improvements. In addition, other innovative

educational approaches which is in line with cultural contexts such as engagement with family members are also being trialled. Notably post 2011, more studies had been conducted to explore the effects of peer learning, motivational interviewing and goal-setting which were more akin to the current Western interventions (74).

Summary

Clearly, Asia is a region with very diverse population, culture and socio-economic status. The brief literature review of the region highlighted various local issues faced by different countries and reported different level of progress in terms of development and delivery of diabetes education (71-74). This further support the need for tailored and contextualised diabetes education programme that takes into account the sociocultural and economic fabric of each population (73, 74). Some of the studies did not mention how they evaluated the key criteria of a structured education programme such as curriculum content, delivery, underlying philosophy, quality assurance and auditing of intervention programme in their publications' (70-72) which is seen as a drawback as adequate appraisals of the studies cannot be done.

2.3.6.3 Diabetes Education Studies using Michigan Diabetes Knowledge Test (MDKT)

Currently, there are more than thirty validated diabetes-related questionnaires (75-79) widely used in diabetes research, including Michigan Diabetes Knowledge Test (MDKT) (79). The MDKT was developed in 1998 (79) and have been widely used by many studies to assess patients' diabetes knowledge (80-88). It is an inexpensive tool to assess patients' knowledge about diabetes and its care. Briefly, the knowledge test include a 14-item general test, a 9-item insulin-use subscale test and a full 23-item test. The test has reliability scores of ≥ 0.7 scores and readability of 6^{th} grade level (79). The authors of MDKT have shown that MDKT is an appropriate tool to make group comparisons. However, its usefulness as an outcome measure for educational interventions remains to be determined (79).

Many studies from developing countries have translated and contextualised the items in MDKT accordingly and administered the test to assess the general level of diabetes knowledge in their diabetes population (82-84, 86, 88). Some direct comparisons can be made between the different groups of diabetes populations in different countries because these studies used MDKT as an assessment tool. For example, the mean score level for correct responses in the MDKT were varied from: 44% (in Nigeria) (89) , 63.1% (in Zimbabwe) (86), 58.9% (in Kuwait) 60% (80) and 64.9% (81) in two different studies in United States. More importantly, these studies could identify important knowledge determinants to facilitate health care providers and policy makers to develop or improve existing diabetes education intervention (80-88).

Recent cross-sectional studies conducted in Malaysia and Middle East (i.e. Kuwait and United Arab Emirates) used MDKT to evaluate the level and determinants of knowledge in diabetes among diabetes patients. The results from these studies showed similar findings, with significantly higher scores of knowledge found in: (i) younger patients (ii) those with higher educational level (iii) those with higher monthly income (iv) those patients who do self-monitoring blood glucose (SMBG) (81, 83, 84, 88) (v) those with longer duration of diabetes (81, 83, 88) and (vi) those with lower HbA1C level (83). In addition, having a family member with diabetes and performing daily insulin injections and doing regular SMBG can also increase patients' awareness and knowledge in diabetes (88). In contrast, relationship between gender and knowledge had been contradictory with some studies reporting (i) lower knowledge among women (90) (ii) higher knowledge among women (81, 82) or (iii) no difference in knowledge level between women and men (83, 86, 88) indicating the complexity of diabetes education and how education delivery must be tailored to patients accordingly, based on a suitable cultural, social, educational context. A study by Murata *et al*, highlighted the diminishing effects of aging on knowledge attainment. Factors such as stroke,

dementia, depression, alcoholism and poor social circumstances which are commonly seen in elderly patients are also associated with impaired learning, explaining the lower knowledge scores among elderly veterans (81).

Summary

The emphasis of the cross-sectional studies focused mainly on (i) determining patients' baseline knowledge on diabetes and (ii) identifying the significant determinants of knowledge (80-88). The rationale of accurately recognising the knowledge determinants will provide some insight on how to make improvement(s) to the existing or future interventional education strategies in diabetes (81, 83, 88).

2.3.7 Gaps in the Current Diabetes Education

In the Diabetes UK report 2005, eight specific areas were identified as gaps which need to be addressed namely one-to-one support, ongoing support, children and adolescents, insulin pump therapy, Black and Minority Ethnic (BME) groups, impaired glucose tolerance, carers and pregnancy (10). For one-to-one support gap, certain modalities such as regular follow-up either face-to-face or by telephone to provide on-going education, practical demonstrations to perform self-care skills (i.e. self-monitoring blood glucose) and provision of practical aids such as charts and reminders (i.e. contextualised log book for blood glucose) have been suggested as tools to support patients (10).

In addition, the Diabetes UK report also highlighted the importance of health care professionals' approach when providing care to patients and consultation skills training be considered for them as part of addressing ongoing support (10). Others had related a range of unsatisfactory complaints faced by patients including discrepancies in self-care education delivery (91) and inadequate information received from health care providers (92).

In the comprehensive Diabetes Australia report 2007, the Australian taskforce team agreed there was a lack of consensus regarding the agreed standardised outcomes and indicators for

diabetes education hence assessment of an education intervention is quite challenging (12). Consequently, the core impact of diabetes education was not assessed very well. This is because, traditionally, the effectiveness of an education programme have relied more on metabolic control measures (i.e. HbA1C, lipids, Body Mass Index) and less often on knowledge, attitudes and quality of life (27, 93).

However, this trend is changing and current research on diabetes education has taken other outcomes measurements into consideration when measuring the effectiveness of an education programme. In a systematic review by Deakin *et al* (94), a group based diabetes education training looked into a variety of outcomes including knowledge, behavioural and psychological components; such as diabetes knowledge, self-care monitoring, self-efficacy, quality of life, psychological changes, medication taking and clinical outcomes.

A more recent systematic review by Dube *et al* on diabetes self-management education programmes in high and low mortality developing countries found interventions to be generally effective with regards to behaviour change, glycaemic control and addressing cultural aspects of the population (95). The authors recommended some measures to address gaps identified in diabetes education research. These recommendations included (i) programmes should be guided by behavioural theories (ii) creating opportunities to train professionals and non-professionals providers especially in resource-poor settings (iii) addressing cultural sensitivity especially deep cultural factors such as understanding of social, historical and psychological sources that can influence patients (iv) to make programmes more accessible to patients with low health literacy (95).

2.4 Diabetes Self-Care Management

2.4.1 Personalised Care Planning

Personalised care planning is a collaborative process between patients and their physicians. It involves a series of conversations between patients and their doctor. The aim of this

exercise(s) is to reach a consensus on the goals and actions for managing the patients' condition (96). The Calgary Cambridge Guide is a comprehensive and practical tool for assessing consultations. In this tool, personalised care planning featured prominently to assist health care provider to achieve a successful personalised care planning (97). Silverman *et al* posited "in order to achieve a shared understanding and incorporating the patients' perspective – health care providers should (i) relate explanation to the patient's illness framework (ii) provide opportunity and encourage patient to contribute (iii) pick up verbal and non-verbal cues and (iv) elicit patients' beliefs, reactions and feelings." Additionally, for "planning and shared decision making – health care providers should (i) share their own thoughts (ii) involve patients by making suggestions rather than giving directives (iii) encourage patients to contribute their thoughts and (iv) negotiate and offer choices to patients while checking if these choices are acceptable (97).

Implementation of personalised care planning chronic conditions such as diabetes, asthma, heart failure, end stage renal failure and chronic depression involves a significant organisational and cultural change (98). This is because most health care providers may be reluctant to initiate this model due to few reasons such as the lack of belief in warranted evidence (99) or too resource-intensive (i.e. time-consuming, burdensome) for both physicians and patients (100). A recent systematic review by Coulter et al found personalised care planning showed modest improvements in certain indicators of physical (i.e. HbA1C, systolic blood pressure, lung function) and psychological (i.e. quality of life) health status and patients' capability to manage their own conditions (i.e. self-efficacy, patient activation, empowerment, perceived interpersonal effort) when compared to usual care (96). Although the effects of personalised care planning was not large, it appeared greater when intervention was more comprehensive, more intensive and well integrated into routine care (96). Coulter *et al* posited no evidence of any harms arising from personalised care planning, although the

quality of evidence was moderate and require further research in the future (96). Specifically, for patients with diabetes, personalised care planning include personalising their blood glucose and HbA1C levels according to their own functional and safety status.

2.4.2 HbA1C as a Glycaemic Indicator and Its Limitations

Ever since large landmark studies like DCCT and UKPDS (101, 102) were published in the 1990's showing intensive blood glucose control, as measured by HbA1C, is effective in preventing long term microvascular complications in both Type 1 and Type 2, HbA1C had been regarded as the gold standard for monitoring glucose control (101-103). Patients from the intensive arm of the DCCT had a 3.3-fold increase in the rate of severe hypoglycaemia, linking clear association between hypoglycaemia with achieved HbA1C (104).

Despite its well-known status, there had been many debates among experts challenging this claim (105). Although HbA1C is a valuable glycaemic measurement for comparing treatment groups in randomised control trial, assessing glycaemic trends in population over time and for cross-sectional comparisons in different populations (105), the accuracy of HbA1C as a marker for glycaemic control complications in *individual patients* had been widely disputed. In their recent study, Beck et al showed, not infrequently HbA1C may underestimate or overestimate mean glucose level quite substantially. The authors posited if HbA1C is to be used to assess glycaemic control, it is critical to know patients' actual mean glucose to understand how well HbA1C is an indicator for glycaemic control. Estimating glycaemic control from HbA1C is essentially like applying population average to an individual and can be misleading (105).

Because HbA1C is an indirect measure of average glycaemia, as such is subject to limitations. One of the main issues with HbA1C value is that it does not give any information on glucose variability and hypoglycaemia in an individual patient (106). The HbA1C level may mask the day-to-day oscillations of severe hypoglycaemia and hyperglycaemia and

"good result" may be recorded in patients with exaggerated swings of hyperglycaemia and hypoglycaemia (107).

In addition, a single value of an average HbA1C has a wide range of mean blood glucose. In their study, Nathan *et al* showed, an HbA1C 7.0%, 9.0% and 11.0% could reflect an average blood glucose between 6.7-10.3 mmol/l, 9.5-13.9 mmol/l and 11.9-17.5 mmol/l respectively (108). It has been postulated the discordance between mean glucose concentrations and HbA1C could be due to inter-individual variation of erythrocyte life span (109, 110). Also the identical value of HbA1C (i.e. 7.0%) could reflect either 100.0% time-in-range or 18.0% time-in-range over a period of three months. Therefore, HbA1C does not capture the important variables such as time spent in different glucose ranges (i.e. low: <3.9 mmol/l; in-range: 3.9-10.0 mmol/l; high: 10.0-22.0 mmol/l) (111).

Other conditions which may affect HbA1C such as (i) abnormal haemoglobin (i.e. S, C, F, E ,D, Leiden etc) (ii) iron deficiency anaemia (iii) chronic renal failure (iv) cirrhosis of the liver (v) blood loss or haemolysis (vi) chronic alcoholism and (vi) specific treatment or medication (i.e. Vitamin C and E, hydroxyurea, iron replacement therapy) (112-114) may influence the interpretation of HbA1C in diabetes control. The problem of haemoglobin variants is a global one. Approximately 7.0% of world population has some form of haemoglobin variant (115). Closer to home, up to 30.0% of South-east Asia population may have at least one heterozygous haemoglobin variant. Hence, all these factors should be carefully taken into consideration when interpreting patients' HbA1C results (115).

2.4.3 Glucose Variability

Glucose variability (sometimes known as glycaemic variability) means swings in blood glucose level. These "glycaemic bumps" had been broadly defined as intra-day glycaemic excursions including episodes of hyper- and hypoglycaemia. Post-prandial hyperglycaemic excursions could also contribute to glucose variability (116). The advent of newer

therapeutics agents such as glucagon like peptide-1 (GLP-1) analogue and dihydropeptidyl peptidase-IV (DPP-IV) inhibitors, with different mechanism of action (i.e. incretin mimetic effect) have highlighted the potential role of glucose variability in glycaemic control (116).

To date, multiple formulas have been used to measure glucose variability including (i) M-value (ii) Mean amplitude of glycaemic excursions (MAGE) (iii) Continuous overlapping net glycaemic action – a variation of continuous glucose monitoring (CGM) (iv) absolute mean of daily differences (v) standard deviation – derived from seven point SMBG (vi) co-efficient of variation (CV) and (vii) serum 1,5-anhydroglucitol (1,5-AG) (116).

Notably, the occurrence of many micro- and macrovascular in diabetes complications had been attributed to hyperglycaemia and dysglycaemia (peaks and nadirs) (117-119). Increasing evidence points to glucose variability as an important contributor to the development of diabetes complications, although this remains controversial (120). Such variability in blood glucose had been associated with extremely high hyperglycaemia, dangerously low hypoglycaemia and significantly impact on patients' well-being and their satisfaction of their diabetes control (121). Hence, it would be sensible to minimise glucose variability as it is associated with reduced patients' satisfaction and increased hypoglycaemia, with the latter being shown to trigger inflammatory response linked to vascular function impairment (103, 122).

In his review, Rayman advocated "Tringle of Diabetes Care" which included three important goals in diabetes management. First, reducing overall glycaemic burden which currently is being assessed by HbA1C. Next, preventing hypoglycaemia as much as possible and thirdly, minimising glucose variability. Ideally, all three targets should be achieve, although this may not be possible nor desirable (107). This model allows health care provider to be more flexible depending on individual patients. For example, target HbA1C should be more stringent in young newly diagnosed diabetes patients, as opposed to an elderly frail patient

with cardiovascular complications, in whom a clear priority would be to avoid potential harm associated with hypoglycaemia (107). In contrast, regardless of the target of HBA1C level, reducing glucose variability by curtailing the peaks and nadirs of patients' blood glucose levels will be beneficial, as both had been linked with increased mortality (103).

2.4.4 Self-Monitoring Blood Glucose (SMBG)

Historically, when blood glucose monitoring device was developed in the 1970s, it was with the sole purpose of enabling patients to check their blood glucose at home. Prior to the blood glucose meters, patients used urine dipstick test to monitor their urinary glucose and ketone levels. Over the past 4 decades, there has been a leap of advances in the development of blood glucose meters and the adoption of SMBG by patients.

The role of SMBG can be viewed from the aspects of patients and physicians. From the patients' perspective, SMBG is an important tool in diabetes management as it is able to (i) provide immediate feedback regarding patients medications, physical activity and dietary intake (ii) establish patient's glucose profile by differentiating fasting, pre-prandial and post-prandial levels (iii) identify hyperglycaemic excursions (iv) identify hypoglycaemia (both aware and unaware episodes) (123, 124) .

From the health care givers' aspect, data from patients' SMBG is an important therapeutic tool that can - and should - be used more effectively to guide patients' treatment plans. Previous studies that reported benefits of SMBG showed that patients' received feedback regarding their behaviours based on their SMBG results (125-127). In contrast, older studies which did not report benefit from SMBG were unabled to link SMBG results with behavioural changes, indicating suboptimum use of SMBG only as a monitoring tool (128, 129).

Frequent SMBG by patients without timely and constructive feedback from health care givers render the act of SMBG useless, does not fulfil SMBG potential uses as per described by the

IDF SMBG Taskforce report (130), does not prevent long term diabetes complications (131) and is not resource-effective.

2.4.4.1 The adjunct role of SMBG with HbA1C

Although HbA1C is useful in monitoring long-term blood glucose control (90 days), SMBG remains relevant especially in reporting fasting and 2 hours post-prandial blood glucose and charting daily glycaemic excursions. Previous study has shown that in patients with equivalent HbA1C, those with higher glycaemic excursions have higher risk of developing microvascular complications (102). In addition, the ACCORD study showed patients with HbA1C of < 6.5% were at greater risk of developing hypoglycaemia and cardiovascular events (132). Hence, whether it is a hypo- or a hyperglycaemia risk status, the short-term role and function of SMBG to capture glycaemic excursions remains relevant for diabetes patients. These factors support the adjunct role of SMBG, as a short-term (i.e. day-to-day or week-to-week) indicator for glycaemic control, as patients learn to navigate and self-manage diabetes in their life.

2.4.4.2 Considerations of SMBG in Special Groups - Elderly

The most recent IDF recommendations (2017) takes into account special groups such as elderly patients, cognitively impaired, terminally ill and advanced chronic disease(i.e. end stage renal disease), those with mental health problems (i.e. depression) and circumstances (i.e. Ramadan) (133).

While achieving near-normal blood glucose levels and preventing long term complications is the priority in younger and more fit patients with diabetes, the same may not apply in older and more frail elderly patients with diabetes. In this group of elderly patients who are taking insulin injections and/or sulphonylureas, the priorities will be to minimise the risk of hypoglycaemia, control uncomfortable symptoms, reduce the risks of falls and maintaining a good quality of life (134). The McKellar Guidelines for Managing Older People developed in

2014, recommended a set of guidelines for elders with diabetes living in residential care. For example in this group, target blood glucose range is between 6-15 mmol/L (i.e. hypoglycaemia is regarded as less than 6 mmol/L and hyperglycaemia is greater than 15 mmol/L) (135). This target range defers from other standard target post prandial blood glucose (i.e. 4.4-8.5 mmol/L) (136). Older people with diabetes treated with insulin injections and/or sulphonylureas have a higher risk of developing hypoglycaemia. The higher risk of hypoglycaemia may also be due to their co-existing medical conditions (i.e. malnutrition, dementia or renal impairment) or their difficulty in recognising hypoglycaemia symptoms (134). Hence, frequency and timing of blood glucose monitoring should be tailored to each individual and would depend on several factors such as their health or disease status, co-morbidities, blood glucose targets, current medicines regimen, quality of life and life expectancy (134, 135) . Blood glucose monitoring should be individualised. In elderly patients whom are managed by diet, lifestyle modifications or metformin alone, blood glucose monitoring is not required unless during acute illness. In contrast, those who are on insulin injections and/or suphonylureas may need to monitor their blood glucose several times a day. The guideline recommend blood glucose monitoring once or twice a day (i.e. either fasting or 2 hours post-prandial) and changing the time of blood testing over a period of a week in order to gain a better idea of patients glucose excursion pattern. Generally, testing for blood glucose at the same time (i.e. before breakfast or before dinner) all the time, without any variation is not helpful as it does not give information about patients' daily glucose variation (134). In a similar vein, most clinical guidelines do acknowledged that glycaemic targets should be individualised to minimise risk of hypoglycaemia, especially in elderly patients and those with high cardiovascular risks (136). In all cases, the safety and functional status of patients should be paramount when treatment plan is discussed and agreed by both patients and physician (96).

2.4.4.3 What is the evidence of SMBG in Diabetes Self-Care Management?

The overarching rationale for individualised SMBG in type 1 and insulin-treated type 2, is based on several aspects, specifically safety (i.e. detection and prevention of hypoglycaemia), efficacy (i.e. improvement of insulin therapy through dose modification) and flexibility for the patients (i.e. exercise and food choices) (137). Although the benefits of SMBG has been well established in the control of type 1 diabetes (101, 138) and insulin-treated Type 2 Diabetes (121, 139-141), its beneficial effects in non-insulin treated Type 2 Diabetes has been hugely controversial (123, 142-146).

2.4.4.3.a Inconclusive results from previous SMBG studies for non-insulin treated Type 2 Diabetes

Previous systematic reviews and meta-analyses have reported that SMBG leads to small improvements in HbA1C levels of 0.22% to 0.31% (142, 143, 147, 148) which will lead to long term reductions in macro-vascular complications and reduction in cost (147, 149). Furthermore, prior to 2005, data on quality of life (QoL), well-being, patient satisfaction and hypoglycaemic episodes were lacking in most SMBG studies. In their meta-analysis, Welschen *et al* investigated the effectiveness of SMBG on non-insulin treated Type 2 Diabetes patients. The authors included studies with at least one of the following outcomes; HbA1C, fasting blood glucose, hypoglycaemia episodes, quality of life, well-being and patient satisfaction. The overall results from the six randomised control trials showed statistically significant decrease of 0.39% in HbA1C compared with control groups (142). This finding is clinically significant. This is because a landmark study (UKPDS) showed a decrease of 0.39% of HbA1C can reduce risk of microvascular complications by 14% (138). However, the authors cautioned for the results of the systematic review to be interpreted with care, as the methods, interventions and sample populations of the meta-analyses studies were heterogeneous in nature (142).

2.4.4.3.b Research limitations and lessons learnt from previous SMBG studies

Some of the recurring issues identified in previous SMBG studies were; (i) inadequate sample size (n < 50) (ii) short duration (< 6 months) to observe any long term effects (legacy effects) (iii) vague or no explanation about patient's response to out-of-range blood glucose results and (iv) inadequate SMBG frequency to provide feedback to patients (123, 142-146).

For example, in earlier studies (101, 121) the benefits of tight control of blood glucose through SMBG on macrovascular outcomes, were seen only a decade later, when the intervention and control arms had converged. This concept of "metabolic memory" or "legacy effect" suggests that although short term benefits of tightly control blood glucose through SMBG were not observed in the initial randomised control trial, the longer term or "legacy effect" of tightly controlled blood glucose which was facilitated through SMBG may be significant (130).

2.4.4.3.c Considerations for future SMBG studies

In a review paper, MgGeogh *et al* had several recommendations for SMBG to be beneficial. Firstly SMBG can be beneficial in poorly-controlled diabetes patients' with a high baseline of HbA1C (≥ 8.0%). Secondly, patients should be taught SMBG education and the appropriate actions to be taken based on their blood glucose results. Thirdly, patients have adequate literacy and numeracy level and are amenable to make necessary behavioural changes in order to improve their metabolic control. Finally SMBG could be beneficial in special instances, such as in initiation or change of treatment, in newly diagnosed patients, during an illness and pregnancy and in patients with hypoglycaemia unawareness (131).

2.4.4.4 SMBG Guideline for Type 2 Diabetes from International Diabetes Federation (IDF)

In response to the contradicting accounts of SMBG studies in non-insulin treated Type 2 Diabetes, the International Diabetes Federation (IDF) together with the SMBG International

Working Group published a guideline in 2009 (130). The overarching aim of the IDF guideline was the emphasis on collaboration between patients and their health care giver especially in reviewing, interpreting and modifying patients' lifestyle and treatment based upon the blood glucose data collected through structured SMBG (130). Table 2.1 below summarises the IDF recommendations for SMBG among non-insulin treated diabetes patients.

Table 2.1 Summary of IDF recommendations for SMBG use in non-insulin treated diabetes patients (130).

1. SMBG be used only when individuals with diabetes (and/or their care-givers) and/or their healthcare providers have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals.
2. SMBG should be considered at the time of diagnosis to enhance the understanding of diabetes as part of individuals' education and to facilitate timely treatment initiation and titration optimisation.
3. SMBG should be considered as part of an ongoing diabetes self-management education to assist people with diabetes to better understand their disease and provide a means to actively and effectively participate in its control and treatment, modifying behavioural and pharmacological interventions as needed, in consultation with their health care provider.
4. SMBG protocols (intensity and frequency) should be individualised to address each individual's specific educational/behavioural/clinical requirements (to identify/prevent/manage/ acute hyper- and hypoglycaemia) and provider requirements for data on glycaemic patterns and to monitor impact of therapeutic decision making.
5. The purpose(s) of performing SMBG and using SMBG data should be agreed between the person with diabetes and the healthcare provider. These agreed-upon purposes/goals and actual review of SMBG data should be documented.
6. SMBG use require an easy procedure for patients to regularly monitor the performance and accuracy of their glucose meter.

First and foremost, IDF strongly recommends that SMBG only be utilised when patients/carers and their physicians *"have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order*

to attain agreed treatment goals". Importantly, the willingness of physicians to alter patients' medication or therapy based on the specific blood glucose excursions (high and low) from the SMBG data can overcome the "clinical inertia" phenomena that contribute to – a certain degree – the poor glycaemic control among Type 2 Diabetes patients (150). This way SMBG can be utilised as a therapeutic tool by physicians and health care givers.

Second *"SMBG should be considered during the time of diagnosis to enhance the understanding of diabetes as part of individuals' education and to facilitate timely treatment initiation and titration optimisation".* Hence, SMBG should be used as a teaching tool to educate patients about their disease and body's physiological response to external stimuli such as physical activity, dietary intake, illness or infection etc.

Although to date, there is no distinct evidence-based of SMBG protocol for non-insulin treated Type 2 Diabetes, IDF recommends a few types of SMBG protocols (i.e. high intensity, "staggered" and low intensity regimens) depending on patients' educational, behavioural and clinical needs. Importantly, the frequency and intensity of the SMBG should be discussed and agreed upon by patients and their respective healthcare givers during face-to-face consultation(s).

The focused SMBG protocols i.e. 5-point or 7-point glucose profiles or "staggered regimens" that include pre-prandial and post-prandial SMBG on consecutive or alternating days ("testing in pairs") are useful to chart patients' daily glucose profile (151). Consequently, once sufficient SMBG data has been obtained and/or patients have achieved a stable and "good" metabolic control, SMBG protocol can be changed to low intensity regimen i.e. meal-based testing or alternatively patients could have a transient SMBG-free period.

2.4.4.5 The new generation of SMBG studies – with structured or staggered SMBG protocol

Following the IDF guidelines and recommendations for SMBG non-insulin treated Type 2 Diabetes patients, a new generation of SMBG studies were published. A recent review paper by Parkin *et al*, outlined ten studies in total, eight of which adopted and utilised the structured SMBG protocol approach appropriately and successfully reported SMBG benefits (152). In contrast, the remaining two studies did not follow the appropriate IDF recommendations and did not show any benefits (152). These newer studies had a different approach to SMBG interventions. These studies utilised focus or structured SMBG protocol to help patients review and interpret their blood glucose results and consequently make the appropriate lifestyle and/or therapeutic changes.

In the review paper by Parkin *et al*, the authors eloquently and convincingly discussed the importance of using structured SMBG protocol to optimise or set off the beneficial effects of SMBG on diabetes overall management (152). Parkin *et al* described how structured SMBG protocol was shown (i) to be useful in newly diagnosed diabetes patients as *per* the St. Carlos Study (153) (ii) to improve glycaemic control in suboptimally controlled non-insulin treated Type 2 Diabetes patients as *per* the STeP (148) and ROSES studies (154) (iii) to improve post-prandial glucose management as *per* Bonomo *et al* (155) and Shiraiwa *et al* (156) (iv) to be associated with reduced cardiovascular risks marker i.e. reduction of carotid intimal-medial thickness as *per* Mohan *et al* (157) (v) to facilitate lifestyle interventions and changes as *per* ROSSO-in-praxi study (158) and (vi) to improve glycaemic control in suboptimally controlled insulin treated Type 2 Diabetes as *per* Kato *et al* (159).

2.4.4.5.a Structured SMBG in newly diagnosed Type 2 Diabetes

The St Carlos Study was a randomised control study on *newly* diagnosed Type 2 Diabetes patients. Duran *et al* utilised SMBG as an educational tool and therapeutic tool to help both

patients to change and adhere to lifestyle changes and facilitate physicians to apply pharmacological treatment respectively. The primary endpoints were to estimate for remission (HbA1C levels of 6.0-6.4%) and/or regression (HbA1C <6.0%) of Type 2 Diabetes (153). At one year, the intervention group had significantly higher rates of remission and regression of Type 2 Diabetes when compared to the control group. In addition, there were greater reductions in median HbA1C values and body mass index, and greater increase in lifestyle score in the intervention group. Remarkably, medications were changed earlier and more frequently (i.e. six times more) in the intervention group. These results strongly suggest that a structured SMBG will empower patients achieve their lifestyle goals (i.e. diet and physical activity) and encourage physicians and patients to use SMBG to optimise diabetes treatment (153).

2.4.4.5.b Structured SMBG in suboptimally controlled non-insulin treated Type 2 Diabetes

The Structured Testing Program (STeP) Study by Polonsky *et al* a cluster-randomised multicentre clinical trial was designed to foster collaboration between patients and their physicians in utilising the SMBG data and modifying patients' treatment accordingly. Primary endpoint was a change in HbA1C over time. Other endpoints were changes in daily glycaemic excursions, patients' psychosocial measures and physicians' practice patterns (148). Patients were randomized to two groups: active control group (ACG) and structured testing protocol group (STG). The STG patients received a simple logbook to record their 7-point blood glucose profile over three consecutive days every quarterly (i.e. in total 12 days per year; 4 times per year). The STG physicians received an algorithm with suggested medications strategies to follow base on their patients SMBG patterns (148). At one year, results showed (i) a significant reduction of mean HbA1C (ii) a significant reduction of glucose levels from baseline at all pre-prandial and post-prandial time points and (iii) greater

improvement in general well-being in the STG group when compared to control (148). Furthermore, there was an increase in SMBG adherence. An impressive majority (70%) of STG patients completed at least 80% of all SMBG measurements. Remarkably, patients also reported they discussed their SMBG results with their respective physicians. The high number adherence to protocol suggests that structured quarterly testing is both useful and advantageous for both patients and physicians (148).

Interestingly, the superior improvement in HbA1C in the STG group occurred with less blood glucose monitoring compared to control group (148). This indeed might be a paradigm shift to move away from SMBG quantity (i.e. testing frequency) to SMBG quality (i.e. meaningful test) which can contribute to positive action (148). In conclusion, the STeP study successfully demonstrated that structured SMBG supports significantly better glycaemic control and improvement in quality of life in non-insulin treated Type 2 Diabetes patients when both patients and physicians collaborate in collecting, reviewing, interpreting SMBG results and making the appropriate therapeutic changes (148).

Similar findings were observed in a pilot study looking at the efficacy of structured SMBG-based intervention on Type 2 Diabetes patients on oral medications in the ROSES study (154). The combined intervention that included (i) a staggered SMBG protocol of 2 weekly profiles per month for 6 months (see Figure 4.2) (ii) education on SMBG and appropriate lifestyle changes based on SMBG pattern and (iii) modest frequency of meetings with diabetes nurses (once in 3 months) was a practical approach for a real world clinical setting (154). The results from the ROSES study showed a significant improvement in both HbA1C and weight loss in the intervention group when compared to control. In contrast to the St Carlos study, more therapy changes was observed in the control group compared to the intervention group. The authors suggested the reason for the glycaemic improvement was

more likely due to lifestyle intervention (i.e. weight loss) led by the diabetes nurses rather than pharmacotherapy changes (154).

2.4.4.5.c Structured SMBG improves post-prandial management

The consequences of uncontrolled post-prandial hyperglycaemia excursions have been associated with development of both microvascular (156) and macrovascular diseases (160-163). In contrast, reductions of post-prandial hyperglycaemia have been shown to be cardio-protective (164-166). The study by Bonomo *et al* investigated the usefulness of SMBG protocol which focuses on pre-prandial and post-prandial glucose in patients already doing SMBG (155). The patients were randomized to a control group with usual care including one blood glucose profile per month (i.e. pre-prandial and 2-hours post-prandial at breakfast, lunch and dinner) and a treatment group with usual care including one glucose profile every two weeks. Evaluation and review of patients' SMBG profiles and HbA1C levels by the same health care team took place at 3 and 6 months. Although higher SMBG adherence was observed in patients from control group (73%) compared to treatment group (44%), adherent treatment group patients showed significant reductions in both pre-prandial and post-prandial blood glucose and HbA1C levels (155). Similar to the STeP study (148), the results from Bonomo *et al* also support "quality versus quantity SMBG" and demonstrated that meaningful SMBG test is more useful and cost-efficient and ultimately have more impact on glycaemic markers (155).

2.4.4.5.d Structured SMBG facilitates lifestyle interventions

Kempf *et al* showed that lifestyle interventions which included measures such as; (i) blood glucose meter with 100 glucose strips (ii) a tape measure for waist circumference (iii) step pedometer and (iv) an instruction booklet containing simple information on diet and physical activity had a positive trend on patients' glycaemic and lipid markers, clinical parameters (i.e. significant weight loss, body mass index, waist circumference, blood pressure), quality of life

and physical activity (158). In this study, physicians contacted patients 4 times during the 6 months study to remind patients to perform the structured 7-point blood glucose profile every 4 weeks. The ROSSO-in-praxi lifestyle interventions study successfully showed a reasonably inexpensive approach in lifestyle interventions (the cost of USD200 per patient) is a possible option and can be easily integrated into general diabetes care.

Finally, Benhalima *et al* concluded SMBG can only be effective if the self-care behaviour is embedded within an education and behavioural package (167). The authors concluded in order for an intervention to be effective, the following three components must be emphasised in the programme; (i) a prescribed SMBG frequency and timing to guide patients (i.e. structured SMBG protocol) (ii) the willingness on the side of the health care personnel to utilise the SMBG results and modify patients' treatments and (iii) appropriate responses from patients based on their SMBG results (167).

Summary

Hence, the recommendations from IDF guideline (130) and other structured SMBG studies discussed above had shaped the development of the current study's SMBG protocol. The salient points extracted from the current literature on SMBG applicable to the current study are as follows; (i) SMBG should only be utilised when patients and physicians have the knowledge, skills and willingness to make treatment adjustments based on SMBG results (ii) SMBG "staggered regimens" such as 5-point or 7-point glucose profiles have been adapted to the current study's SMBG protocol (iii) a well prescribed SMBG frequency and timing can guide both newly diagnosed and established diabetes patients to perform SMBG.

2.4.4.6 SMBG Prevalence Studies and Reimbursement Policies on SMBG

2.4.4.6.a SMBG Prevalence Studies in Malaysia

There had been several small cross-sectional SMBG-related studies conducted in various different government hospitals and clinics in Peninsular Malaysia recently (8, 168-170). The

participants were insulin-treated Type 2 Diabetes patients and the SMBG prevalence varied from 15.3% (170) to 66% (169). Other studies showed SMBG prevalence amongst diabetes patients attending private health care system to be within the range of 6.9% to 21.0% (171). These results indicated the different SMBG practices among diabetes patients attending both the public and private sectors.

The result of a cross-sectional SMBG knowledge study in an urban government hospital found that more SMBG education programs are needed for Type 2 Diabetes patients (168) The authors (168) defined SMBG process as self-measurement and self-regulations and categorised SMBG knowledge into (i) *technical skills* (ii) *utilisation of glucose level measurement* and (iii) *home monitoring*. They posited patients must be able utilise their blood glucose results by altering their treatment or diet/lifestyle according to their blood results (168). This is consistent with the IDF guidelines for SMBG (130). Another cross-sectional study found poor association between patients' SMBG frequency and improvement of their HbA1C (169). The reason for this can probably be attributed to the lack of self-adjustment of insulin dose or diet by patients since more than half (i.e. 54%) of patients did not alter their treatment based on their blood glucose results (169). Similarly in another study, only a third (i.e. 30%) of patients changed their medications based on the results of their blood glucose (170). In both these studies (169, 170), inadequate use of SMBG resources have not helped in improving patients' overall diabetes control. This is an important point of emphasis, for diabetes educators and researchers to take note when treating patients and designing future diabetes education studies respectively. In patients who did perform SMBG, majority (83.5%) monitored less than once per day and 16.5% monitored at least once a day (170) both of which were less than those recommended by IDF guideline for Type 2 Diabetes (130). In addition, the significant predictors for SMBG-practice in Malaysia were patients with (i) higher education level (ii) higher total family income, (iii) longer duration of diabetes and

(iv) those on insulin treatment (170). Mastura *et al* also found the most likely reason for low SMBG among Malaysian patients is inadequate counselling and support pertaining all aspects of SMBG – i.e. teaching of basic skill and competency, finding a suitable protocol or regimen and lack of advice or guidance in results interpretation and modification of therapy. To date there is no subsidies or reimbursement policy for SMBG devices and glucose strips from the government in Malaysia (170).

Summary

There had been a few published studies regarding SMBG practices and prevalence in Malaysia (66, 168-170). SMBG practices are varied among diabetes patients attending public and private health care sectors in Malaysia. Both cross-sectional studies by Mastura *et al* and Siti *et al* had found between 30-50% of patients performing SMBG did not utilise their glucose level measurement. They posited for more diabetes education on SMBG to be developed and implemented in the future (169, 170).

2.4.4.6.b Comparison of SMBG-practices worldwide and Its Influencing Factors

A recent paper by the SMBG International Working Group on comparing SMBG-practices in Type 2 Diabetes patients across 14 countries showed that various factors such as (i) country and region of residence (ii) diabetes treatment type and (iii) relative cost to patients - have an impact on whether SMBG is perform or not (172). The 14 countries involved in this survey included North America (USA and Canada), South America (Argentina), Europe (UK, Germany, Hungary, Netherlands, Italy, Norway,), Australasia (Australia, India, Pakistan, China) and Africa (Tanzania). For insulin-treated Type 2 Diabetes patients, the prevalence of SMBG-practice was high (>80%) in most countries with data except the three Asian countries and possibly Tanzania (has no available data). The lowest SMBG-practice was in India (0.2%) where there is no reimbursement and the relative cost of glucose strip is the highest among the countries surveyed. (Cost strip I$; USA I$0.48-1.22; Canada I$0.36-0.77;

Argentina I$2.27-2.83; Germany I$0.44-0.78; Hungary I$0.40; Italy I$0.78-1.19; Netherlands I$0.54-1.08); Norway I$0.59; UK I$0.50-0.53; Australia I$0.35; India I$2.49-3.11; Pakistan I$1.28; China I$1.92-2.40; Tanzania I$0.55-0.67) (172).

Notably, glucose strips appears to be a major barrier for SMBG-practice with the lowest occurring in countries with the highest relative cost. Norway and United Kingdom are the only two countries that provide free glucose strips to non-insulin treated Type 2 Diabetes patients and these two countries reported the highest SMBG-practice. Suprisingly, in the remaining countries surveyed, majority of the non-insulin treated Type 2 Diabetes patients also performed SMBG. Hence, there was an unexpectedly high level of SMBG-practice among non-insulin treated Type 2 Diabetes patients worldwide suggesting that physicians and/or patients support self-monitoring.

2.4.4.6.c Monitoring Frequency and Reimbursement Policies

Monitoring frequency also varied prominently from country to country depending on the national reimbursement policy or the lack of it. Among the non-insulin treated Type 2 Diabetes patients, those in India did not monitor at all while those from Germany and Argentina monitored 14 times/week despite only partial reimbursement of test strips. Among the insulin-treated Type 2 Diabetes patients, those in India used SMBG once every 2 weeks while those in Germany and Argentina monitored 18-20 times/week (172).

SMBG reimbursement policies varied noticeably not only by country but also by region or province within countries. For example the SMBG reimbursement policies were remarkably varied based on an individuals' health insurance coverage, their health structure benefit and also financial income (172). In Norway and the UK, SMBG is free of charge with a physician's prescription. In Australia, co-payment for SMBG depends on patients' income. In China, the policy reimbursement for SMBG can either be partial, variable or none at all. In

contrast countries like Pakistan and Tanzania, there is no existing SMBG reimbursement plan for patients.

In the USA, reimbursement depends on patients' health insurance coverage with 60% getting free strips, 31% subsidised strips and 9% paying in full (172).

Comparatively in Germany, reimbursement plan varies according to region and health insurance coverage. In general, a limited number of glucose strips (100-200 every 3 months) are reimburse for insulin-treated patients and up to 600 strips for patients who are on intensive insulin therapy. In Italy and Hungary, insulin-treated patients are reimburse fully for their glucose strips and while non-insulin treated patients are reimburse partially in Italy but not in Hungary (172).

Another recent paper by International Central-Eastern European Expert Group (137), representing 10 countries with relatively limited financial resources from Central and Eastern European, highlighted the disparity in the SMBG-practice compared to other more financially affluent Western European countries. The reports from these papers (137, 170, 172) suggest the strong influences of reimbursement programme policies, health care insurance coverage and national healthcare structure in determining patients' engagement in self-care behaviour (i.e. SMBG) and physicians approach in managing diabetes (173).

2.4.4.6.d SMBG barriers and gaps

The debate on the cost-effectiveness of SMBG continues to be a concern among researchers, health care givers and providers and policy makers because SMBG requires patients or a third party (government subsidies and health insurance coverage) to purchase blood glucose meters, blood glucose strips and lancets on a continuous basis (174, 175). During a SMBG-specific conference held in Canada, the lack of qualitative studies on patients' perspective pertaining SMBG-practice was identified as important (176).

Previous qualitative research studies on patients' perspective found, although SMBG raised awareness regarding blood glucose levels (in both hyperglycaemia and hypoglycaemia episodes) and this modified patients' self-management behaviours, SMBG can also be a trigger for feelings of anxiety, guilt and self-blame. In addition, physicians' interest in patients' SMBG reading also played a key role in whether patients practice SMBG or not (177, 178).

In a qualitative paper by Gucciardi *et al*, the authors concluded that given the huge financial implications of SMBG and some negative emotional connotations that comes with SMBG-practice, it is important for healthcare providers to be sensitive or aware of patients' clinical, social and financial context, prior to engaging patients to perform SMBG especially among non-insulin treated Type 2 Diabetes (173).

Summary

The debate regarding the sustainability of SMBG practices revolves around its cost. SMBG practices varies greatly around the world depending on factors such as (i) availability of reimbursement policies for glucose strips and blood glucose meters (ii) a well-supported insurance framework system within a country for patients to fully or partially claim overall cost for SMBG. Countries with the high SMBG practices provides full or partial reimbursement policies while countries with the lowest SMBG practices does not have any of these support system available. There remains a great disparity in SMBG practices around the world, due to the high cost attached to SMBG.

2.5 Tele-health

2.5.1 What is Tele-health?

The term "tele-medicine" was coined in the 1970s and carried the meaning of "healing at a distance" (179). The World Health Organisation (WHO) included four essential elements to tele-medicine or tele-health namely to (i) provide clinical support (ii) overcome geographical

barrier and connect users from different location (iii) use of various types of information and communication technology and most importantly (iv) to improve health outcomes (180).

2.5.2 The Evidence of Tele-health in Diabetes Management

Technology such as mobile phones had been used to provide on-going diabetes self-management support and education (181-191). On-going interactions between diabetes educators and patients is a valuable tool to help patients make and maintain behaviour changes which are essential in achieving good glycaemic control and subsequently reducing diabetes complications (181).

2.5.2.1 Improvement in Clinical, Behavioural and Psychological Outcomes

Pro-actively contacting patients to provide feedback and diabetes management has been shown to improve risk reduction behaviours, including HbA1C, albuminuria and cholesterol testing (182). Telephone follow-up studies have been shown to promote behaviour change (183, 192-194), improve self-efficacy (187), coping skills and problem solving (189) and demonstrated a reduction in HbA1C (189), when patients set personal goals for their own management and become more engage in problem solving skills in order to prevail challenges which they regularly faced (188).

A systematic review by Holtz and Laukner reported self-efficacy as an outcome by 24% of studies, and all found non-significant improvement. Patients who are more engaged with their diabetes condition demonstrate higher self-efficacy in managing their illness on a daily basis through the use of mobile phones (190).

The Sweet Talk study by Franklin *et al* which was informed by "social cognitive theory" found that a text-mesaging sytem used to support young people with type 1 diabetes improved patients self-efficacy and adherence to treatment (191). A recent a large meta-analysis of 55 RCTs strongly confirmed patients served by tele-medicine programmes

showed a greater reduction of HbA1C levels compared to those received conventional diabetes management (195).

2.5.2.2 Methods of Delivery

A recent study by Greenwood *et al* compared advantageous two telehealth modality (i.e. personal telephone contact and secure messaging system: SMS) versus face-to-face consultations. Their results showed comparable outcomes among the telehealth groups which received three brief contacts compared to the group which attended the clinic appointment. However, authors suggested greater contact frequency (i.e. more than once every three months) to keep patients motivated and assist them in their behaviour change (189).

2.5.2.3 Suitable Target Groups for Telehealth

A meta-analysis study showed effects of tele-medicine programmes were more pronounced in certain target groups compared to others; (i) Type 2 Diabetes patients *versus* type 1 (ii) those above the age of 40 years old and (iii) a telemedicine program of 6 months or less. The authors speculated not all diabetes patients benefit equally from tele-medicine and targeting the right patients may be more cost effective (195). In the present study, telephone contact will be used to monitor patients' knowledge retention and SMBG.

Summary

Telehealth and diabetes management have been conducted in many countries and have shown good results in terms on clinical, psychological and behavioural outcomes. However, telehealth and diabetes management have not been done to a great extent in Malaysia. This platform is promising as an adjunct to the traditional face-to-face consultation. The literature review on telehealth have helped inform the current study regarding suitable methods of delivery and target groups which may benefit from this type of follow-up. Interestingly, none of the studies reported on diabetes knowledge level via telehealth. In the current study, I am also going to use telephone follow-up to track patients' knowledge level.

2.6 Health Behaviours in Diabetes Management

Diabetes management requires multidisciplinary approaches which include behavioural changes such as dietary and lifestyle modifications and self-care monitoring skills (e.g. SMBG) and patients must be involved with these processes in order to achieve optimal control. Previous studies have also shown providing patient with knowledge *alone* will not ensure healthy-behavioural changes (57, 196, 197). Green *et al* confirmed that although Type 2 Diabetes patients and high risk respondents for diabetes reported good attitudes and knowledge towards health, majority of them were unabled to translate these positive qualities into healthy behaviours changes such as physical activity and weight loss (198). Because of the complexity of the diabetes management, it would be prudent to be cognizant and consider the prominent theories of health behaviour which have been widely used in many health-related researches including in diabetes self-care management.

2.7 Theories of Health Behaviour

Theories of health behaviour can be classified by a range of application (i.e. general, health-specific, domain-specific, behaviour-specific) or formal structure (i.e. stage, non-stage theories) (199). General theories like Theory of Planned Behaviour (TPB) by Azjen (200) and its predecessor Theory of Reasoned Action (TRA) by Fishbein & Azjen (201) can be applied to a wide-range of behaviours, not necessarily health-related. While some models are more specific to health-related behaviours and others are more focused (i.e. domain-specific) and has narrower range of applications (199).

Over the past five decades, many health behavioural models had been developed to describe, predict and ultimately change health behaviours. Established health behaviour models such as Health Belief Model (HBM) by Rosenstock (202); Social Cognitive Theory (SCT) by Bandura (203); Transtheoretical Model (TTM) by Prochaska and DiClemente (204) and more

recently Health Action Process Approach (HAPA) by Schwarzer (205) all have their origins from the field of psychology.

Though it has been argued that a general theory like Theory of Planned Behaviour (TPB) (199) would better candidate for research on health behaviour, in this current study we have considered three health-specific models; Health Belief Model (202), Social Cognitive Theory (203) and Health Action Process Approach (205) to predict and explain health-related behaviour change.

2.7.1 Health Belief Model (HBM)

HBM was based on a socio-psychological model. This model assumes that a person (or a patient) will take a health-related action if they (i) sense that a detrimental state can be prevented (ii) expect that they can prevent a detrimental state with a positive action and (iii) believe that they can effectively execute the positive action. HBM consist of six major constructs namely (i) *perceived susceptibility* - i.e. when people perceive themselves at risk of an illness or complication (ii) *perceived severity* - i.e. when people perceive that the illness or complications is serious (iii) *perceived benefits* - i.e. when people believe they can prevent a detrimental illness with a positive action (iv) *perceived barriers* - i.e. when there are self-identified psychosocial barriers and costs to performing the behaviour (v) *cues to action* - i.e. when there is a consistent stimuli within the environment which can promote positive behaviour and (vi) *self-efficacy* - i.e. when people have the confidence in their own ability to effectively execute the positive action (202). Of note, the importance of self-confidence in successful behaviour change led to the addition of self-efficacy construct to the original Health Belief Model by Bandura (203, 206). In the current study, Health Belief Model was used in developing the diabetes education module – MY DEMO (207).

2.7.2 Social Cognitive Therapy and Self-efficacy

Self-efficacy is defined as the confidence, or lack thereof, in one's ability to perform a task or behaviour in order to accomplish a specific goal. Self-efficacy is a major construct for Bandura's Social Cognitive Theory (203) and Transtheoretical Model (TTM) (204). It has been widely measured to understand behaviour changes related to many components of diabetes self-care regimen (208-210). Over the last three decades, there has been growing evidence about the importance of self-efficacy in glycaemic control (211-213), health related quality of life (214), coping and problem solving, blood glucose monitoring, adherence in self-care, diet and exercise (215).

On the other hand, *outcome expectancies* (which is an overlapping constructs with HBM) reflects one's belief that performing a particular behaviour will result in a particular consequence. According to Bandura's SCT, both *self-efficacy* and *outcome expectancies* can influenced behaviour change, and it can be strengthened or weakened by four information sources namely (i) *performance accomplishments* – which are derived from personal prior experience (ii) *vicarious experience* – which includes seeing others doing a similar task or behaviour (i.e. role playing) (iii) *verbal persuasion* –which entails encouraging one's ability to master a behaviour change and belief that the behaviour change is beneficial and (iv) *physiological feedback* – which allows highly self-efficacious patient to view behaviour change as positive (i.e. exercise improves endorphin levels and weight loss) and those with low self-efficacy view behaviour change as negative (i.e. exercise causes pain and fatigue).

Self-efficacy is a common construct adopted by the many behaviour models including HBM and HAPA. To reiterate, self-efficacy is defined as the confidence or belief one has in their ability to perform a task or behaviour change (206). As cited by Luszcyznska and Schwarzer in their paper (216) Marlatt *et al* suggested self-efficacy can be subdivided into the different stages of behaviour such as *action* self-efficacy, *coping* self-efficacy and *recovery* self-

efficacy (217). Notably, studies have shown self-efficacy remains as an important feedback mechanism throughout both motivation and volition stages (205, 216). Patient with highly perceived self-efficacy has greater self-confidence in performing certain behaviour, tend to visualise success and are guided in their action. Self-efficacious patients are more resilient when face with difficult situations and tend to recover quicker when they are derailed from a specific behaviour. In contrast, patients with low perceived self-efficacy tends to anticipate failure and suffer from performance deficiencies and this may lead him/her to prematurely terminate his/hers specific behaviour (216, 218, 219).

2.7.3 Health Action Process Approach (HAPA)

Changing a health-related behaviour requires the initial motivation to set goal(s) and consequently a self-regulated process to ensure these goal(s) are achieved successfully. The HAPA model explicitly addresses this two-step process by considering what happens after a person has formally made the intention to change a behaviour (205, 216). Luszcyznska and Schwarzer subdivided the process of changing health behaviours into 2 phases; motivation and volition phase. In the motivation phase, patient forms an intention to adopt certain behaviour. In this earlier phase, *outcome expectancy* (balancing pros and cons of an unhealthy behaviour) and *risk perception* (fear factor of a condition e.g. complications) play a limited role in initiation of behaviour. In the volition phase, patient will consider how (s)he is going to translate his/her intention into a behaviour change (216). The execution of behaviour is enhanced by *implementation intention* strategies such as planning the "where, when, how" of a behaviour-change. This process is important as it allows necessary cognitive links between situational circumstances (the "if) and desired behaviour (the "when") (218). In their study, Sheeran and Orbell successfully used implementation intentions to increase women's attendance in a cervical cancer screening programme (219).

Summary

The Health Belief Model had been well established as a health-specific model and many diabetes-related studies (including diabetes education studies) had been used this model in the past. The HBM constructs such as (a) perceived susceptibility (b) perceived severity (c) perceived benefits (d) perceived barriers (e) cues to action (e) self-efficacy were relevant and resonated with the content of the education module developed in the current study. Hence, the HBM constructs were embedded within the education module and the Telephone contact questions. However, the HBM constructs were not measured directly - except for the two components of self-efficacy (Maintenance SE & Recovery SE).

The HAPA model guided the development of the measurement tools in the current study (i.e. Behavioural Questionnaires). The major constructs in HAPA such as (a) Outcome expectancies (b) Risk perception (c) Recovery SE (d) Maintenance SE (e) Action planning/implementation intention – were helpful in informing and unpacking the processes involved in behaviour change (i.e. SMBG).

2.8 Overall Summary

After taking into consideration the major topics covered in the literature review section (i.e. background of diabetes, prevalence of diabetes, diabetes education, diabetes self-care management, telehealth and theories of health behaviour), I was better informed regarding the scope of the diabetes problem and the overall picture of diabetes education both abroad and locally in Malaysia. From the literature review I identified existing gaps in the diabetes education field in Malaysia – both from the point of view of the lacking of content material, ad-hoc delivery of diabetes education within primary care settings and the varied practice of SMBG among type 2 diabetes patients. By being cognizant of the various education theories and applying its principles during the development of MY DEMO, have to a degree fulfilled one of the key criteria for structured education programme advocated by Diabetes UK. Also

emphasis from Diabetes Australia and supporting evidences from many of the diabetes education studies had driven home the point that glycaemic control (specifically HbA1C) should not be the most important measurement in assessing the value and effectiveness of an education programme. This common theme which was strongly discussed throughout the literature review had made me prioritize the parameters which were used to evaluate the effectiveness of the education programme. The "new generation" SMBG studies with the structured schedules and improvement in diabetes control informed me on how the SMBG schedule for the current study should be. The potential of telehealth platform also had been highlighted in the literature review and remains an untapped mode for diabetes management and education in Malaysia. Finally, the complex diabetes management which require multiple health behavioural modifications needed a holistic behavioural approach. For the current study, I had chosen the health-specific behavioural theories (i.e. Health Belief Model, Health Action Process Approach, Social Cognitive Theory) to guide me in the development of both the education module as well as the behavioural measurement tools (i.e. Behavioural Questionnaires). I found specific constructs (i.e. self-efficacy, action planning, outcome expectancies, risk perceptions) from the HAPA model were useful in developing tools to evaluate the education programme. With regards to research design, a randomised control study would have been ideal for the current study but this was not possible. Though, I am cognizant of the advantages of a randomised control study, the reason current study is a prospective non-control design is to allow as many research participants as possible to be involved in the education intervention. However, a control design for the timing of education delivery is part of the study and will be discussed further in the coming chapter. Overall, the literature review have helped me gained a better insight in the planning, development and implementation of the current study.

3.0 METHODOLOGY

3.1 Research Design

MY DARLING was a prospective intervention study which was implemented over a period of 3.5 years and was divided into three phases; developmental, recruitment and implementation. Figure 3.1 illustrates the research design and the flow of the study.

3.1.1 Justification for non-control design

As per discussion in Chapter 2, the availability of a contextualised diabetes education module in Malaysia was quite limited. Since the overarching aim of this current study was to develop a contextualised education module, it was considered important to "roll out" the intervention to all participants. Hence, the diabetes education module (MY DEMO) and Telephone Contact (TC) follow-up was offered to all participants.

A controlled-design for the timing of the SMBG delivery was established. Patients were divided into two groups before SMBG intervention started. The first group attended Module II a month after Module I and started their SMBG immediately. In contrast, the second group attended Module II six months post Module II before starting SMBG. The rationale behind this controlled-design (i.e. different SMBG timing delivery) is to assess if the timing of SMBG delivery will impact the diabetes outcomes.

3.1.2 Justification for SMBG intervention

Although all seven self-care practices recommended by AADE7 were embedded in the education module (i.e. Module I) of the current study, only SMBG component was selected for the second part of the intervention (i.e. Module II). Firstly, from the literature review in Chapter 2, it was clear that more diabetes education was needed in Malaysia. Specifically, the lack of SMBG education had been highlighted by several of the small to moderate cross-sectional studies and showed patients were not utilising their glucose management to modify their treatment (168, 169). This was supported by the poor association between SMBG

frequency and improvement of HbA1C (169). However, this is in contrast with findings of Ming et al which found SMBG frequency improve HbA1C control (66). Furthermore, while intervention studies on healthy eating (69) and physical activity (68) had been conducted in Malaysia, the SMBG studies conducted were mostly cross-sectional (168-170). For these reasons, SMBG self-care practice was selected as the intervention for this current study, in an attempt to narrow the gap between knowledge and skill of SMBG with the optimum utilisation of blood glucose results.

Due to the lengthy recruitment period, for most part of the study, the recruitment and implementation phases occurred simultaneously in the four ambulatory clinical settings. As per a "real world" setting, the interventions were implemented in a staggered manner in each clinical site depending on the completion of the recruitment process. It took 3.5 years to complete the recruitment and fulfill the required sample size. The following sections (3.2 till 3.8) and its subsections will give further explanation about each phase of the research design.

All patients were invited to attend Module I in their respective ambulatory health care settings. After attending Module I, all patients were stratified according to their socio-demographic factors (i.e. sex, age group, education level and duration of disease) and were allocated to their interventional groups (i.e. Group 1 and Group 2). As mentioned earlier, Group 1 started their SMBG a month after attending Module I while Group 2 started their SMBG 6 months after attending Module I. Figure 3.1 and Figure 3.2 illustrate the research design and flowchart for the current study. In addition, the Telephone Contact intervention was commenced a month after Module I. All patients were followed up according to the Telephone Contact schedule for 18 months.

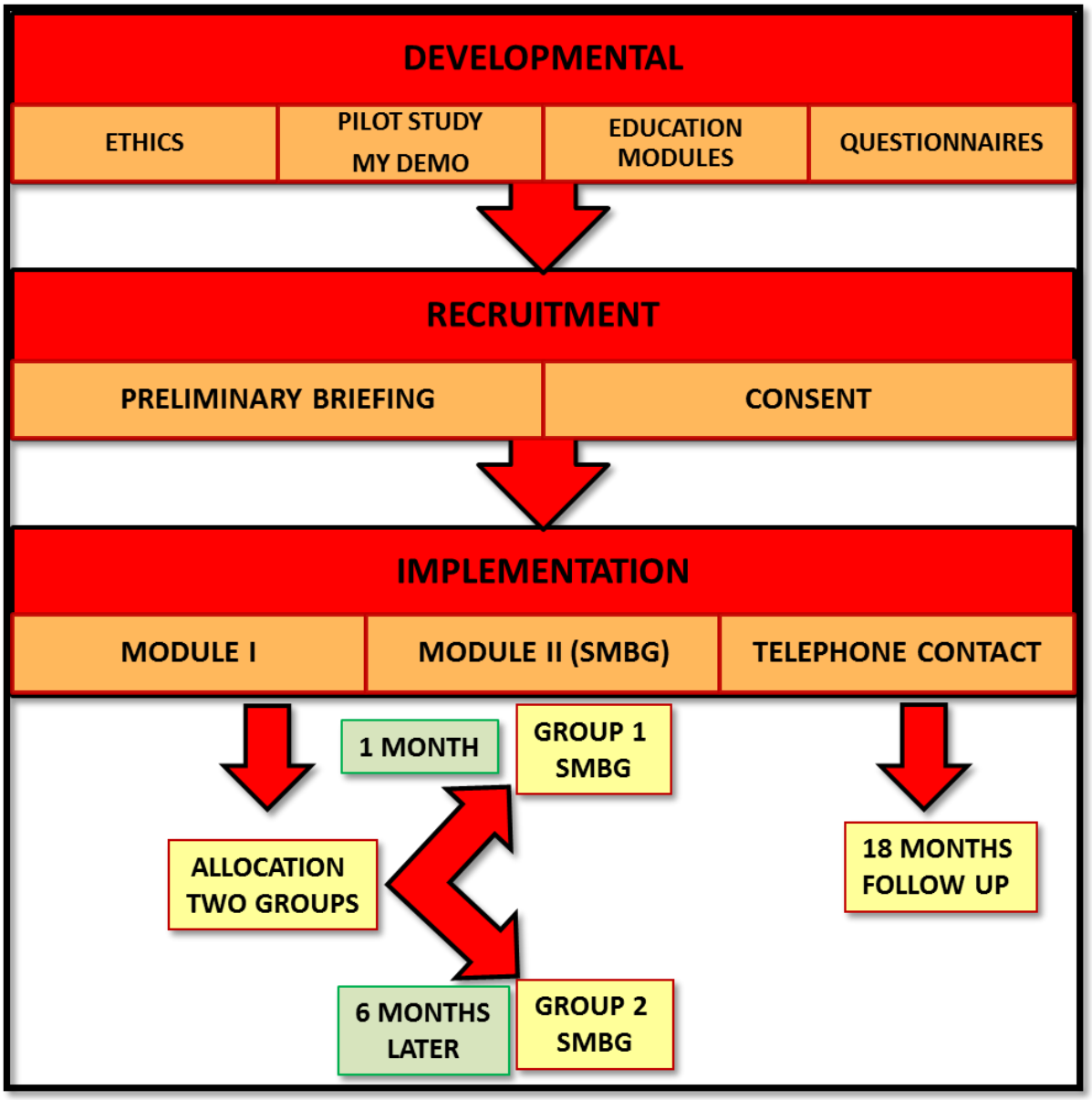


Figure 3.1 The flowchart of the research study design.

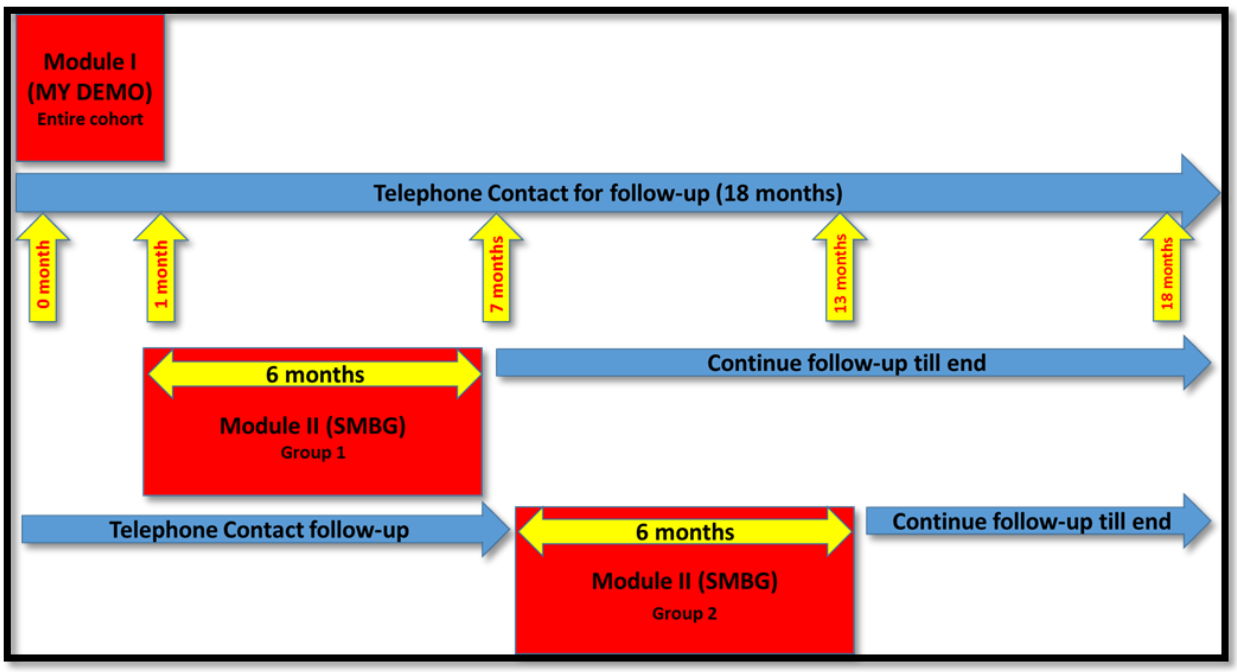


Figure 3.2 The flowchart of the research study design - Implementation

3.2 Participants

3.2.1 Sample Size Calculations

The estimated sample size of the study was guided by previous SMBG studies. Briefly several systematic reviews were appraised. This systematic review by Welschen *et al* included six randomised controlled trials of SMBG in Type 2 Diabetes patients without insulin treatment (142). The review showed the global effect of SMBG on HbA1C level was statistically and clinically significant with a reduction of greater than 0.30% of HbA1C level in treatment group when compared to control. Based on the statistical and systematic reviews, a control trial sample size was calculated (i.e. power of 80% and alpha 0.05, 2-tailed) for a reduction of HbA1C of 1.0% ± 1.08% for treatment group and reduction of HbA1C of 0.54% ± 1.4% for control group. The sample size required is 118 per group. An attrition rate of 20% was factored in, giving the total number of patients required as n=284.

3.2.2 Participants Sociodemographics

A total of N=446 Type 2 Diabetes patients (male 53.5%; n=238 and female 46.6%; n=208) were seen at the ambulatory clinics from May 2012 till December 2015 and invited to participate into the study. The percentage of patients who were invited to participate from the 4 ambulatory governmental clinical sites; KK Tanglin (Kuala Lumpur) 76.7%; KK Tampoi (Johor Bahru) 13.5%; KK Seksyen 7 (Shah Alam) 5.6%; KK Kelana Jaya (Petaling Jaya) 4.3%. There were 72.0% Malays, 23.8% Indians and 4.2% Chinese. Although the study's ethnic demographic distribution does not reflect the national ethnic demographic (220), it is representative of the higher diabetes prevalence of among the Indian ethnic group. Previous studies have also shown ethnic variety in diabetes prevalence (221, 222) with an increase of diabetes seen in the ethnic Indian group. In addition, there was a smaller proportion of Chinese ethnic group which avail the public health care sector *versus* those who attend the private health care sector which has also been reported in the national survey (223). Of the 286 Type 2 Diabetes patients which completed Module I, majority were middle-age; 40-60 years of age (64.0%) with medium term disease duration; 5-10 years (60.5%) and completed secondary level education (54.9%). 53.1% male and 46.9% female patients. Table 3.1 summarises the socio-demographics of patients which attended Module I.

Table 3.1 Patients socio-demographics.

Socio-demographics	Categories	Frequency (%) (N=286)
Gender	Male Female	152 (53.1) 134 (46.9)
Age group	Young (<40 years) Middle Age (40 – 60 years) Elderly (>60 years)	17 (5.9) 183 (64.0) 86 (30.1)
Duration of disease	Short (< 5 years) Medium (5 – 10 years)	30 (10.5) 173 (60.5) 83 (29.0)

	Long (>10 years)	
Level of education	Primary or below Secondary Tertiary	38 (13.3) 157 (54.9) 91 (31.3)

3.2.3 The Interventional Groups (Group 1 and 2)

The patients from Module I (n=286) were allocated to two well-matched groups; Group 1; 47.2% (n=135) and Group 2; 52.8% (n=151). There were no significant differences (p> 0.05) between the two groups; gender (p=0.952); level of qualification (p=0.734); duration of diabetes (p=0.948); age groups (p=0.368). Table 3.2 shows the two well-matched intervention groups.

Table 3.2 Patients socio-demographics for Group 1 and Group 2.

Socio-demographics (n=286)	Categories	Group 1 (n=135) n (%)	Group 2 (n=151) n (%)	*p* value
Gender	Male Female	72 (53.3) 63 (46.7)	80 (53.0) 71 (47.0)	0.952
Education Level	Primary and below Secondary Tertiary and above	20 (14.8) 74 (54.8) 41 (30.4)	18 (11.9) 83 (55.0) 50 (34.1)	0.734
Disease duration	Short (< 5 years) Medium(5-10 years) Long (> 10 years)	15 (11.1) 81 (60.0) 39 (28.9)	15 (9.9) 92 (60.9) 44 (29.1)	0.948
Age group	Young (< 40 years) Middle(40-60 years) Elderly (> 60 years)	8 (5.9) 81 (60.0) 46 (34.1)	9 (6.0) 102 (67.5) 40 (26.5)	0.368

3.2.4 Attrition rate

Of the 446 patients invited to participate in the study, 64.13% (n=286) attended the first intervention (Module I). The remaining 35.87% (n=160) declined to participate in the study. From the 100% (n=286) that attended the First Visit for Module I; (i) 98.25% (n=281) started Telephone Contact follow-up a month post Module I and (ii) 90.21% (n=258) attended the Second Visit and began Module II. As previously explained in Chapter 3 Section 3.1.3, all patients started Telephone Contact one month post Module I intervention. However, for Module II and SMBG intervention; the two intervention groups (Group 1 and 2) started 6 months apart, with Group 1 starting 6 months earlier than Group 2.

From those patients (n=286) who attended the Second Visit and started Module II, 11.89% (n=34) did not to attend the Final Visit despite multiple phone calls and were lost to follow-up. Consequently 69.58% (n=199) completed the Telephone Contact at 18 months and 75.52% (n=216) completed the 6 months SMBG intervention respectively.

Of the remaining 28.67% (n=82) that did not complete both Telephone Contact and SMBG intervention; 0.36% (n=1) died before SMBG completion, 1.07% (n=3) were removed from the study (1 active cancer; 1 pregnant; 1 literacy and numeracy issues), 1.40% (n=4) withdrew from the study (3 moved to other cities; 1 had needle phobia) and 25.87% (n=74) were loss to follow-up. Figure 3.3 illustrates patient attrition rates from the study.

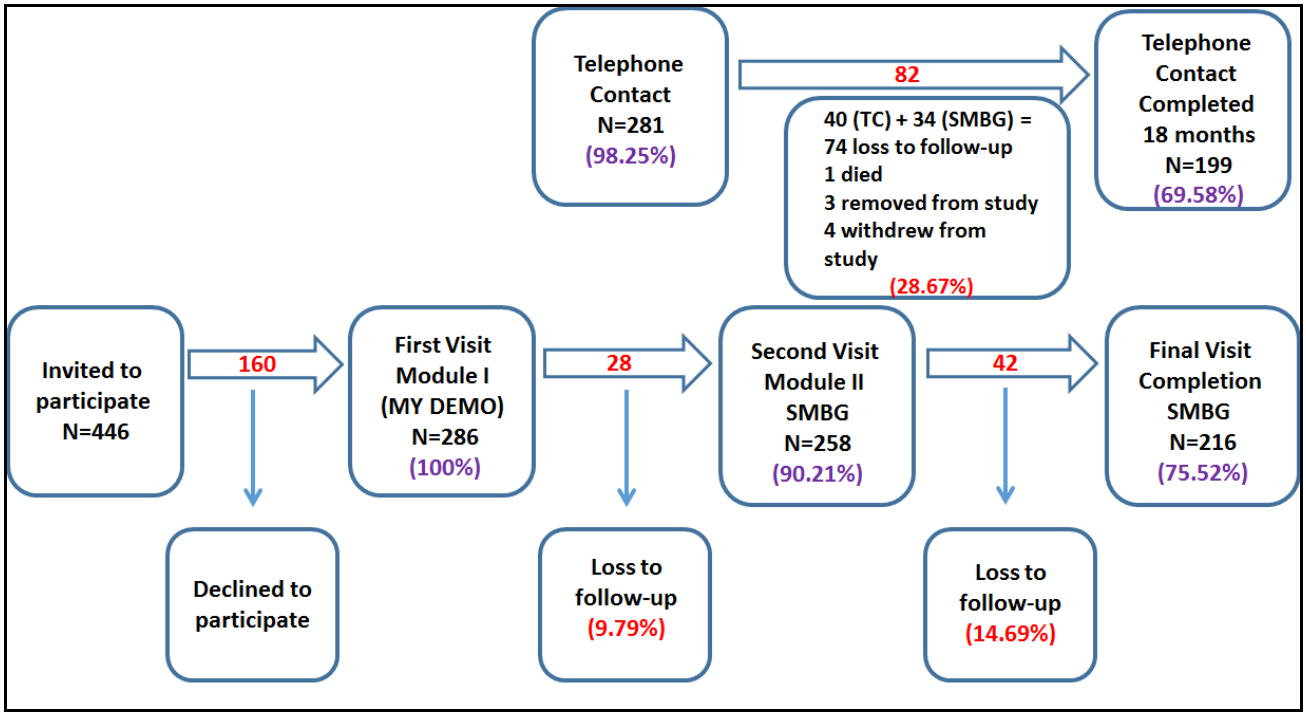


Figure 3.3 Flow chart of patients' attrition rate from the three interventions.

3.2.4.1 Causes for SMBG Non-Compliance

Of the 258 patients that attended Module II and received the blood glucose meter packages, 34 of them did not to attend the Final Visit despite multiple phone calls and were consequently lost to follow-up. For the remaining eight patients; 1 died before SMBG completion, 3 were removed from the study (1 active cancer; 1 pregnant; 1 literacy and numeracy issues) and 4 withdrew from the study (3 moved away to other cities; 1 had needle phobia). Figure 3.4 shows the causes of SMBG Non-Compliance in the study.

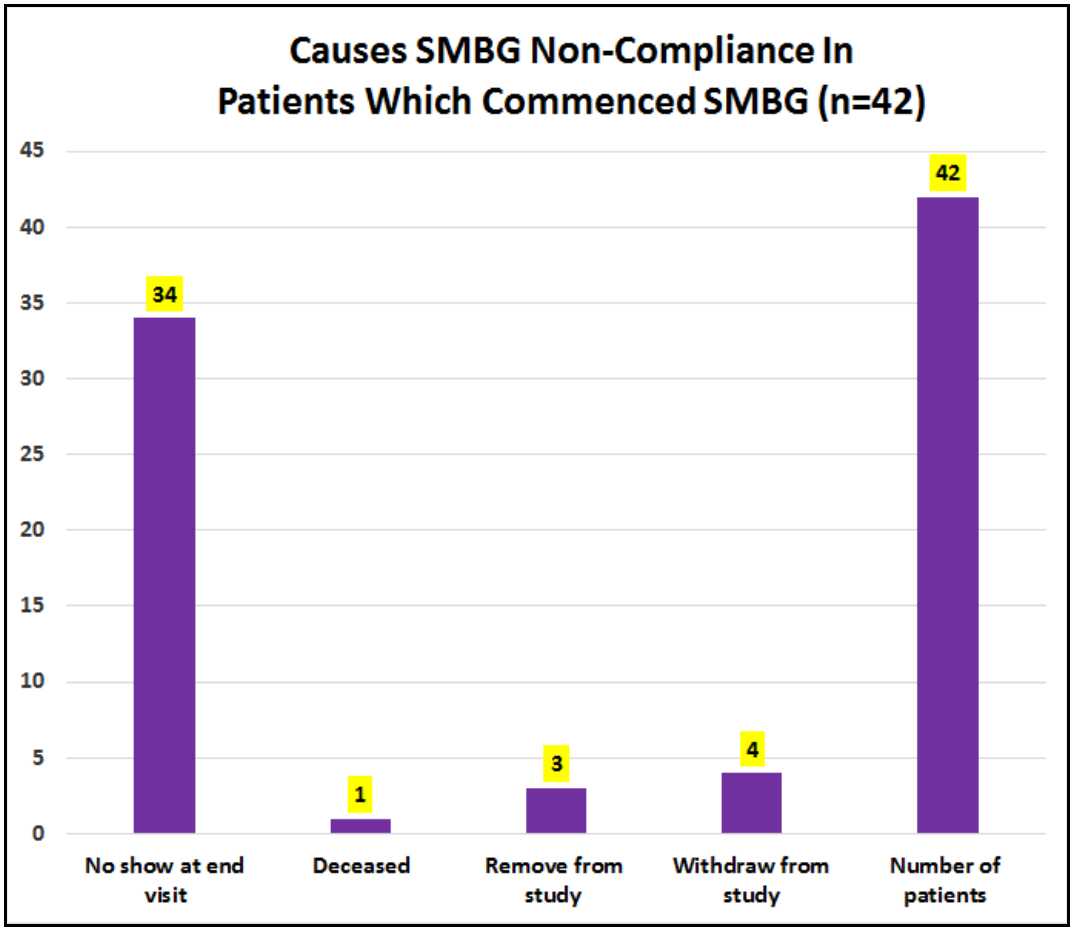


Figure 3.4 Causes for SMBG Non-Compliance among patients who commenced SMBG (Module II).

Of the 216 patients that completed SMBG intervention, 15.74% (n=34) were in the Non-Compliant category (0-29.99%) (See Figure 4.7.1). From this category, 24 patients attended end visit *without* their SMBG logbook, blood glucose meter nor any remaining glucose strips. Some of the self-reported reasons given by patients during the end visit included (i) loss or stolen blood glucose meters (n=13) (ii) house flooded (n=1) (iii) competing commitments (n=10; i.e. hospitalisation, work, travel, house chores *etc*). As there were no objective mechanisms for measuring SMBG Compliance Index, these results were reported as 0% compliance. The remaining 10 patients did not adhere to SMBG protocol and had no specific explanation(s) for their poor SMBG compliance.

3.2.5 Inclusion and Exclusion Criteria

The inclusion criteria included those Type 2 Diabetes patients; (i) with poor glycaemic control (HbA1C ≥ 8.0%) (ii) well-versed in *Bahasa* Malaysia (iii) with satisfactory literacy and numeracy skills (iv) reachable through mobile phone or house land line (v) who are SMBG-naive or inexperienced (SMBG ≤ once in 3 months). The reason why the inclusion criteria require patients to utilise their own mobile phone (or fixed landline) is because studies have opposed using an unfamiliar device or carrying an additional device. This is because it might burdened patients and lead to different patterns of usage than if they had used their own phones (190). In addition, both insulin-treated and non-insulin treated patients were included in the present study as long as they fulfilled the above inclusion criteria. Exclusion criteria included (i) women who are pregnant and (ii) those with malignancy.

3.3 Interventions

3.3.1 The Developmental Phase of Education Modules and Measurement Tools

The first part of the study involved the development of education modules (i.e. Module I and Module II) and measurement tools (i.e. Diabetes Knowledge Questionnaire, Behavioural Questionnaire and a large suite of Telephone Contact questions). In addition, a pilot study for the education module MY DEMO was also conducted during the developmental phase of MY DARLING (not shown in Figure 3.1). The detail of the pilot study have been published by Ahmad *et al* in 2014 (207). Ethics application and approval also took place during the developmental phase.

3.3.1.1 The Development of Diabetes Education Module - MY DEMO (Module I)

The development and validation of the diabetes education programme had been described earlier by Ahmad *et al* (207). Malaysian Diabetes Education Module (MY-DEMO) was the first contextualised module developed in *Bahasa* Malaysia or *Malay* language. The theoretical framework of MY DEMO was based on the Health Belief Model (HBM) (224). In

addition, key constructs from HBM were embedded within MY DEMO to enhance patient's understanding of their diabetes condition. Figure 3.5 illustrates the key components in MY DEMO.

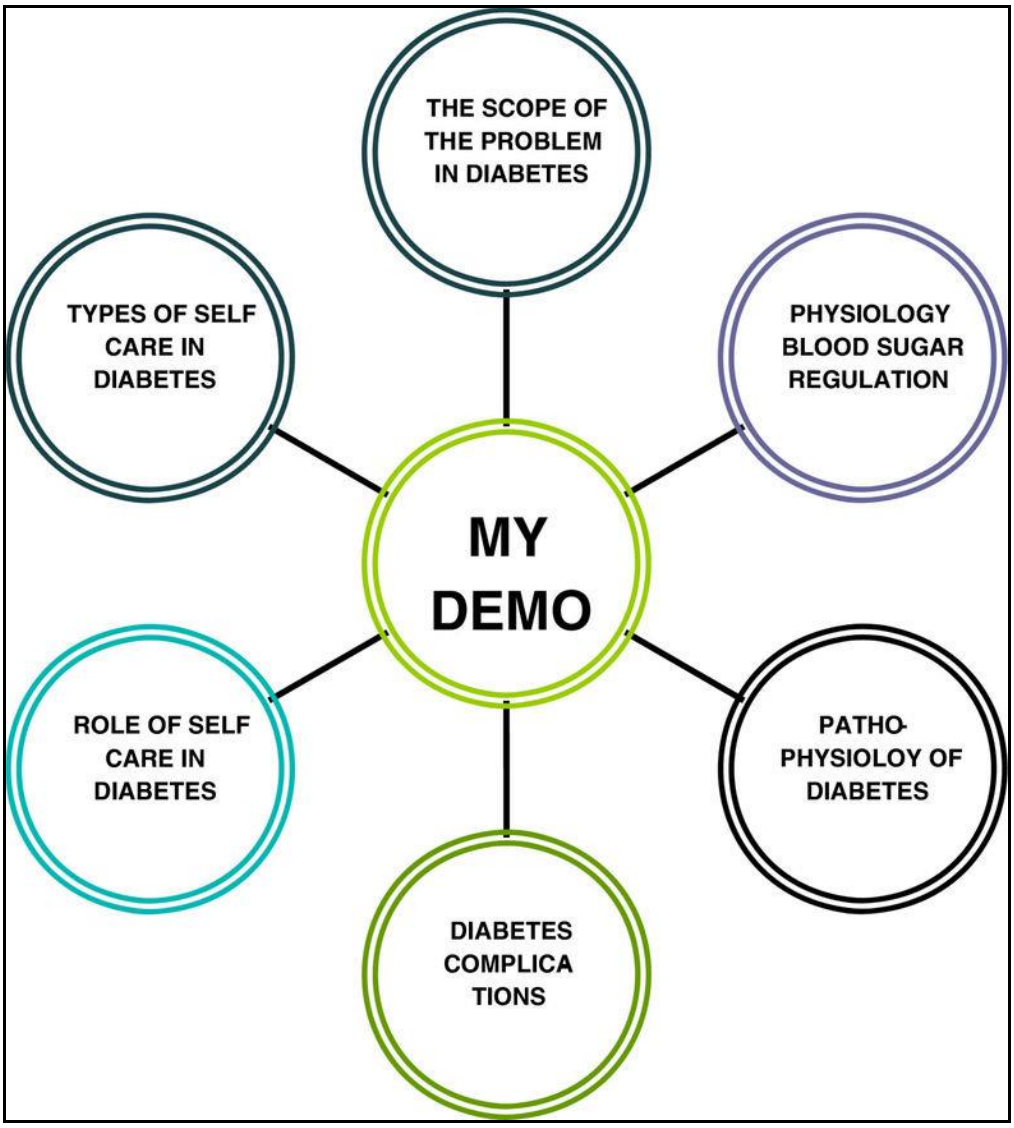


Figure 3.5 Key Components in MY DEMO (207)

3.3.1.1.a Culturally tailored components in MY DEMO development

The first key concept highlighted was the common misnomer used to describe diabetes. There was an emphasis on the term "sweet blood" (*darah manis* in Malay) rather than "sweet urine" to caution subjects that early detection of diabetes is the key to prevent diabetes

complications. The terminology “sweet urine” is a common reference for diabetes amongst the three main races in Malaysia (*kencing manis* in Malay, *innupe neer* in Tamil and *tang-niow* in Mandarin), as most people associate the diabetes condition with glycosuria and not hyperglycaemia. Other core topics such as patho-physiology of diabetes, the recognition of diabetes symptoms and signs, complications and prevention of diabetes were also emphasized using *Bahasa* Malaysia. Visual and colorful diagrams were employed to illustrate the complex and essential concepts which can lead to insulin resistance. The two figures below were used in MY DEMO to visually illustrate the core concepts of glucose metabolism (Figure 3.6) and diabetes pathophysiology (Figure 3.7) in an easy and uncomplicated manner to participants.

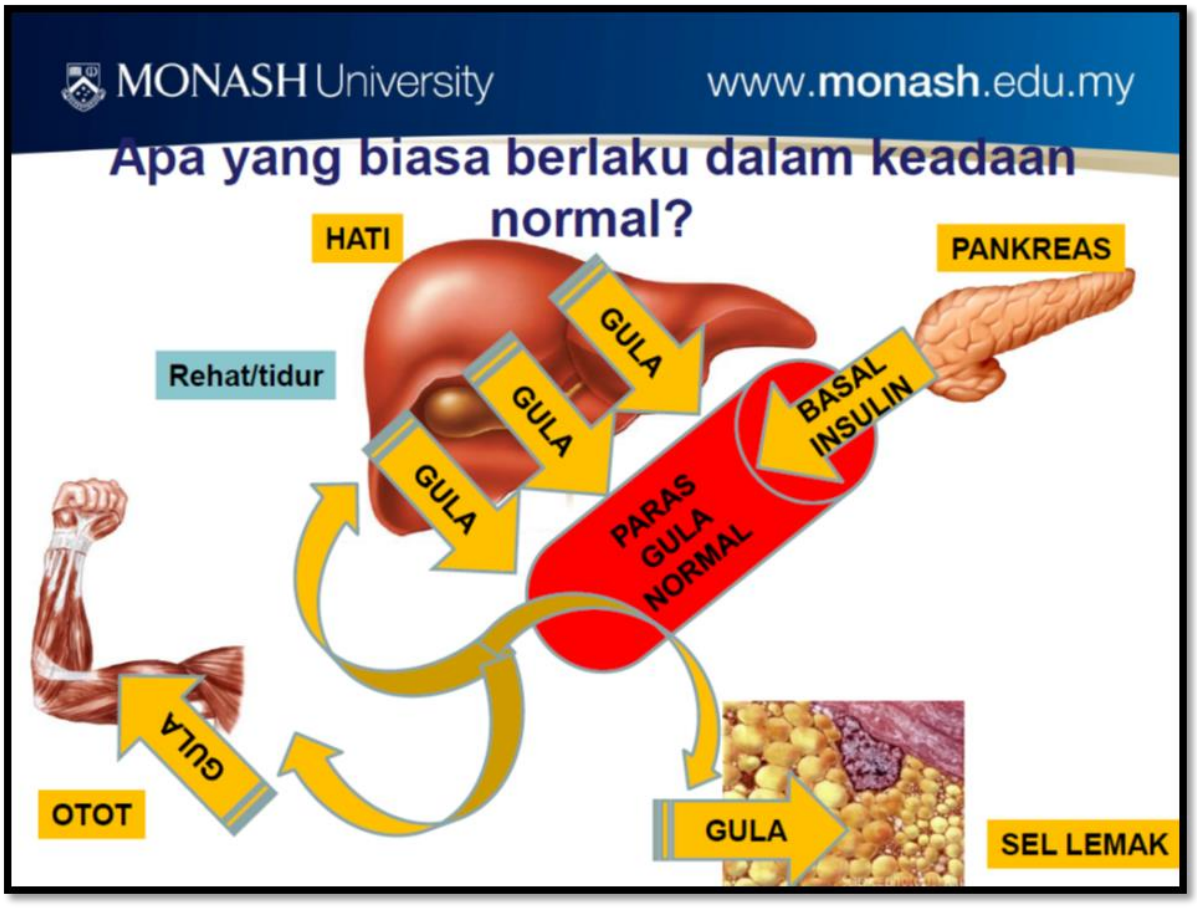


Figure 3.6 One of the educational slides in MY DEMO illustrating normal glucose metabolism (in *Bahasa* Malaysia)

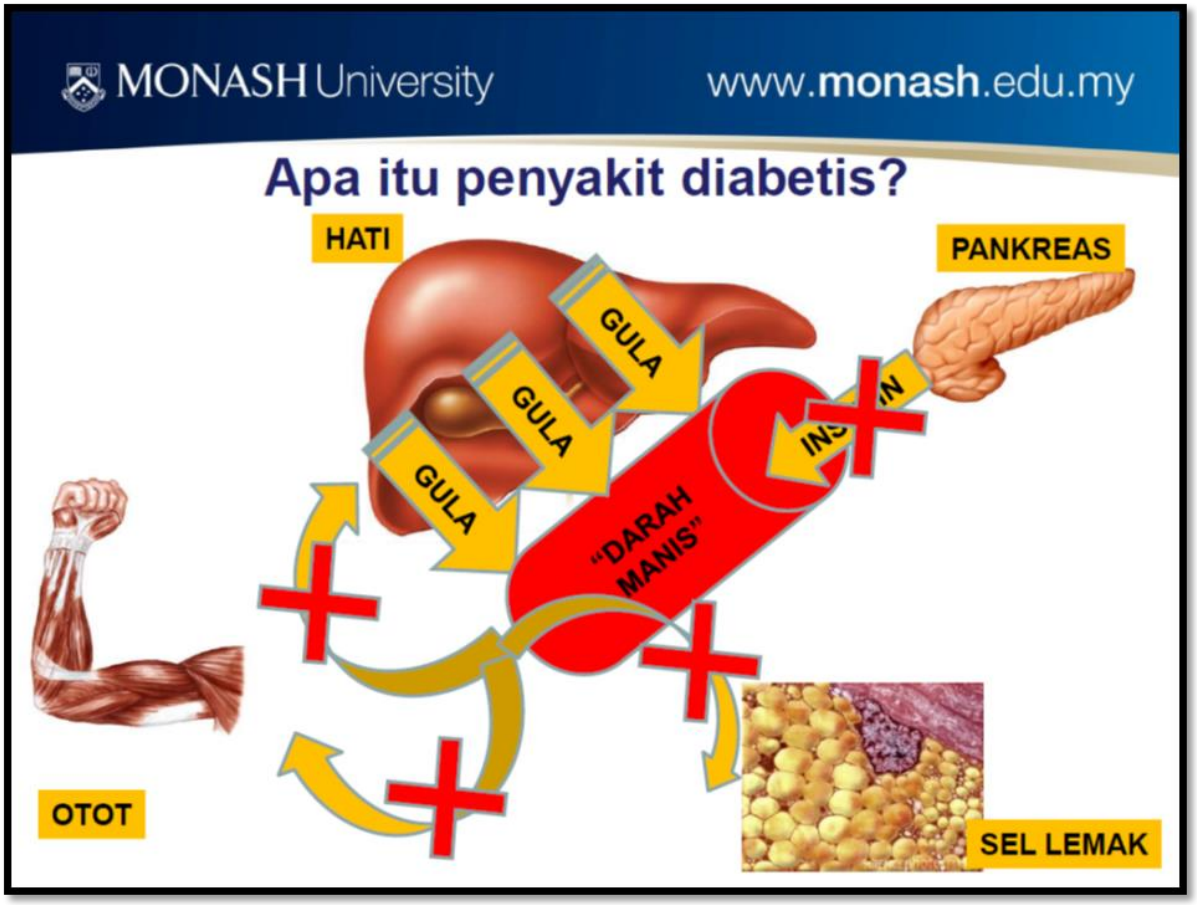


Figure 3.7 One of the educational slides in MY DEMO illustrating abnormal glucose metabolism and diabetes pathophysiology (in *Bahasa* Malaysia)

Simple analogies were used to enhance understanding of the role of insulin by explaining how the insulin "key" can open the cell "door" and help normalize blood sugar level in the body. In addition, the authors likened the "national transport system" as an equivalent to a vascular system in the body which can be damaged due to prolonged and uncontrolled hyperglycaemia. The diabetes complications such macro-vascular and micro-vascular diseases were clearly illustrated using visual aids such photographs, anatomical diagrams and animations. The HBM constructs such as perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy were embedded in the module during the development of MY DEMO.

3.3.1.1.b Different learning styles and delivery of MY DEMO

Every effort was made to ensure the diabetes content can be easily followed by participants. Some of the key elements of plain language defined by Kandula *et al* are; a) delivering important information first b) breaking complex information into understandable chunks c) using simple language and d) defining technical terms were adopted during MY DEMO delivery [34]. MY DEMO was delivered through a one-hour didactic lecture followed by another hour of dialogue session to the group participants. Different types of format were used during MY DEMO delivery to address different types of learning styles that might be employed by different participants [35-36].

3.3.1.2 The Development of SMBG Video (Module II)

The second education tool developed was a short 9.5 minutes SMBG video in *Bahasa* Malaysia and English. However, only the *Bahasa* Malaysia video was used in the study for language consistency purposes and in accordance to the inclusion criteria. The SMBG video included detail explanation of generic procedures of SMBG such as the importance of handwashing, checking the expiry date of glucose strips, selecting the site of fingerprick and changing fingerprick sites to minimise pain. In addition, specific instructions about the blood glucose meter such as the volume of blood needed, the dial for the depth of skin and the symbol of blood icon on the blood glucose meter screen were also highlighted in the SMBG video. Unlike the other blood glucose meters available in Malaysia, the blood glucose meters provided in this study did not require calibration of glucose strips, and hence reduces a procedural barrier in SMBG. The decision to make a detail SMBG video in *Bahasa* Malaysia was considered as study patients are SMBG-naive or have very little knowledge and experience in SMBG. In addition, a previous SMBG prevalence study had reported most Malaysians patients have very little knowledge and lack of counselling in all aspects of SMBG (170).

Prior to the intervention, the SMBG video was piloted to small group of diabetes patients (15 to 20) who attended KK Tanglin for their regular treatment and follow-up. The feedback received from the pilot group were generally positive and only minor changes were incorporated to the SMBG video before it was used in the intervention study.

3.3.1.3 Justification for Diabetes Knowledge Questionnaire (DKQ)

In most studies (80-85), Michigan Diabetes Knowledge Test were used to assess patients' level of knowledge at a singular point interval (i.e. cross-sectional studies) – making it a suitable assessment tool – to capture a "snapshot view" of patients' general knowledge rather than to assess patients' level of knowledge over a period of time (80-88). Although MDKT have been shown to be versatile and useful to make group comparisons its usefulness as an outcome measure for educational interventions remains to be determined (79).

In addition, other knowledge studies using contextualised MDKT were also culturally (i.e. Middle East and African region) and linguistically (i.e. Arabic, Shona and Zulu languages) unsuitable as it was used in a different study context to Malaysia (82, 84, 86).

Considering the above, and because one of the aims of the current study was to assess any change in patients' level of knowledge (i.e. increase, sustain or decay) over the period of follow-up (i.e. 18 months) it was deemed unsuitable to assess patients knowledge retention or decay using the same tool test.

3.3.1.4 Development of Diabetes Knowledge Questionnaire (DKQ) for Telephone Contact sessions

The Diabetes Knowledge Questionnaires (DKQ) was developed using a cohort of questions for the Telephone Contact sessions. During the developmental phase a total of eighty nine items were generated based on the education module (MY DEMO). These items were broadly categorised into two sections; (i) background knowledge of diabetes and (ii) self-care.

The item generation and face and content validation for DKQ was done in consultation with a panel of specialists. All DKQ items were reviewed by a 3-person panel comprising of an endocrinologist, a general practitioner and a basic scientist. Initially, each panellist reviewed the items independently and ranked each item based on a difficulty index (i.e. easy, moderate, complex). Consequently, a face-to-face discussion between the author and three panellists took place, to reach a consensus regarding the suitability of the items and the complexity index for the Telephone Contact questions. Following a consensus, 18 items (8 background; 10 self-care) were ranked easy; 42 items (25 background; 17 self-care) ranked moderate; 31 items (18 background; 13 self-care) ranked complex.

A small pilot study was then conducted to test the telephone contact questions among the general population at a local town hall centre, in the state of Selangor on two occasions. In total, 51 participants attended MY DEMO talk and completed a pre-test and post-test questions. A 30-45 minute question and answer session was conducted afterwards by the author with the participants. Queries regarding the education module and participants' feedbacks and suggestions pertaining the telephone contact questions and education module were answered and taken into consideration. Following the pilot test, further modifications were made to the telephone contact questions. Some of the questions were rephrased to make it easier to be understood when asked over a telephone.

In order to keep the Telephone Contact session concise and completed in a reasonably short period of time (i.e. 10 to 15 minutes), it was decided that six questions will be asked during each session. Of the six questions, 4 to 5 items will test patients' background knowledge of diabetes and 1 to 2 items will test patients' knowledge of self-care components. Each question had three options (i.e. a, b, c) with one correct answer. To ensure consistency between Telephone Contact sessions, some questions (i.e. same stem) were asked several

times throughout the follow-up, although the options (i.e. a, b, c) were changed to minimise any bias or memorisation.

Finally 168 items were developed and finalised for the Telephone Contact follow-up. Further details regarding the pilot study for MY DEMO and development of the Diabetes Knowledge Questionnaire (DKQ) has also been described by the author in her recent work (207). All the questions asked during Telephone Contact sessions were based on the education module content MY DEMO. The HBM constructs such as perceived benefit, perceived severity and cues to action (225) were also embedded within these Telephone Contact questions. Refer to **Appendix 7.1, 7.2, 7.3, 7.4, 7.5** and **7.6** for examples of some of the DKQ used during the telephone contact follow-up.

3.3.1.4.a The Topics and Sub-topics in DKQ for Telephone Contact

Based on the content of MY DEMO and ADA recommendations (28), a total of 168 items were generated, validated and divided to 10 major topics. Table 3.3 shows the number of questions for each theme topics and sub-topics in DKQ.

Table 3.3 The number of questions in each topic and sub-topics in DKQ used in Telephone Contact sessions.

Theme of Diabetes Questions	Number of TC Questions
(1) General topics on diabetes	46
▪ *Factors that elevate blood glucose level*	*5*
▪ *Factors that reduce blood glucose level*	*2*
▪ *Healthy food and eating*	*12*
▪ *Basic nutrient composition in food*	*3*
▪ *Active lifestyle*	*5*
▪ *Effects on insulin hormone*	*8*
▪ *Risk factors of Type 2 Diabetes*	*8*
▪ *Pancreas gland*	*3*
(2) Diabetes pathophysiology	16

(3) Diabetes symptoms	11
(4) Diabetes complications	26
(5) Prevention of diabetes complications	12
(6) Blood glucose levels	9
(7) Hypoglycaemia – definition (2) & symptoms (7)	9
(8) Self-care practices - benefits of exercise	15
(9) Self-care practices – foot-care	14
(10) Self-care practices – SMBG	10
Total number of questions	**168**
Italics show the number of questions and sub-topics from general topic of diabetes	

3.3.2 Development of Telephone Contact follow-up protocol

Table 3.4 below outlines the Telephone Contact protocol. The duration of follow-up was 18 months with the first month having the highest frequency of Telephone Contact (once a week for a month); followed by bi-monthly frequency from the second (M2) to the tenth month (M10); monthly from the eleventh (M11) to the fourteenth month (M14); once in two months for the remaining 4 months.

Table 3.4 Telephone Contact protocol.

Duration of study (18 months)	**Frequency of TC (N=28)**
First Month	4 per month
Second to Ten Month	2 per month
Eleventh to Fourteenth Month	1 per month
Sixteenth & Eighteenth Month	1 per 2 months

Table 3.5 details the denotation which will be used in Chapter 4 to report the performance score (%) of each telephone contact questions.

Table 3.5 Denotation for the Telephone Contact protocol.

Months	Denotation for each month	Denotation for each Telephone Contact	Frequency of Telephone Contact
First	M1	M1_1; M1_2; M1_3; M1_4	Four contacts per month
Second	M2	M2_1; M2_2	Two contacts per month
Third	M3	M3_1; M3_2	
Fourth	M4	M4_1;M4_2	
Fifth	M5	M5_1; M5_2	
Sixth	M6	M6_1; M6_2	
Seventh	M7	M7_1; M7_2	
Eighth	M8	M8_1; M8_2	
Ninth	M9	M9_1; M9_2	
Tenth	M10	M10_1; M10_2	
Eleventh	M11	M11_1	One contact per month
Twelfth	M12	M12_1	
Thirteen	M13	M13_1	
Fourteen	M14	M14_1	
Sixteenth	M16	M16_1	One contact per 2 months
Eighteenth	M18	M18_1	

A minimum of 28 Telephone Contacts were made to each patient, if patient was available to answer the Telephone Contact on the first attempt. More often than not, patients were not able to receive the phone calls due to other competing commitments (i.e. work-related, driving, unwell, hospitalisation, asleep, having a meal *etc*). On average, each patient received at least three telephone calls to complete answering all the six questions in one Telephone Contact session. Hence, 84 telephone calls were made to each patient during the 18 months period.

3.3.3 The Development of a Modified "Staggered SMBG" protocol

As discussed in Chapter 2, the "Staggered SMBG" protocol included monitoring pre-prandial and post-prandial blood glucose on consecutive or alternating days ("testing in pairs") is useful in charting patients' daily glucose excursions (151). For this study, the "Staggered SMBG" protocol recommended by the International Diabetes Federation (IDF) for type 2 non-insulin diabetes patients (130) was modified to suit the context, course and the available

funds for the study. Patients were scheduled to do a total of 114 blood tests in 6 months with an emphasis on 2 hours post-prandial blood tests (60.0% of SMBG were 2 hours post-prandial).

Patients were asked to record all their blood tests for 6 months into a SMBG logbook paper tool provided. Tables 3.6.1, 3.6.2 and 3.6.3 shows the "high intensity – 8 times a week", "medium intensity – 5 times a week" and "low intensity – 3 times a week" protocol respectively as per Tables 3.6.1, 3.6.2 and 3.6.3. The yellow boxes and red boxes denote fasting and post-prandial SMBG respectively.

In the recent STeP study by Polonsky, it was shown that by providing patients a simple paper tool to guide them to perform 7-point blood glucose profile helped patients to adhere to SMBG protocol (148). Hence, for this study it was decided that patients also received a paper tool to help them keep a record of their SMBG tests in a timely and systematic manner.

Table 3.6.1 Modified "Staggered SMBG" protocol in the first 6 weeks of SMBG intervention – 8 times a week (high intensity).

	Pre-breakfast	**2 hours post breakfast**	**Pre-lunch**	**2 hours Post-lunch**	**Pre-dinner**	**2 hours Post-dinner**
Monday		X				
Tuesday						
Wednesday				X		
Thursday	X					X
Friday		X				
Saturday			X			
Sunday	X	X				
Yellow box denotes fasting SMBG ***Red box denotes post-prandial SMBG***						

Table 3.6.2 Modified "Staggered SMBG" protocol in the second 6 weeks of SMBG intervention – 5 times a week (medium intensity)**.**

	Pre-breakfast	2 hours post breakfast	Pre-lunch	2 hours Post-lunch	Pre-dinner	2 hours Post-dinner
Monday	X					
Tuesday			X			
Wednesday						
Thursday		X				
Friday				X		
Saturday						X
Sunday						
Yellow box denotes fasting SMBG ***Red box denotes post-prandial SMBG***						

Table 3.6.3 Modified "Staggered SMBG" protocol in the third 6 weeks of SMBG intervention – 3 times a week (low intensity).

	Pre-breakfast	2 hours post breakfast	Pre-lunch	2 hours Post-lunch	Pre-dinner	2 hours Post-dinner
Monday		X				
Tuesday						
Wednesday	X					
Thursday						
Friday		X				
Saturday						
Sunday						
Yellow box denotes fasting SMBG ***Red box denotes post-prandial SMBG***						

The patients followed a reducing SMBG protocol over the period of six months. As patients were SMBG novices, they performed the highest number of SMBG in the first 6 weeks of the intervention (i.e. eight times per week). This gave patients the opportunity to practise their SMBG skills and increase their confidence in their own skill. A randomised study by Shiraiwa *et al* found even "occasional" post-prandial SMBG of less than 10 times per month

showed significant reduction in HbA1C levels at 4 months compared to those who did not perform any SMBG at all (156). Hence, the number of SMBG frequency of this study is supported by previous structured SMBG studies (148, 156). Table 3.7 summarises the modified "Staggered SMBG" protocol.

Table 3.7 The modified "Staggered SMBG" protocol.

Duration of SMBG (6 months)	Frequency of SMBG
1st 6 weeks	**8 times per week** 3 X before food/fasting 5 X 2-hours post-prandial
2nd 6 weeks	**5 times per week** 2 X before food/fasting 3X 2-hours post-prandial
3rd 6 weeks	**3 times per week** 1X before food/fasting 2X 2-hours post-prandial
4th 6 weeks	**3 times per week** 1X before food/fasting 2X 2-hours post-prandial

Although, there is an ongoing debate regarding post-prandial glucose (PPG) in Type 2 Diabetes (226, 227), the recent guidelines from the American Diabetes Association recommended assessment of PPG in within a window of 1-2 hours post meal (228). In addition, a growing body of evidence from clinical studies have suggested that post-prandial hyperglycaemia was associated with retinopathy, cardiovacular risk, oxidative stress, cognitive dysfunction and certain types of cancer (226, 229-231).

Although the earlier SMBG studies concerns revolved around the suitability of SMBG for insulin-naive versus insulin-established patients; the more recent arguments pivots mainly on the importance of diabetes education and comprehensive explanation to patients about corrective actions to be taken based on patients SMBG blood glucose patterns, regardless whether they are on insulin or not (167, 232). In this present study, poorly-controlled Type 2 Diabetes patients, regardless of their insulin treatment profile were included as long as they

fulfilled the other study criteria. This is because the overarching aim of the present study was to develop and assess the diabetes education module *per se*.

The recent Global Guideline for Type 2 Diabetes on SMBG issued by IDF stated that self-monitoring should *only* be considered if and when the patient (i) is prepared to learn the new skills (ii) is willing to record their sugar levels and (iii) is willing to respond appropriately to their blood glucose results (233). Benhalima *et al* concluded from their meta-analyses that one of the issues found in most of the SMBG studies was the lack of a clear rationale and justification regarding the frequency and timing in their SMBG protocols (167). Therefore, it is paramount for patients to understand the importance of the timing and frequency in order for them to be motivated to perform the SMBG. In this present study, patients had the opportunity to learn the step-by-step detail of performing SMBG through the SMBG video and recording of blood glucose pattern was facilitated by providing patients with specific SMBG protocol and SMBG logbook.

3.4 Measurements

3.4.1 Measurement for Knowledge using Diabetes Knowledge Score (DKS)

A total of 168 questions were asked to each patient during Telephone Contact follow-up. All questions were related to Module I (MY DEMO) and were broadly divided into ten recurring themes as detailed in previous Section 3.3.1.3 and Table 3.3. The Diabetes Knowledge Score (DKS) reflects the percentage of patients' knowledge at 18 months were categorized into the 5 categories. The **5 categories** of DKS were as followed; 95.0-100.0% *Excellent*; 72.0-94.9% *Very Good*; 48.0-71.9% *Good*; 24.0-47.9% *Unsatisfactory*; 0-23.9% *Poor*.

Table 3.8 Categories for Diabetes Knowledge Score (DKS)

Categories	Percentage (%)
Excellent	95.0-100.0
Very Good	72.0-94.9
Good	48.0-71.9
Unsatisfactory	24.0-47.9
Poor	0-23.9

3.4.2 Measurement for Performance Score of Telephone Contact questions

The performance score for each question reflects how well the question was being answered by all patients during the Telephone Contact follow-up. All 168 questions from the ten theme topics were analysed to measure the number of correct answers identified by all patients during each Telephone Contact session follow-up. The overall perfomance for each topic were also categorized based on the similar DKS mentioned in the previous section. In order to create some variety and minimise repetition, some of the questions were repeated every two or three months and answer options were interchanged.

To measure the percentage of performance score for each question, the number of accurate answers given by patients was divided by the number of patients which were succesully contacted per each Telephone Contact session. In other words, the number of patients accounted for is the same as the patient's retention rate in the Telephone Contact follow-up.

The overall performance score of each topics were also graded into **5 categories**; ≥ 95.0% (95.0-100.0%) *Excellent*; ≥ 72.0% (72.0-94.9%) *Very Good*; ≥ 48.0% (48.0-71.9%) *Good*; ≥ 24.0% (24.0-47.9%) *Unsatisfactory*; < 24.0% (0-23.9%) *Poor*.

Table 3.9 Categories for overall performance score for each topic

Categories	Percentage (Range)
Excellent	≥ 95.0 (95.0-100.0)
Very Good	≥ 72.0 (72.0-94.9)
Good	≥ 48.0 (48.0-71.9)
Unsatisfactory	≥ 24.0 (24.0-47.9)
Poor	< 24.0 (0-23.9)

3.4.3 Behavioural Measurement Tools - Development of Behaviour Questionnaires (BQ) - Baseline BQ, 3 month BQ, 6 month BQ

Three behavioural questionnaires were developed to measure patients' action planning and recovery and maintenance self-efficacy in SMBG. The item generation was done in consultation with two psychologists within the department. As discussed in the Chapter 2, the behavioural questionnaires embedded elements from the Health Action Process Approach (HAPA) because the HAPA model provided a good framework to distinct between the two important phases for behaviour; motivational and volitional (216, 234) which was part of the study research design.

The **baseline BQ** consisted of eight items (2 items on risk perception; 2 items on outcome expectancy; 4 items on action planning) in total and was developed to measure the motivational and volitional components of a newly adopted SMBG behaviour. Risk perception and outcome expectancy are important predictors for behavioural intention and hence important to measure during the early stages of implementation, before patients start their SMBG intervention. On the other hand, action planning or implementation intention takes into account the volitional phase. Patients were asked to make detail plan about the "how, when, where and how often" they should perform their SMBG at baseline. There is a

large body of evidence that supports action planning as a powerful predictor for health behaviour (225, 235).

The **3** and **6 month BQ** consisted of four items on action planning. In addition, the 6-month BQ also included an item on patients' maintenance self-efficacy and two items on recovery self-efficacy. Maintenance self-efficacy refers to patients' perceived capability to maintain a newly adopted behaviour in the advent of unexpected barriers such as competing engagements in patients' busy daily lives (234). Recovery self-efficacy measures patients' conviction whether they can resume the behaviour after suffering from a setback or failure (i.e. in SMBG) (234).

For all the items on the three BQs, patients were asked to answer the questions based on the 5-point Likert scale; 1- Strongly Disagree; 2 – Disagree; 3 – Unsure; 4 – Agree and 5 Strongly Agree. All three BQ were developed in *Bahasa* Malaysia and English Language. All patients completed the *Bahasa* Malaysia BQ for language consistency purposes. Table 3.2 gives details of the types of questions asked during the three time-point intervals of SMBG duration. Refer to **Appendix 8.1 and 8.2** for bilingual Baseline, **Appendix 9.1 and 9.2** for bilingual 3 months and **Appendix 10.1 and 10.2** for bilingual 6 months Behavioural Questionnaires respectively.

Table 3.10 Psychological determinants in Behavioural Questionnaires to measure motivation to change (risk perception and outcome expectancy) & self-regulatory processes (action planning, maintenance self-efficacy & recovery self-efficacy).

Timeline	Psychological determinants (number of items)	Variables measured
Baseline	Risk Perception (2) Motivational	Compared to other diabetes patients what's the chances of you:-
		▪ Having a fasting BG of < 7.0 mmol/L?
		▪ Having a 2 hours post-prandial BG of > 10.0 mmol/L?
	Outcome Expectancy (2) Motivational	▪ My wellbeing will be improved by regular SMBG
		▪ My diabetes complications will be delayed by regular SMBG
	Action Planning (4) Volitional	In the next 2 weeks, I will make detail plans about:-
		▪ How I will do my SMBG?
		▪ When I will do my SMBG?
		▪ Where I will do my SMBG?
		▪ How often I will do my SMBG?
Middle	Action Planning (4) Volitional	In the last 2 weeks, I had made detail plans about:-
		(same as above)
End	Action Planning (4) Volitional	In the last 2 weeks, I had made detail plans about:-
		(same as above)
	Maintenance Self-efficacy (1)	▪ I am certain I can continue with my SMBG even with my busy daily schedule
	Recovery Self-efficacy (2)	I am able to return to SMBG even after stopping for:-
		▪ 3 months
		▪ Over 6 months

3.4.4 Blood glucose meter and SMBG Logbook Paper Tool

Each patient received a complete FreeStyle-Optium blood glucose meter manufactured by Abbot, two boxes of FreeStyle Optium glucose strips (n=114 strips) and a SMBG logbook paper tool for the 6 months SMBG intervention. As per discussed in the earlier section in Chapter 2, by providing research patients with known facilitators (i.e. blood glucose meter and glucose strips), this would most likely effect patients' behaviour in performing SMBG in a positive manner. This should be factored in when interpreting patients' SMBG Compliance at the end of the study.

3.5 Recruitment Phase

Following the development of the modules and tools for the study, the recruitment process started in the second quarter of 2012. In total, patients were recruited from four urban government ambulatory centres (i.e. *Klinik Kesihatan* or KK – Community Clinic) located in the west coast of Peninsular Malaysia. The four ambulatory centres were in Kuala Lumpur (1 KK), Selangor (2 KK) and Johor Bahru (1 KK). These four clinics are urban catchment area for Type 2 Diabetes patients along the west coast of Peninsular Malaysia. Figure 3.8 below displays the four clinical study sites.

Figure 3.8 The four clinical sites located on the West Coast of Peninsular Malaysia.

3.5.1 Recruitment Process

The recruitment process was done by convenience sampling at the four clinical sites. Patients were stratified randomly according to their age group, duration of disease and level of education. Initially patients were recruited from "one-stop diabetes centres" in two of the ambulatory clinical sites (KK Tanglin and KK Tampoi). The primary care nurses were briefed pertaining the aim of the study and the inclusion and exclusion criteria. Consequently, the primary care nurses approached many of the walk-in patients who were eligible and fulfilled the inclusion criteria. The primary care nurses then briefly explained to potential patients about the study. The patients who agreed to join the study, were given the explanatory statements (**Appendix 5**) and signed the consent form (**Appendix 6**).

In total 446 patients were invited to attend Module I. However, the initial response from patients from the two clinical sites (i.e. KK Tanglin and KK Tampoi) was poor. 36% of patients declined to attend the first part of the education module. The poor attendance in diabetes education programme had been reported elsewhere too (236, 237).

3.5.2 Modifications Process

Consequently, some modifications were done to address and improve patients' participation. Firstly, two additional clinical sites were added to the original two sites to facilitate recruitment measures. The two additional clinic sites were KK Shah Alam and KK Kelana Jaya both located in Selangor. As mentioned in the Ethics Approval Section (3.2), an extension for ethics was requested for the additional two clinical sites.

Secondly, multiple face-to-face (19) briefing sessions (from November 2013 till June 2015) were provided at the 3 clinical sites. Albeit this extra step was resource-intensive, the retention rate of patients recruited post face-to-face briefing sessions improved. Figure 3.9 shows the retention rate of 57.19% (2012) increases to 81.25% in 2013 and 2014. Recruitment continued till December 2015 with an extra briefing step until the number of patients who attended Module I reached the required sample size (n=286).

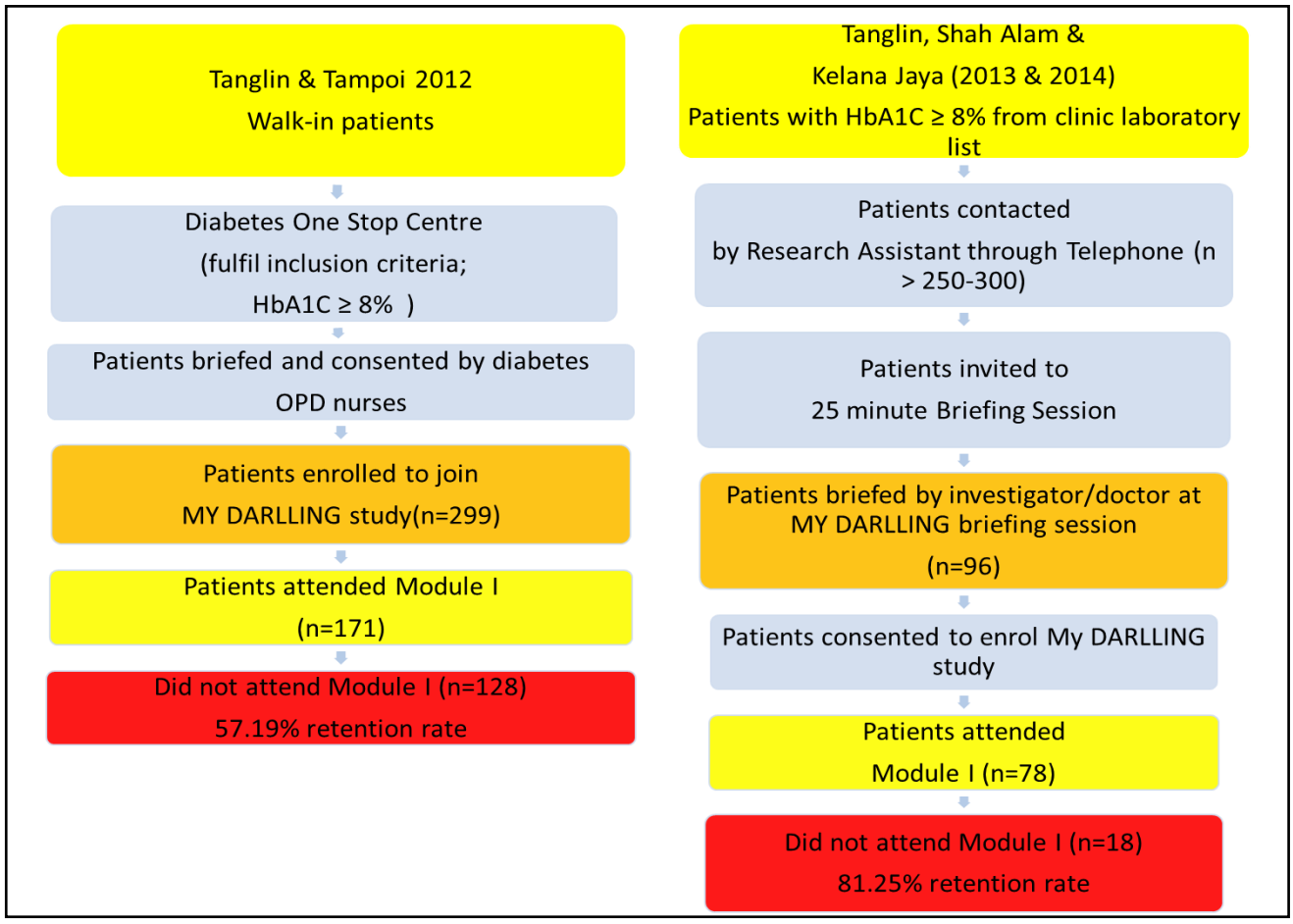


Figure 3.9 Comparison between the two recruitment processes in MY DARLING study and the differences in the percentage of retention rate.

3.6 Implementation of Study Interventions – First Visit

3.6.1 Anthropometry measurements

Anthropometry measurements such as weight, height, waist circumference (WC) and body mass index (BMI) and blood pressure were measured at the first visit. Patients were in light clothing and barefooted when measurements were taken. Patients' weight were measured using digital weighing scale and height was measured using a portable body meter. The height and weight of patients were used to calculate the BMI. The WC was measured using non-elastic tape measure. Blood pressure was measured using automatic blood pressure monitor. The most recent (≤ 3 months) HbA1C result of patients' were obtained from their medical record. Socio-demographic details such as age, sex, ethnicity, level of education and duration of disease were also recorded.

3.6.2 Diabetes Education Intervention Session (MY DEMO) – Module I

Patients attended the diabetes education module for 60 minutes. The succinct session presented in *Bahasa* Malaysia was adapted to the needs and understanding of patients and also, the availability of physical space and time in a typically busy primary care setting. In addition, all the sessions (n=23) throughout the 3.5 years were delivered by the author to minimise any variations in the education module and considered as high fidelity education programme. The X-PERT study in the UK was similarly delivered by a single educator to established Type 2 Diabetes patients (17).

3.6.3 One month after First Visit - Telephone Contact Follow-Up

A month after Module I intervention, each patient was contacted on the telephone and the Telephone Contact intervention was commenced and continued for 18 months. Patients were questioned on many aspects they had learned from the diabetes module (Module I). Each Telephone Contact session took 15 minutes to complete. Patients were asked six multiple choice questions with the three options (i.e. a, b, c). Patients were encouraged to answer all the six multiple choice questions. Feedback was given at the end of Telephone Contact and any incorrect responses were explained to patients at the end of the Telephone Contact. To avoid any bias or memorization on the part of the patient, a twenty percent variability was made for different set of Telephone Contact questions. In total, each patient had to answer 168 questions and received a minimum of 28 telephone call sessions for 18 months.

3.7 Implementation of Study Interventions - Second Visit

3.7.1 SMBG Video – Module II

During the second visit, patients watched a 9.5 minute video on SMBG. At the end of the video, patients were asked to evaluate the clarity of the SMBG video. This evaluation exercise was to address any gaps patients might have about the actual process of doing SMBG or queries about the blood glucose meter device and the other tools.

3.7.2 Behavioural Questionnaires - Baseline and at 3 months

3.7.2.a Baseline

At the second visit, patients reflected why they are starting to perform SMBG, and carefully considered the steps they need to take while embarking the new task. At the end of the SMBG video, patients completed a baseline questionnaire on behaviour measurements. The behavioural component measurements were on (i) risk perception (ii) outcome expectancy (iii) implementation intention (iii) maintenance and recovery self-efficacy (234). Patients graded the questions based on a 5-point Likert scale; 1- Strongly Disagree; 2 – Disagree; 3 – Unsure; 4 – Agree and 5 Strongly Agree.

3.7.2.b At 3 months

Mid-point through the SMBG intervention (i.e. at 3 months), patients were contacted through Telephone Contact and were asked regarding their action planning for SMBG. The rationale for a mid-point assessment for action planning was to gauge how patient was doing with their SMBG. Patients who were having small issues with the SMBG intervention were identified at mid-point and counselled through the telephone. Patients with complex problems (i.e. faulty machine, loss of logbook etc) were advised to return to the clinics so their issues can be resolved quickly and efficiently.

3.7.3 Blood glucose meter and SMBG Logbook

The blood glucose meter packages were distributed to all patients once patients had completed watching the 9.5 minute SMBG video, listened to the SMBG protocol briefing and finished the baseline Behavioural Questionnaires. All the items in the blood glucose meter package including the 114 glucose strips were counter-checked by patients and the author. Patients received a written instruction regarding the SMBG schedule and a simple logbook as a tool to record their blood glucose levels. The simple tool of a structured SMBG scheduling was also used by other studies for a successful SMBG intervention (158, 167).

3.8 Implementation - Final Visit

3.8.1 Blood test – End HbA1C

Patients returned to their respective ambulatory health care clinics for the final HbA1C blood test. The point-of care (POC) device Afinion AS100 analyser was used to measure the final HbA1C. Previous studies have confirmed POC device Afinion have met the generally accepted performance criteria for HbA1C with the Coefficient Variation (CV) of < 3.0% (238-240). A small amount (> 0.5ml) of capillary blood was drawn from patient's finger and the results were available almost immediately (three minutes). Patients were informed about their HbA1C results and were given the appropriate advice and referred to the appropriate health care givers.

3.8.2 Behavioural Questionnaires - Final at 6 months

Patients completed the 6-month Behavioural Questionnaires which assessed their (i) action planning (ii) maintenance self-efficacy and (iii) recovery self-efficacy. Similarly, patients were asked to grade their response based on a Likert scale from 1 to 5 (1- Strongly Disagree; 2 – Disagree; 3 – Unsure; 4 – Agree and 5 Strongly Agree).

3.8.3 SMBG Logbook Submission

Patients submitted the SMBG logbook during the final visit (i.e. frequency of SMBG, fasting and post-prandial blood glucose). Patients brought any remainder glucose strip(s) so it can be accounted for. The number of remaining glucose strips were deducted from the number of SMBG frequency reported in the logbook, and the remaining strips were returned to patients for their future use provided the strips have not expired. A Compliance Index was measured by dividing the number of times patients perfomed SMBG (i.e. recorded in the SMBG logbook) with the total number of glucose strips given (i.e. n=114).

3.9 Statistical Analysis

Mean and standard deviation were calculated for continuous variables. Frequency tables were constructed for categorical variables. The paired t-test was used to determine the mean difference

for the primary outcome HbA1C. The independent paired t-test was used to determine the mean difference of the primary outcome HbA1C for the two interventional groups. The Pearson Chi-squared test was used to determine any association between the two groups and the SMBG Compliance Index. Pearson correlation test was employed to determine the association between SMBG frequency with; (i) total action planning (ii) maintenance self-efficacy (iii) recovery self-efficacy (iv) motivational constructs (i.e. risk perception and outcome expectancy). The interpretation of magnitudes for correlation coefficients (r) of psychological determinants above was informed by Hemphill (241) where $r<0.20$ is small, $0.20<r<0.30$ is moderate and $r>0.30$ is large. Based on meta-analytic review conducted by previous studies (241) fewer than 3% fulfilled the conventional benchmark of $r =0.50$ for a large effect size set by Cohen (242).

In order to determine which factor(s) contributed to the improvement of diabetes control, multiple linear regression test was used. The data analysis was performed using IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. $p<0.05$ was taken as the level of significance.

Multilevel modelling (MLM) was used and analysis was conducted in R to assess knowledge decay with time. Briefly (i) A *"NULL" model* with a person random effect was developed (Model 0) (ii) *Model 0* with the addition of a time (week) fixed effect (Model 1) (iii) *Model 1* with the addition of a time (week) random effect (*Model 2*) (iv) Consequently an ANOVA was used to test the difference between Model 0 and Model 1, and Model 1 and Model 2. The full model was developed with a person random-effect; week (TC duration), gender, qualification, duration of disease and age group were used as fixed-effects. The MLM analysis was performed using R Version 3.2.4. R Core Team (2016). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. $p<0.05$ was taken as the level of significance.

3.10 Ethics Approval

The study received ethics approval from Malaysian Ethics Research Committee (NMRR-10-1131-7882) **(Appendix 1)** and Monash University Human Research Ethics Committee (MUHREC) (CF12/0365-2012-000-157) **(Appendix 2)**. The study commenced in second quarter of 2012 after the ethics approval was obtained. An extension of ethics application was submitted in first quarter of 2013 to increase the number of clinical sites from two (KK Tanglin, Kuala Lumpur and KK Tampoi, Johor Bahru) to four (KK Shah Alam and KK Kelana Jaya) in Selangor **(Appendix 3)** to facilitate recruitment process.

3.11 Research Funding

MY DARLING study received external funding from the Ministry of Higher Education (MOHE), Malaysia. The total amount received from the Exploratory Research Grant Scheme (ERGS) was MYR158,700 over a period of three years. Project number: ERGS/1/2011/SKK/MUSM/02/2 and account number: 2500062-000-00. The funding scheme was from the 10th Malaysian Plan Programme in Research and Education. **(Appendix 4)**

4.0 RESULTS

4.1 Glycaemic Control

Out the 286 Type 2 Diabetes patients which joined Module I, 75.52% (n=216) patients attended and completed both Module I and II (Refer to Figure 4.1). These patients attended the end visit and had their HbA1C measured. The HbA1C results taken at beginning (*beg*) and end *(end)* of the study showed a significant reduction of greater than 1% for the entire cohort.

4.1.1 Reduction of Mean HbA1C

The paired t-test for the entire cohort (n=216) showed mean HbA1C was reduced by 1.24% from 10.06% ± 1.44 *(beg)* to 8.82% ± 1.81 *(end)* and HbA1C reduction is both clinically and statistically significant (p=0.0001). The paired t-test for both groups showed similar significant reduction of HbA1C values greater than 1.0% (p=0.0001). HbA1C reduction for Group 1 from 10.16% ± 1.44 *(beg)* to 8.82 ± 1.74 *(end)* and Group 2 from 9.98% ± 1.44 *(beg*) to 8.83 ± 1.90 *(end)*. Table 4.1 compares the mean HbA1C (%) and HbA1C (%) reduction for the entire cohort and both groups.

Table 4.1 Mean HbA1C Difference and HbA1C reduction for the entire cohort, group 1 and group 2.

Glycaemic Control	Beg Mean HbA1C (%) (± Std Dev)	End Mean HbA1C (%) (± Std Dev)	Reduction HbA1C (%) (± Std Dev)	Significance (p value)
Both Cohorts (n=216)	10.06 % ± 1.44	8.82 % ± 1.81	1.24 % ± 2.03	0.0001
Group 1 (n=103)	10.16 % ± 1.44	8.82 % ± 1.74	1.34 % ± 1.98	0.0001
Group 2 (n=113)	9.98% ± 1.44	8.83 % ± 1.90	1.14 % ± 2.07	0.0001

4.1.2 Comparison of HbA1C Reduction in Group 1 and Group 2

Independent t-test showed no significant difference in the HbA1C % reduction between Group 1 and Group 2 (p=0.486). Table 4.2 compares the HbA1C (%) reduction between both groups.

Table 4.2 Comparison between HbA1C (%) reduction in Group 1 and 2.

Glycaemic Control	Group 1 (n=103)	Group 2 (n=113)	Significance (*p* value)
Reduction HbA1C (%) (± Std Dev)	1.34 % ± 1.98	1.14 % ± 2.07	0.486

4.2 Telephone Contact follow-up – Patients' Retention Rate

From the 286 patients whom completed Module I; 1 patient died and 4 others were not contactable post Module I. A total of 281 (98.25%) patients started the 18 months Telephone Contact follow-up as per the Telephone Contact protocol explained in **Section XX**. Figure 4.1 illustrates the reducing trend of retention rate over the period of the 18 months and give details about the total number of patients and the percentage of patients from the first contact in month 1 (M1_1) till the last contact in month 18 (M18_1); Month 1 (281; 98.3%); Month 2 (272; 95.1%): Month 3 (262; 91.2%); Month 4 (259; 90.6%); Month 5 (255; 89.2%); Month 6 (250; 87.4%); Month 7 (214; 74.8%); Month 8 (220; 76.9%); Month 9 (219; 76.6%); Month 10 (216; 75.5%); Months 11 and 12 (209; 73.1%); Month 13 (202; 70.6%); Month 14 (201; 70.3%); Months 16 and 18 (199; 69.6%). At 18 months, 199/286 patients or 69.6% completed the Telephone Contact follow-up.

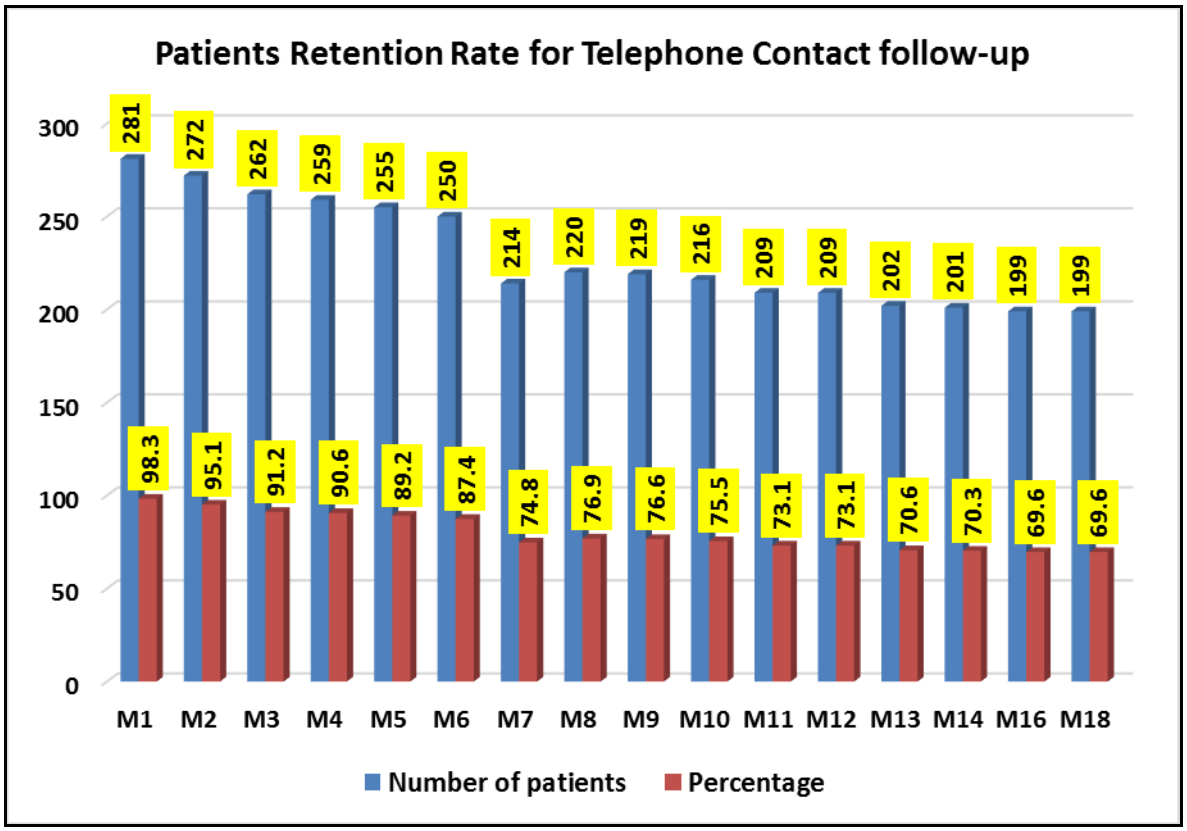


Figure 4.1 Percentage of retention rate among patients during 18 months Telephone Contact follow-up.

4.3 Knowledge - Diabetes Knowledge Score (DKS) at 18 months

The number questions asked during the Telephone Contact follow-up was 168. The maximum and minimum DKS were 167/168 and 44/168 respectively. The mean, median and mode DKS were 139.8, 148.0, 154.0 (achieved by 15 patients) respectively. The DKS were graded into **5 categories (percentage range)**; 95.0-100.0% *Excellent*; 72.0-94.9% *Very Good*; 48.0-71.9% *Good*; 24.0-47.9% *Unsatisfactory*; 0-23.9% *Poor*. Of the 216 patients; 2.8% (n=6) scored Excellent; 83.8% (n=181) scored Very Good; 8.3% (n=18) scored Good; 5.1% (n=11) scored Unsatisfactory; none (n=0) scored Poor. Figure 4.2 illustrates patients' Diabetes Knowledge Score (DKS) at 18 months.

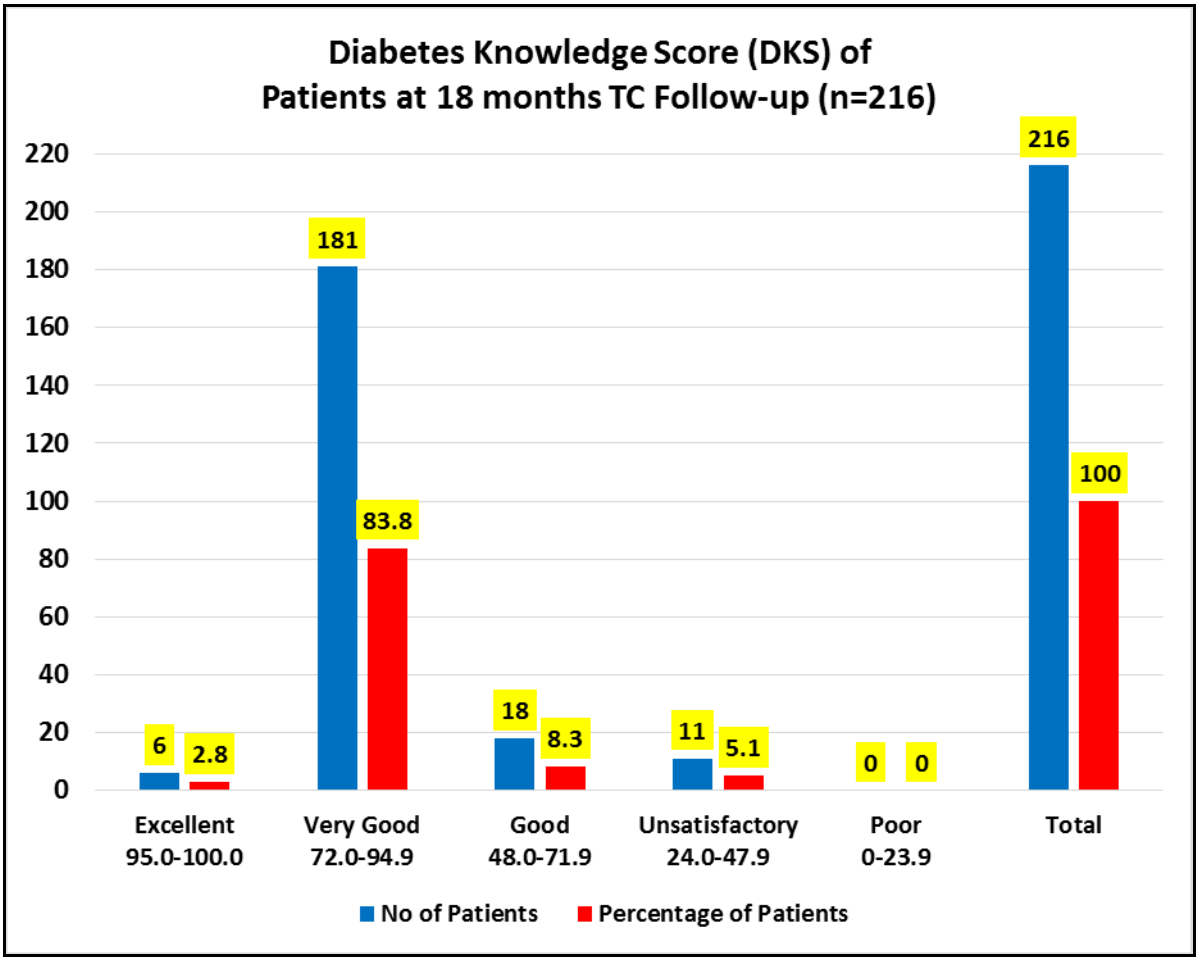


Figure 4.2 Diabetes Knowledge Score (DKS) of patients at 18 months of Telephone Contact follow-up.

4.3.1 Knowledge retention pattern

Multilevel modelling (MLM) was used and analysis was conducted in R to assess if there were any change in patients' knowledge level. The full model was developed with person as random-effect while week (Telephone Contact duration), gender, qualification, duration of disease and age group were used as fixed-effects. The results showed the average knowledge achieved by patients at each Telephone Contact session remained consistent and high (≥85.0%) throughout the entire study. There was no reduction in patients' average knowledge score over the course of the study. Figure 4.4 shows the knowledge retention over 18 months follow-up.

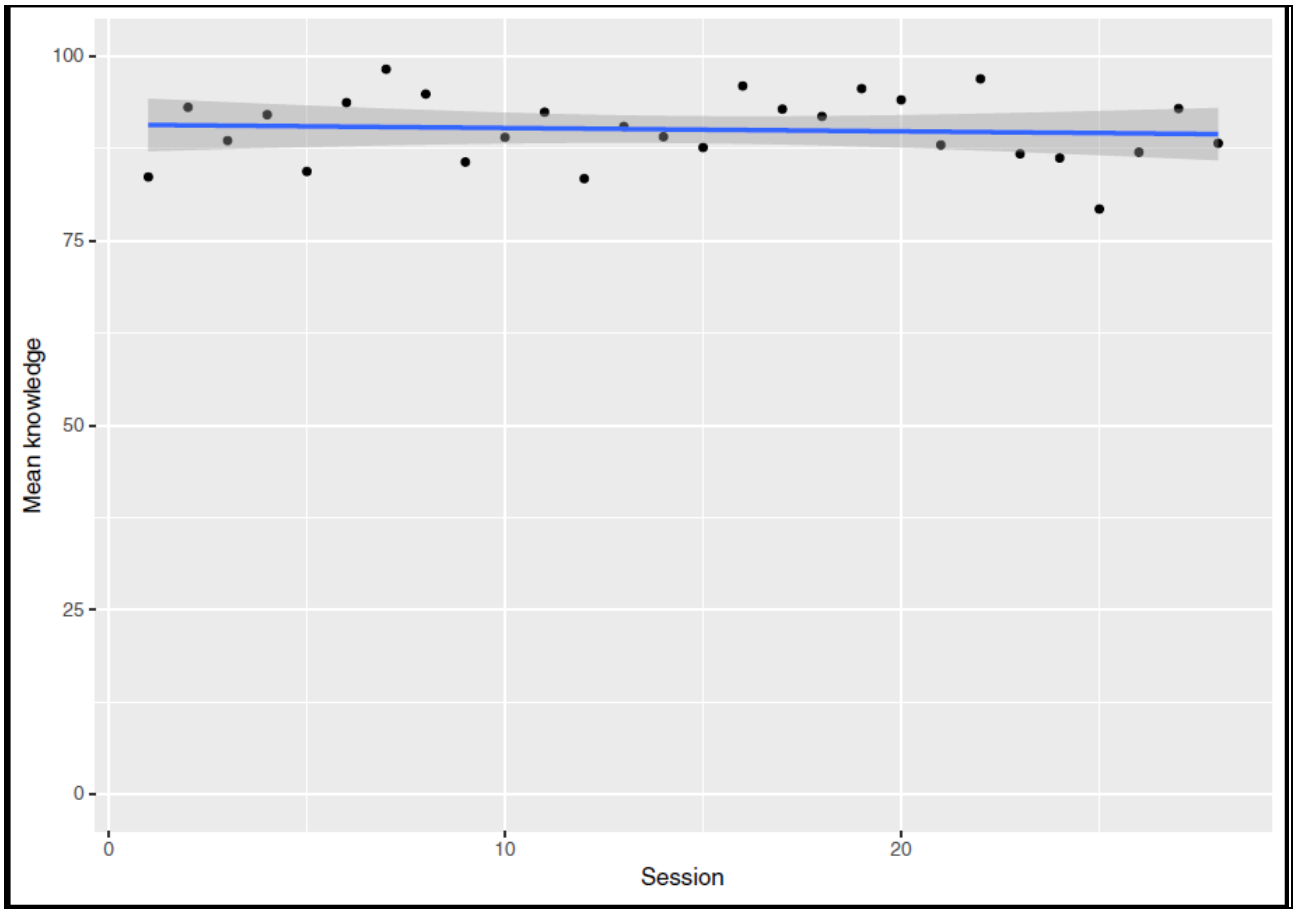


Figure 4.3 Modelling of knowledge retention of patients during 18 months Telephone Contact follow-up.

4.3.3.1 Education level and disease duration effects on knowledge score

The results also showed education and disease duration effects on patients' knowledge scores. Specifically, after controlling for other predictors, knowledge declined steadily and significantly over time. Table 4.3 highlights the effects of education and disease duration on knowledge scores. *Higher education* was associated with significantly greater knowledge scores. For instance, there was a 0.5 point and 0.7 point increase with secondary education and tertiary education respectively. In addition, the *longer the patient had diabetes*, the better their knowledge about the disease. Patients with medium duration diabetes had 0.15 point improvement compared to those with long term disease had 0.24 point improvement. Of note, there were no significant effects of gender and age group on patients' knowledge scores observed from the analysis.

Table 4.3 Education level and duration of disease effects on knowledge score.

Effects	Value	Std Error	t value	p value
Week	-0.0014	0.0005	-2.7597	0.0058*
Secondary Qualification	0.4764	0.05949	8.0081	0.0001*
Tertiary Qualification	0.6804	0.06371	10.6794	p<0.0001*
Gender (Female)	0.0188	0.0397	0.4733	0.6364
Medium Disease Duration	0.1532	0.0667	2.2975	0.0224*
Long Disease Duration	0.2415	0.0723	3.3399	0.0010*
Age Group Middle	0.0656	0.0851	0.7713	0.4412
Age Group Old	-0.0764	0.0896	-0.8527	0.3946
p<0.05(significant)*				

4.4 The performance score of each theme topics from the Telephone Contact questions

The performance score for each question reflected how well the question was answered by all patients during the Telephone Contact follow-up. The following ten figures (4.4.1 – 4.4.10) illustrates the individual performance score (percentage) of each questions from each theme topics. The summary for all performance scores topics are will be highlighted in following Section 4.4.11 and Table 4.14.

4.4.1 General topics of diabetes

A total of 46 general topics of diabetes questions were asked in the Telephone Contact sessions. This topic had the largest number of questions (46/168 questions). There were also eight sub-topics within the general topic of diabetes namely as highlighted in **Section 3.3.1.3.1 Table 3.3**. The mean performance score for this topic was 95.1%, with minimum score 85.4% and maximum score 100.0% respectively. The overall performance for this topic was excellent, with a mean score of ≥

95.0%. Figure 4.4.1 below illustrates the individual performance score for each question from this topic.

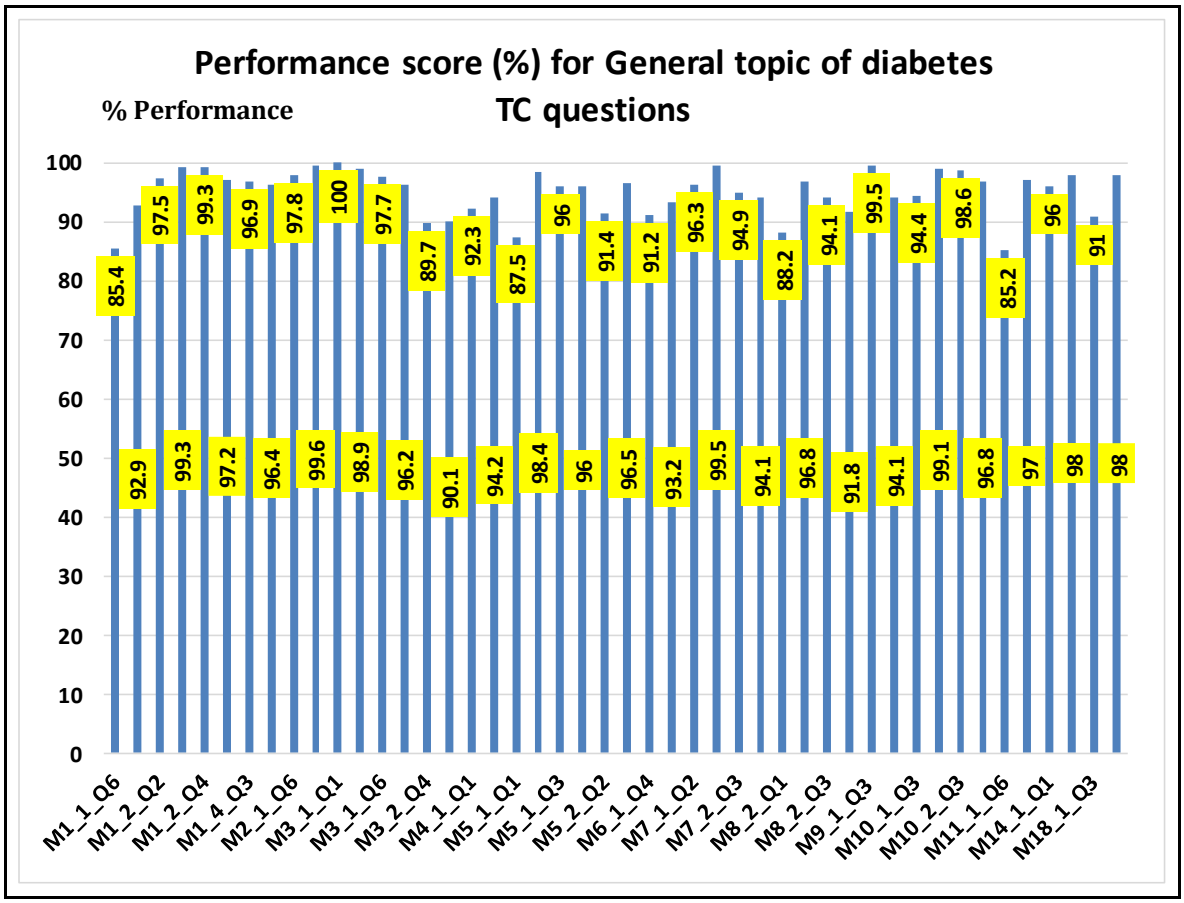


Figure 4.4.1 Performance score for general topics on diabetes.

For the sub-topic insulin hormone, the performance score of nine questions remained consistently high (i.e. ≥ 95.0%) indicating an excellent grasp of understanding of the role of insulin in diabetes. Table 4.4 below shows the detail questions and the performance score of each question from the sub-topic effects of insulin hormone.

Table 4.4 Performance score for sub-topic effects of insulin hormone.

TC session	Question	Option a	Option b	Option c	% correct
M1_2_Q2	Which hormone is responsible in lowering blood sugar?	Steroid	*Insulin*	Oestrogen	97.5
M3_1_Q4	Which hormone is responsible in lowering blood sugar?	Steroid	Glucagon	*Insulin*	98.9
M4_2_Q4	Which hormone is responsible in lowering blood sugar?	Steroid	Glucagon	*Insulin*	94.2

M5_1_Q2	Which hormone is responsible in lowering blood sugar?	*Insulin*	Glucagon	Adrenaline	98.4
M8_2_Q2	Which hormone is responsible in lowering blood sugar?	*Insulin*	Glucagon	Adrenaline	96.8
M10_1_Q4	Which hormone is responsible in lowering blood sugar?	Steroid	*Insulin*	Glucagon	99.1
M16_1_Q4	Which hormone is responsible in lowering blood sugar?	Steroid	Glucagon	*Insulin*	98.0
M18_1_Q4	Which hormone is responsible in lowering blood sugar?	Steroid	*Insulin*	Glucagon	98.0
Word(s) in Italic denotes the correct answer.					

4.4.2 Diabetes pathophysiology

A total of 16 questions on diabetes pathophysiology were asked during the Telephone Contact sessions. The mean performance score for this topic was 81.3%, with minimum score of 39.2% and maximum score 97.2% respectively. The overall performance for this topic was very good, with a mean score of ≥ 80.0%. Figure 4.4.2 below illustrates the individual performance score for each question from this topic.

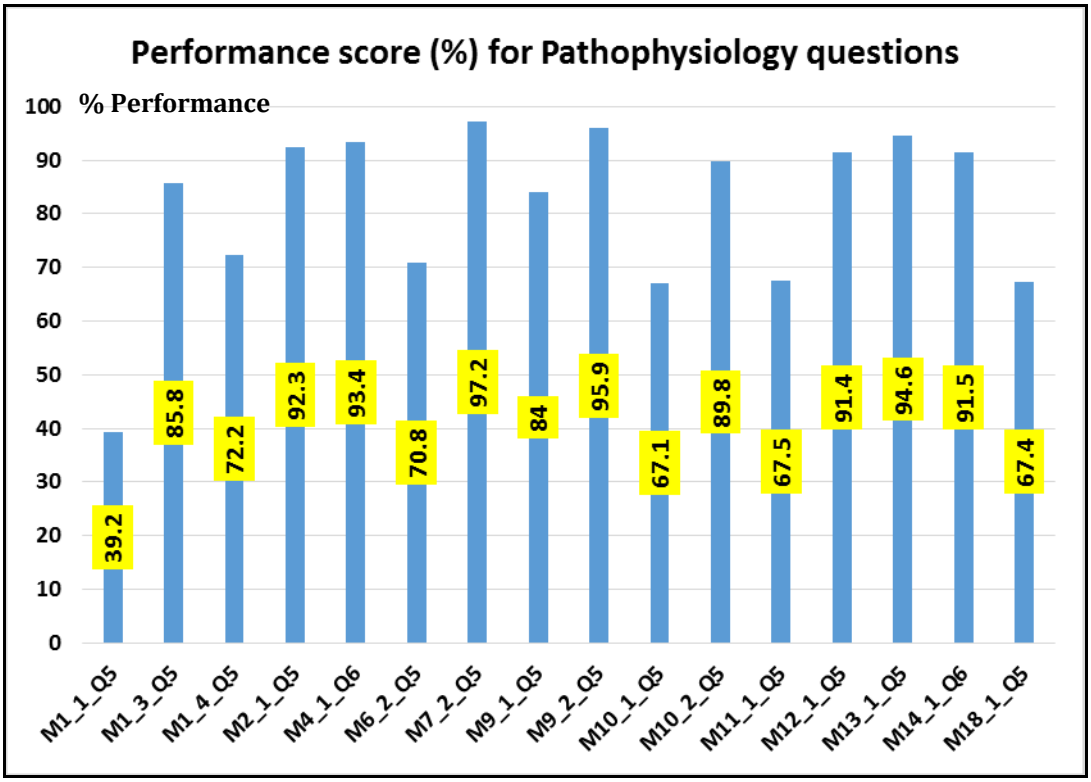


Figure 4.4.2 Performance score for diabetes pathophysiology.

The structure and content of the pathophysiology question emphasised the concept of hyperglycaemia. The stem of the question was kept consistent as *"What is the cause of "sweet blood" or hyperglycaemia in diabetes patients?"* throughout the Telephone Contact sessions. Only the answer options were modified to test patients' comprehension. All but four (4/16) questions scored good or very good. Table 4.5 below shows the three questions with score ≤ 72.0% (good) and one question with score ≤ 48.0% (unsatisfactory).

Table 4.5 Performance score of diabetes pathophysiology with three lower scores.

TC session	Question	Option a	Option b	Option c	% correct
M1_1_Q5	What is the cause of "sweet blood" or hyperglycaemia in diabetes patients?	Fat cells are able to absorb the sugar from the blood vessels	*The muscle cells are **not** able to absorb sugar from the blood vessels*	Pancreas gland is producing insulin as per normal	39.2
M10_1_Q5	What is the cause of "sweet blood" or hyperglycaemia in diabetes patients?	*Fat cells are **not** able to absorb the sugar from the blood*	The muscle cells are able to absorb sugar from the blood vessels	Pancreas gland is producing insulin as per normal	67.1
M11_1_Q5	What is the cause of "sweet blood" or hyperglycaemia in diabetes patients?	Fat cells are able to absorb the sugar from the blood	Pancreas gland is producing insulin as per normal	*The muscle cells are **not** able to absorb sugar from the blood vessels*	67.5
M18_1_Q5	What is the cause of "sweet blood" or hyperglycaemia in diabetes patients?	The muscle cells are able to absorb sugar from the blood vessels	*Fat cells are **not** able to absorb the sugar from the blood*	Pancreas gland is producing insulin as per normal	67.4
Word(s) in Italic denotes the correct answer.					

4.4.3 Diabetes symptoms

A total of 11 questions were asked on diabetes symptoms during the Telephone Contact sessions. The mean performance score for this topic was 94.8%, with minimum score of 80.4% and maximum score 98.9% respectively. The overall performance for this topic was very good, with a mean score of ≥ 80.0% indicating a very good grasp of understanding of common diabetes symptoms. Majority of patients correctly identified increased urination, thirst and blur vision as diabetes symptoms throughout the Telephone Contact follow-up. Figure 4.4.3 below illustrates the individual performance score for each question from this topic.

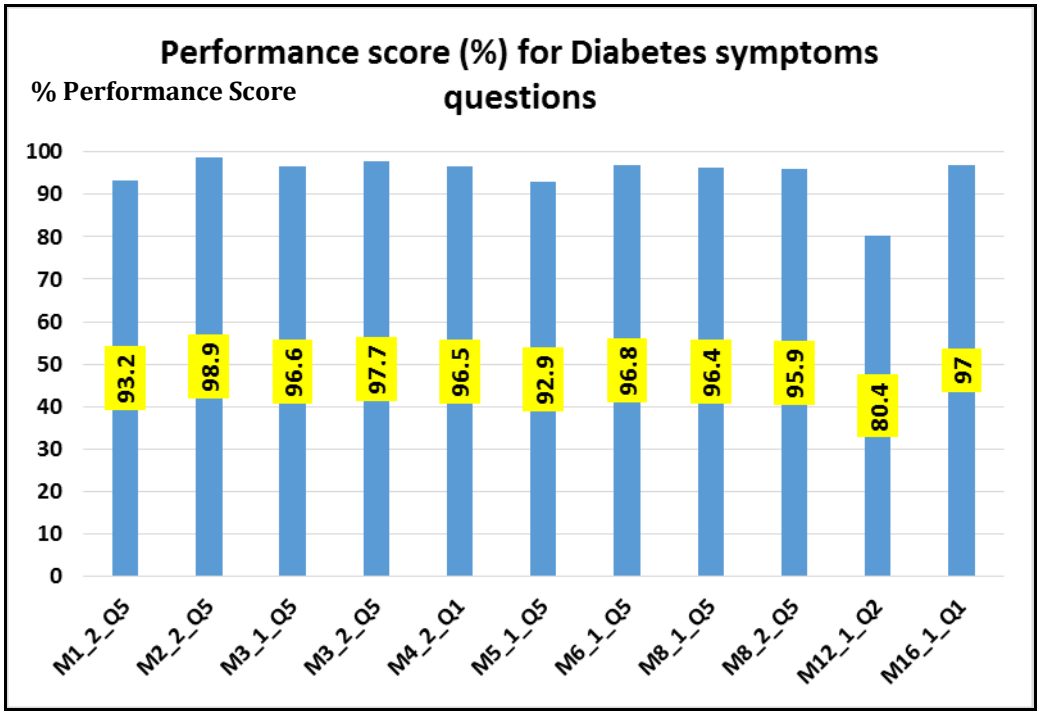


Figure 4.4.3 Performance score for diabetes symptoms.

Table 4.6.1 and Table 4.6.2 show majority of patients correctly identified urine frequency, thirst and blur vision as diabetes symptoms.

Table 4.6.1 Performance score of diabetes symptoms – urinary frequency and nocturia.

TC session	Question	Option a	Option b	Option c	% correct
M1_2_Q5	Diabetes symptoms include	No urination at all	Urinate infrequently	*Urinate frequently*	93.2
M3_1_Q5	Diabetes	*Urinate*	Urinate	Does not	96.6

	symptoms include	*frequently at night*	infrequently at night	urinate at all	
M5_1_Q5	Diabetes symptoms include	*Thirst*	Urinate infrequently at night	Urinate infrequently during the day	92.9
M8_2_Q5	Diabetes symptoms include	*Thirst*	Urinate infrequently at night	Urinate infrequently during the day	95.9
Word(s) in Italic denotes the correct answer.					

Table 4.6.2 Performance score of diabetes symptoms – blur vision.

TC session	Question	Option a	Option b	Option c	% correct
M2_2_Q5	Diabetes symptoms include	Good vision	*Blur vision*	Good hearing	98.9
M4_2_Q1	Diabetes symptoms include	Good vision	*Blur vision*	Good hearing	96.5
M16_1_Q1	Diabetes symptoms include	Good vision	*Blur vision*	Good hearing	96.8
Word(s) in Italic denotes the correct answer.					

4.4.4 Diabetes complications

A total of 26 questions were asked on diabetes complications during the Telephone Contact sessions. The mean performance score for this topic was 93.3%, with minimum score of 69.3% and maximum score 100.0% respectively. The overall performance for this topic was very good, with a mean score ≥ 80.0% indicating a very good grasp of understanding of diabetes complications. Figure 4.5.4 below illustrates the individual performance score for each question from this topic.

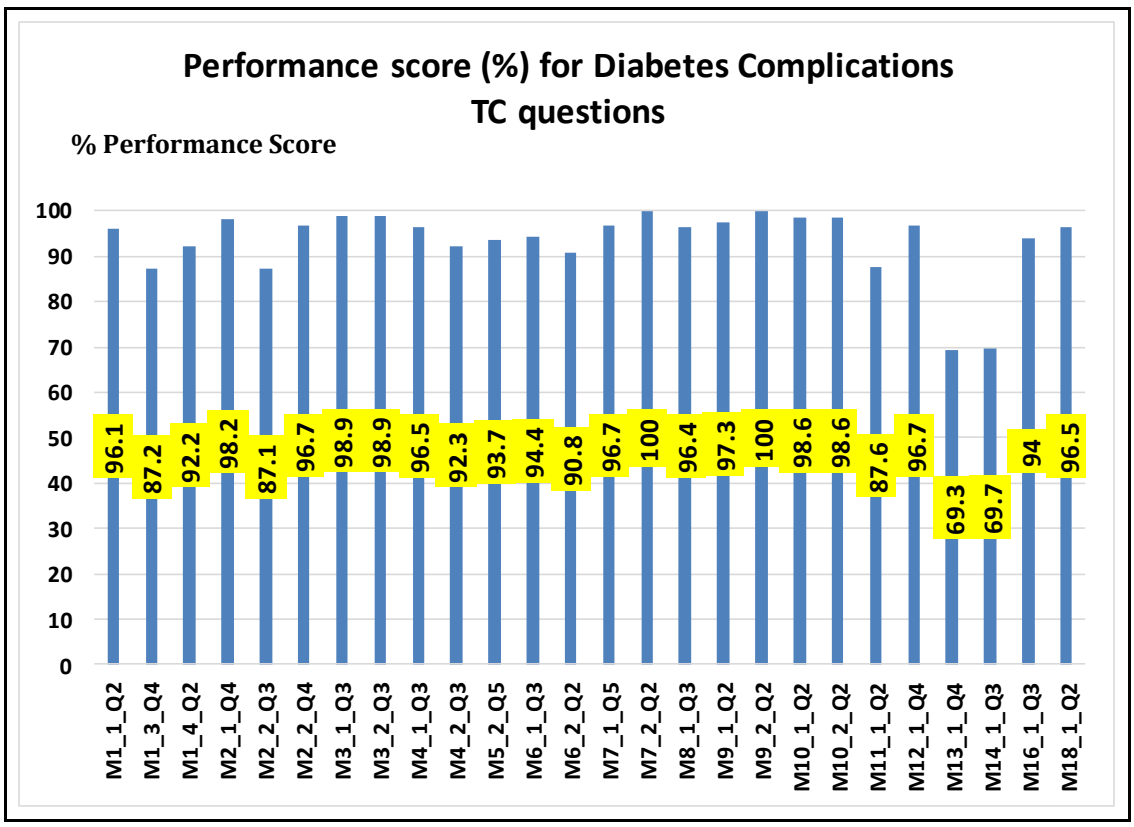


Figure 4.4.4 Performance score for diabetes complications.

Similar to diabetes pathophysiology, the structure of the stem question – *"In diabetes, the "sweet blood" or hyperglycaemia can cause damage to all the blood vessels* – emphasised the concept of hyperglycaemia and the complications it can potentially cause. Table 4.7.1 and Table 4.7.2 below show majority of patients correctly identified loss of vision and heart disease or heart attack as a common micro- and macrovascular complications of diabetes.

Table 4.7.1 Performance score of diabetes complications – loss of vision.

TC session	Questions	Option a	Option b	Option c	% correct
M1_1_Q2	Which of these is a common diabetes complication?	Loss of smell	Loss of hearing	*Loss of vision*	96.1
M5_2_Q5	Which of these is a common diabetes complication?	Loss of memory	Loss of hearing	*Loss of vision*	93.7
M7_1_Q5	Which of these is a common diabetes complication?	Loss of memory	Loss of hearing	*Loss of vision*	96.7
Word(s) in Italic denotes the correct answer.					

Table 4.7.2 Performance score of diabetes complications – heart disease.

TC session	Questions	Option a	Option b	Option c	% correct
M2_2_Q3	Which of these organs can be damaged?	Lungs	*Heart*	Stomach	87.1
M4_2_Q3	Which of these organs can be damaged?	Lungs	*Heart*	Stomach	96.5
M6_1_Q3	Which of these organs can be damaged?	Lungs	Nose	*Heart*	94.4
M7_2_Q2	Which of these is a common diabetes complication?	Nose transplant	Knee transplant	*Heart attack*	100.0
M8_1_Q3	Which of these organs can be damaged?	Lungs	Nose	*Heart*	96.4
M9_2_Q2	Which of these is a common diabetes complication?	Nose transplant	Knee transplant	*Heart attack*	100.0
M16_1_Q3	Which of these organs can be damaged?	Lungs	*Heart*	Stomach	94.0
Word(s) in Italic denotes the correct answer.					

All but two (2/26) questions on diabetes complications scored very good or excellent. Table 4.7.3 below shows the individual questions and performance score of the two questions which scored ≤ 72.0%.

Table 4.7.3 Performance score of diabetes complications – neuropathy

TC session	Questions	Option a	Option b	Option c	% correct
M13_1_Q4	Which of these organs can be damaged?	Ear	*Nervous system*	Urinary bladder	69.3
M14_1_Q3	Which of these is a common diabetes complication?	Kidney stones	*Erectile dysfunction*	Facial numbness	69.7
Number(s) in Italic denotes the correct answer.					

4.4.5 Prevention of diabetes complications

A total of 12 questions on prevention of diabetes complications were asked during the Telephone Contact sessions. The mean performance score for this topic was 80.0%, with minimum score of 46.0% and maximum score 97.9% respectively. The overall performance for this topic was very good, with a mean score of ≥ 80.0% indicating a very good grasp of understanding of prevention of

diabetes complications. Figure 4.4.5 below illustrates the individual performance score for each question from this topic.

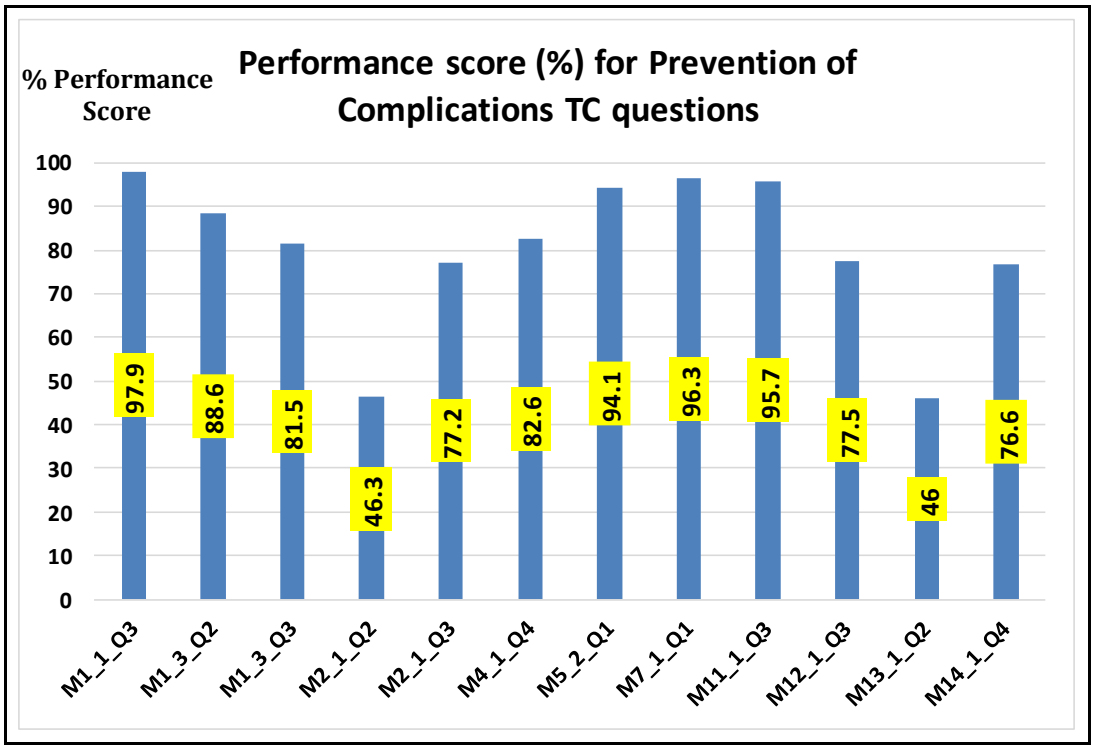


Figure 4.4.5 Performance score for prevention of diabetes complications.

All but two (2/12) questions on diabetes complications scored very good or excellent. Table 4.8 below shows the individual questions and performance score of the two questions which scored unsatisfactory ≤ 48.0%.

Table 4.8 Performance score of prevention diabetes complications – weight loss

TC session	Questions	Option a	Option b	Option c	% correct
M2_1_Q2	To prevent obesity or overweight and prevent diabetes complications, how many percent of body weight should you lose?	1-2%	*5-10%*	15-20%	46.3
M13_1_Q2	To prevent obesity or overweight and prevent diabetes complications, how many percent of body weight should you lose?	1-2%	*5-10%*	15-20%	46.0
Number(s) in Italic denotes the correct answer.					

4.4.6 Blood glucose levels

A total of 9 questions were asked on blood glucose levels during the Telephone Contact sessions. The mean performance score for this topic was 81.3%, with minimum score of 73.2% and maximum score 88.2% respectively. The overall performance was very good, with a mean score of ≥ 80.0% indicating a very good grasp of understanding of blood glucose levels. Figure 4.4.6 below illustrates the individual performance score for each question from this topic.

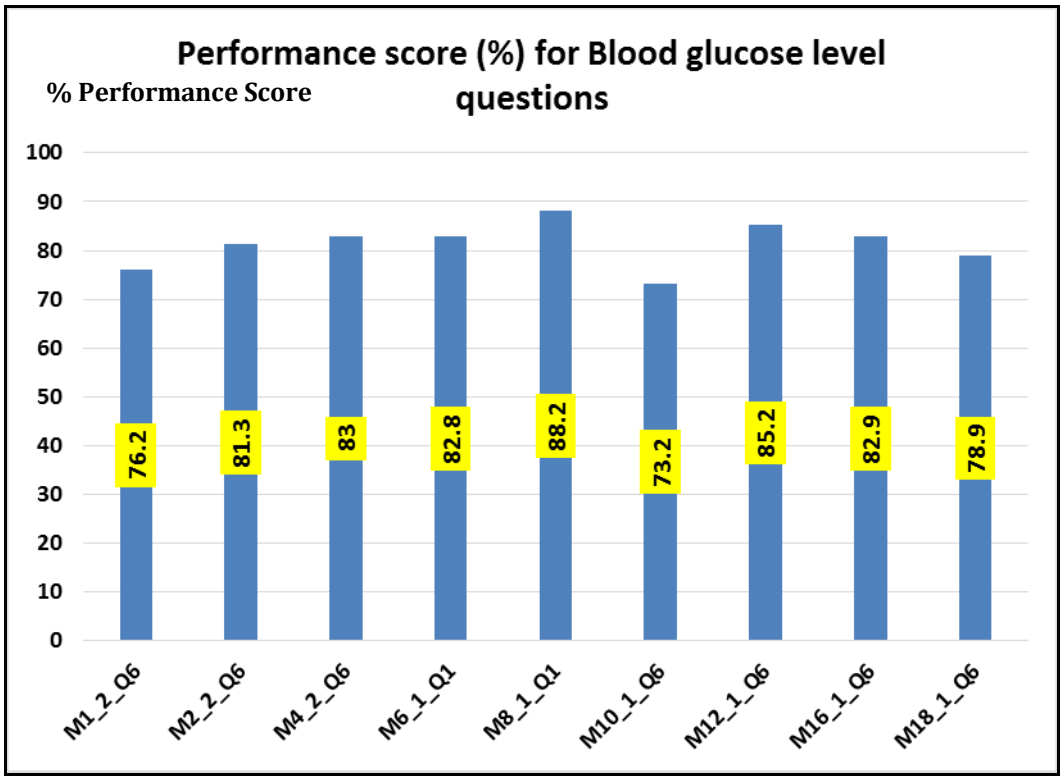


Figure 4.4.6 Performance score for blood glucose levels.

Patients correctly identified the acceptable range for blood glucose for 2 hours after meal, fasting and hypoglycaemia. Tables 4.9.1, 4.9.2 and 4.9.3 below show the individual performance score for the various blood sugar range correctly identified by patients.

Table 4.9.1 Performance score of blood glucose levels – (i) 2 hours post-prandial.

TC session	Questions	Option a	Option b	Option c	% correct
M1_2_Q6	What is considered the normal blood glucose level **2 hours after a meal**?	10-12 mmol/l	8-10 mmol/l	*6-8 mmol/l*	76.2
M6_1_Q1	What is considered the normal blood glucose level **2 hours after a meal**?	10-12 mmol/l	8-10 mmol/l	*6-8 mmol/l*	82.8
M8_1_Q1	What is considered the normal blood glucose level **2 hours after a meal**?	10-12 mmol/l	8-10 mmol/l	*6-8 mmol/l*	88.2
Number(s) in Italic denotes the correct answer.					

Table 4.9.2 Performance score of blood glucose levels – (ii) fasting blood glucose.

TC session	Questions	Option a	Option b	Option c	% correct
M2_2_Q6	What is considered the normal **fasting blood glucose**?	< 2 mmol/l	2-4 mmol/l	*4-6 mmol/l*	81.3
M4_2_Q6	What is considered the normal **fasting blood glucose**?	< 2 mmol/l	2-4 mmol/l	*4-6 mmol/l*	83.0
M12_1_Q6	What is considered the normal **fasting blood glucose**?	2-4 mmol/l	*4-6 mmol/l*	6-8 mmol/l	85.2
M16_1_Q6	What is considered the normal **fasting blood glucose**?	< 2 mmol/l	2-4 mmol/l	*4-6 mmol/l*	82.9
Number(s) in Italic denotes the correct answer.					

Table 4.9.3 Performance score of blood glucose levels – (iii) hypoglycaemia.

TC session	Questions	Option a	Option b	Option c	% correct
M10_1_Q6	Which of this blood glucose is considered as **hypoglycaemia**?	< 5 mmol/l	< 4 mmol/l	*< 3 mmol/l*	73.2
M18_1_Q6	Which of this blood glucose is considered as **hypoglycaemia**?	< 5 mmol/l	< 4 mmol/l	*< 3 mmol/l*	78.9
Number(s) in Italic denotes the correct answer.					

4.4.7 Hypoglycaemia

A total of 9 questions on hypoglycaemia were asked during the Telephone Contact sessions. The mean performance score for this topic was 71.9%, with minimum score of 38.8% and maximum score 93.5% respectively. The overall performance of this topic is good, with a mean score of almost 72.0%. Figure 4.4.7 below illustrates the individual performance score for each question from this topic.

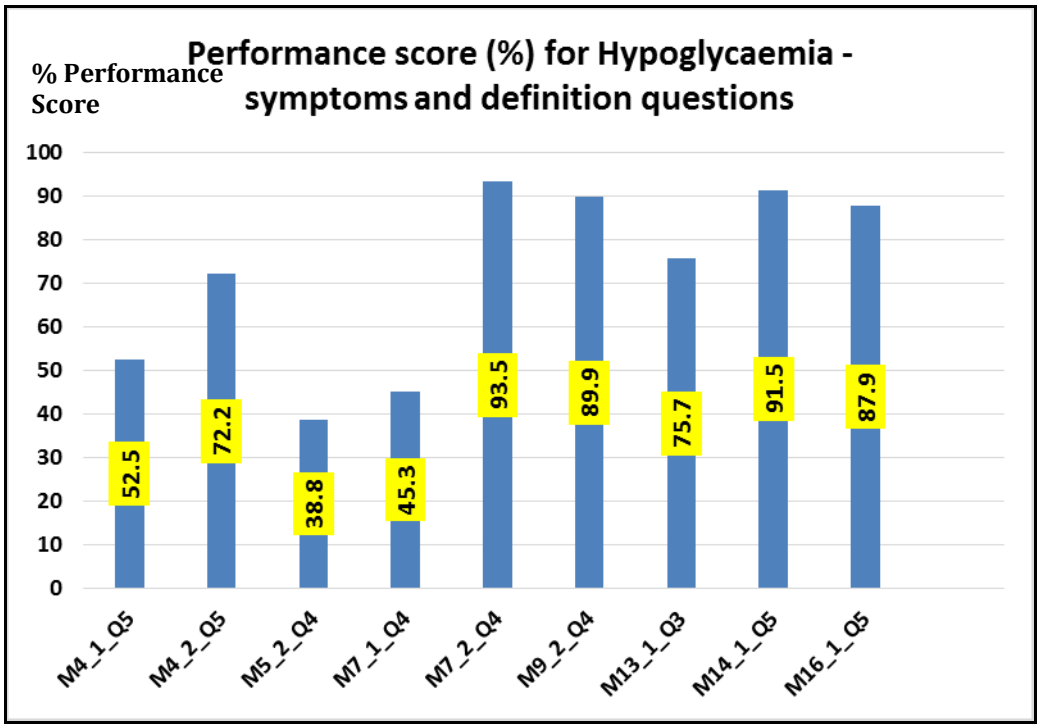


Figure 4.4.7 Performance score for hypoglycaemia - symptoms and definition.

Table 4.10 below shows majority of patients (93.5% in M7; 89.9% in M9) recognised shivering as a symptom of hypoglycaemia. In contrast, less patients recognised hunger (52.5% in M1) and fatigue (38.8% in M5; 45.3% in M7) as symptoms of hypoglycaemia.

Table 4.10 Performance score for hypoglycaemia symptoms.

TC session	Questions	Option a	Option b	Option c	% correct
M4_1_Q5	Hypoglycaemia symptom includes	*Feeling hungry*	Feeling thirsty	Feeling full	52.5
M4_2_Q5	Hypoglycaemia means your blood glucose level is	*Low*	Normal	High	72.2
M5_2_Q4	Hypoglycaemia symptom includes	Feeling thirsty	*Feeling tired*	Increase urination at	38.8

				night	
M7_1_Q4	Hypoglycaemia symptom includes	Feeling thirsty	*Feeling tired*	Increase urination at night	45.3
M7_2_Q4	Hypoglycaemia symptom includes	*Shivering*	Increase urination	Not passing urine at all	93.5
M9_2_Q4	Hypoglycaemia symptom includes	*Shivering*	Increase urination	Not passing urine at all	89.9
Word(s) in Italic denotes the correct answer.					

4.4.8 Self-care - benefits of exercise

A total of 15 questions on benefits of exercise were asked during the Telephone Contact sessions. The mean performance score for this topic was 96.9%, with minimum score of 93.2% and maximum score 98.5% respectively. The overall performance for this topic was excellent, with a mean score of ≥ 95.0% indicating an excellent understanding of benefits of exercise as part of self-care in diabetes. Figure 4.4.8 below illustrates the individual performance score for each question from this topic.

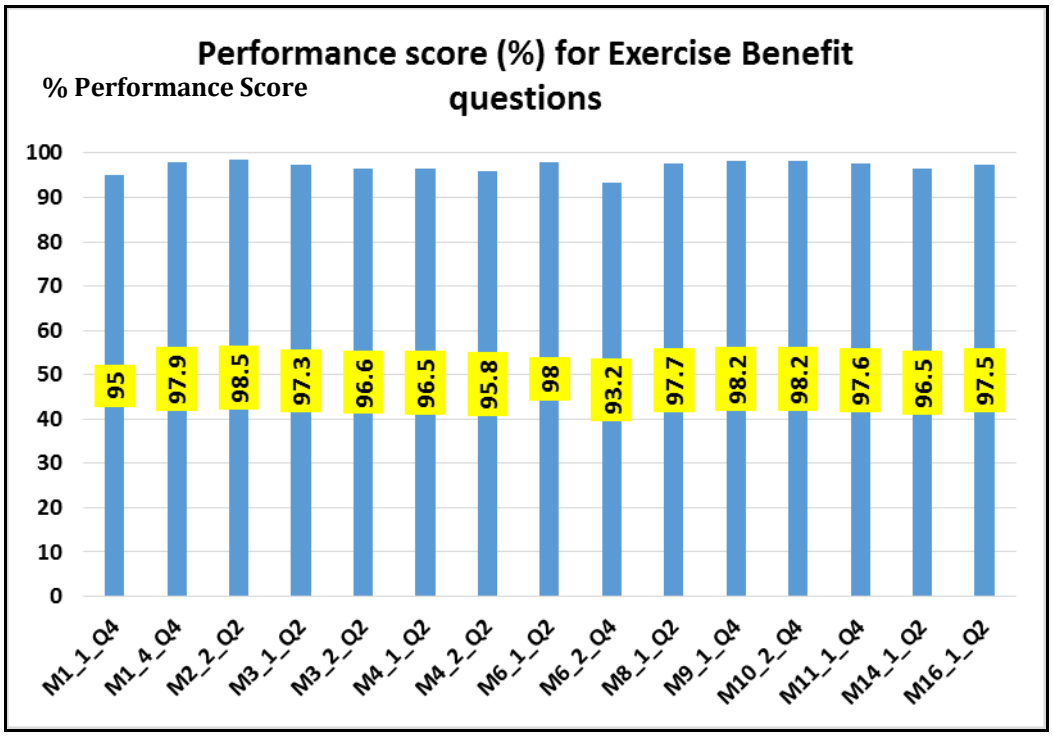


Figure 4.4.8 Performance score for self-care practices - benefits of exercise.

The question on effects of exercise on enhancing insulin sensitivity and lowering blood glucose were excellently answered by patients throughout the follow-up period. Table 4.11.1 below describes the individual performance score for questions on effects of exercise on enhancing insulin sensitivity; the results showed sustained high score of ≥ 95.0% throughout the Telephone Contact follow-up period.

Table 4.11.1 Performance score benefits of exercise – effects of exercise on enhancing insulin sensitivity.

TC session	Questions	Option a	Option b	Option c	% correct
M1_1_Q4	The benefit of exercise includes	*Increasing the effects of insulin in the body*	Increasing blood glucose level	Increasing blood pressure	95.0
M3_1_Q2	The benefit of exercise includes	Decrease performance at work	Impair mood	*Increasing the effects of insulin in the body*	97.3
M4_2_Q2	The benefit of exercise includes	Decrease performance at work	Impair mood	*Increasing the effects of insulin in the body*	95.8
M11_1_Q4	The benefit of exercise includes	Increasing blood glucoselevel	*Increasing the effects of insulin in the body*	Increasing blood pressure	97.6
M16_1_Q2	The benefit of exercise includes	Decrease performance at work	Impair mood	*Increasing the effects of insulin in the body*	97.5
Word(s) in Italic denotes the correct answer.					

Similarly, Table 4.11.2 below describes the individual performance score for questions on effects of exercise on lowering blood glucose; the results also showed sustained high score of ≥ 95.0% throughout the Telephone Contact follow-up.

Table 4.11.2 Performance score benefits of exercise – effects of exercise on lowering blood glucose.

TC session	Questions	Option a	Option b	Option c	% correct
M1_4_Q4	The benefit of exercise includes	*Decreasing blood glucose level*	Increasing joint pains	Increasing blood cholesterol level	97.9
M6_2_Q4	The benefit of exercise includes	*Decreasing blood glucose level*	Increasing joint pains	Increasing blood cholesterol level	93.2
M9_1_Q4	The benefit of exercise includes	*Decreasing blood glucose level*	Increasing joint pains	Increasing blood cholesterol level	98.2
M10_2_Q4	The benefit of exercise includes	*Decreasing blood glucose level*	Increasing joint pains	Increasing blood cholesterol level	98.2
Word(s) in Italic denotes the correct answer.					

4.4.9 Self-care - foot-care

A total of 14 questions on foot-care were asked during the Telephone Contact sessions. The mean performance score for this topic was 94.0%, with minimum score of 86.1% and maximum score 100.0% respectively. The overall performance for this topic was very good with a mean score of ≥ 80.0% indicating a very good understanding of the importance of foot-care in diabetes. Figure 4.4.9 below illustrates the individual performance score for each question from this topic.

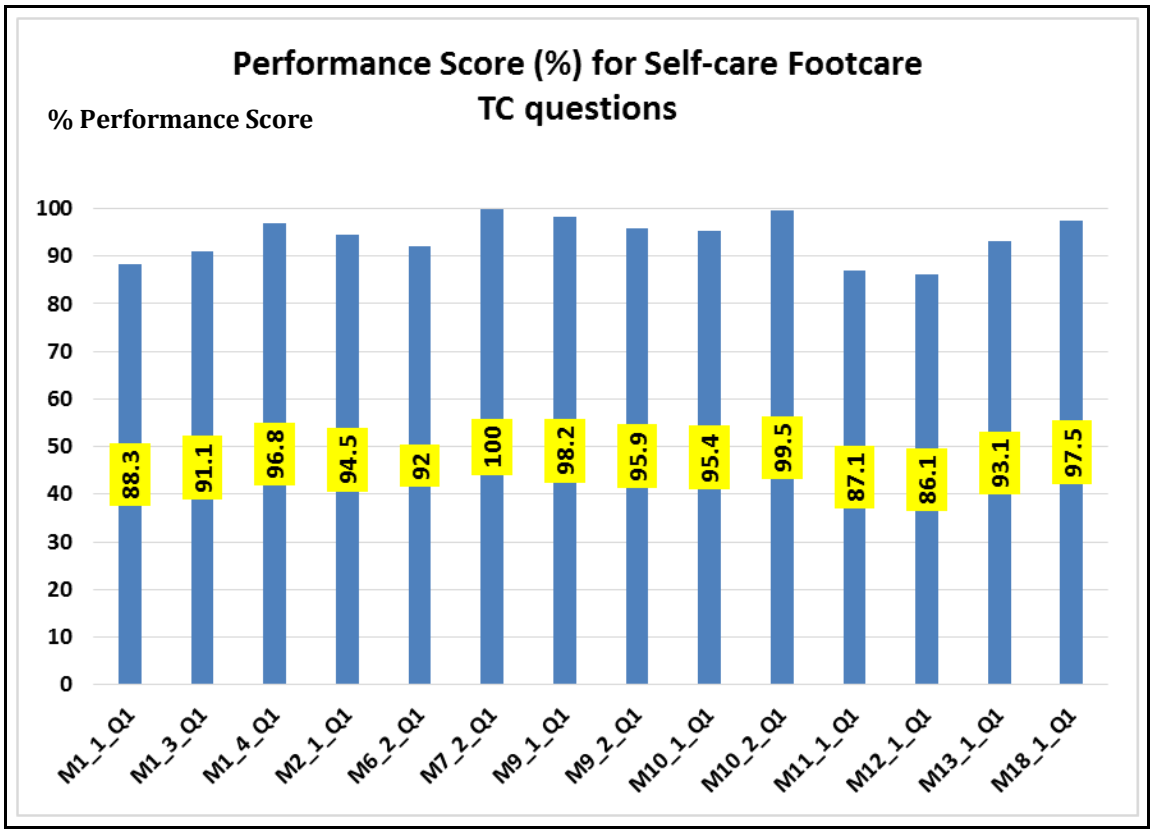


Figure 4.4.9 Performance Score for Self-care practices - foot-care.

Table 4.12.1, 4.12.2, 4.12.3 and 4.12.4 below show the individual questions and the performance score of each question from the foot-care sub-topics (i) keep space between toes dry (ii) wash feet daily (iii) keep feet and ankles moisturise and (iv) what should you avoid doing? The results below showed sustained high score of ≥ 90.0% throughout the follow-up.

Table 4.12.1 Performance score for foot-care – (i) keep space between toes dry.

TC session	Questions	Option a	Option b	Option c	% correct
M1_3_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	*Ensure that spaces between your toes are always dry*	Wash your feet once a week	91.1
M1_4_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	*Ensure that spaces between your toes are always dry*	Wash your feet once a week	96.8
M6_2_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	*Ensure that spaces between your toes are always dry*	Wash your feet once a week	92.0
M9_1_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	*Ensure that spaces between your toes are always dry*	Wash your feet once a week	98.2
M10_2_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	*Ensure that spaces between your toes are always dry*	Wash your feet once a week	99.5
Word(s) in Italic denotes the correct answer.					

Table 4.12.2 Performance score for foot-care – (ii) wash feet daily.

TC session	Questions	Option a	Option b	Option c	% correct
M7_2_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	*Wash your feet daily*	Ignore any wound or ulcer on your feet	Not wearing any shoes when going out/outdoors	100.0
M9_2_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	*Wash your feet daily*	Ignore any wound or ulcer on your feet	Not wearing any shoes when going out/outdoors	95.9
Word(s) in Italic denotes the correct answer.					

Table 4.12.3 Performance score for foot-care – (iii) keep feet and ankles well moisturised.

TC session	Questions	Option a	Option b	Option c	% correct
M2_1_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Ignore any wound or ulcer on your feet	Not wearing any shoes when going out/outdoors	*Always use cream to moisturise your feet and ankles*	94.5
M10_1_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	Ignore any wound or ulcer on your feet	*Always use cream to moisturise your feet and ankles*	95.4
M18_1_Q1	Foot-care is important in diabetes. What should you do to look after your feet?	Not wearing any shoes when going out/outdoors	Ignore any wound or ulcer on your feet	*Always use cream to moisturise your feet and ankles*	97.5
Word(s) in Italic denotes the correct answer.					

In addition, patients also correctly identified thigs they should avoid in foot-care such as: (i) ignoring wound or ulcer on the foot (87.1% in M11) (ii) using ill-fitting shoes (86.1% in M12) and (iii) not wearing any footwear when going out/outdoors (93.1% in M13). Table 4.13.4 below shows the individual questions and the performance score of each question.

Table 4.12.4 Performance score for foot-care – what should you avoid doing?

TC session	Questions	Option a	Option b	Option c	% correct
M11_1_Q1	Foot-care is important in diabetes. ***What should you avoid?***	Wash your feet daily	*Ignore any wound or ulcer on your feet*	Use suitable footwear when going out/outdoors	87.1
M12_1_Q1	Foot-care is important in diabetes. ***What should you avoid?***	*Using ill-fitting shoes when going out/outdoors*	Ensure that spaces between your toes are always dry	See a doctor when you have a wound or ulcer on your feet	86.1
M13_1_Q1	Foot-care is important in diabetes. ***What should you avoid?***	See a doctor when you have a wound or ulcer on your feet	Examine your feet everyday	*Not wearing any shoes when going out/outdoors*	93.1
Word(s) in Italic denotes the correct answer.					

4.4.10 Self-care - SMBG

A total of 10 questions on SMBG were asked during the Telephone Contact sessions. The mean performance score for this topic was 87.8%, with minimum scores of 79.6% and maximum score 96.4% respectively. The overall performance for this topic was very good, with a mean score of ≥ 80.0% indicating a very good understanding of the importance and processes involved in SMBG among this cohort of patients who were SMBG-naive or inexperience prior to joining the current study. Figure 4.4.10 below illustrates the individual performance score for each question from this topic.

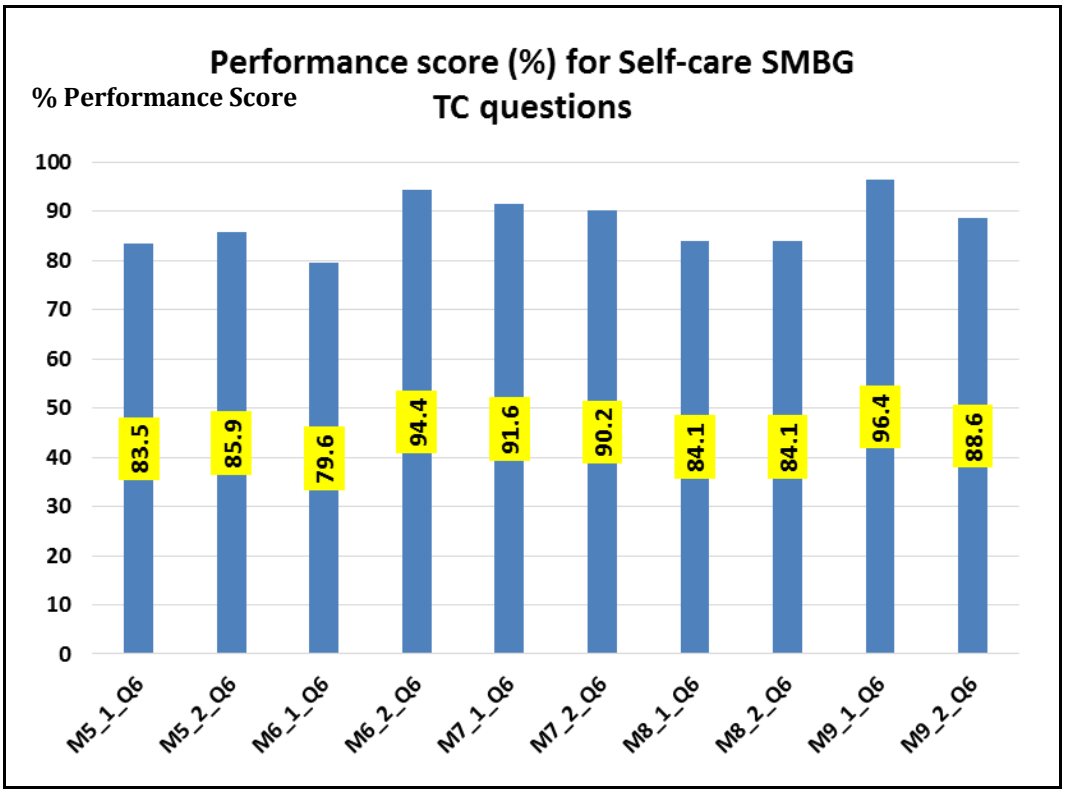


Figure 4.4.10 Performance score for self-care practices – SMBG.

Table 4.13 below shows the individual questions and the performance score of each question.

Table 4.13 Performance score for SMBG.

TC session	Questions	Option a	Option b	Option c	% correct
M5_1_Q6	Before doing your SMBG, you must ensure that expiry date is still valid, this is because a glucose strip which is expired:-	Can be used in the future	Will give accurate reading	*Will not give accurate reading*	83.5
M5_2_Q6	What should you do as soon as you complete checking your blood glucose?	*Record your blood glucose reading immediately*	Record your blood glucose levels once a week	Record your blood glucose levels once a month	85.9
M6_1_Q6	What is the icon seen on the blood glucose meter screen to indicate the machine is ready to be use?	Glucose	Finger	*Blood drop*	79.6
M6_2_Q6	Before you check your blood glucose you must wash your:-	*Hands*	Glucose strips	Lancet	94.4
M7_1_Q6	What should you do as	*Record your*	Record your	Record your	91.6

	soon as you complete checking your blood glucose?	*blood glucose reading immediately*	blood glucose levels once a week	blood glucose levels once a month	
M7_2_Q6	Regarding the site of finger prick, you should:	Always prick your thumb	*Always prick at different sites of the finger*	Always prick your index finger	90.2
M8_1_Q6	What is the icon seen on the blood glucose meter screen to indicate the machine is ready to be use?	Glucose	Finger	*Blood drop*	84.1
M8_2_Q6	Before doing your SMBG, you must ensure that expiry date is still valid, this is because a glucose strip which is expired:-	Can be used in the future	Will give accurate reading	*Will not give accurate reading*	84.1
M9_1_Q6	Before you check your blood glucose you must wash your:-	*Hands*	Glucose strips	Lancet	96.4
M9_2_Q6	Regarding the site of finger prick, you should:-	Always prick your thumb	*Always prick at different sites of the finger*	Always prick your index finger	88.6
Word(s) in Italic denotes the correct answer.					

4.4.11 Summary of the performance scores for the ten theme topics

In summary, the mean performance score percentage for all the ten theme topics were as follow; general questions on diabetes 95.1%; diabetes pathophysiology 81.3%; diabetes symptoms 94.8%; diabetes complications 93.3%; prevention of diabetes complications 80.0%; blood glucose level 81.3%; hypoglycaemia 71.9%; self-care - benefits of exercise 96.9%; self-care - foot-care 94.0%; self-care - SMBG 87.8%. All ten topics achieved performance score in either very good (i.e. 8 topics) or excellent (i.e. 2 topics) category. The results showed majority of patients had a very good or excellent grasp of understanding in most of aspects of MY DEMO module. There were five questions (5/168) within the ten topics (i.e. diabetes pathophysiology – 1 item; prevention of

complications – 2 items; hypoglycaemia – 2items) which scored unsatisfactory (i.e. ≤ 48.0%). Notably, no questions received a poor score (i.e. ≤ 30.0%) throughout the Telephone Contact follow-up. Table 4.14 below summarises the mean, lowest and highest percentage scores performed by each theme topics in a descending order.

Table 4.14 The performance score of each theme topics with mean, lowest and highest percentage scores in descending order.

No	Theme Topics	Mean Score (%)	Lowest Score (%)	Highest Score (%)
1	Self-care – benefits of exercise	96.9	93.2	98.5
2	General Topic on Diabetes	95.1	85.2	100
3	Diabetes symptoms	94.8	80.4	98.9
4	Self-care – foot-care	94.0	86.1	100
5	Diabetes complications	93.3	69.3	100
6	Self-care - SMBG	87.8	79.6	96.4
8	Blood glucose levels	81.3	73.2	88.2
9	Diabetes pathophysiology	81.3	39.2	97.2
7	Prevention of diabetes complications	80.0	46.0	97.9
10	Hypoglycaemia – symptoms and definition	71.9	38.8	93.5

4.5 Self-monitoring blood glucose (SMBG)

4.5.1 SMBG frequency at 6 months for the entire cohort

In total, 216 patients completed their 6 months SMBG intervention. Patients performed 114 SMBG as per SMBG protocol for 6 months. Figure 4.5 shows the mean and median SMBG frequency were 98.7 and 108 times respectively. The minimum number of SMBG was zero and 24 patients (11.1%) did not performed SMBG even once during the 6 months. The maximum number of SMBG performed was 328 by one patient. More than half of patients (52.8%) never missed to perform their SMBG during the 6 months. A fifth of patients (20.4%) performed more than the required amount (> 114 times) during the 6 months by purchasing their own glucose strips.

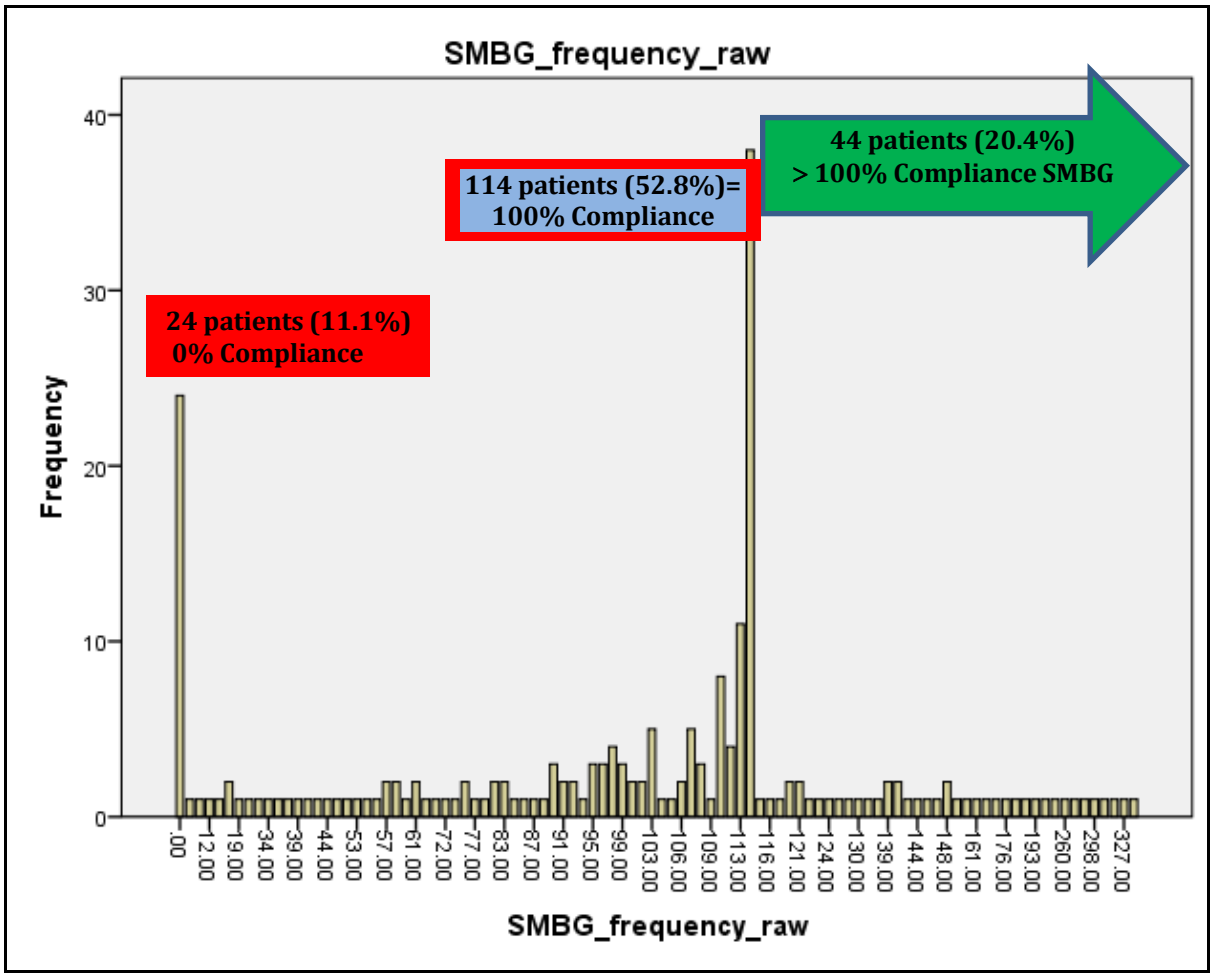


Figure 4.5 The number of SMBG performed by patients (SMBG frequency).

4.5.2 Compliance Index for SMBG at 6 months for the entire cohort

The Compliance Index percentage was calculated based on the frequency of blood results done by each patient (i.e. from SMBG logbook or remainder of glucose strips) divided by the total number of glucose strips given which was 114. Figure 4.6.1 shows the overall SMBG compliance for all patients at 6 months. Three quarters of patients (75.0%) were Strongly-Compliant, Compliant and Moderately-Compliant to their SMBG protocol. The remaining quarter of patients (25.0%) were Poorly-Compliant and Non-Compliant to the SMBG protocol. In essence, more than two thirds of patients (66.2%) had ≥ 80.0% Compliance Index score during the 6 months SMBG intervention. Notably, 15.7% of patients (n=34) had Compliance Index < 30.0%.

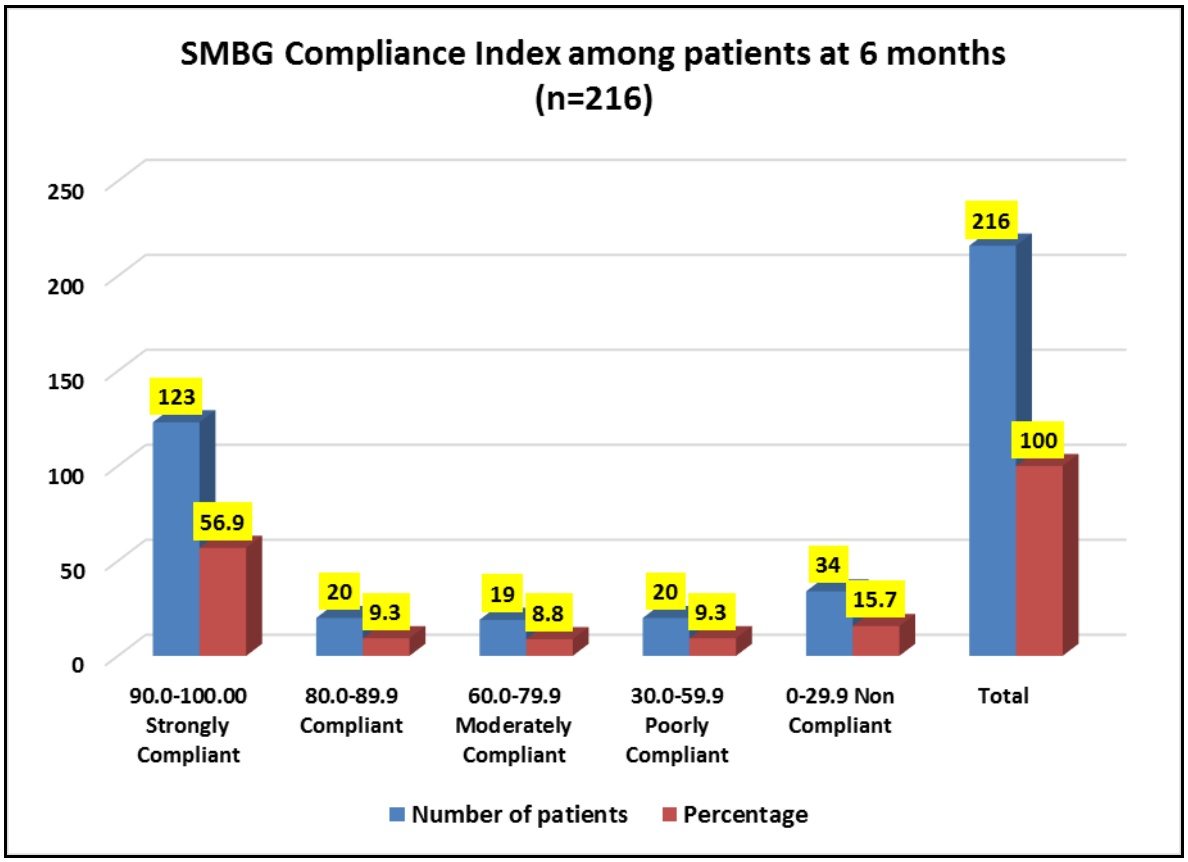


Figure 4.6.1 SMBG Compliance Index in all patients at 6 months.

4.5.3 Compliance Index for SMBG in Group 1 and Group 2 at 6 months

There were no significant association between patient groups and the Compliance Index achieved by first group compared to the second group (p = 0.455). Both groups achieved similar Compliance Index score over the period of 6 months.

Within Group 1 (n=103), Compliance Index achieved by Strongly-Compliant, Compliant and Moderately-Compliant groups were 71.3%, whereas 13.9% were Poorly-Compliant or Non-Compliant.

Within Group 2 (n=113), Compliance Index achieved by Strongly-Compliant, Compliant and Moderately Compliant grpoups were 78.8%, whereas 11.1% were Poorly-Compliant or Non-Compliant.

Figure 4.6.2 shows the SMBG compliance patients in Group 1 and Group 2 at 6 months.

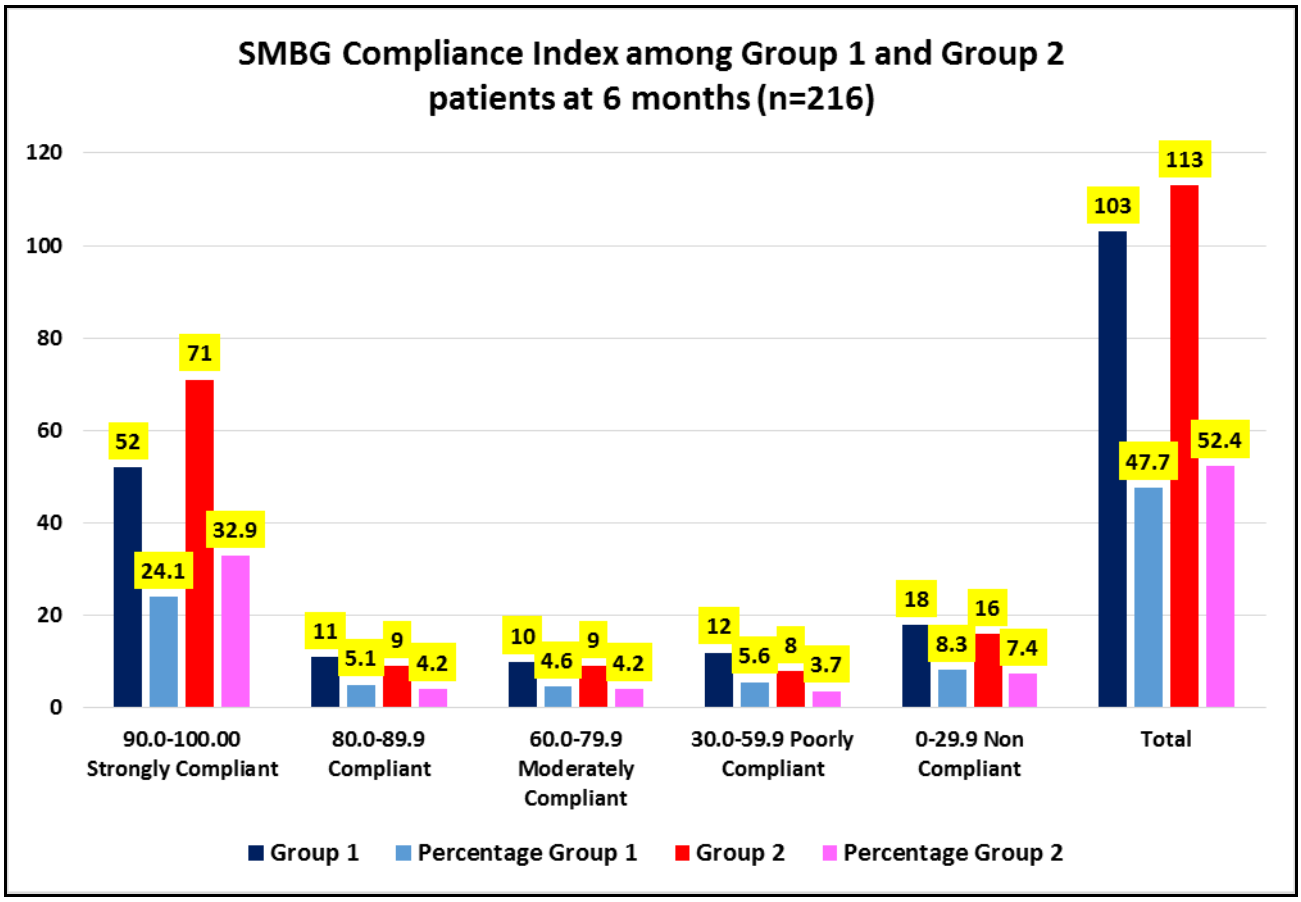


Figure 4.6.2 SMBG Compliance Index of patients in Group 1 and Group 2 at 6 months.

4.5.4 Compliance Index for SMBG in male and female patients at 6 months

There were no significant difference in Compliance Index achieved by male and female patients (p=0.276). Both groups achieved similar mean Compliance Index at 6 months. Mean SMBG compliance indices were 77.7% and 72.5% for male and female patients respectively. For the following: (i) 56.4% (31.9% males and 24.5% females) patients were Strongly-Compliant; (ii) 9.3% (5.1% males and 4.2% females) were Compliant; (iii) 8.8% (5.6% males; 3.2% females) were Moderately Compliant; (iv) 9.3% (4.2% males; 5.1% females) were Poorly-Compliant; (v) 16.2% (7.9% males and 8.3% females) were Non-Compliant; to the SMBG protocol. Figure 4.6.3 shows the Compliance Index for SMBG in both males and female patients at 6 months.

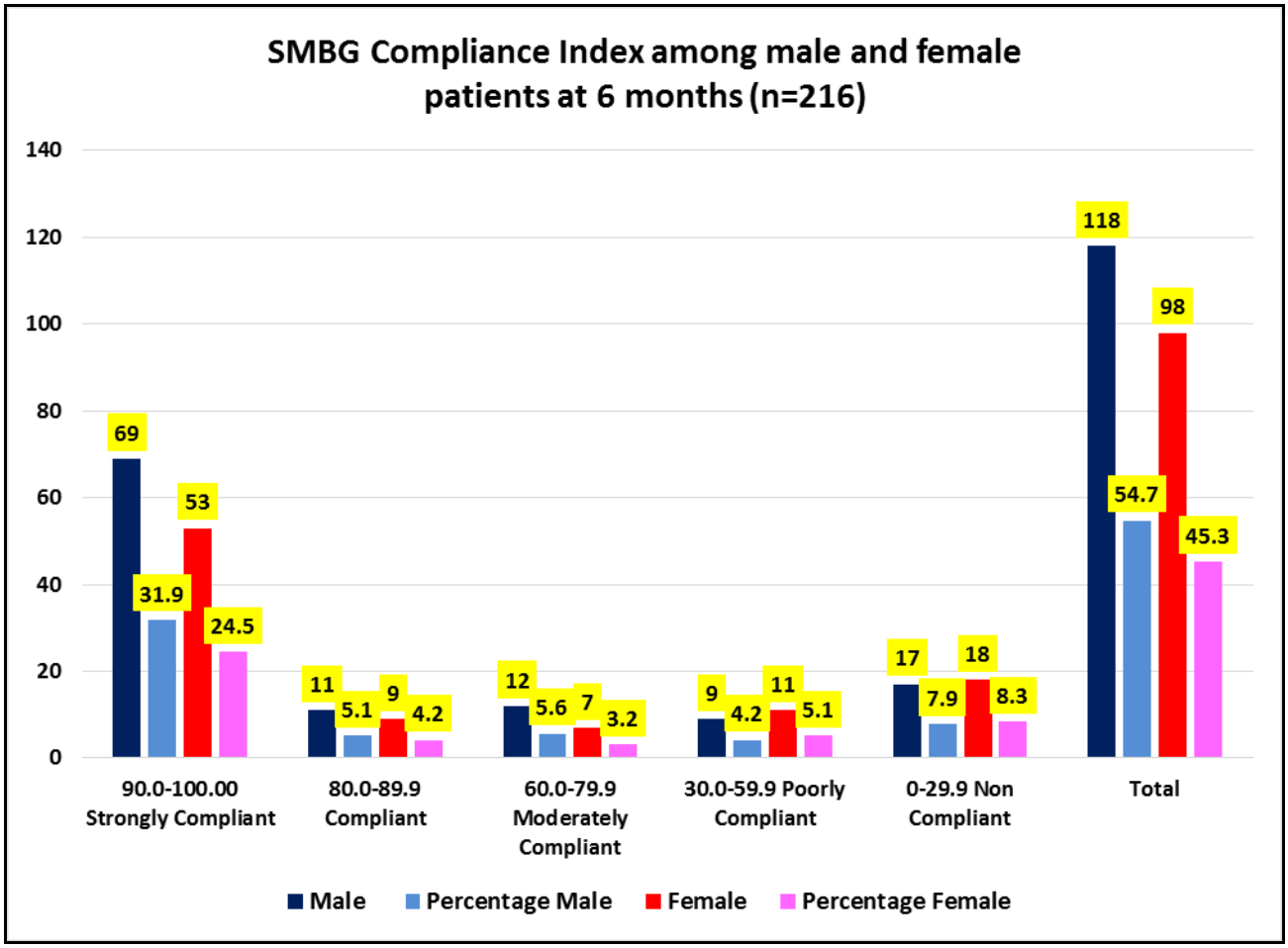


Figure 4.6.3 SMBG Compliance Index in male and female patients at 6 months.

4.5.5 Psychological Determinants for SMBG

Patients completed a baseline behavioural questionnaire at the second visit, before they started doing SMBG. The questions in the behavioural questionnaire was to prepare the SMBG-naive patients for their upcoming new task. The behavioural components included constructs from Health Belief Model (HBM) and Health Action Process Approach (HAPA) such as (i) risk perception (ii) outcome expectancy (iii) action planning/implementation intention (iv) recovery self-efficacy and (v) maintainence self-efficacy (225) (234, 235). Patients were asked to grade the questions based on a 5-point Likert scale; 1- Strongly Disagree; 2 – Disagree; 3 – Unsure; 4 – Agree and 5 Strongly Agree.

Of the 216 patients who completed SMBG, 204 completed the behavioural assessment at all three points (i) baseline (face-to-face second visit) (ii) middle (3 month telephone contact) (iii) at six months (face-to-face end visit). The remaining 12 patients were excluded from this analysis as they had missed either the 3-month or the 6-month evaluation or both despite multiple attempts to contact them.

4.5.5.1 (i) Baseline- Risk perception (Normoglycaemia and Hyperglycaemia)

Patients (n=204) were asked to assess the control of their blood glucose by asking about the likelihood of their blood glucose being within a certain range during fasting and after a meal (Risk Perception). Figure 4.7 shows majority of patients (72%) thought their fasting blood glucose will be < 7.0 mmol/L compared to other diabetes patients, despite all of the patients in this study having poor glycaemic control (HbA1C > 8.0%).

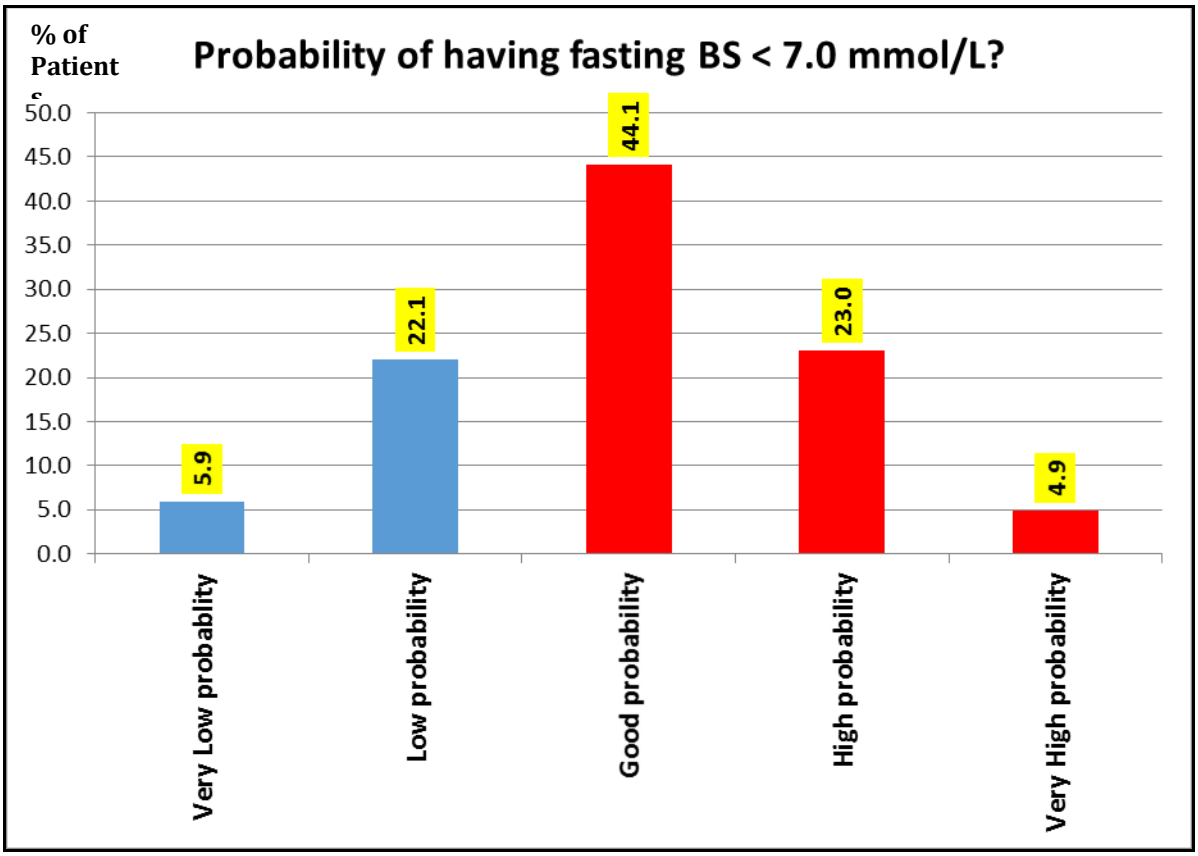


Figure 4.7 Baseline risk perception of disease (normoglycaemia).

Figure 4.8 illustrates an overwhelming majority (93.1%) of patients believe their blood glucose will be greater than 10mmol/L compared to other diabetes patients.

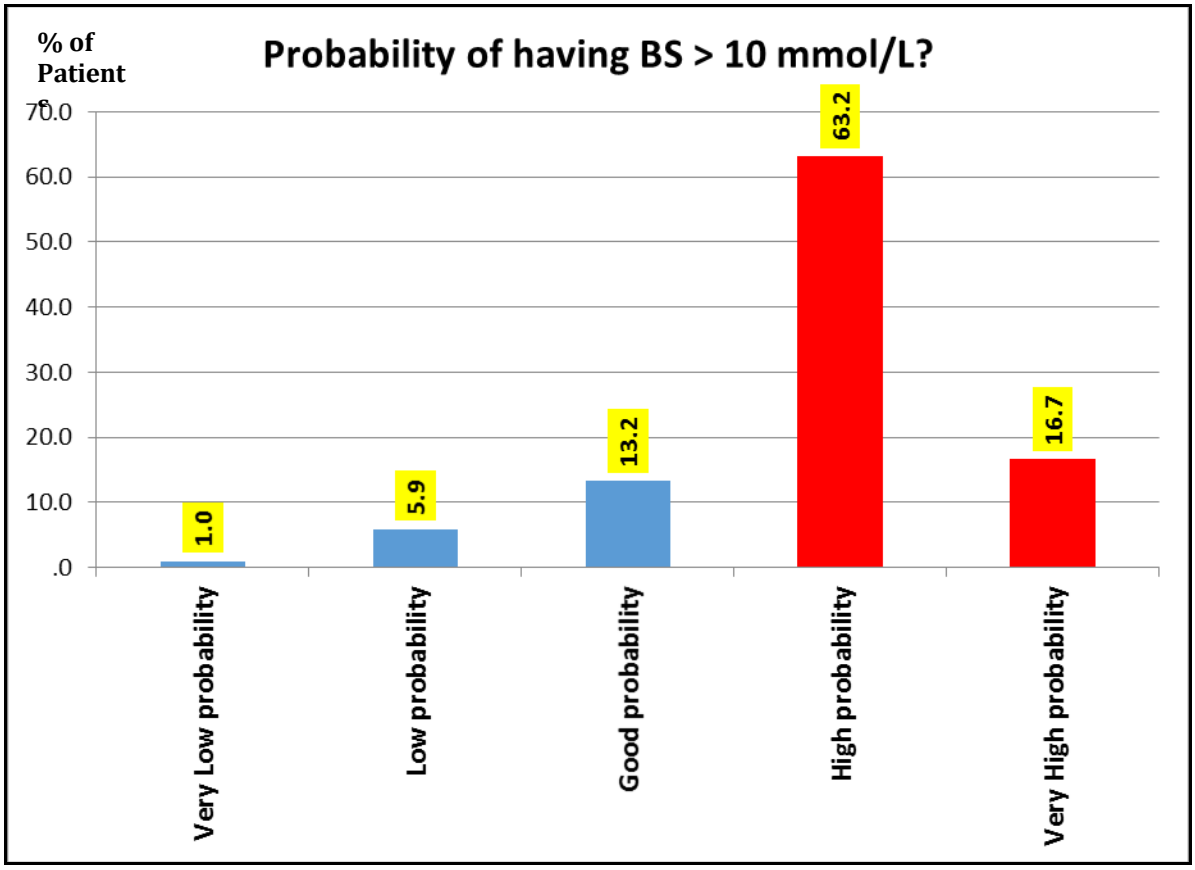


Figure 4.8 Baseline risk perception of disease (hyperglycaemia).

4.5.5.2 (ii) Baseline - Outcome expectancy

Patients (n=204) were asked to assess the benefits of adopting SMBG as a regular self-care management (Outcome expectancy). Figure 4.9 shows majority of patients Agree or Strongly Agree that SMBG will increase their well-being (90.2%).

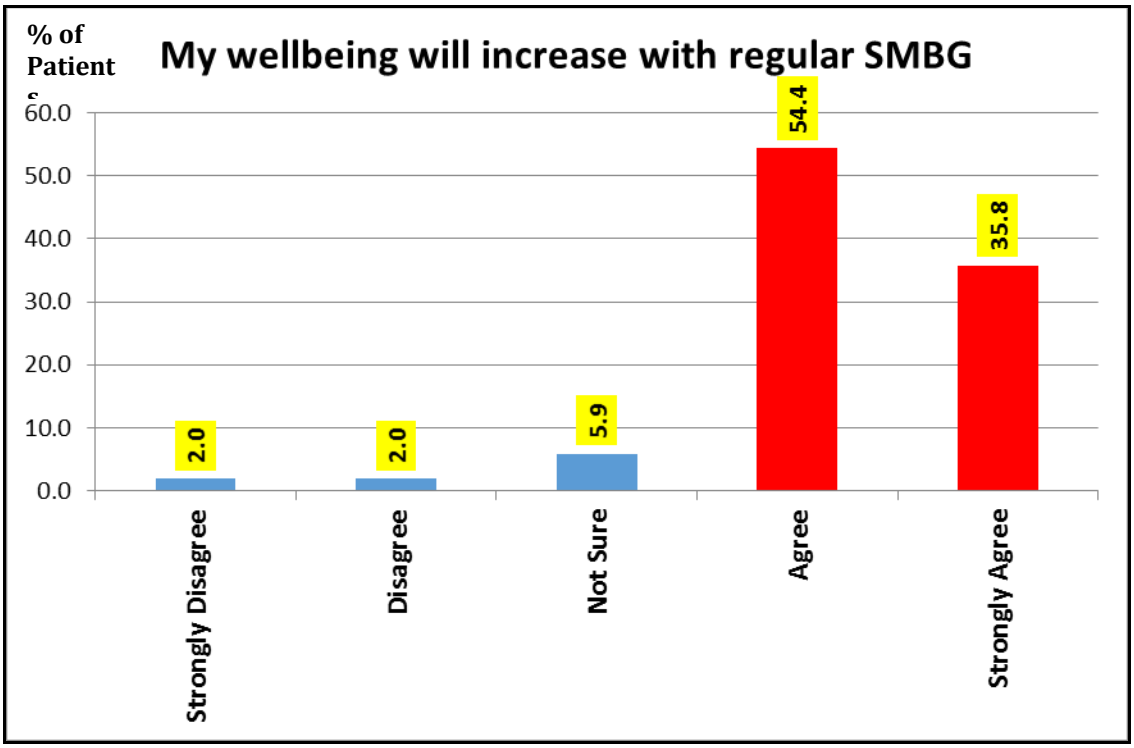


Figure 4.9 Baseline outcome expectancy (well-being with SMBG).

Figure 4.10 shows majority of patients Agree or Strongly Agree that SMBG will delay their diabetes complications (82.4%).

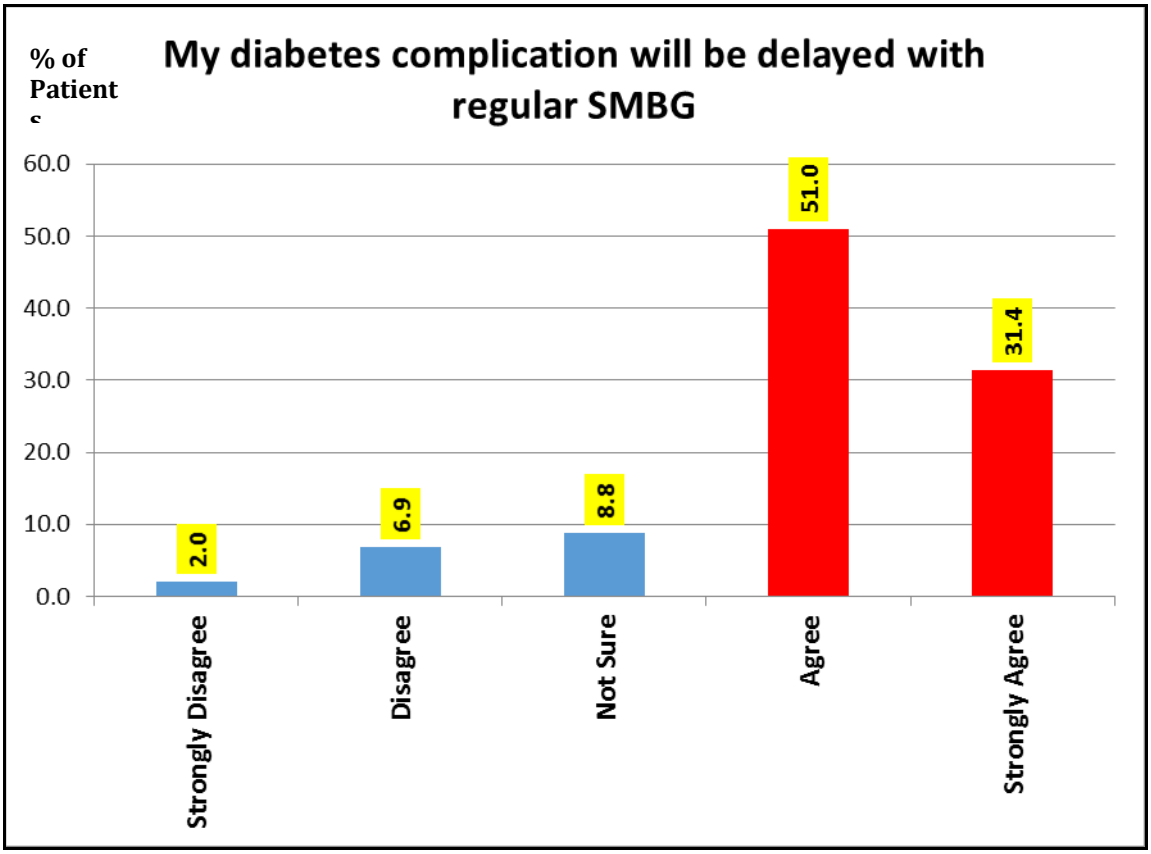


Figure 4.10 Baseline outcome expectancy (SMBG delay complications).

4.5.5.3 (iii) Baseline – Action planning

As study patients were SMBG-naive (n=204), they were asked to consider the various aspects of SMBG action plan like *how*, *when*, *where* and *how often* which they were unfamilar with over the coming 6 months at baseline (216). Figures 4.11.1, 4.11.2, 4.11.3 and 4.11.4 show majority of patients Agree or Strongly Agree to make detail plans regarding (i) *how* they will monitor their blood glucose (95.60%) (ii) *when* they will monitor their blood glucose (97.00%) (iii) *where* they will monitor their blood glucose (93.20%) and (iv) *how often* they will monitor their blood glucose (94.60%) respectively. The results of the baseline action planning indicated patients were well prepared for the next phase which is the implementation phase of SMBG.

Figure 4.11.1 Baseline action planning – How I will do my SMBG?

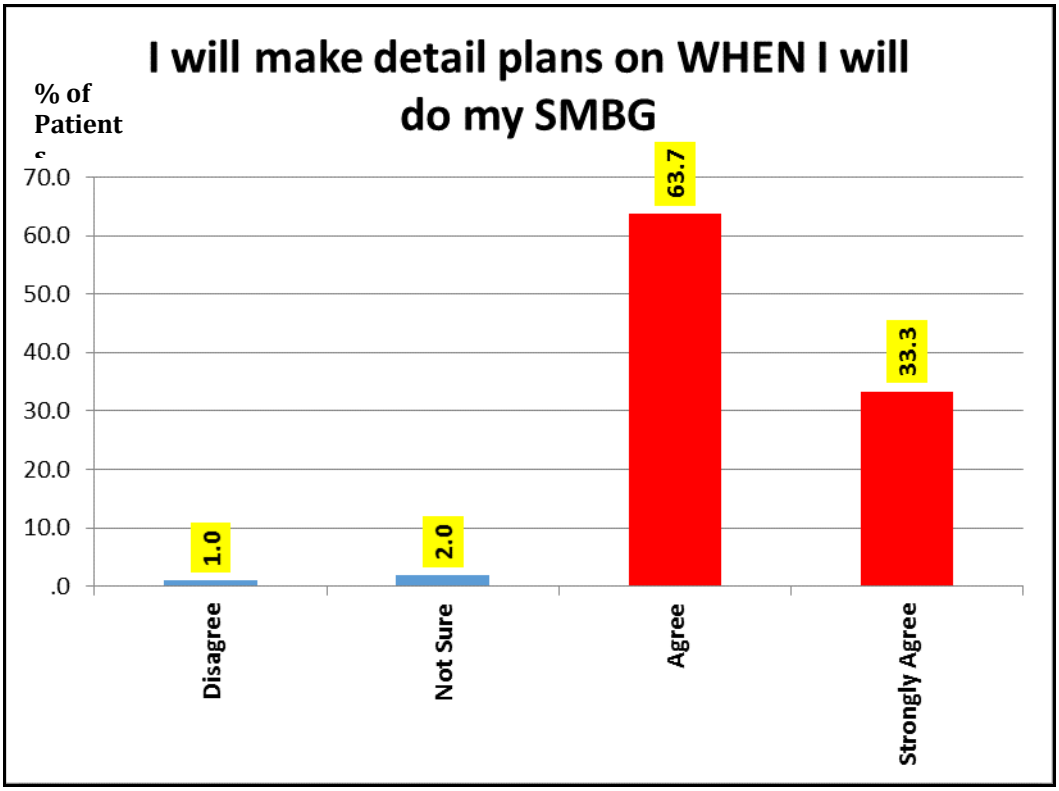


Figure 4.11.2 Baseline action planning– When I will do my SMBG?

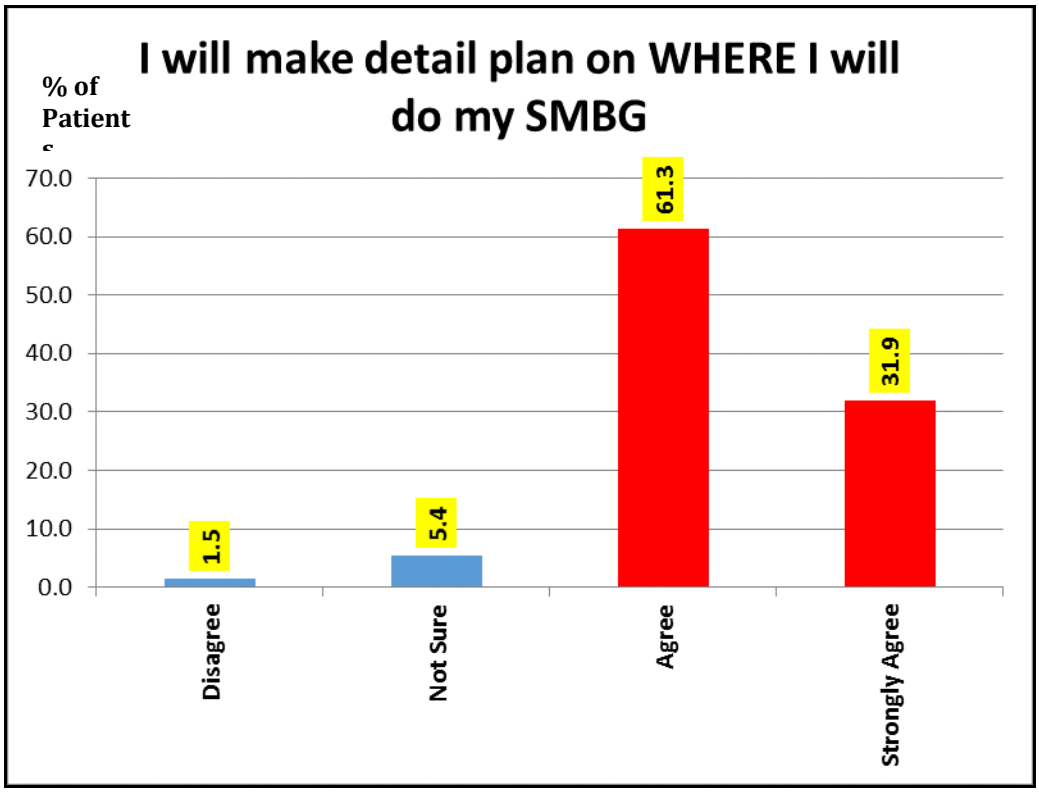


Figure 4.11.3 Baseline action planning – Where will I do my SMBG?

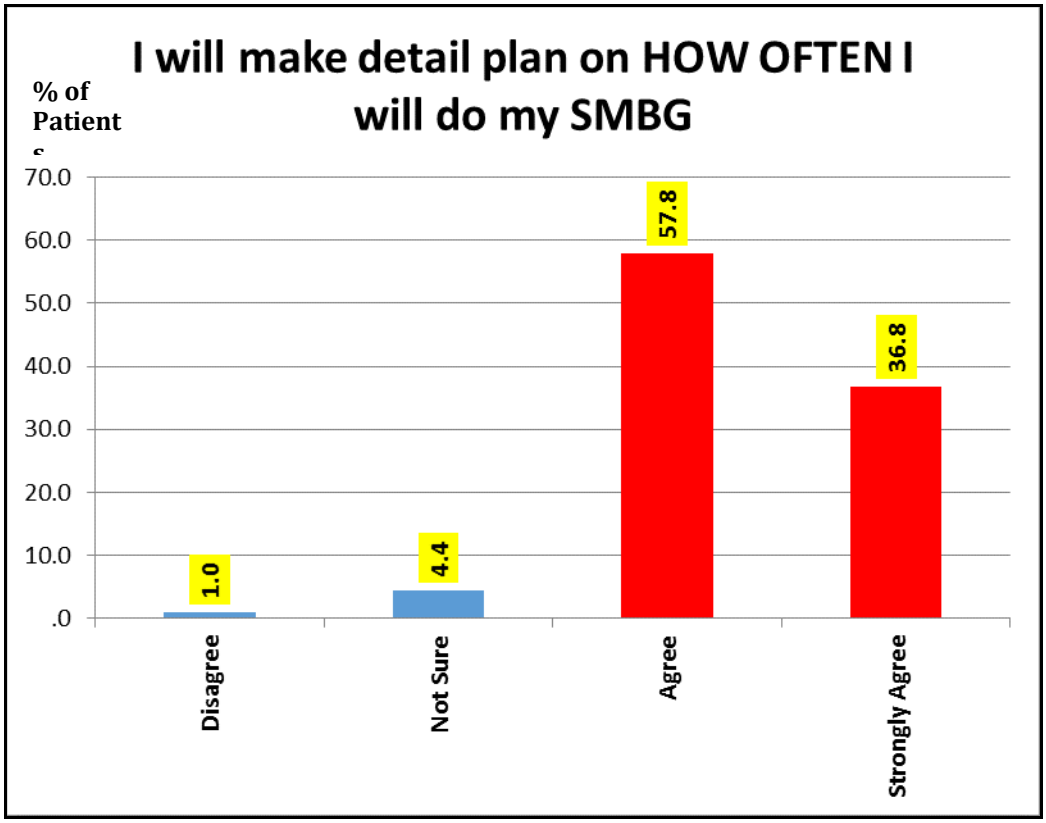


Figure 4.11.4 Baseline action planning – How often will I do my SMBG?

4.5.5.4 Three months – Action Planning

Patients (n=204) were contacted at 3 months through the telephone and action planning questions were asked. Figures 4.12.1, 4.12.2, 4.12.3 and 4.12.4 show the results of the action planning level at 3 months SMBG intervention. The results revealed majority of patients Agree or Strongly Agree that they had made detail plans regarding (i) *how* they monitored their blood glucose (92.20%) (ii) *when* they monitored their blood glucose (90.70%) (iii) *where* they monitored their blood glucose (88.30%) and (iv) *how often* they monitored their blood glucose (91.10%) during the first three months of the SMBG intervention. Although the overall pattern showed a slight decrease in patients' action planning level compared to baseline, majority of patients still Agree or Strongly Agree with the SMBG action plan indicating that they were continuing with their SMBG protocol.

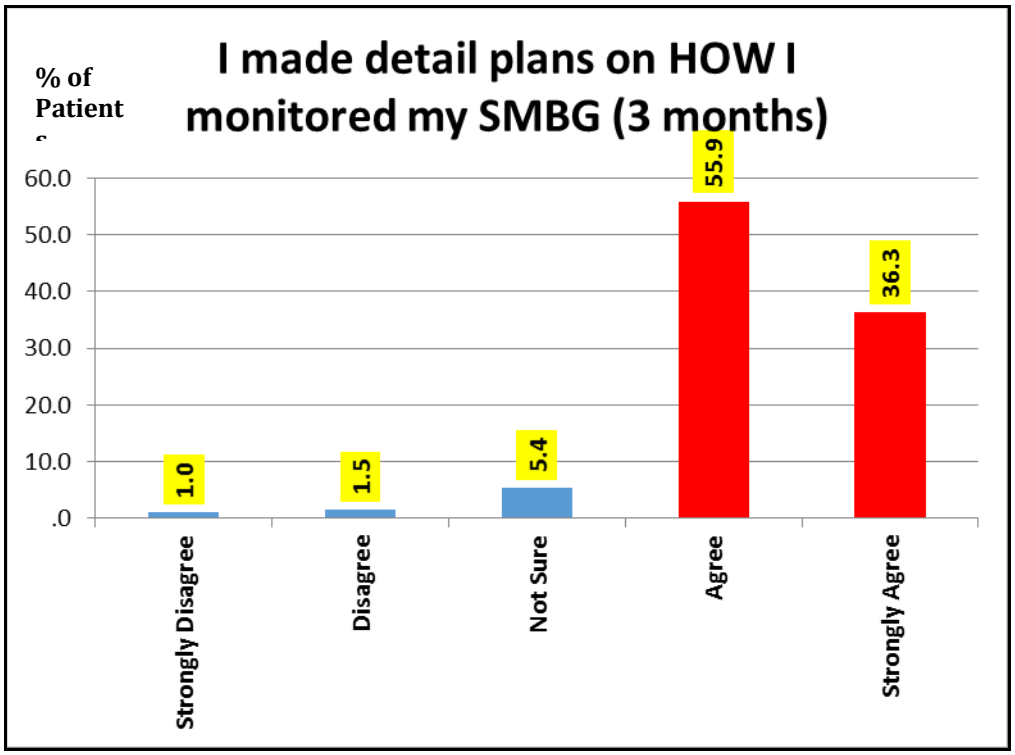


Figure 4.12.1 Three months - action planning – How I monitored my SMBG?

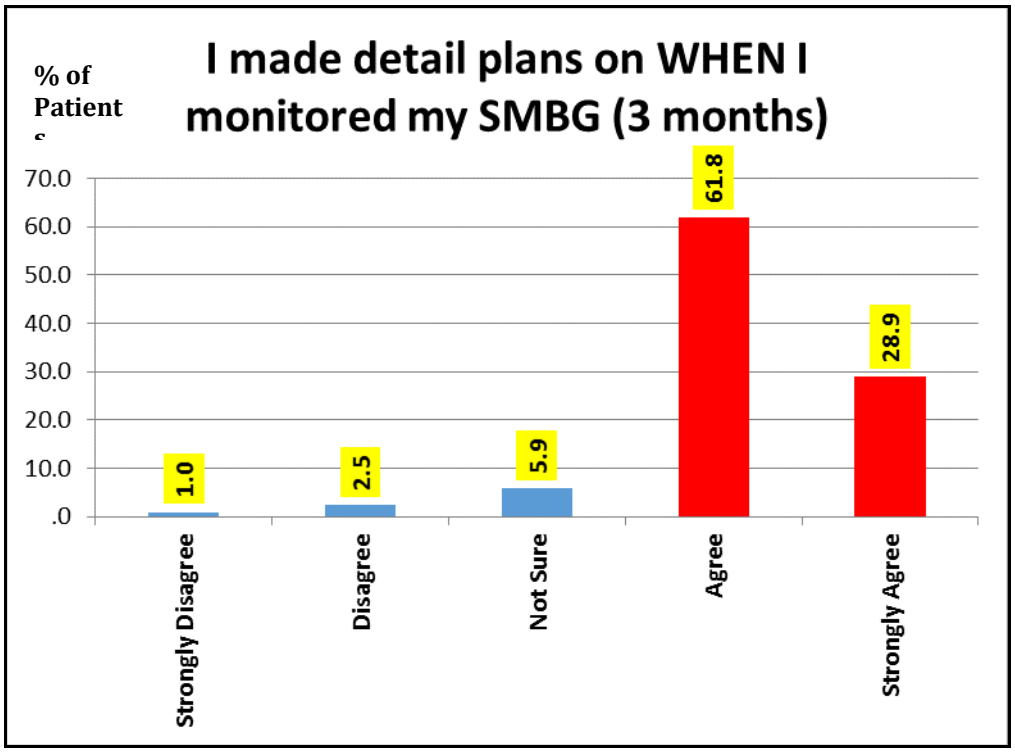


Figure 4.12.2 Three months - action planning – When I monitored my SMBG?

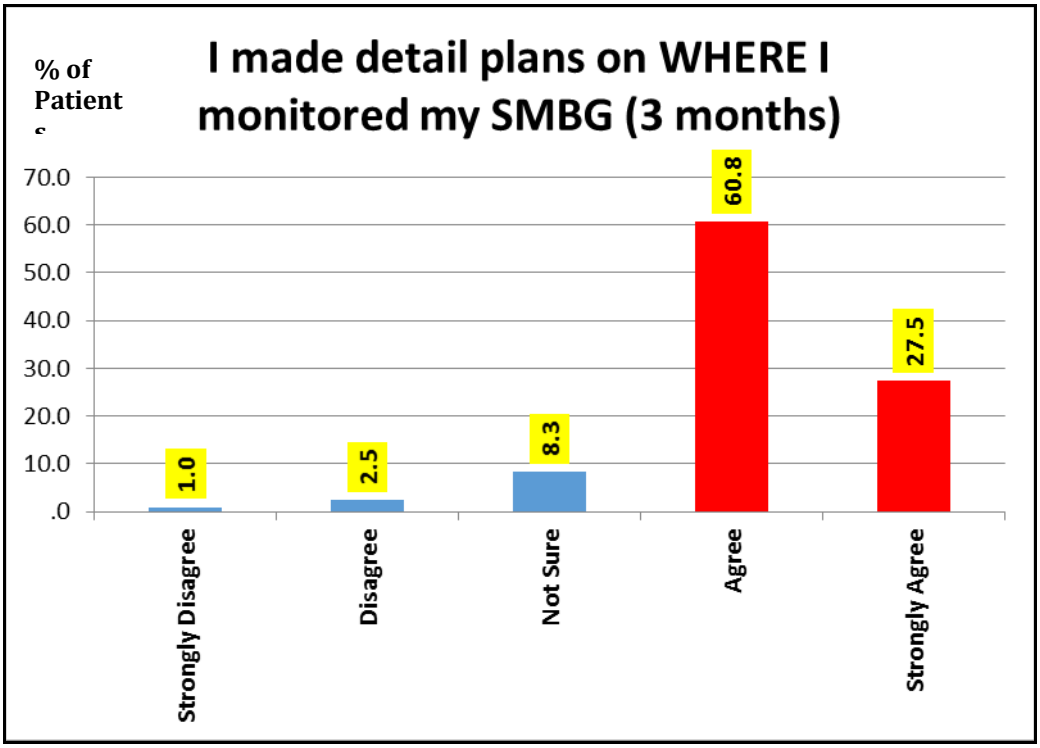


Figure 4.12.3 Three months - action planning – Where I monitored my SMBG?

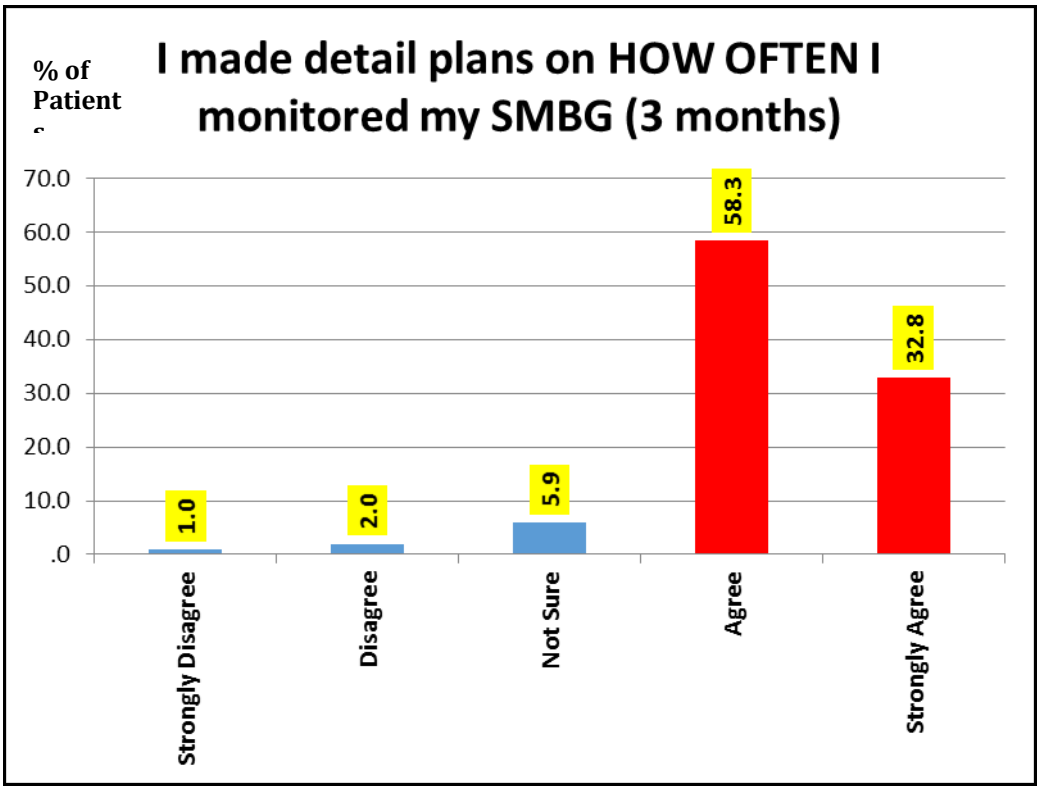


Figure 4.12.4 Three months - action planning– How often I monitored my SMBG?

4.5.5.5 Six months – Action planning

At the final visit, patients (n=204) were asked to reflect upon their previous SMBG task and were asked about the action planning questions. Figures 4.13.1, 4.13.2, 4.13.3 and 4.13.4 show the results of action planning level at 6 months SMBG intervention. The result revealed majority of patients Agree or Strongly Agree that they had made detail plans regarding (i) *how* they monitored their blood glucose (89.97%) (ii) *when* they monitored their blood glucose (86.30%) (iii) *where* they monitored their blood glucose (88.20%) and (iv) *how often* they monitored their blood glucose (84.30%) during the second three months of the SMBG intervention. Similarly, the overall pattern showed a further decrease in patients' pre-action self-efficacy level at 6 months compared to baseline and at 3 months. However, majority of patients still Agree or Strongly Agree with the SMBG action plan indicating they continued with their SMBG protocol until the end of the 6-month duration.

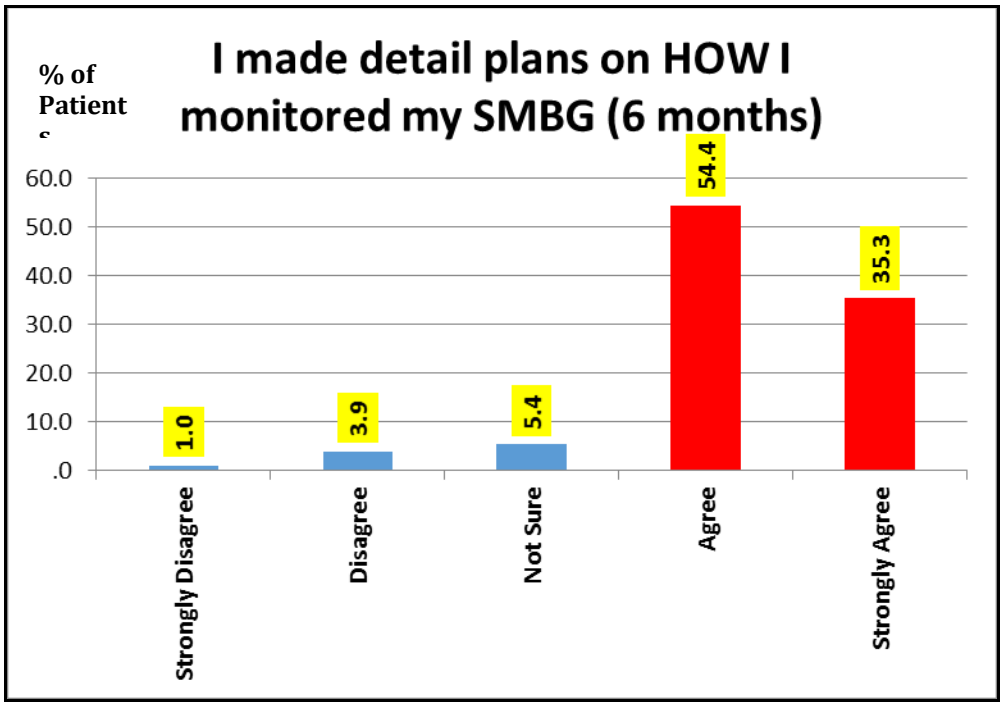


Figure 4.13.1 Six months - action planning – How I monitored my SMBG?

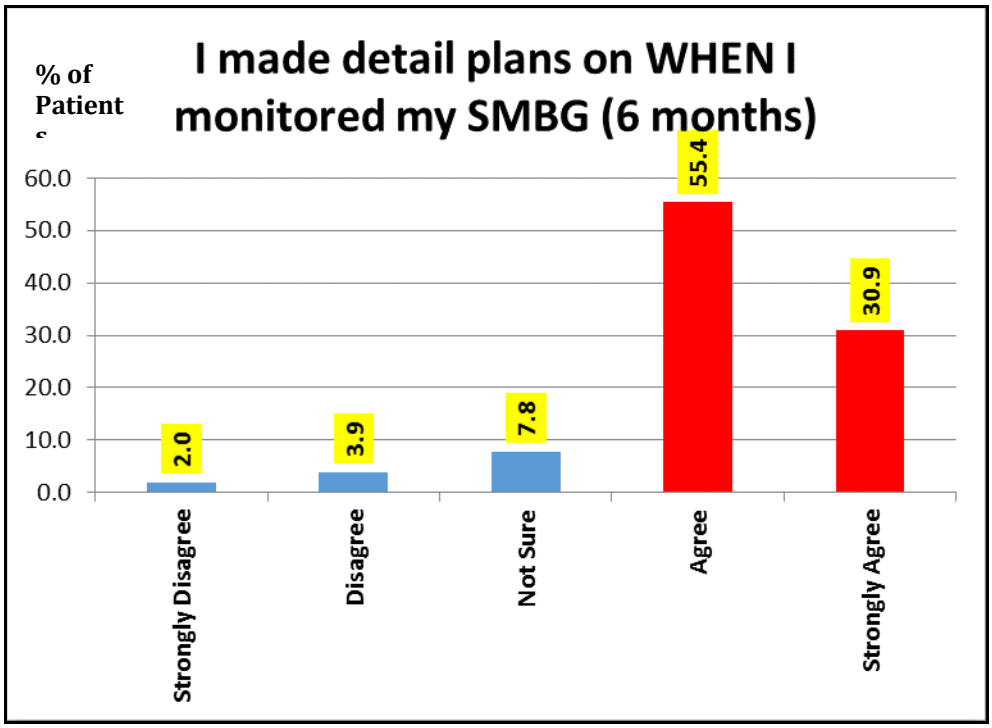


Figure 4.13.2 Six months - action planning – When I monitored my SMBG?

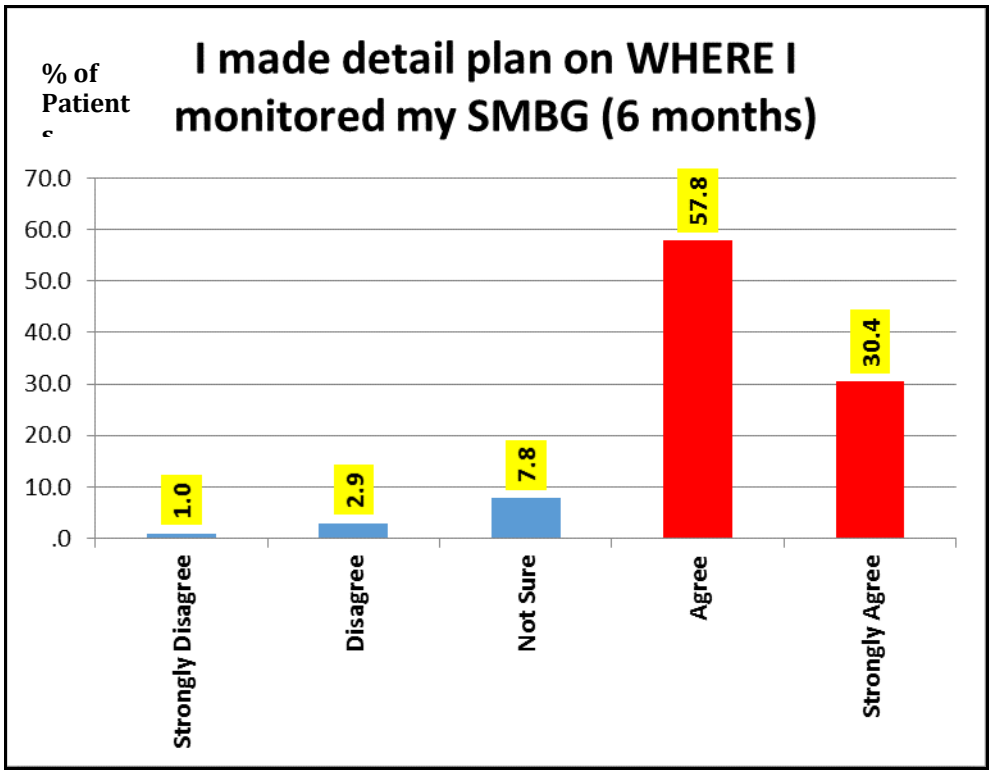


Figure 4.13.3 Six months - action planning – Where I monitored my SMBG?

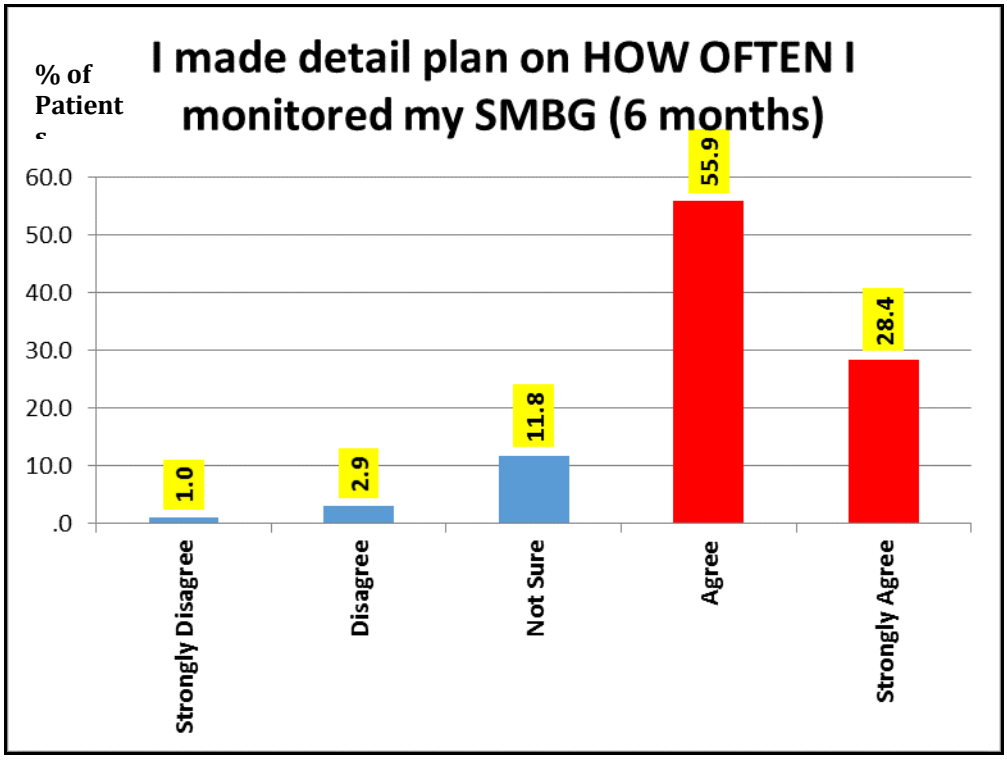


Figure 4.13.4 Six months - action planning – How often I monitored my SMBG?

4.5.5.6 Six months – Maintenance Self-efficacy & Recovery Self-efficacy

At 6 months, patients (n=204) were also asked to assess their commitment in doing SMBG (Maintenance self-efficacy) and whether they will be able to continue with SMBG even after a period of relapse (Recovery self-efficacy) (216). Figure 4.14 (Maintenance self-efficacy) and Figures 4.15.1 and 4.15.2 (Recovery self-efficacies) show majority of the study patients scored high in all the three questions. Majority of patients Agree or Strongly Agree to continue with regular SMBG regardless of their busy life (85.80%) and they would be able to recommence regular SMBG after a 3-month (84.30%) and 6-month (82.40%) hiatus.

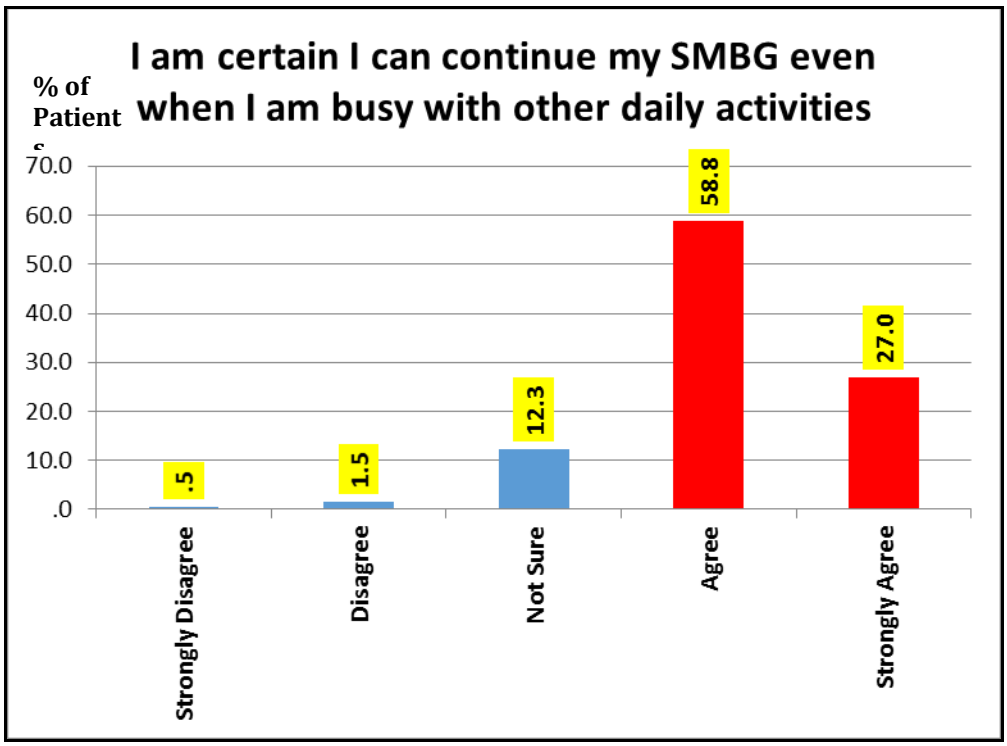


Figure 4.14 Maintenance self-efficacy at 6 months.

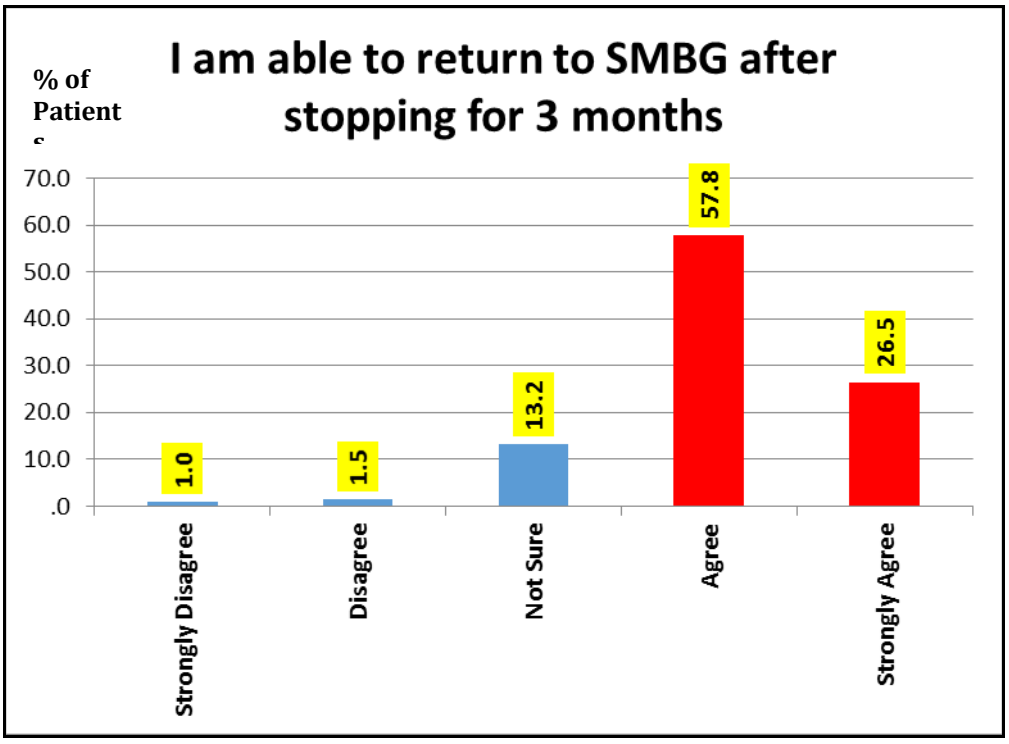


Figure 4.15.1 Recovery self-efficacy at 3 months.

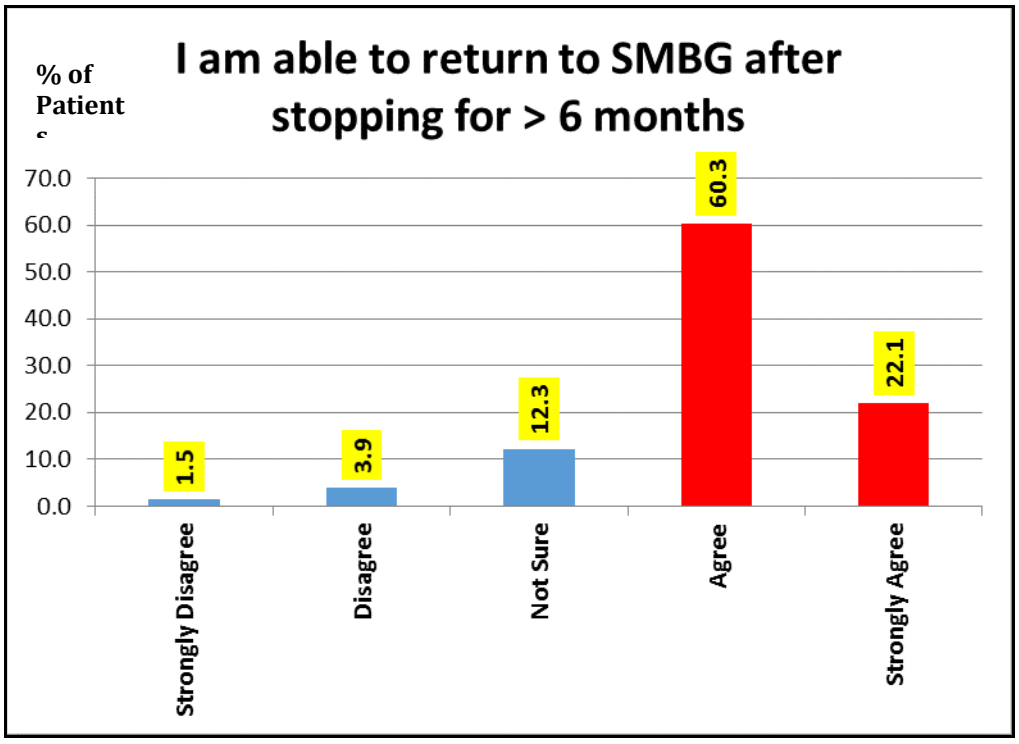


Figure 4.15.2 Recovery self-efficacy more than 6 months.

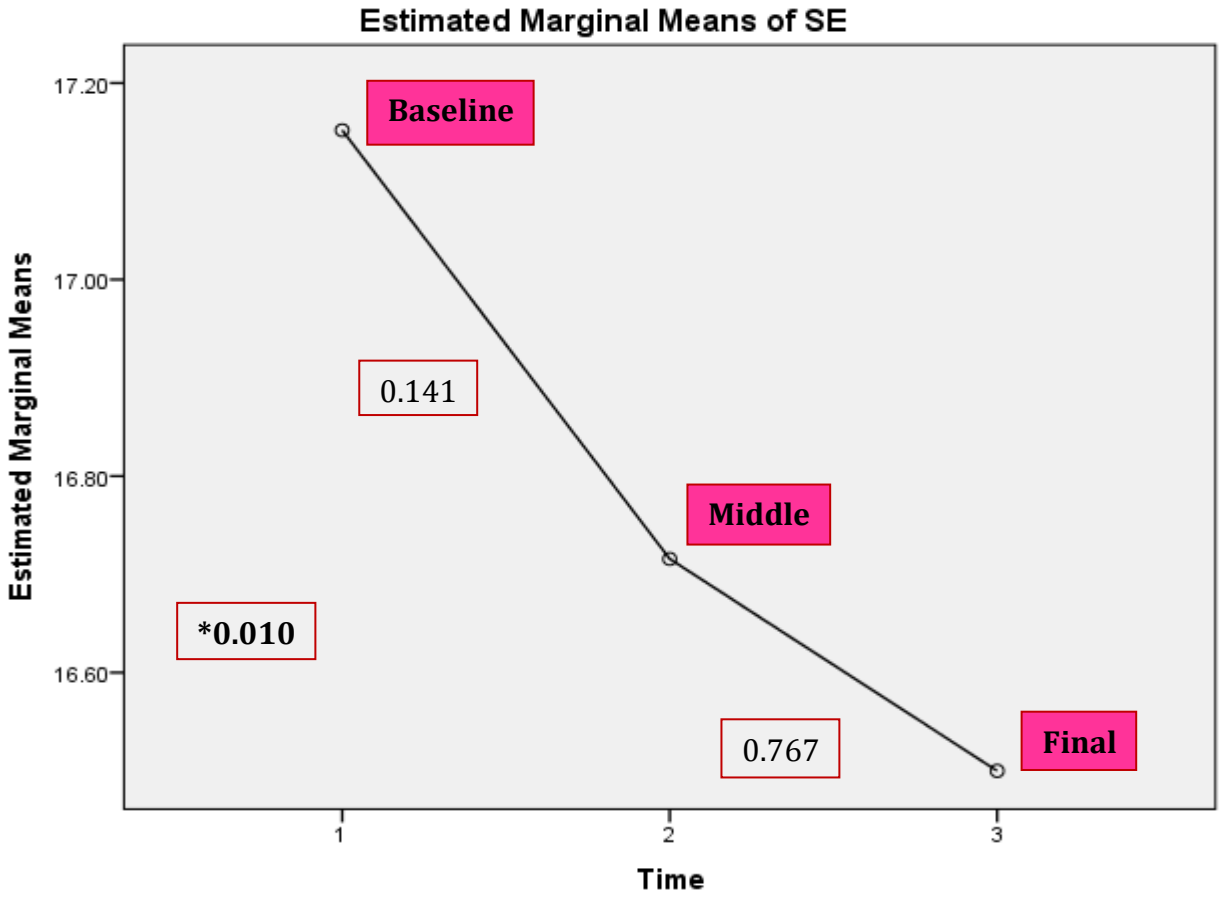
4.5.6 Action planning decay

Repeated measures ANOVA test between action planning at baseline, 3 months and 6 months showed a general decline in patients' action planning. Patients' action planning was highest at the beginning (of Module II - SMBG). Table 4.15 shows a statistically significant reduction in patients' action planning from baseline to 6 months (p=0.010) but not from baseline to 3 months (p=0.141) or from 3 months to 6 months (p=0.767).

Table 4.15 Action planning decay at 6 months.

Mean Difference of Action Planning at baseline, middle & end (n=204)				
Pairwise Comparisons		**Mean difference**	***p* value**	***95 % CI***
Baseline	Middle	0.436	0.141	-0.091 - 0.963
Baseline	End	0.652	0.010*	0.122 - 1.182
Middle	End	0.216	0.767	-0.241 - 0.672
p<0.05 (significant)*				

Figure 4.16 illustrates the decline in patients' action planning over the 6 months SMBG intervention. The steeper reduction of action planning observed on the graph, was from baseline till the third month indicating reduction of action planning occurred the most in the first part of the intervention. Consequently, a smaller decline of action planning was seen from the 3rd month until the 6th month. Although the general decline from baseline to middle and from middle to end was not statistically significant, the overall decline of action planning from baseline until the 6th month was statistically significant (p=0.010).



Nb. The zero on the y-axis had of the above graph had not been illustrated. The reason for this is to emphasis the change of action planning in the range showed above.

Figure 4.16 Action planning decay from baseline until the end of 6 months

4.6 Correlation Analysis

4.6.1 Correlation between SMBG frequency and psychological determinants I

The results showed statistically significant (p=0.001), moderate correlations between total action planning, maintenance self-efficacy and recovery self-efficacies (at 3 months and 6 months) with SMBG frequency. Table 4.16 and 4.17 below detail the correlation and significance between the psychological determinants and SMBG frequency.

Table 4.16 Correlation between SMBG frequency and psychological determinant I (i.e.total action planning and maintenance and recovery self-efficacies).

Correlation psychological determinants I and SMBG	r	r^2	p
Total Action planning	0.25	0.06 (6.0%)	0.001*
Maintenance SE	0.22	0.05 (5.0%)	0.002*
Recovery SE 1 (stop at 3 month)	0.22	0.05 (5.0%)	0.002*
Recovery SE 2 (stop > 6 month)	0.25	0.06 (6.0%)	0.001*
r < 0.20 is small; 0.20-0.30 is moderate; > 0.30 is large *p*<0.05 (significant)*			

4.6.2 Correlation between SMBG frequency and psychological determinants II

The results showed statistically unsignificant ($p<0.05$), large negative correlations ($r>0.30$) between outcome expectancies with SMBG frequency at baseline. In addition there was a statistically unsignificant ($p<0.05$), weak negative correlations ($r>0.30$) between risk perceptions with SMBG at baseline.

Table 4.17 Correlation between SMBG frequency and psychological determinants II (i.e. Risk perception and Outcome expectancy)

Correlation psychological determinants II and SMBG	r	r^2	p
Risk Perception 1	- 0.02	0.0004	0.15
Risk Perception 2	- 0.24	0.0576	0.73
Outcome Expectancy 1	- 0.95	0.9025	0.18
Outcome Expectancy 2	- 0.95	0.9025	0.17

r < 0.20 is small; 0.20-0.30 is moderate; > 0.30 is large *p*<0.05 (significant)*

4.6.3 Correlation analysis between Diabetes Knowledge and HbA1 level & SMBG Frequency

The results showed statistically significant (p=0.004), weak correlation between diabetes knowledge with SMBG frequency (r=0.12, p=0.004, r^2= 0.04) and statistically insignificant (p=0.6), weak correlation (r<0.2) between diabetes knowledge and glycaemic control. Table 4.18 details the correlation and significance between SMBG Frequency and Glycaemic Control with Diabetes Knowledge.

Table 4.18 Correlation between Diabetes Knowledge and HbA1C & SMBG Frequency

Correlation diabetes knowledge with:	r	r^2	p
SMBG frequency	0.12	0.04 (4.0%)	0.004*
HbA1C	0.03	0.01 (1.0%)	0.6
r < 0.20 is small; 0.20-0.30 is moderate; > 0.30 is large *p*<0.05 (significant)*			

4.7 Significant predictor for glycaemic control

The result of the multiple linear regression test showed that the only significant predictor of glycaemic control among this cohort of suboptimally controlled diabetes patients was the short duration of disease (p=0.001). Other variables such as patients' age, ethnicity, education level, waist circumference, medium and long term duration of disease as well as patients' knowledge score (i.e. a month post-intervention) were not significant in predicting patients' glycaemic control. Table 4.19 shows the final model from the multiple linear regression test using 'Enter' method showing short duration of disease as the sole significant predictor for glycaemic control. Similar findings were

also found when using stepwise method analysis confirming short duration of disease as the sole predictor of glycaemic control in this cohort of study (n=216).

Table 4.19 Significant predictor and other non-significant predictors of glycaemic control.

Variables	Unstandardized Coefficients		Standardized Coefficients	t	p
	B	Std. Error	Beta		
Primary Education	0.224	0.529	0.036	0.423	0.673
Duration Short (< 5 y)	1.967	0.567	0.262	3.470	0.001*
Duration Medium (5-10 y)	0.412	0.314	0.100	1.313	0.191
Ethnicity Malay	-0.331	0.345	-0.071	-0.960	0.338
Ethnicity Chinese	-0.275	0.711	-0.029	-0.387	0.699
Waist Circumference	0.005	0.012	0.029	0.435	0.664
Diabetes Knowledge Score (1 month)	0.609	0.325	0.148	1.873	0.062
Age	0.021	0.017	0.086	1.197	0.233

5.0 DISCUSSION

5.0 Summary of research findings

The positive impact of the education intervention programme was reflected by the global improvements in patients' ***glycaemic control***, ***SMBG compliance***, ***psychological determinants*** (i.e. action planning and maintenance and recovery self-efficacy) and diabetes knowledge.

Glycaemic control There was a significant within group improvement of patients' glycaemic control, with a reduction of HbA1C of greater than 1.0% (p=0.0001). The only significant predictor for glycaemic control in this study was short duration of disease (p=0.001).

SMBG In addition, 66.2% of patients had Compliance Index score of ≥ 80.0% during the six months of SMBG intervention. Majority of patients (75.0%) were strongly compliant, compliant and moderately compliant to the modified SMBG protocol at 6 months.

Psychological determinants There were high level of total action planning (i.e. baseline, 3 months and 6 months) and SMBG self-efficacy scores (i.e. maintenance and recovery) among patients. These results indicated study patients were encouraged to perform action planning and had increased self-efficacy to continue with SMBG even if they had stopped monitoring for 3 to 6 months. Correlation between action planning and SMBG frequency were statistically significant (p=0.001) and moderately correlated ($0.20<r< 0.30$) indicating the potential role of action planning in SMBG. However, only a small correlation between Diabetes Knowledge and SMBG frequency ($r<0.20$) and not statistically significant ($p<0.05$) were found.

Diabetes knowledge and Telephone follow-up Majority of patients scored Very Good (72.6%) or Excellent (7.8%) in their Diabetes Knowledge Score at the end of the 18 months follow-up. All the ten diabetes topics tested from the education module performed very well with mean performane scores of ≥ 70.0%. There was a high retention rate of almost seventy percent (69.6%) for telephone contact follow-up at 18 months.

5.1 Primary Outcome - Glycaemic Control

5.1.1 Improvement of glycaemic control

In this present study, there was a within group reduction of HbA1C of *greater* than 1.0%. The within group reduction of HbA1C were clinically and statistically significant (p=0.0001). Established landmark studies have proved that reduction of HbA1C can reduce the risk of both micro- and macro- vascular complications in established diabetes patients particularly when glycaemic control has been sustained (101, 121, 138).

The results of the current confirmed that poorly-controlled SMBG-naive patients benefited from attending the diabetes education intervention delivered in their respective ambulatory health care centres. The impact of the education programme was reflected by the overall improvement of patients' HbA1C level of 1.24% ± 2.03.

5.1.2 Timing of SMBG intervention on glycaemic control

Although the timing of the SMBG delivery was 6 months apart, both groups showed significant reduction (p=0.0001) in their glycaemic control. The results also found no significant difference (p=0.486) in the glycaemic improvement between the two groups although the timing of SMBG intervention was different. However, due to the study design (i.e. non-controlled) no conclusion pertaining the effectiveness of the education intervention on HbA1C can be drawn.

5.1.3 Significant predictor of glycaemic control

The only significant predictor for glycaemic control was short duration of disease. Other factors such as patients' age, ethnicity, education level, waist circumference, medium and long term duration of disease and patients' knowledge score were not significant in predicting patients' glycaemic control. However, due to the smaller sample size of patients (10.5%) with shorter duration of disease compared to the entire cohort, this result should be interpreted with some caution. Similarly, in their study Chan *et al* also found short disease duration a predictor for good

glycaemic control, together with other predictors such as patient access to SMBG and self-management education from diabetes educators (243).

5.2 Telephone Contact follow-up

The retention rate of patients in Telephone Contact remained relatively high with almost 70% at 18 months. The positive high trend in patients retention rate suggests that majority of patients remained engaged and committed to the programme for at least eighteen months. The findings suggest that Telephone Contact is a suitable modality for diabetes education and management follow-up.

5.3 Knowledge

5.3.1 Diabetes Knowledge Scores (DKS)

The results of the Diabetes Knowledge Score (DKS) is encouraging and suggested patients benefited from attending the MY DEMO diabetes education programme. As previously reported, the median score for Diabetes Knowledge Questionnaires (DKQ) scores was 148/168. At 18 months, an overwhelming majority patients scored Very Good (83.8%) or Excellent (2.8%) in the DKS category. Only a small number of patients scored Unsatisfactory (5.1%), and none (0%) were in the Poor category. In essence, majority of patients retained their diabetes knowledge at 18 months.

5.3.2 Knowledge Retention

The main finding from the knowledge component of the study were: (i) majority of patients benefited from the diabetes education module and achieved and retained relatively high score of diabetes knowledge (i.e. majority of patients scoring $\geq$ 70%) and (ii) the level of knowledge remained consistent with no decline throughout the period of 18 months.

This is the first diabetes education intervention study which had conducted a detail "knowledge level tracking" among patients. To date, there have not been any published studies showing a detail knowledge decline over a relatively long follow-up period. Although the three large structured diabetes education studies (17, 18, 64) reported an overall increase in diabetes knowledge beyond

18 months post intervention (i.e. 3 years for DESMOND study; 14 months for X-PERT study and 4 years for ROMEO study), the authors did not report in detail the increase in the knowledge level pattern among patients. Furthermore, the emphasis of previous studies which investigated knowledge level among diabetes patients (79) focused mainly on cross-sectional studies of patients' baseline diabetes knowledge level (80-88) and identifying the significant knowledge determinants associated with diabetes knowledge scores. Hence, in majority of the diabetes education studies, only "snapshot views" of patients' general knowledge of diabetes were captured, rather than an overall trend of knowledge pattern over a period of time (80-88). A comprehensive literature search on diabetes knowledge studies did not reveal any new studies investigating diabetes knowledge retention or decay similar to the current study findings.

Hence, this novel information provides an objective evidence of what actually happens to patients' knowledge over a period of time. This information is significant as it can lend some new insight to diabetes educators and researchers, especially when developing and implementing an integrated diabetes education programme. Given that diabetes is a chronic disease with complex issues, it will be imperative and challenging for physicians and health care providers to keep patients engaged with on-going education and simultaneously help them to manage their conditions better

5.3.2.1 Attitude and belief towards diabetes education

One possibility to explain knowledge retention over time is that of patients' positive general attitude and belief towards the intervention. Older studies by Anderson et al and Beeney *et al* have suggested the ability of patients to learn and retain knowledge is highly influenced by their attitudes and beliefs (186, 187). In contrast, Murata *et al* found patients' attitude at the beginning of an intervention is more positive and receptive compared to later part of the follow-up intervention (56) leading to a slight decline in their knowledge towards the end of the study intervention.

5.3.2.2 Application of diabetes knowledge to daily activities

It is well accepted that knowledge is best learnt and retained when one applies the knowledge to their daily life. Hence, it is reasonable to speculate that the study patients' internalised and applied their newly acquired knowledge into their daily life. The sustained knowledge seen in patients positively suggest that most patients were able to apply what they had learnt into their daily activity, particularly with regards to SMBG.

5.3.2.3 Time-frame for diabetes education support

Our current finding which showed patients retained their knowledge throughout the study duration has not been able to contribute or inform the optimum time-frame for diabetes education. Previous studies had advocated on-going diabetes education as an integral part of patients' diabetes management plan (10, 15, 16, 62, 65, 74) and AADE recommends an annual assessment of the seven self-care behaviours on patients to assist patients in their self-management (28).

5.3.3 Performance score of individual questions from each topic

Individual questions were asked to assess various content of the education module. The analysis of individual questions from each topic or subtopics showed encouraging results. Almost all of individual questions (163 of 168) from the ten topics achieved mean scores between 70.0-97.0%. Five of ten topics (i.e. benefits of exercise, general topic on diabetes, diabetes symptoms, foot-care and diabetes complications) achieved mean score ≥ 90.0%. The remaining five topics (i.e. SMBG, blood glucose levels, diabetes pathophysiology, prevention of diabetes complications and hypoglycaemia) achieved score ≥ 70.0%.

Although, many previous studies (80-88) had reported patient's level of knowledge at one interval (i.e. cross-sectional knowledge level), this current study was able to show the level of knowledge retention for at least 18 months after the first intervention. The sustained high scores achieved by individual questions at various time interval (i.e. month 1 to month 18) reflected patients' knowledge trajectory from the beginning to the end of the study. Although the current study does

not have a control group, it is reasonable to surmised from the sustained high performance score of the individual questions (n=168), that study patients had a good grasp of the content and concepts which were embedded within the MY DEMO education module.

5.3.4 Unsatisfactory performance score for a few questions

A small number of questions (5/168) scored unsatisfactory (≤48.0%). These questions were from three topics; hypoglycaemia, diabetes pathophysiology and prevention of diabetes. The possible explanations for the gap of knowledge on hypoglycaemia could be that patients had never experienced hypoglycaemia in the past or they were unaware of the hypoglycaemia signs and symptoms. This is partly because study patients were SMBG-naive and had never monitored their blood glucose prior to joining this study. Knowledge deficit in identification of hypoglycaemia and blood glucose levels had also been identified in many previous studies (82-84, 86, 244).

Regarding diabetes pathophysiology questions, the aims of these questions were to highlight (i) the ill-effects of prolonged hyperglycaemia (ii) basic pathogenesis of glucose metabolism (iii) insulin resistance and to link the basic concepts of mechanism of action with common diabetes medications such as biguanide and insulin. There were visual and verbal elaboration of the basic diabetes pathophysiology in MY DEMO. Given the complexity of the diabetes pathophysiology, only 1/16 question scored unsatisfactory. This indicate that with a structured education, diabetes patients can learn and retain the knowledge although it might be complex. This topic is relevant as the lack of the understanding of this topic might hinder patients from adhering to the complex regimen of diabetes treatment plan.

In contrast, there were some confusion in 2/12 questions on prevention of diabetes complication. The options stated range of percentage (i.e. 5-10%, 10-15%, 15-20%) of weight an overweight or obese patient need to lose. In hindsight, these two questions might have been confusing or difficult for patients to understand. Some patients answered in quantum (i.e. 2 kg, 3kg) rather than in range of percentage stated by the options. For those who answered correctly, they would have to convert

quantum to percentages which require another step of numerical processing. This finding is a useful reminder for myself regarding writing and selecting the suitable question.

5.3.5 Knowledge determinants - education level and disease duration effects

The results of the study showed that higher education level and longer disease duration have a positive effect on patients' knowledge score. Patients who received secondary and tertiary education scored higher than those who received primary education or no formal education. In addition, the longer the disease duration the higher the patients' knowledge score. Both findings had also been shown in many previous studies (81, 83, 84, 88) as knowledge determinants.

A large body of evidence from previous studies have shown that socio-demographic indices such as gender, age, house-hold income, level of education, duration of diabetes, types of treatment received and access to health education are all significantly associated with patients' diabetes knowledge level (80-88). In contrast with previous studies, in this study age and gender was not shown to have any effects on knowledge scores. Notably, relationship between gender and knowledge have also been contradictory with some studies reporting (i) lower knowledge among women (90) (ii) higher knowledge among women (81, 82) or (iii) no difference in knowledge level between women and men (83, 86, 88) indicating unequal access to diabetes education between men and women in some regions of the world.

Hence for diabetes education to be effective, the content and delivery of the programme must be tailored to the context of patients' cultural, social and educational environment.

5.3.6 Correlation between diabetes knowledge and glycaemic control

The relationship between diabetes knowledge and glycaemic control *per se* was statistically not significant with weak correlation. Although both measurable outcomes improved in the current study, the correlation between diabetes knowledge and glycaemic control remained weak. One of the reason for this could be glycaemic control is a clinical indicator which has many other contributory factors. As per the Australian national consensus, clinical outcomes (i.e. HbA1C) and

cost effectiveness (i.e. out of pocket expenses) may not feature as dominant actors on diabetes education outcomes (12). Hence it is unsurprising for the weak correlation between diabetes knowledge and glycaemic control to be found in this current study.

5.4 Self-Monitoring Blood Glucose (SMBG)

5.4.1 SMBG Compliance Index

The result of the SMBG frequency and SMBG Compliance Index among the poorly-control SMBG-naive diabetes patients showed an overwhelming majority (73.3%) of the patients adopted the new SMBG behaviour for the 6 months period. More than half of the patients achieved 100% SMBG Compliance and a fifth of patients monitored their blood glucose more frequently then what was required ($n \geq 114$) for the study. Remarkably, these patients (20.4%) bore the extra-cost themselves in order to purchase the extra glucose strips.

Both groups achieved similar high SMBG Compliance Index (Group 1 71.3%; Group 2 78.8%), although the second group started SMBG 6 months after Module I. There were no significant difference in the SMBG Compliance ($p=0.455$) between the two groups. The similar results indicated the timing of the diabetes education delivery did not influence patients in adopting a new self-care behaviour (i.e. SMBG) or their adherence to the SMBG protocol.

In addition, the SMBG Compliance found in this study was higher what had been previously reported by other local studies (169-171). Of note, in this study all patients were provided with a certain number of glucose strips to perform the blood glucose monitoring for 6 months. As shown in previous studies, provision of glucose strips is one the main facilitator for SMBG-practice (178).

5.4.2 SMBG Facilitators

In the current study, patients were provided glucose strips and a comprehensive explanation about the "what, why, where and how" of blood glucose monitoring. The current study concurs with previous studies (178) which had shown provision of glucose strips to patients have greatly facilitate SMBG-practice. In addition, the current study also provided step-by-step guidance on how

to perform SMBG correctly as well as introducing to patients some psychological and behavioural concepts such as action planning and self-efficacy to motivate patients to begin a new task – i.e. SMBG-practice. In the previous study, it was reported that less than a third of patients received any kind of diabetes education and most patients felt grossly under supported when it comes to counselling in SMBG-practice (170).

5.4.3 Psychological determinants for SMBG

At the onset of the study an overwhelming majority of patients believed SMBG will increase their well-being (90.2%) and delay their diabetes complications (82.4%). Hence, strong behavioural intentions were established at the beginning of the SMBG task by majority of the patients. Most likely this strong belief motivated the patients to embark on the new task although they were novices. Established motivational constructs for behavioural intention such as "risk perception" and "outcome expectancy" from Bandura's Self-efficacy theory (206, 225) were included in the baseline BQ. The rationale was to get patients to carefully consider all the things related to the upcoming task (i.e. SMBG).

The overall results pertaining action planning for SMBG was encouraging. Patients scored consistently high for the three action planning intervals (i.e. baseline, three months, six months). This positive results indicate that action planning facilitated SMBG for the patients who were new to the task. However, a small but significant decline in action planning were observed over the 6 months duration. This might be explained by patients increase ability to plan for SMBG, as they become more familiar with the tasks.

The high scores for maintenance self-efficacy and recovery self-efficacy score were important as they indicate patients were willing to continue with SMBG even when after they have stopped for a period of time (i.e. 3 months, 6 months). Ideally, a 12-18 month follow-up study to ascertain how many patients were successful in the maintenance phase, would be beneficial, to measure if there are any legacy effects gain from this present study.

5.4.4 Post-prandial blood glucose monitoring - Asymptomatic Hyperglycaemia

In the present study, emphasis was placed on educating patients regarding their individual daily glycaemic excursions by getting patients to perform 2-hour post-prandial blood glucose monitoring more frequently (i.e. 60% is 2-hour post-prandial). Clinically, in patients with equivalent HbA1C, those with higher glycaemic excursions and higher 2-hour post-prandial blood glucose have a higher risk of developing micro- vascular complications (102).

One of the aims of the SMBG protocol was for the patients to appreciate the abstract concept of asymptomatic hyperglycaemia and be more mindful about their daily dietary and beverage intake. Incidentally, Malaysia is well-known for its status as a food haven and a variety of delicious foods and sweetened beverages is available around the clock for the public to consume creating a big challenge for patients to follow a strict and healthy diet deemed compatible with diabetes.

Based on the asymptomatic nature of hyperglycaemia, most patients have very little awareness and knowledge about their daily glycaemic excursions although this can be harmful and expedite diabetes-related complications (14, 245, 246). In the present study, the modified "staggered SMBG protocol" was designed to allow patients to capture the 2-hour post-prandial blood glucose daily excursions. For the first time, SMBG-naive patients had the first-hand experience of checking and recording their individual daily post-meal daily excursions onto their logbook for 6 months. Hence for the first time, most of the SMBG-naive patients to recognise their post-prandial blood glucose surge phenomena.

5.4.5 Correlation between Psychological Determinants with SMBG

Correlation between action planning, maintenance self-efficacy and recovery self-efficacy with SMBG frequency were moderate ($0.20<r<0.3$) and statistically significant ($p<0.05$). Although correlations were moderate, action planning and self-efficacy components are important in understanding how and why patients initiate and continue the newly adopted self-care behaviour. Previous studies have shown multiple factors influencing (i.e. time, costs, skills, self-efficacy,

knowledge, previous experiences) patients' SMBG Compliance (172, 173, 175-178). Henceforth, it is unsurprising for correlation values (r^2) for action planning and self-efficacies to contribute only a small percentage (i.e. 6.5% total action planning; 5.0% for maintenance SE; 5.0% for recovery SE at 3 months; 6.5% for recovery SE at 6 months) towards the SMBG Compliance. In this case, although the percentage of correlation were small (≤6.5%), health care providers must be cognizant of the importance of action planning and self-efficacy in initiating and maintaining behavioural changes. Consequently, it is important for health care providers to appreciate while patients learn and execute action planning and maintain self-care practices, they also need on-going support and education to sustain their confidence and ability to perform the multitude of task required to manage their condition.

5.5 Practical Applications

5.5.1 The development of an education module – MY DEMO

The first objective of the research study was achieved with the development of a contextualised and integrated diabetes education module (MY DEMO; Module I & Module II) which was based on the Health Belief Model (HBM)(202) and Health Action Process Approach (HAPA)(205). MY DEMO had been tailored to suit diabetes patients in Malaysia and can be offered to patients as an on-going diabetes education support.

As mentioned previously, there has been an obvious gap in the availability of a structured and contextualised education module in Malaysia. Apart from one structured self-care programme on SMBG developed by Ming (67), there have been no other structured education module published in Malaysia. Hence, MY DEMO was developed as a much needed educational tool to fill the gap in the diabetes education landscape of Malaysia. Significantly, the results of this present study confirmed the improvement in patients' metabolic control, knowledge and self-care monitoring behaviour (i.e. SMBG).

5.5.2 Development of study protocols

In the current study, two protocols were used ensure intervention was conducted smoothly. The Telephone Contact protocol provided timely guidelines for patients to be contacted on specific interval during the 18 months follow-up. The modified "staggered SMBG protocol" was also developed to help patients structure their SMBG schedule around their daily and weekly activities. The SMBG protocol was classified based on the frequency of SMBG per week (i.e intense, moderate and least frequent) to help patients follow the protocol during the study. Both physicians and patients could continue using the modified SMBG protocol to manage patients' condition in their respective ambulatory health care settings in the future. SMBG is simply a tool to inform patients about their blood glucose levels. Ultimately, patients need education and further support regarding what they should do when faced with abnormal glucose levels (148, 167). In addition, the plethora of new generation SMBG studies outlined by Parkin *et al* (152)strongly advocate structured SMBG regimen to facilitate behavioural change from SMBG.

5.5.3 SMBG-focus tools

A well-rounded SMBG-focus tools had been developed in the current study. The overarching importance of SMBG were embedded in the education module (Module I) and educational SMBG video (Module II) which was developed. A contextualised SMBG logbook paper tool was developed to guide patient record their blood glucose levels in a systematic manner. This simple paper tool can be used in collaboration with physicians to help monitor daily blood glucose excursions in a more objective manner. This is aligned with the IDF recommendation for SMBG use in non-insulin treated diabetes patients (130).

5.6 Strengths

5.6.1 Long follow up

A strength of MY DARLING study is the relatively long period of follow-up (i.e. 18 months) to observe patients' knowledge level pattern. To date, there has not been any published study which specifically tracked patients' knowledge level pattern over a relatively long period. As mentioned earlier, the useful observation discovered from the 18-month Telephone Contact follow-up showed sustained knowledge score throughout the duration of the study.

5.6.2 A targeted and tailored SMBG programmes

Previous literature reviews on SMBG studies have consistently found mixed results pertaining to HbA1C improvement *per se*, with some supporting (131, 143, 146) and others opposing (132, 247, 248). This is unsurprising because the aim of these studies were to either confirm or refute the benefit of SMBG in glycaemic control. Issues related to inadequate research design and the lack of guidance from physicians when it comes to responses to out-of-range blood glucose levels (123, 142, 144-146) also made the SMBG findings obscure. Earlier qualitative studies by Peel *et al* and Gucciardi *et al* found non-insulin treated diabetes patients may become demotivated, anxious and feel guilty due to "out-of-range" blood glucose levels when timely and expert feedback from health care givers are absent (173, 177).

In the same context, the result of the present study supports that behavioural change such as adoption of SMBG is possible among SMBG-naive patients who received adequate and regular support though a contextualised education module and long-term Telephone Contact follow-up.

In this present study, patients followed a modified "staggered SMBG" protocol for 6 months and supplied with glucose strips, which facilitated majority of them to achieve a high satisfactory SMBG Compliance rate. However, in this study, a fifth (20.37%) of patients did more SMBG than what was required of them by purchasing the glucose strips from their own out-of-pocket expenses. Furthermore, an overwhelming majority of patients reported that they will continue to perform

SMBG regardless of their busy schedule and will resume SMBG behaviour even after stopping for 3 months or 6 months. These encouraging reports suggest that once patients become highly motivated and convinced that certain behaviour(s) are beneficial to them, typical barriers such as costs did not feature prominently.

The recent findings from Polonsky *et al* (148), Bonomo *et al* (155) and Shiraiwa *et al* (156) tackled the sustainable cost issue of SMBG by shifting the emphasis from SMBG quantity (testing frequency) to SMBG quality (meaningful test). The results showed "occasional SMBG" (156) and "quality versus quantity SMBG" is more useful and cost-efficient and ultimately have better impact on glycaemic markers (148, 155). Patient's cognizance that the onus is on them to adjust their behaviours and make the necessary changes is critical in order to achieve the desired glycaemic and clinical outcome (130). Importantly, there must be an on-going collaboration between physicians and patients to discuss and make lifestyle, dietary and therapeutic changes based on the blood glucose data acquired from SMBG (130).

Hence, in summary the high adoption rate SMBG achieved in this study is reassuring and expected. This is because, the educational tools were designed to support patients to be well prepared mentally with the necessary cognitive skills so they can link potential obstacles to SMBG in their daily situational scenarios (e.g. busy working schedule, inappropriate office space, lack of privacy *etc*.) with ways to execute the goal behaviour (e.g. 2 hour post-prandial blood test) (218). The modified SMBG protocol also guided the SMBG-naive patients to incorporate the new self-care monitoring behaviour into their day-to-day and week-to-week activity with relative ease (130). Hence, these practical steps in turn helped patients to adhere to the SMBG protocol.

5.7 Limitations

5.7.1 Non-Control Design

One of the main limitations of this current study is that it is not a randomised control trial. Both intervention groups (Group 1 and Group 2) received the identical educational intervention at the beginning of the study and was followed up via Telephone Contact for 18 months. Although, the nature of this current prospective study is unable to measure the effectiveness of the education program, it does strongly suggest that patients who attended the education module and completed the SMBG intervention benefited from the above interventions. This was confirmed by the results of the blood test, knowledge scores and behavioural measurements. There was a significant within-group reduction of HbA1C, a high proportion of patients achieved high knowledge scores and performed frequent SMBG during the entire study follow-up. Nevertheless, future randomised control study will be much needed to measure the effectiveness of the newly developed education module and its measurement tool tests.

5.7.2 Recruitment Bias

Another limitation of the current study was recruitment bias. As explained in Section 3.5.2, a modification process was implemented to improve recruitment to achieve adequate sample size. Two steps were taken to address the recruitment issues. One was to increase the clinical sites from two to four, the other was to have an "extra" face-to-face briefing session with potential participants. For the two extra clinical sites (i.e. KK Shah Alam and KK Kelana Jaya), there were no issues with regards to patients' demographics or the type of treatment they received. This is because all four clinical sites are under of Ministry of Health, and is consistent it terms of its framework, delivery and treatment of patients.

Regarding the briefing session, potential participants who fulfilled the study criteria had a chance clarify any issues with myself before making a decision to join the study. Hence, motivated patients who attended the "extra" briefing session, had a better understanding of how the current study will

be implemented. Nevertheless, not all patients who attended the "extra" briefing session agreed to join the education module (See Figure 3.3. 81.25% retention rate in modified process). This indicate that post modification process, majority of patients who joined the study, were motivated to learn about their condition and make a change in their lifestyle. Hence, there is a possibility that the positive changes that were reported in the current study is partially attributable to patients' own motivation.

5.7.3 Response Bias

The results for the risk perception for normoglycaemia and post-prandial hyperglycaemia showed response bias towards high probability. The two questions were conceptually different and the results were mixed. The first question showed majority (72.0%) of patients showed a bias towards high probability for having a fasting blood glucose being < 7.0 mmol/l. This inferred that patients think they have a high probability of achieving satisfactory glycaemic control. Although, patients knew their diabetes control had been out-of-target (HbA1C >8.0%), the results indicated a bias towards high probability their fasting blood glucose was normal.
In contrast, the following question showed a greater majority (93.1%) of patients showed bias towards high probability for having a post prandial blood glucose being > 10.0 mmol/l. This inferred that patients think they have a high probability of their diabetes control being out-of-target. In this case, majority of patients identified correctly that their post prandial blood glucose was higher than 10mmol/l, in line with their out-of-target glycaemic control (HbA1C >8.0%).
In both cases however, there was bias against high probability. In the first instance of normoglycaemia, response bias indicated optimistic bias among patients. Unrealistic optimism is the general rule in the literature on risk perception (249, 250) except in smoking where the findings had been quite mixed (251). Sutton posited the importance to differentiate the factors or conditions which brings about optimism or pessimism bias. Certain national, cultural, secular factors can play a role in response bias. Additionally, differences in

methodology (e.g. self-completion versus face-to-face interview, direct versus indirect measures, numerical risk estimates versus comparative risk estimates) may also be important in response bias phenomena (251, 252).

Studies have also shown, when patients were asked questions using direct measures in comparative risk estimates questionnaires, results have shown fairly consistent tendency for optimism bias - such as found in the current study (251).

The application of this findings have highlighted that some patients still show some lack of understanding with regards to their own glycaemic control. The reasons may be due to; (i) methodology issues (i.e. patients may not understand the question) (ii) lack of experiential learning (i.e. patients simply do not know what their blood glucose since they were SMBG naïve) (iii) content issue (i.e. patients are confused about the blood glucose target range). This posed as a good reminder for myself and other physicians and health care provider to discuss this important topic with patients especially during face-to-face consultations.

5.7.4 Attrition rate

The initial number of patients who declined to participate in the study at the beginning was high (35.87%). The lack of interest among diabetes patients to attend diabetes education programmes have also been reported in other studies in the United Kingdom (64, 253). Interestingly, in the current study, once the patients had signed up into the education program (n=286), the attrition rate of patients remained modest for each step of the intervention. Although some small reduction in numbers of patients were observed during the study duration, the overall patient retention rate was fairly good. This was reflected by the high retention rates for Telephone Contact (69.58%) and SMBG (75.52%) at the end of the study. Given that Type 2 Diabetes is a complex and chronic disease, which require patients to be driven and committed in their diabetes treatment and education plan in the long-term, these findings are encouraging and shows that study patients were motivated and engaged with the programme till the end of the study.

However, the poor response from a third of the patients (35.87%) who declined to participate in this study in the first place, reflects a realistic scenario of "real world" intervention carried out in busy ambulatory health care settings. The endemic issue of poor participation and engagement among patients who probably needs the most assistance (i.e. suboptimum control) in managing their condition is an important reminder for the author (and other diabetes educators) to continue to pursue in this diabetes education endeavour (254).

5.8 Synopsis

Diabetes education and self-care are cornerstones to diabetes management (7) (6) (57). The failure of controlling the diabetes epidemic in Malaysia (1, 11, 222, 255-258) signals an urgency for effective well-rounded intervention(s) to combat the consequences of the disease, one of it being a structured diabetes education programme such as MY DEMO.

The current study has shown that an education module which integrated both knowledge and self-care monitoring components had successfully improved patients' glycaemic control. An attempt to determine which component of the education module contributed more to the glycaemic improvement suggest that diabetes is a one dimensional condition which can be sufficiently treated using a single modality. This will not give a true impression regarding the versatility and heterogeneity nature of this condition.

Two decades of research and meta-analytic reviews have shown although diabetes education is necessary, it is not sufficient to enhance self-care behaviours in people with diabetes (259-262). Hence, diabetes education programme efforts should also encompass behavioural strategies to motivate and empower patients to care for themselves effectively and independently (84). Therefore, in designing MY DEMO education programme, there was a deliberate effort to integrate diabetes knowledge and self-care behaviour (i.e. SMBG) intervention. The results of the study showed that majority of the patients had gained more knowledge and adopted the new self-care

monitoring behaviours and consequently there was a significant improvement in the overall glycaemic control of patients.

Both knowledge indicators (i.e. Diabetes Knowledge Score) and psychological determinants (i.e. action planning, maintenance and recovery self-efficacy) had been included to measure outcomes of the intervention. The measurable indicators in this study is aligned with the National Consensus Position on "Outcomes and Indicators for Diabetes Education" (12).

To reiterate, the hypothesis of the present study states "Poorly-controlled Type 2 Diabetes patients who are SMBG-naive or SMBG-inexperienced, when intervened with diabetes education and self-care monitoring skills (i.e. self-monitoring blood glucose) will improve their metabolic outcome, diabetes-related knowledge and self-care behaviour and these improvements will be sustained for at least one year to 18 months".

Hence, the research hypothesis had been affirmatively answered by the significant reduction of HbA1C achieved among sub-optimally controlled, SMBG-naive Type 2 Diabetes patients who successfully completed the intervention module. In addition, majority of the patients also achieved high level of diabetes knowledge score, adopted the SMBG behaviour successfully with high level engagement and self-efficacy. Majority of patients also remained engaged throughout the telephone contact follow-up and the intervention period.

6.0 CONCLUSIONS

My following conclusion remarks will include (i) recommendations and solutions to the problem statement (ii) further challenges to consider in developing and improving the diabetes care delivery framework and (iii) some future research plans related to findings of this current study.

6.1 Recommendations and Solutions to the Problem Statement

6.1.1 The availability and suitability of MY DEMO

As part of a *solution* to address the obvious lack of resources in diabetes education programmes in this country, I would recommend MY DEMO be utilised as a stand-alone education tool or as part of a larger diabetes education toolkit. In developing and delivering MY DEMO, I was cognizant of the busy public health care system setting. Consequently MY DEMO is a much shorter programme compared to the ones delivered in the UK (15-17) and Europe (18) settings. This module is tailored to suit Malaysian patients and compatible with the local health care providers and the busy health care setting.

6.1.2 The implementation of MY DEMO

The results of the current study supports the positive impact of MY DEMO education programme among diabetes patients attending the four ambulatory health care settings. The next logical step to consider will be to identify a distribution network system to disseminate MY DEMO to as many primary stakeholders (i.e. patients with diabetes) as possible.

For this to happen, other main stakeholders namely the health service providers (i.e. local health care providers e.g. Community Clinics or *Klinik Kesihatan*), the health care providers (i.e. primary care nurses and medical assistants) and community diabetes educators must firstly be informed of the availability of the module and an option to utilise MY DEMO in their respective health care settings.

6.1.2.1 Preparation phase: Coordinated meetings and discussions with various Stakeholders

For the implementation of MY DEMO to be successful, policy makers (i.e. Ministry of Health) and a range of stakeholders such as local health service providers (e.g. Community Clinics or *Klinik Kesihatan*), health care providers (i.e. primary care nurses and medical assistants) and other primary stakeholders (e.g. diabetes patients) should meet during the planning stage. Feedback from the meetings between primary stakeholders and health care providers will give some insights to the local health service providers to plan the programme more smoothly.

A flexible programme which can be conducted over a period of time will be more accessible for patients (i.e. diabetes education programme offered weekly for the first 6 weeks of the year) is a practical point to consider during the planning phase. This is because one of the most challenging issues faced by some national education programmes is the lack of participation and poor attendance among patients (236, 237, 253).

6.1.2.2 Implementation phase: Proposal to combine diabetes education with the annual diabetes screening programme

One of the strengths of diabetes care management in Malaysia is the annual screening programme (11). The impressive screening rates reported by Diabcare 2013 audit (11) indicated that diabetes screening programmes in Malaysia is robust and effective. Hence, it would be worthwhile to share the existing screening platform to ensure diabetes education programmes are also systematically delivered at majority or all government ambulatory health care settings.

I am proposing to combine the delivery of a contextualised diabetes education together with the annual screening programme through an existing delivery care system. A paper was recently published from this current study proposing this combined mechanism to be adopted in various local health state departments to help coordinate and deliver a regular structured diabetes education programme to patients (263).

Likewise, the AADE also recommended the seven identified self-care behaviours and diabetes knowledge be assessed, at least on an annual basis (264) (29). By combining the annual screening and diabetes education programme together, patients' knowledge and understanding of diabetes can be assessed while their diabetes complications status are being examined.

Other factors such as patients' coping strategies, self-care practices, general well-being and quality of life which are also important in diabetes management can also be evaluated during this visit.

6.1.2.3 Implementation phase: Training programmes for health care providers

Another salient point to consider would be the training of the primary health care givers. In the Malaysian public primary health care setting, diabetes education are provided mainly by primary care nurses and medical assistants.

The Diabetes Australia 2007 report recommended using goals, outcomes and indicators from the National Consensus Position to determine the inputs and contents that will go into diabetes training (12). Undeniably, the degree of depth of diabetes education training may vary between various groups of health care providers. However, it is important to ensure these training programmes are made available to those who are seeing diabetes patients regularly in the primary health care setting (12).

One of the gaps identified by Naqib (91) and Colagiuri *et al* (92) was the inconsistencies in information delivery from health care providers to patients. Regardless of their level of expertise and experience, health care providers such as primary care nurses and medical assistants could benefit from diabetes training. In turn, basic, accurate and up-to-date information and advice regarding diabetes and its management dispensed by health care providers to patients will be consistent (91, 92).

With reference to training of health care personnel for MY DEMO, the contextualised module contains minimum medical jargon and content is in Bahasa Malaysia. These will help to overcome any language barrier among most the primary care nurses and medical assistants as most are

conversant in Bahasa Malaysia. Importantly, the underlying philosophy of the education module and the content of curriculum will be relatively easy to deliver and explain to the health care providers during the training programmes.

Hence, at this juncture, I see a golden opportunity to bridge the education transfer gap by leveraging on an existing mechanism. To reiterate, it is crucial for health care service providers to maximise the screening appointments into an opportunity to educate patients regularly, at least on an annual basis. The primary care nurses and medical assistants who have played key roles in carrying out screening programmes, can help educate patients using MY DEMO during these annual visits once they have been adequately trained about the programme.

6.1.2.4 Implementation phase: Potential Role as Master Trainer

As part of the solution to address the lack of educators or trainers in Malaysia, I envision a role I can fulfil as a master trainer to relevant health care personnel. Being the custodian and author of MY DEMO education modules and tools, I could play a leading role in training the trainers' programme. As per the key criteria for a structured education programmes recommended by Diabetes UK (10), I am able to emphasize the underlying philosophy and outline contents, processes and deliveries of the programme in a succinct manner during the training session(s). The fact that the education modules were developed and written in two languages means they can be delivered in both Bahasa Malaysia and English.

My role as a Master trainer will be an important stepping stone in helping to consolidate the existing human resources within the scope of diabetes education field from both the public and private healthcare sectors in Malaysia. Hence, the research outcome from my thesis can be a potential source of income generation for my institution for years to come. From the point of view of nation building, I am able to contribute my expertise by training healthcare personnel in the diabetes education field. In addition, the bilingual nature of the education module is clearly an added advantage. This is because it allows a bigger scope of training and utility of the module, both

within Malaysia and the South East Asia region - particularly Indonesia and Brunei which shares a similar language as Bahasa Malaysia.

6.1.3 Self-monitoring Blood Glucose

6.1.3.1 Implementation phase: Modified "Staggered SMBG" protocol

As previous studies have shown, many barriers including cost of glucose strips, have prevented most patients from continuing their blood glucose monitoring (172, 173, 175-178, 265, 266). In this study, patients were supplied with glucose strips and followed a modified "staggered SMBG" protocol for 6 months, resulting in an overwhelming majority of patients successfully completing their SMBG tasks. However, the question is will these patients continue to perform SMBG in the future without any financial help or subsidy, in order to control their diabetes.

Based on the context of the "staggered regimen" of the present study, I recommend SMBG to be tailored within the proper context of a patient's day-to-day activities so that there is a targeted response for patients' behaviours. By structuring the SMBG protocol to patients' daily routine (i.e. 2-hour post meal) patients are able to grasp how their behaviours and decision-making within their own environment can directly (or indirectly) influence their blood glucose level.

Recent studies have demonstrated the practice of "quality vs quantity" monitoring of blood glucose as more useful and cost-effective and ultimately have a greater impact on patients' metabolic control (148, 155, 156). To recap, it would be futile for patients to perform SMBG indiscriminately without any reference to their day-to-day context, or without any guidance from their respective diabetes educators or health care providers about how to respond correctly to out-of-range blood glucose levels.

6.1.3.2 Recommendation for a partial or full reimbursement SMBG policy

To date, Malaysia does not have any reimbursement policies on SMBG. A large body of evidence have shown that reimbursement policies, (i.e. through government subsidies and health insurance coverage) in countries which provide glucose strips to patients for SMBG, the number of SMBG-

practices were higher when compared to countries with partial or no reimbursement policies at all (137) (172-175).

Hence, I recommend for the government to consider a full or partial reimbursement policy on SMBG for patients attending government ambulatory health care settings. With full or partial financial support on SMBG-related tools (i.e. glucose strips, glucose meter and lancets) from the government, more patients can perform SMBG to improve their diabetes metabolic control, as seen in developed nations such as the UK and Norway (172). Ultimately, an improvement in patients' glycaemic control will delay or minimise diabetes-related complications and will potentially reduce the escalating cost and burden of the disease in the country.

6.2 Going forward: Challenges for structured diabetes education in Malaysia

6.2.1 Patient-related and service delivery barriers in diabetes education programmes

In the recent public document by Diabetes UK, one of the major issues the country is facing with their nationwide diabetes education programmes is the lack of participation among diabetes patients (253). Regardless of a well-designed curriculum and contents, patients' attendance to nationwide diabetes education programmes such as DAFNE and DESMOND remained disappointingly low with only 2% of Type 1 Diabetes and 6% of Type 2 Diabetes attending the programmes (253). Similarly, I faced similar challenges with regards to high attrition rate during the recruitment and implementation phases of MY DARLING study.

Learning the lessons from previous studies pertaining lack of participation and attendance in education programmes, the two main themes identified were patient-related barriers and service delivery barriers (254, 267, 268). Predictable reasons given by patients for poor or non-attendance were competing work commitments, childcare issues, forgetfulness, ill-health, lack of interest, education unnecessary, inconvenient date, location and time of the session.

On the other hand, some of the barriers recognised from the health care service delivery aspect included unclear process of invitation to a programme, a rigid appointment system and

administrative errors (254, 267, 268). Lucas *et al* also suggested "…for some it might 'not be the right time' to attend an education programme (268). For this group of people it was demonstrated that by proactively re-offering them to attend the programme will not increase the uptake. For this reason it will be good create a pathway to allow patients to self-refer themselves when they are ready to attend (268). In addition, a recent systematic review by Hourigan et al advocated innovative ways of delivering diabetes education to encourage patients' engagement while maintaining high standards of quality and efficiency of an education programme (254).

From the Malaysian context, the strength of our diabetes delivery care system, in terms of high annual screening rate could potentially mitigate some of the common challenges faced in diabetes education programmes such as poor attendance. By taking advantage of a well-paved mechanism such as the annual screening programme, patients can also attend an on-going diabetes education.

Another lesson to learn from previous education programmes are finding more innovative ways to promote programmes to the general public (i.e. by not using off-putting terminology such as "structured education"). There was also a lack of explanation by general practitioners regarding the importance of attending the diabetes education programmes which discouraged patients from attending the programmes (253, 267).

A recent survey on barriers to uptake of diabetes education study showed, although social determinants such as educational attainment, employment status and gender can influence attendance to structured education programme, the key factor to patients' attendance is the attitude of health care professionals to the education programme itself (269). Explanation and encouragement from primary care physicians in primary health care settings for patients to attend diabetes education will most likely have a positive impact on patients' attendance.

Therefore, it is paramount to get the "buy in" or support from the local primary care physicians in the clinical site before an education programme can take place. This is the reason why early dialogue with primary health care providers (i.e. primary care physicians, primary care nurses and

medical assistants) are crucial in the beginning phase of the education programme as per recommended in the earlier section.

6.2.2 Measurement of quality: Identifying individual, population and service indices to evaluate diabetes education programmes

By having a standardised benchmark for diabetes education, it will be easier for local health care providers to conduct and evaluate the diabetes education programmes in their own clinical settings. In addition, it will also pave way to a more focused and guided research on diabetes education which will eventually elevate the level of diabetes knowledge and self-care among patients.

Instead of reinventing the wheel, it will be less resource-intensive to review previous studies on measurement and indicators for diabetes education programmes. As discussed in Chapter 2, the National Diabetes Services Schemes in Australia had conducted a comprehensive national survey to address the best way to assess the effectiveness of a diabetes education programmes. Consequently, the consensus report recommended various population level indicators and service level indicators to measure education programmes in Australia (12).

My recommendation would be for a panel of local diabetes experts and other main stakeholders (i.e. especially people with diabetes) to review the existing set of indicators, including the Australian consensus and decide whether it would be relevant to the Malaysian context. Potentially, once a consensus is reached, an improved, modified and contextualised set of indicators could serve as a local or national guideline to local and government health agencies respectively. This holistic concept which is novel to Malaysia could realistically bridge the diabetes education gap and potentially revolutionised the way diabetes care delivery is implemented in Malaysia.

Information about the proportion of patients who had received diabetes education and which group of health care providers (i.e. diabetes educators, dietitian, family health practitioner/general practitioner, pharmacist, district nurses *etc*) delivered the programmes in the previous 12 months will be beneficial for health care service providers to take note (12).

From the individual aspect, information about the proportion of patients with current (i) diabetes knowledge score improvement (ii) self-management or behaviour change score improvement and (iii) a well-being/quality of life score improvement and who are actively and confidently involved in diabetes self-care practices would be insightful for health care providers and health service providers to measure (12). By incorporating MY DEMO education programmes annually during screening period, individual indicators recommended above such as knowledge and SMBG Compliance and self-efficacy can also can also be measured to give insightful information about patients' overall understanding of diabetes and how this can help them manage their conditions better.

6.3 Going Forward: Future research considerations in diabetes education studies

Given the advance and rapid level of technology and communications development which encompasses the world population today, it will be folly not to capitalise on this technology wave and use it to the advantage for medical, health and education purposes.

6.3.1 Tele-health platform

While the primary aim of the Telephone Contact in this study was to assess patients' knowledge retention, it became evident during the study that Telephone Contact can potentially function as a platform to provide on-going education support, in between physical clinical visits. In the current congested clinical setting in Malaysia, it will be worth exploring the role of Telephone Contact in the ambulatory health care settings. For example, Rankin *et al* advocated tele-heath as an important tool for physicians to regularly communicate with their patients especially when dealing with complex educational components such as calorie counting and adjusting insulin doses (62).

6.3.2 Social-media platform

From the results of the performance of the ten theme topics, it was evident that there were a few areas where patients showed knowledge deficit namely in the topics of diabetes pathophysiology, hypoglycaemia symptoms and normal and abnormal blood glucose levels. As mentioned earlier,

despite concise visual and verbal explanation of these topics patients were unable to grasp certain concepts.

One of the solutions will be to "unpack" difficult topics such as the above and present the contents in smaller and more manageable "chunks" of information to help improve patients' understanding. With the advancement of social media platforms, the "go to" place for most people would be to their smartphones and other electronic devices.

It will be really exciting to extend the MY DEMO content into a short videos and quizzes which can be accessed by majority of patients who have the smartphones. A small suite of short videos addressing the difficult topics mentioned above could be developed to help patients understand this better. With the vast utilization of social media in Malaysia and globally, diabetes educators should develop, optimise and disseminate content materials on this widely available, cheap and hugely popular platform.

6.3.3 Legacy effect of MY DARLING study

Finally, my contribution to the diabetes education research landscape in Malaysia was the development of a diabetes education tool which can be used to help improve glycaemic control in the diabetes population.

My future aim is to help create a system or framework which can ease the process of contents, deliveries and evaluations of structured diabetes education programmes in Malaysia. With the aid of modern technology it will be easier create applications which can measure patients' knowledge, behavioural, metabolic and psychological indicators in the future. These feedback in turn can be used to help evaluate, improve and deliver high quality diabetes education programmes in Malaysia. My hope will be to see an overall improvement in the entire spectrum of diabetes management including diabetes education, self-care practices and psychological well-being, which will lead to an improvement in metabolic control and ultimately minimise or delay diabetes-related complications.

7.0 REFERENCES

1. Ahmad B, BAK K, Md Zain AZ, Hussain NA, Quek KF. Influencing factors of glycaemic control in patients attending different types of urban health care settings in Malaysia. Diabetes Res Clin Pract. 2011;93(1):e12-4.
2. Letchuman GR, Wan Nazaimon WM, Wan Mohammad WB, Chandran LR, Tee GH, Jamaiyah H, et al. Prevalence of Diabetes in Malaysian National Health and Morbidity Survey III 2006. Med J Malaysia. 2010;65(3):173-9.
3. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(1):4-14.
4. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. IDF Diabetes Atlas. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137-49.
5. Chan JC, Cho NH, Tajima N, Shaw J. IDF Diabetes Atlas. Diabetes in the Western Pacific region – past, present and future. Diabetes Res Clin Pract. 2014;103(2):244-55.
6. Mensing C, Boucher J, Cypress M. National standards of diabetes self-management education. Diabetes Care. 2000;23(5):682-9.
7. Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment: Results of a randomized controlled trial. Diabetes Care. 1995;18(7):943-9.
8. Mafauzy MZ, Chan SP. The status of diabetes control in Malaysia: Results of DiabCare 2008. Med J Malaysia. 2008;66(3):175-81.
9. Hussein Z, Taher SW, Glicharan Singh HK, Chee WSS. Diabetes care in Malaysia: Problems, New Models and Solutions. Ann Glob Health. 2015;81(6):851-62.
10. Diabetes UK. Structured patient education in diabetes: report from the patient education working group 2005 [Available from: http://webarchive.nationalarchives.gov.uk/20130105204013/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4113195.
11. Mohamed M, Hussein Z, Nazeri A, Chan SP. A cross-sectional study of hospital based diabetes delivery and prevention of diabetes related complications in Malaysia. Med J Malaysia. 2013;71(4):177-85.
12. Diabetes Australia. Outcomes and Indicators for Diabetes Education A National Consensus Position 2007 [Available from: https://static.diabetesaustralia.com.au/s/fileassets/diabetes-australia/281a322b-44df-43f8-b407-39dca2136011.pdf.
13. American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. Diabetes Care. 2004;27(Supp 1):5-10.
14. Alberti KG, Zimmet PZ. Definition, Diagnosis and Classification of Diabetes Mellitus and Its Complications Part 1: Diagnosis annd Classification of Diabetes Mellitus Provisional Report of a WHO Consultation. Diabet Med. 1998(15):539-53.
15. Davies MJ, Heller S, Skinner TC, Campbell MJ, Carey ME, Cradock S, et al. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. Brit Med J. 2008;336(7642):491-5.
16. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. Brit Med Journal. 2002;325:746.
17. Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the diabetes X-PERT programme makes a difference. Diabet Med. 2006;23:944-54.
18. Trento M, Gamba S, Gentile L, Grassi G, Miselli V, Morone G, et al. Rethink Organisation to iMprove Education and Outcomes (ROMEO): A multicentre randomised trial of lifestyle intervention by group care to manage type 2 diabetes. Diabetes Care. 2010;33(4):745-7.
19. American Diabetes Association. Gestational Diabetes. Diabetes Care. 2004;27(1):S88-90.
20. Wan Nazaimoon WM, Aziz Al-Safi I, Amir SMK, Ikram SI, Kamarul IM, BAK K, et al. Prevalence of overweight and obesity among adult Malaysians: An update. Asia Pac J Clin Nutr. 2011;20(1):35-41.
21. Beulens JW, Grobbe DE, Nealb B. The global burden of diabetes and its complications: an emerging pandemic. Eur J Cardiovascular Prev Rehabil. 2010;17(Supp):3-8.

22. American Diabetes Association. Economic costs of diabetes in the U.S. in 2007. Diabetes Care. 2007;31(6):596-615.
23. Logminiene Z, Norkus A, Valius L. Direct and indirect diabetes costs in the world. Medicina (Kaunas). 2004;40(1):16-26.
24. Pharmaceutical Services Division, Ministry of Health Malaysia. The Cost of Diabetes Care for Ambulatory Patients in Malaysian Ministry of Health Facilities 2014 [19-30]. Available from: https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/cost-diabetes-care-ambulatory-patients-malaysian-ministry-health-facilities.pdf.
25. Mulcahy K, Peeples M, Tomky D, Weaver T. National Diabetes Education Outcomes System: application to practice Diabetes Educ. 2000;26(6):957-64.
26. Tomky D, Weaver T, Mulcahy K, Peeple M. Diabetes education outcomes: what educators are doing. Diabetes Educ. 2000;26(6):951-4.
27. Peeples M, Mulcahy K, Tomky D, Weaver T. The conceptual framework of the National Diabetes Education Outcomes System (NDEOS). Diabetes Educ. 2001;27(4):547-62.
28. AADE Position Statement. AADE7TM Self-care Behaviours. Diabetes Educ. 2008;34:445-50
29. Mulcahy K, Maryniuk M, Peeples M, Peyrot M, Tomky D, Weaver T, et al. Diabetes self-management education core outcomes. Diabetes Educ. 2003;29(5):768-70.
30. Skinner T, Carey M, Cradock S, Daly H, Davies M, Doherty Y. Diabetes education and self-management for ongoing and newly diagnosed (DESMOND): process modelling of pilot study. Patient Educ Couns. 2006;64:369-77.
31. National Institute for Health and Care Excellence, (NICE). Diabetes in adults (QS6) [Report]. 2011 [1-55]. Available from: http://www.creativesupport.co.uk/creative-academy/wp-content/uploads/2015/12/Diabetes-in-Adults.pdf.
32. Consultative Section on Diabetes Education. International Curriculum for Diabetes Health Professional Education. Brussels: International Diabetes Federation 2008.
33. Jurgen A. Adult learning theories and medical education: a review. MMJ. 2009;21(1):11-8.
34. Knowles A. Andragogy in Action; Applying modern principles of adult learning. . San Francisco: Jossey-Bass; 1984.
35. Walker M, Harris D. Principles of Adult Learning. 1st ed. Peyton J, editor. Manticore: Manticore Europe Linited; 1998.
36. Chambers R, Wall D. Teaching Made Easy - A manual for health professionals. Oxford: Radcliffe Medical Press; 2000.
37. Kolb DA. Experiential Learning: Experience as the source of learning and development. Eaglewood Cliffs: Prentice-Hall; 1994.
38. Al-Wahaibi A, Almahrezi A. An Application of Educational Theories and Prinicples of Teaching and Learning Communication Skills for General Practitioners in Oman. OMJ. 2009;24(2):119-27.
39. Leventhal H, Nerenz DR, Steele DJ, Taylor SE, Singer JE. Illness representation and coping with health threats. In Handbook of Psychology and Health. Baum A, editor. Killsdale N. J.: Lawrence Erlbaum Associates; 1984.
40. Skinner TC, Cradock S, Arundel F, Graham W. Four Theories and a Philosophy: Self-Management Education for Individuals Newly Diagnosed with Type 2 Diabetes. Diabetes Spectr. 2003;16(2):75-80.
41. Hampson SE. Illness representations and the self-management of diabetes. In Perceptions of Health and Illness. Petrie KJ, Weinman JA, editors. Amsterdam The Netherlands,: Harwood Academic Publishers; 1997.
42. Chaiken S, Wood W, Eagly A. Principles of Persuasion. In Social Psychology: Handbook of Basic Principles. Higgins ET, Kruglanski AW, editors. New York: Guilford Press; 1996.
43. Deci EL, Ryan RM. The support of autonomy and the control of behavior. In Motivational Science: Social and Personality Perspectives. Higgins ET, Kruglanski AW, editors. Philadelphia: Psychology Press; 2000. 128-46 p.
44. Bailey SC, Brega AG, M. CT, Elasy T, Herr H, Kaphingst K, et al. Update on Health Literacy and Diabetes. Diabetes Educ. 2014;40(5):581-604.
45. Health Literacy. A Precription to End Confusion: The National Academic Press; 2004.
46. Kutner MA. The health literacy of America's adults: results from 2003 National Assessment of Adult Literacy. In: Education USDo, editor. National Centre for Education Statistics2014.

47. Osborn CY, Cavanaugh K, Wallston KA, Rothman RL. Self-efficacy links health literacy and numeracy with glycaemic control. J Health Commun. 2010;15(Supp 2):146-58.
48. Cowan CF. Teaching patients with Low Literacy Skills. In: Lowenstein AJ, Bradshaw MJ, editors. Fuszard's Innovative Teaching Strategies in Nursing. 3rd ed. Sudbury, Massachusetts: Jones and Bartlett Publishers; 2004. p. 278-89.
49. Kim SH, Lee A. Health literacy sensitive diabetes self-management interventions: A systematic review and metan-analysis. Worldviews on Evidence-Based Nursing. 2016;13(4):324-33.
50. Howe CJ, Walker D, Watts J. Use of Recommended Communication Techniques by Diabetes Educators. Health Literacy Reseach Practice. 2017;1(4):e145-e51.
51. Schwartzberg JG, Cowett A, VanGeest J, Wolf MS. Communication techniques for patients with low health litearcy: A survey of physicians, nurses and pharmacists. Am J Health Behav. 2007;31(Supp 1):S96-S104.
52. Sarkar U, Karter AJ, Liu JY, Moffett HH, Adler NE, Schillinger D. Hypoglycaemia is more common among type 2 diabetes patients with limited health literacy: the Diabetes Study of Northern California (DISTANCE). J Gen Intern Med. 2010;25(9):962-8.
53. Al-Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health Literacy and Health Outcomes in Diabetes: A Systematic Review. J Gen Intern Med. 2012;28(3):444-52.
54. Seligman HK, Wang FF, Palacios JL. Physician notification of their diabetes patients' limited health literacy. A randomized, controlled trial. J Gen Intern Med. 2005;20(11):1001-7.
55. Hass L, Maryniuk M, Beck J. Standards Revision Task Force National Standards for diabetes self-management education and support. Diabetes Care. 2012;35(11):2393-401.
56. Diabetes Educator Competencies Work Group. Competencies for Diabetes Educators and Diabetes Paraprofessionals. A companion document to the practice levels for diabetes educators and diabetes paraprofessionals. Chicago: American Association of Diabetes Educators; 2016.
57. Norris SL, Engelgau MM, Venkat Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomised controlled trials. Diabetes Care. 2001;24:561-87.
58. UK Healthcare. UK Healthcare Commission Report. Managing diabetes: Improving services for people with diabetes 2007 [Available from: https://www.yearofcare.co.uk/sites/default/files/pdfs/Managing_diabetes.pdf.
59. Cooper H, Booth K, Gill G. Using combined research methods for exploring diabetes patient education. Patient Educ Couns. 2003;51(1):45-52.
60. Speight J, Amiel SA, Bradley C, Heller S, Oliver L, Roberts S, et al. Long term biomedical and psychosocial outcomes following dose adjustment for normal eating (DAFNE) structured education to promote intensive insulin therapy in adults with sub-optimally controlled Type 1 diabetes. Diabetes Res Clin Pract. 2010;89:22-9.
61. McIntyre HD, Knight BA, Harvey DM, Noud MN, Hagger VL, Gilshenan KS. Dose Adjustment for Normal Eating (DAFNE) – an audit of outcomes in Australia. Med J Aust. 2010;192(11):637-40.
62. Rankin D, Heller S, Lawton J. Understanding information and education gaps among people with Type 1 diabetes: A qualitative investigation. Patient Educ Couns. 2011;83:87-91.
63. Leventhal H, Singer R, Jones S. Effects of fear and specificity of recommendation upon attitudes and behaviour. J Pers Soc Psychol. 1965;2:20-9.
64. Khunti K, Gray LJ, Skinner T, Carey ME, Realf K, Dallosso H, et al. Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. Brit Med J. 2012;344:e2333.
65. Cooper H, Booth K, Gill G. A trial of empower-based education in type 2 diabetes – Global rather than glycaemic benefits. Diabetes Res Clin Pract. 2008;82:165-71.
66. Ming YT, Magarey J. Self-care practices of Malaysian adults with diabetes and suboptimal glycaemic control. Patient Educ Couns. 2008;72:252-67.
67. Tan MY, Magarey JM, Chee SS, Lee LF, Tan MT. A brief structured programme enchances self-care practices and improves glycaemic control in Malaysians with poorly controlled diabetes. Health Educ Res. 2011;26(5):896-907.

68. Shariff-Ghazali S, Browning CJ, Shajahan Y. Effectiveness of personalised feedback alone or combined with peer support to improve physical activity in sedentary older Malays with type 2 diabetes: a randomised controlled trial. Front Public Health. 2015;3(178).
69. Azimah MN, Radzniwan R, Zuhra H, Khairani O. Have we done enough with diabetic education? A pilot study. Malays Fam Physician 2010;5(1):24-40.
70. Al-Haddad MA, Ibrahim M, Sulaiman SAS, Maarup N. The impact of two diabetes educational programs on patients with diabetes in Malaysia. Journal of Clinical Diagnostic Research. 2009;3:1633-40.
71. Tham KY, Ong JJY, Tan DKL, How KY. How much do diabetic patients know about diabetes mellitus and its complications? Ann Acad Med Singapore. 2004;33(4):503-9.
72. Muhammad Adil A, Hakeem R, Asar F, Abdul Hakeem S. Diabetes education and care in a developing country: Observations from Karachi, Pakistan. Prim Care Diabetes. 2015;9:48-53.
73. Mehta NV, Trivedi M, Maldonado LE, Saxena D, Humhries DL. Diabetes knowledge and self-efficacy among rural women in Gujarat, India. Rural Remote Health 2016;16(1):3629.
74. Choi TST, Davidson ZE, Walker KZ, Lee JH, Palermo C. Diabetes education for Chinese adults with type 2 diabetes: A systematic review and meta-analysis of effect of glycaemic control. Diabetes Res Clin Pract. 2016;116:218-29.
75. Bradley C. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. Qual Life Res. 1999;8:79-91.
76. Meadows KA, Fromson B, Gillespie C, Brewer A, Carter C, Lockington T. Development, validation and application of computer-linked knowledge questionnaires in diabetes education. Diabet Med. 1998;5:61-7.
77. Grootenhuis PA, Snoek FJ, Heine RJ, Bouter M. Development of a type 2 diabetes symptom checklist: a measure of symptom severity. Diabet Med. 1994;11:253-61.
78. Snoek FJ, Mollema ED, Heine RJ, Bouter LM, van der Ploeg HM. Development and validation of the diabetes fear of injecting and self-testing questionnaire (D-FISQ): first findings. Diabet Med. 1997;14:871-6.
79. Fitzgerald JT, Funnel MM, Hess GE, Barr PA, Anderson RM, Hiss RG. The realibility and validity of a brief diabetes knowledge test. Diabetes Care. 1998;21(5):217-29.
80. Colleran KM, Starr B, Burge MR. Putting diabetes to the test: analysing glycaemic control based on patients' diabetes knowledge. Diabetes Care. 2003;26(7):2220-1.
81. Murata GH, Shah JH, Adam KD, Wendel CS, Bokhari SU. Factors affecting diabetes knowledge in type 2 diabetes veterans. Diabetologia. 2003;46(8):1170-8.
82. Moodley LM, Rambiritch V. An assessment of the level of knowledge about diabetes mellitus among diabetic patients in primary healthcare setting. S Afr Fam Prac. 2007;49(10):16a-d.
83. Al-Qazaz H, Sulaiman SA, Hassali MA, Shafie AA, Sundram S. Diabetes knowledge and control of glycaemia among type 2 diabetes patients in Penang, Malaysia. J Pharm Health Serv Res. 2012;3:49-55.
84. Hashim MJ, Mustafa H, Ali H. Knowledge of diabetes among patients in the United Arab Emirates and trends since 2001: a study using the Michigan Diabetes Knowledge Test. East Mediterr Health J. 2016;22(10):742-8.
85. West JD, Goldberg KL. Diabetes self-care knowledge among outpatients at a Veterans Affairs medical centre. Am J Health-Syst Pharm. 2002;59:849-52.
86. Mufunda E, Wikby K, Bjorn A, Hjelm K. Level and determinants of diabetes knowledge in patients with diabetes in Zimbabwe: a cross-sectional study. Pan Afr Med J 2012;13(78).
87. Obirikorang Y, Obirikorang C, Anto EO, Acheampong E, Batu EN, Stella AD. Knowledge of complications of diabetes mellitus among patients visiting the diabetes clinic at Sampa Government Hospital, Ghana: a descriptive study. BMC Public Health. 2016;16:1-8.
88. Al-Adsani AM, Moussa MA, Al-Jasem LI, Abdella NA, Al-Hamad NM. The level and determinants of diabetes knowledge in Kuwaiti adults with type 2 diabetes. Diabetes Metab. 2009;35(2):121-8.
89. Jasper US, Ogundunmade BG, Opara MC, Akinrolie O, Pyiki EB. Determinants of diabetes knowledge in a cohort of Nigerian diabetics. J Diabetes Metab Disord. 2014;13(1):39.
90. Hawthorne K, Tomlinson S. Pakistani Moslems with type 2 diabetes mellitus: effect of sex, literacy skills, known diabetic complications and place of care on diabetic knowldge, reported self-monitoring management and glycaemic control Diabet Med. 1999;16:173-5.

91. Naqib J. Patient education for effective diabetes management: report, recommendations and examples of good practice. London: Diabetes UK; 2002.
92. Colagiuri R, Goodall S. Information & education for people with diabetes: a best practice strategy. Canberra: Diabetes Australia; 2004.
93. Fain JA, Nettles A, Funnell MM, Charron D. Diabetes patient education research: an integrative literature review. Diabetes Educ. 1999;25(6):7-15.
94. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2005;2(CD003417).
95. Dube L, Van den Broucke S, Housiaux M, Dhoore W, Rendall-Mkosi K. Type 2 diabetes self-management education programs in high and low mortality developing countries. A systematic review. Diabetes Educ. 2015;41(1):69-85.
96. Coulter A, Entwistle VA, Eccles A, Ryan S, Sheppard S, Perera R. Personalised care planning for adults with chronic or long-term health conditions (Review). Cochrane Database of Systematic Reviews [Internet]. 2015; (3):[1-29 pp.].
97. Silverman J, Kurtz S, Draper J. Skills for communication with patients: Radcliffe Medical Press; 1998.
98. 2011 YoC. Year of Care Programme. Report of findings from the pilot programme. 2011.
99. Blakeman T, Macdonald W, Bower P, Gately C, Chew-Graham C. A qualitative study of GPs' attitudes to self-management of chronic disease. Br J Gen Pract. 2006;56(527):407-14.
100. Coulter A, Collins A. Making Shared Decision-Making a Reality. No decision about me, without me. London; 2011.
101. Nathan DM, Cleary PA, Backlund JY, Genuth SM, Lachin JM, Orchard TJ, et al. The Diabetes Control and Complication Trial/Epidemiology of Diabetes Intervention and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes and cardiovascular treatment in patients with type 1 diabetes. N Engl J Med 2005;353:2643-53.
102. Diabetes Control Complication Trial (DCCT)/Epidemiology Diabetes Complications (EDIC) Writing Group. Effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. JAMA. 2002;287:2563-9.
103. Nathan DM, DCCT/EDIC Research Group. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. Diabetes Care. 2014;37:9-16.
104. Diabetes Control and Complication Trial Research Group. Hypoglycaemia in the Diabetes Control and Complication Trial. Diabetes. 1997;46:271-86.
105. Beck RW, Connor CG, Mullen DM, Wesley DM, Bergenstal RM. The Fallacy of Average: How Using HbA1C Alone to Assess Glycaemic Control Can Be Misleading. Diabetes Care. 2017;40:994-9.
106. American Diabetes Association. Glycaemic Targets. Section 6. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017;40(Supp 1):S48-S56.
107. Rayman G. Glycaemic control, glucose variability and the Triangle of Diabetes Care. Br J Diabetes. 2016;16(Supp 1):53-6.
108. Nathan DM, Kuenen J, Borg R, Zheng H, Schoenfeld D, A1c-Derived Average Glucose (ADAG) Study Group. Translating the A1C Assay Into Estimated Average Glucose Values. Diabetes Care. 2008;31(8):1473-8.
109. Rose T. The End of Average: How We Succeed in a World That Values Sameness. New York: Harper Collins; 2015.
110. Cohen RM, Franco RS, Khera PK. Red cell lifespan heterogeneity in haematologically normal people is sufficient to alter HbA1C. Blood. 2008;112:4284-91.
111. Brown A, Kennedy L, Runge A, Close K. diaTribeLearn Making Sense of Diabetes [Internet]. Close K, Brown A, Kwon J, editors2016. [cited 2018]. Available from: https://diatribe.org/beyonda1c.
112. Bry L, Chen PC, Sacks DB. Effects of hamoglobin variants and chemically modified on assays for glycated haemoglobin. Clin Chem. 2001;47:153-63.
113. Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan D, Peterson CM. American Diabetes Association Technical Review on Tests of Glycaemia. Diabetes Care. 1995;18:896-909.
114. Sundram RC, Selvaraj N, Vijayan G. Increased plasma malondialdehyde and fructosamine in iron deficiency anaemia: effect of treatment. Biomed Pharmacother. 2007;61:682-5.

115. Lorenzo-Medina E, De-La-Iglesia S, Ropero P, Nogueira-Salgueiro P, Santana-Benitez J. Effects of haemoglobin variants on haemoglobin A1C values measured using high-performance liquid chromatography method. J Diabetes Sci Technol. 2014;2014(8):1168-76.
116. Krishna SVS, Kota SK, Modi KD. Glycaemic variability: Clinical Implications. Indian J Endocrinology Metab. 2013;17(4):611-9.
117. Stratton IM, Adler AI, Neil HAW, Mathews DR, Manley SE, Cull CA. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. Brit Med J. 2000;321:405-12.
118. Raz I, Wilson PW, Strojek K, Kowalska I, Bozikov V, Gitt AK. Effects of prandial versus fasting glycaemia on cardiovascular outcomes in type 2 diabetes: The HEART 2D trial. Diabetes Care. 2009;32:381-6.
119. Kota SK, Kota SK, Jammula S, Panda S, Modi KD. Effect of diabetes on alteration of metabolism in cardiac myocytes: therapeutic implications. Diabetes Technol Ther. 2011;13:1155-60.
120. Frontoni S, Di Bartolo P, Avogaro A. Glucose variability: An emerging target for the treatment of diabetes mellitus. Diabetes Res Clin Pract. 2013;102:86-95.
121. Holman RH, Paul SK, Bethel MA, Matthews DR, Neil HAW. UK Prospective Diabetes Study Group 80: 10 year follow-up of Intensive glucose control in Type 2 Diabetes. N Engl J Med 2008;359:1577-89.
122. Ceriello A, Novials A, Ortega E. Hyperglycaemia following recovery from hypoglycaemia worsens endothelial damage and thrombosis activation in type 1 diabetes and in healthy controls. Nutr Metab Cardiovasc Dis. 2014;24:116-23.
123. Dailey G. Assessing glycaemic control with a self-monitoring of blood glucose and Hemoglobin A1C measurements. Mayo Clinic Proc February 2007;82(2):229-36.
124. Boutati EL, Raptis S. Self-monitoring of blood glucose as part of integral care of type 2 diabetes. Diabetes Care 2009;32(Supp 2):205-10.
125. Muchmore DB, Springer J, Miller M. Self-monitoring of blood glucose in overweight type 2 diabetic patients. Acta Diabetol. 1994;31(4):215-9.
126. Estey AL, Tan MH, Mann K. Follow-up intervention: its effect on compliance behaviour to a diabetes regimen. Diabetes Educ. 1990;16(4):291-5.
127. Wing R, Epstein L, Norwalk M, Scott N. Self-regulation in the treatment of type II diabetes. Behav Ther. 1988;19:11-23.
128. Newman WP, Laqua D, Engelbrecht D. Impact of glucose self-monitoring on glycohaemoglobin values in a veteran population. Arch Intern Med. 1990;150(1):107-10.
129. Allen BT, DeLong ER, Feussner JR. Impact of self-glucose monitoring on non-insulin-treated patients with type II diabetes mellitus. Randomised controlled trial comparing blood and urine testing. Diabetes Care. 1990;13(10):1044-50.
130. International Diabetes Federation Taskforce. Workshop of the International Diabetes Federation Clinical Guidelines Taskforce in collaboration with the SMBG International Working Group. Guideline on Self-monitoring of blood glucose in non-insulin treated type 2 diabetes 2009 [Available from: www.smbg-iwg.com.
131. McGeogh G, Derry S, Moore R. Self-monitoring of blood glucose in type 2 diabetes: what is the evidence? Diabetes Metab Res Rev. 2007;23:423-40.
132. Gerstein HC, Miller ME, Byington RP, Goff DCJ, Bigger JT, Buse JB, et al. Action to Control Cardiovascular Risk in Diabetes Study Group (ACCORD): Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 2008;358(24):2549-59.
133. IDF Working Group. International Diabetes Federation. Recommendations For Managing Type 2 Diabetes In Primary Care, 2017. Brussels; 2017.
134. Diabetes Program Expert Reference Group. Diabetes Management in Aged Care: A practical Handbook National Diabetes Services Scheme (NDSS) Older People Living. Tasmania: Diabetes Australia; 2016.
135. Dunning T, Duggan N, Savage S. The McKellar guidelines for managing older people with diabetes in residential and other care settings. Geelong: Centre for Nursing and Allied Health Research Deakin University and Barwon Health

2014.
136. CPG Secretariat. Clinical Practice Guideline. Management of Type 2 Diabetes Mellitus Putrajaya: Medical Development Division Ministry of Health Malaysia; 2015.
137. Czupryniak L, Barkai L, Bolgarska S, Bronisz A, Broz J. Self-monitoring of blood glucose in diabetes: From evidence to clinical reality in Central and Eastern Europe - Recommendations from International Central-Eastern European Expert Group Diabetes Technol Ther. 2014;17(7):460-75.
138. UKPDS Group. UK Prospective Diabetes Study Group 33: Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk complications in patients with type 2 diabetes. Lancet. 1998;352:837-53.
139. Karter AJ, Ackerson LM, Darbinian JA, D'Agostino Jr RB, Ferrara A. Self-monitoring of blood glucose levels and glyaemic control: the Northern California Kaiser permanente diabetes registry. Am J Med. 2001;111(1):1-9.
140. Nathan DM, McKitrick C, Larkin M, Schaffran R, Singer DE. Glycaemic control in diabetes mellitus: have changes in therapy made a difference? Am J Med. 1996;100(2):157-63.
141. Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan DM, Peterson CM. Tests of glycaemia in diabetes. Diabetes Care. 2004;27(Supp 1):91-3.
142. Welschen LM, Bloemendal E, Nijpels G. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. Diabetes Care. 2005;28:1510-7.
143. Schwedes U, Siebolds M, Mertes G. Meal related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin treated type 2 diabetic patients. Diabetes Care. 2002;25(11):1928-32.
144. Sarol JJ, Nicodemus NJ, Tan K. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. Curr Med Res Opin. 2005;21:173-84.
145. Davis W, Bruce D, Davis T. Is self-monitoring of blood glucose appropriate for all type 2 diabetic patients? The Freemantle Diabetes Study. Diabetes Care. 2006;29(8):1764-70.
146. Guerci B, Drouin P, Grange V, Bougneres P, Fontaine P, Kerlan V, et al. Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the Auto-Surveillance Intervention Active (ASIA) study. Diabetes Metab. 2003;29:587-94.
147. Klonoff DC. Benefits and limitations of self-monitoring of blood glucose. J Diabetes Sci Technol 2007;1(1):130-2.
148. Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, non-insulin treated type 2 diabetes patients. Diabetes Care. 2011;34(2):262-7.
149. Palmer AJ, Dinneen S, Gavin JRI, Gray A, Herman WH, Karter AJ. Cost utility in a UK setting of self-monitoring of blood glucose in patients with type 2 diabetes. Curr Med Res Opin. 2006;22(5):861-72.
150. Grant RW, Buse JB, Meigs JB. Quality of diabetes care in U.S. academic medical centers: low rates of medical regimen change. Diabetes Care. 2005;28:337-442.
151. Parkin CG, Hinnen D, Campbell RK, Geil P, Tetrick DL. Effective use of paired testing in type 2 diabetes: practical applications in clinical practice. Diabetes Educ. 2009;35(6):915-27.
152. Parkin CG, Buskirk A, Hinnen DA, Axel-Schweitzer M. Results that matter: Structured vs. unstructured self-monitoring of blood glucose in type 2 diabetes. Diabetes Res Clin Pract. 2012;97:6-15.
153. Duran A, Martin P, Runkle I, Perez N, Abad R. Benefits of self-monitoring blood glucose in the management of new-onset type 2 diabetes mellitus: the St. Carlos Study, a prospective randomised clinical-based interventional study with parallel groups. J Diabetes. 2010;2(3):203-11.
154. Franciosi M, Lucisano G, Pellegrini F, Cantarello A, Consoli A. ROSES: role of self-monitoring of blood glucose and intensive education in patients with type 2 diabetes not receiving insulin. A pilot randomised clinical trial. Diabet Med. 2011;28(7):789-96.
155. Bonomo K, De Salve A, Fiora E, Mularoni E, Massucco P. Evaluation of a simple policy for pre- and post- prandial blood glucoseself-monitoring in people with type 2 diabetes not on insulin. Diabetes Res Clin Pract. 2010;87(2):246-51.
156. Shiraiwa T, Takahara M, Kaneto H, Miyatsuka T, Yamamoto K. Efficicacy of occasional self-monitoring of postprandial blood glucose levels in type 2 diabetic patients without insulin therapy. Diabetes Res Clin Pract. 2010;90(3):e91-2.

157. Mohan V, Ravikumar R, Poongothai S, Amutha A, Sowmya S. A single-centre, open, comparative study of the effect of using self-monitoring of blood glucose to guide therapy on preclinical atherosclerotic markers in type 2 diabetic subjects. J Diabetes Sci Technol. 2010;4(4):942-8.
158. Kempf K, Kruse J, Martin S. ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. Diabetes Technol Ther. 2010;12(7):547-53.
159. Kato NK, Kato M. Use of structured SMBG helps reduce A1C levels in insulin-treated diabetic patients. Diabetes. 2011;60(Supp 1):A235-352.
160. Sorkin JD, Muller DC, Fleg JL, Andres R. The relation of fasting and 2 h postchallenge plasma glucose concentrations to mortality: data from the Baltimore longitudinal study of aging with a critical review of the literature. Diabetes Care. 2005;28(11):2626-32.
161. DECODE Study Group. Glucose tolerance and cardiovascular mortality: comparison of fasting and 2-hour diagnostic criteria. Arch Intern Med. 2001;161(3):397-405.
162. Levitan E, Song Y, Ford E, Liu S. Is nondiabetic hyperglycaemia a risk factor for cardiovascular disease? A meta-analysis of prospective studies. Arch Intern Med. 2004;164(19):2147-55.
163. Hanefield M, Fischer S, Julius U, Schulze J, Schwanebeck U. Risk factors for myocardial infarction and death in newly detected NIDDM: the Diabetes Intervention Study, 11-year follow-up. Diabetologia. 1996;39(12):1577-83.
164. Hanefield M, Catagay M, Petrowitsch T, Neuser D, Petzinna D. Acarbose reduces the risk for myocardial infarction in type 2 diabetic patients: meta-analysis of seven long-term studies. Eur Heart J. 2004;25(1):10-6.
165. Esposito K, Giugliano D, Nappo F, Marfella R. Regression of carotid atherosclerosis by control of postprandial hyperglycaemia in type 2 diabetes mellitus. Circulation. 2004;110(2):214-9.
166. Laakso M. Cardiovascular disease in type 2 diabetes from population to man to mechanisms: the Kelly West Award Lecture 2008. Diabetes Care. 2010;33(2):442-9.
167. Benhalima K, Mathieu C. The role of blood glucose monitoring in non-insulin treated type 2 diabetes: What is the evidence? Prim Care Diabetes. 2012;6(3):179-85.
168. Huri HZ, Wen OC, Pendek R. Self-monitoring of blood glucose among type-2 diabetes patients in Malaysia. Asian Biomed. 2008;2(4):335-40.
169. Zahari Sham SY, Thambiah SC, Samsudin IN, Ng OC, Yong SW, Razmin NI. Practice of Self-Monitoring Blood Glucose Among Insulin-treated Diabetic Patients in Hospital Serdang. Malaysian Journal of Medicine and Health Sciences. 2016;12(2):35-40.
170. Mastura I, Mimi O, Piterman L, Teng CL, Wijesinha S. Self-monitoring of blood glucose among diabetes patients attending government health clinics. Med J Malaysia. 2007;62(2):147-51.
171. Mustafa B, Mohammad WW, Diabetes Data Collection Project (Diabcare-Malaysia) Study Group. The current status of diabetes management in Malaysia. J ASEAN Fed Endo Soc. 1998;16(Supp 2):1-13.
172. Davis WA, Bot S, Davis TME, Farmer A, Gagliardino JJ. Self-monitoring of blood glucose in type 2 diabetes: An inter-country comparison. The SMBG International Working Group. Diabetes Res Clin Pract. 2008;82(3):e15-8.
173. Gucciardi E, Fortugno M, Senchik A, Beanlands H, Mccay E. Self-monitoring of blood glucose in Black Carribean and South Asian Canadians with non-insulin treated type 2 diabetes mellitus: a qualitative study of patients' perspectives. BMC Endoc Disord. 2013;13(46).
174. Cameron C, Virani A, Dean H, Evans M, Dolovich L. Utilisation and expenditure in blood glucose strips in Canada. Can J Diabetes 2010;34:34-40.
175. Gomes T, Juurlink DN, Shah BR, Paterson JM, Mamdani MM. Blood glucose test strips: options to reduce usage. Can Med Assoc J. 2010;182:35-8.
176. Institute of Health Economics. Consensus statement on self-monitoring in diabetes: Institute of Health Economics, Alberta, Canada, November 14-16, 2006 Int J Technol Assess Health Care. 2007;23:146-51.
177. Peel E, Parry O, Douglas M, Lawson J. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. Br J Gen Pract. 2004;54:183-8.
178. Peel E, Douglas M, Lawson J. Self-monitoring of blood glucose in type 2 diabetes: Longitudinal qualitative study of patients' perspectives. British Med J. 2007;335:493-8.

179. Strehle EM, Shabde N. One hundred years of telemedicine: does this new technology have a place in paediatrics? Arch Dis Child. 2006;91(12):956-9.
180. World Health Organisation. Telemedicine: Opportunities and developments in member states: Report on second global survey on eHealth 2009 Geneva2010 [Available from: http://www.who.int/goe/publications/goe_telemedicine_2010.pdf.
181. Glasgow RE, Eakin EG, Toobert DJ. How generalizable are the results of diabetes self-management research? The impact of participation and attrition. Diabetes Educ. 1996;22:573-4, 81-82, 84-85.
182. Fitzner K, Greenwood D, Payne H, Thomson J, Vukovljak L, McCulloch A, et al. An assessment of patient education and self-management in diabetes disease management: two cases studies. Popul Health Manag 2008;11(6):329-40.
183. Wu L, Forbes A, Griffiths P, Milligan P, While A. A telephone follow-up to improve glycaemic control in patients with type 2 diabetes: systematic review and meta-analysis of controlled trials. Diabet Med. 2010;27:1217-25.
184. Eakin EG, Reeves MM, Marshall AL, Dunstan DW, Graves N, Healy GN, et al. Living well with diabetes: a randomised controlled trial of a telephone-delivered intervention for maintenance of weight loss, physical activity and glycaemic control in adults with type 2 diabetes. BMC Public Health 2010;10(452).
185. Fjeldsoe BS, Marshall AL, Miller YD. Behaviour change interventions delivered by mobile phone short-message service. Am J Prev Med 2009;36:165-73.
186. Boren SA, De Leo G, Chanetsa FF, Donaldson J, Krishna S, Balas EA. Evaluation of a diabetes education call centre intervention. Telemed J E Health 2006;12:457-65.
187. Nesari M, Zakermoghadam M, Rajab A, Bassampour S, Faghihzadeh S. Effect of telephone follow-up on adherence to a diabetes therapeutic regimen Jpn J Nurs Sci 2010;7:121-8.
188. Sacco WP, Morrison AD, Malone JI. A brief, regular, proactive telephone "coaching" intervention for diabetes: rationale, description and preliminary results J Diabetes Complications. 2004;18:113-8.
189. Greenwood DA, Hankin AI, Parise CA, Spier V, Olveda J, Buss KA. A comparison of in-person,telephone, and secure messaging for type 2 diabetes self-management support. Diabetes Educ. 2014;40(4):516-25.
190. Holtz B, Lauckner C. Diabetes management via mobile phones: A systematic review. Telemed and E-Health 2012;18(3):175-84.
191. Franklin VL, Waller A, Pagliari C, Greene SA. A randomised controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. Diabet Med. 2006;23:1332-8.
192. Eakin E, Reeves M, Marshall A, Dunstan D, Graves N, Healy G. Living well with diabetes: a randomised controlled trial of a telephone-delivered intervention for maintenance of weight loss, physical activity and glycaemic control in adults with type 2 diabetes. BMC Public Health. 2010;10(452).
193. Fjeldsoe B, Marshall A, Miller Y. Behaviour change interventions delivered by mobile phone short-message service. Am J Prev Med. 2009;36:165-73.
194. Boren S, Leo GD, Chanetsa F, Donaldson J, Krishna S, Balas E. Evaluation of a diabetes education call centre intervention. Telemed J E Health. 2006;12:457-65.
195. Dejun Su S, Junmin Zhou Z, Kelly MS, Tzeyu LM, Mohammad S, Wilson F, et al. Does telemedicine improve treatment outcomes for diabetes? A meta-analysis of results from 55 randomised controlled trials. Diabetes Res Clin Pract. 2016;116:136-48.
196. Kim S, Love F, Quistberg D, Shea J. Association of health literacy with self-management behaviour in diabetes. Diabetes Care. 2004;27(12):2980-2.
197. Heisler M, Piette J, Spencer M, Kieffer E, Vijan D. The relationship between knowledge of recent HbA1C values and diabetes understanding and self-management. Diabetes Care. 2005;28:812-22.
198. Green AJ, Bazata DD, Fox KM, Grandy S. Health-related behaviours of people with diabetes and those with cardiometabolic risk factors: results from study to help improve early evaluation and management of risk factors Leading to Diabetes (SHIELD). Int J Clin Pract 2007;61(11):1791-7.
199. Sutton S. Determinants of Health-Related Behaviours: Theoretical and Methodological Issues. In: Sutton S, Baum A, Johnston M, editors. The SAGE Handbook of Health Psychology: SAGE Publications Ltd 2008.
200. Azjen I. The theory of planned behaviour. Org Behav Hum Dec. 1991;50:179-211.
201. Fishbein M, Azjen I. Belief, attitude, intention, and behaviour: An introduction to theory and research. Reading, MA: Addison-Wesley; 1975.

202. Rosenstock IM, Stecher VJ, Becker MH. Social Learning Theory and Health Belief Model. Health Educ Q. 1988;15(2):175-83.
203. Bandura A. Self-efficacy: Toward a unifying theory of behaviour change. Psychol Rev. 1977;84:191-215.
204. Prochaska JO, DiClemente CC. Stages and processes of self-change in smoking: Toward an intergrative model of change. J Consult Clin Psychol. 1983;51:390-5.
205. Schwarzer R. Self-efficacy in the adoption and maintenance of health behaviours: theoretical approaches and a new model. Schwarzer R, editor. Washington, DC: Hemisphere; 1992. 217-43 p.
206. Bandura A. A Self-Efficacy: The Exercise of Control. New York: Freeman; 1997.
207. Ahmad B, Ramadas A, Quek KF, Anuar Zaini MZ. A pilot study: The development of a culturally tailored Malaysian Diabetes Education Module (MY-DEMO) based on the Health Belief Model. BMC Endoc Disord 2014;13(31).
208. Sarkar U, Fisher L, Schillinger D. Is Self-efficacy Associated with Diabetes Self-Management Across Race/Ethnicity and Health Literacy? Diabetes Care. 2006;29(4):823-9.
209. Mishali M, Omer H, Heymann AD. The importance of measuring self-efficacy in patients with diabetes. Family Practice. 2011;28:82-7.
210. Strychar I, Elisha B, Schmitz N. Type 2 Diabetes Self-Management: Role of Diet Self-Efficacy. Can J Diabetes. 2012;36:337-44.
211. Talbot F, Nouwen A, Gingras J, Gosselin M, Audet J. The assessment of diabetes-related cognitive and social factors: the multidimensional diabetes questionnaire. J Behav Med. 1997;20:291-312.
212. Griva K, Myers LB, Newman S. Illness perceptions and self-efficacy beliefs in adolescents and young adults with insulin-dependent diabetes mellitus. Psychol Health. 2000;15:733-50.
213. Grey M, Boland EA, Davidson M, Yu C, Sullivan-Bolyai S, Tamborlane WV. Short-term effects of coping skills training as adjunct to intensive therapy in adolescents. Diabetes Care. **1998**;21:902-8.
214. Aalto A, Uutela A, Aro AR. Health related quality of life among insulin-dependent diabetics: disease-related and psychosocial correlates. Patient Educ Couns. 1997;30:215-25.
215. Rubin RR, Peyrot M, Saudek CD. The effect of a diabetes education program incorporating coping skills training on emotional well-being and diabetes self-efficacy. Diabetes Educ. 1993;19:210-4.
216. Luszcyznska A, Schwarzer R. Planning and self-efficacy in the adoption and maintenance of breast self-examination: A longitudinal study on self-regulatory cognitions. Psychol Health 2003;18(1):93-108.
217. Marlatt GA, Baer JS, Quigley LA. Self-efficacy and addictive behaviour. In: Bandura, A. (Ed), Self-efficacy in Changing Societies. NY: Cambridge University Press; 1995. p. 289-15.
218. Gollwitzer PM. Implementation intentions: strong effects on simple plans. Am Psychol 1999;54:493-503.
219. Sheeran P, Orbell S. Using implementation intentions to increase attendance for cervical cancer screening. Health Psychol. 2000;19:283-9.
220. Department statistic M. Malaysian population census. Department of Statistic Malaysia; 2006.
221. Chew BH, Mastura I, Lee PY, Sri Wahyu T, Cheong AT, Zaiton A. Ethnic differences in glycaemic control and complications: The adult diabetes control and management (ADCM), Malaysia. Med J Malaysia. 2011;66(3):244-8.
222. Ismail IS, Nazaimoon W, Mohammad W, Letchuman R, Singaraveloo M. Ethnicity and glycaemic control are major determinants of dyslipidaemia in Malaysia. Diabet Med. 2001;18(501-508).
223. Ministry of Health Malaysia. National Health Morbidity Survey III Kuala Lumpur: MOH Malaysia; 2006 [Available from: http://iku.moh.gov.my/images/IKU/Document/REPORT/2006/DiabetesMellitus.pdf.
224. Glanz K, Lewis FM, Rimer BK. Chapter 3: The Health Belief Model. Health behaviour and health education: theory, research and practice. 2nd ed. San Francisco, CA: Jossey Bass; 2008.
225. Jones CJ, Smith H, Llewellyn C. Evaluating the effectiveness of health belief model interventions in improving adherence: a systematic review. Health Psychol Rev. 2014;8(3):253-69.
226. Ceriello A, Colagiuri S, Gerich J, Tuomilehto J. Guideline for management of post-meal glucose. Nutr Metab Cardiovasc Dis 2008;18(Supp):17-33.
227. American Diabetes Association. Post prandial blood glucose. Diabetes Care. 2001;19:775-8.
228. American Diabetes Association. Standards of medical care in diabetes – 2012 Diabetes Care. 2012;15(Supp):11-32.

229. Aryangat A, Gerich J. Type 2 Diabetes: postprandial hyperglycaemia and increased cardiovascular risk. Vasc Health Risk Manag. 2010;6:145-55.
230. Monnier L, Mas E, Ginet C, Michael F, Villon L, Cristol JP, et al. Activation of oxidative stress by acute glucose fluctuations compared with sustained chronic hyperglycaemia in patients with type 2 diabetes. JAMA. 2006;295(14):1681-7.
231. Wright E, Scism-Bacon J, Glass L. Oxidative stress in type 2 diabetes: the role of fasting and postprandial hyperglycaemia. Int J Clin Pract. 2006;60:308-14.
232. Clar C, Barnard E, Cummies E, Royle P, Waugh N. Self-monitoring of blood glucose in type 2 diabetes: systematic review. Health Technol Assess 2010;14:1-140.
233. International Diabetes Federation Clinical Guideline Task Force. Global Guideline for Type 2 Diabetes 2012 [Available from: https://www.idf.org/e-library/guidelines/79-global-guideline-for-type-2-diabetes.
234. Sniehotta FF, Scholz U, Schwarzer R. Bridging the intention-behavior gap: Planning, self-efficacy, and action control in the adoption and maintenance of physical exercise. Psychol Health. 2005;20(2):143-60.
235. Araujo-Soares V, McIntyre T, Sniehotta FF. Predicting changes in physical activity among adolescents: the role of self-efficacy, intention, action planning and coping planning. Health Educ Res. 2009;24(1):128-39.
236. Health and Social Care Information Centre. National Diabetes Audit - 2014-2015: Report 1, Care Processes and Treatment Targets 2016 [Available from: https://www.hqip.org.uk/resources/national-diabetes-audit-2013-2014-2014-2015-report-1-care-processes-and-treatment-targets/.
237. Health and Social Care Infromation Centre. National Diabetes Audit - 2013-2014: Report 1, Care Processes and Treatment Targets 2014 [Available from: https://digital.nhs.uk/catalogue/PUB19900.
238. Lenters-Westra E, Slingerland R. Three of 7 Hemoglobin A1C Point-of-Care Instruments Do Not Meet Generally Accepted Analytical Performance Criteria. Clinical Chemistry. 2014;60(8):1062-72.
239. Lenters-Westra E, Slingerland R. Six of Eight hemoglobin A1C Point-of-Care Instruments Do Not Meet the General Accepted Analytical Performance Criteria. Clinical Chemistry. 2010;56(1):44-52.
240. Wan Mohd Zin R, Ahmad Kamil Z, Tuan Soh T, Embong M, Wan Mohamud W. Hemoglobin A1C: comparing performance of two point-of-care devices with laboratory analyser. BMC Research Notes. 2013;6(540):1-4.
241. Hemphill JF. Interpreting the Magnitudes of Correlation Coefficients. American Psychologist. 2003;58(1):78-80.
242. Cohen J. Statistical power analysis for the behavioural sciences. 2nd, editor. Hillsdale, N. J. : Erlbaum; 1988.
243. Chan J, Gagliardino JJ, Baik SH, Chantelot JM, Ferrera SR, Hancu N, et al. Multifaceted determinants for achieving glycaemic control: The international diabetes management practice study (IDMPS) diabetes care. Diabetes Care. 2009;32:227-33.
244. Kapur A, Bjork S, Nair J, Kelkar S, Ramachandran A. Cost of Diabetes in India. Diabetes Care. 1997;20:1183-97.
245. Mooy JM, Grootenhuis PA, de Vries H, Valkenburg HA, Bouter LM, Kostense PJ. Prevalence and determinants of glucose tolerance in a Dutch population. The Hoorn Study. Diabetes Care. 1995;18:1270-3.
246. Harris MI. Undiagnosed NIDDM: clinical and public health issues. Diabetes Care. 1993;16:642-52.
247. Davidson M, Castellanos M, Kain D, Duran P. The effect of self-monitoring of blood glucose concentrations on glycated haemoglobin levels in diabetic patients not taking insulin: a blinded, randomised trial. Am J Med. 2005;118:422-5.
248. Farmer A, Wade A, Groyder D, Yudkin P, French D, Craven A. Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. Brit Med J. 2007;335(7611):132-9.
249. Weinstein ND. Unrealistic optimism about future life events. Journal of Personality and Social Psychology. 1980;39(5):806-20.
250. Waters EA, Klein WM, Moser RP, Yu M, Waldron WR, McNeel TS, et al. Correlates of unrealistic risk beliefs in a nationally representative sample. J Behav Med. 2011;34(3):225-35.
251. Sutton SR. How accurate are smokers' perceptions of risk? Health, Risk & Society. 1999;1(2):223-30.

252. Sheppard JA, Klein WM, Waters EA, Weinstein ND. Taking stock of unrealistic optimism. Perspect Psychol Sci. 2013;8(4):395-411.
253. Diabetes UK. State Of The Nation 2016: Time to take control of diabetes 2016 [Available from: https://diabetes-resources-production.s3-eu-west-1.amazonaws.com/diabetes-storage/migration/pdf/Diabetes%2520UK%2520State%2520of%2520the%2520Nation%25202016.pdf.
254. Horigan G, Davies M, Findlay-White F, Chaney D, Coates V. Reasons why patients referred to diabetes education programmes choose not to attend: a systematic review. Diabet Med. 2017;34(1):14-26.
255. Chuang LM, Tsai ST, Huang BY, Tai TY. The Diabcare-Asia Study Group.The status of diabetes control in Asia - a cross sectional survey of 24317 patients with diabetes mellitus in 1998. Diabetes Medicine. 2002;19:978-85.
256. Ismail IS, Wan Nazaimoon WM, Wan Mohammad WB, Letchuman R, Singaraveloo M. Socioeconomic determinants of glycaemic control in young diabetic patients in Peninsular Malaysia. Diabetes Res Clin Pract. 2000;47:57-69.
257. Mafauzy M. Diabetes control and complications in private primary healthcare in Malaysia. Med J Malaysia. 2005;60:212-7.
258. Mafauzy M. Diabetes control and complications in public hospitals in Malaysia. Med J Malaysia. 2006;61(4):477-83.
259. Grey M, Schreiner B, Pyle L. Development of diabetes education program for youth with type 2 diabetes. Diabetes Educ. 2009;35:108-16.
260. Hampson S, Skinner T, Hart J. Behavioural interventions for adolescents with type 1 diabetes: how effective are they? Diabetes Care. 2000;23:1416-22.
261. Brown SA. Quality reporting in diabetes patient education research: 1954-1986. Res Nurs Health. 1990;13:52-62.
262. Padgett D, Mumford E, Hynes M. Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. J Clin Epidemiol. 1998;41:1007-30.
263. Ahmad B, Md Zain AZ, Quek KF. Type 2 diabetes patients are more amenable to change following a contextualised diabetes education programme in Malaysia. Diab Met Syndr: Clin Res Rev. 2017;Suppl(2):901-6.
264. Koopman-van den Berg DJ, van der Bijl JJ. The use of self-efficacy enhancing methods in diabetes education in the Netherlands. Sch Inq Nurs Pract. 2001;15(3):249-57.
265. Adams AS, Mah CM, Soumerai SB, Zhang F, Barton MB, Degnan DR. Barriers to self-monitoring of blood glucose among adults with diabetes in an HMO: A cross sectional study. BMC Health Serv Res. 2003;3(6):1-8.
266. Fisher WA. Barriers and behaviors in blood glucose monitoring. US Endocrinol. 2007;2:51-3.
267. Lawal M. Telephone interviews of patients on factors affecting attendance in multidiscplinary diabetes education centres:P290. Diabet Med. 2013;30(3):116.
268. Lucas S, Brenchley King H, Patterson T, Winter C, Collett N. Structured education: why people choose not to attend:P317. Diabet Med. 2013;30(3):123.
269. Harris S, Mulnier H, Amiel S. The barriers to uptake of diabetes education study 2017 [Available from: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30440-3/fulltext.

Appendix 1 Ethics Approval from Ministry of Health, Malaysia.

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

[redacted]

[redacted]

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
[redacted]

Ruj. Kami : (2) dlm.KKM/NIHSEC/08/0804/P11-23
Tarikh : 2 Mac 2011

Dr Badariah Ahmad
Universiti Monash
Kampus Sunway

Puan,

NMRR-10-1131-7882
Malaysian Diabetes and Research on Lifelong Lifestyle Intervention Group (MY DARLLING) Study: The impact of knowledge on diabetes and metabolic control and intervention of self care skills in diabetes management

Lokasi Projek: Poliklinik Johor Bahru / Hospital Sultanah Aminah / Hospital Putrajaya / Poliklinik Tanglin / Klinik Diabetes Monash / Hospital Pantai / Klinik-klinik GP

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) tiada halangan, dari segi etika, ke atas pelaksanaan kajian tersebut. JEPP mengambil maklum bahawa kajian tersebut mempunyai intervensi klinikal yang rendah ke atas subjek dan melibatkan pengumpulan data melalui soal selidik sahaja.

3. Segala rekod dan data subjek adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah hospital di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Puan perlu akur dan mematuhi keputusan tersebut.

4. Laporan tamat kajian dan sebarang penerbitan dari kajian ini hendaklah dikemukakan kepada Jawatankuasa Etika & Penyelidikan Perubatan selepas tamatnya kajian ini.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menurut perintah,

[redacted]

(DATO' DR CHANG KIAN MENG)
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia

Appendix 2 Ethics Approval from MUHREC, Australia.

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**13 July 2012**
Project Number:	**CF12/0365 - 2012000157**
Project Title:	**Malaysian Diabetes and Research on Lifelong Lifestyle Intervention Group (MY DARLLING) study: the impact of knowledge on diabetes and metabolic control and intervention of self-care skills in diabetes management**
Chief Investigator:	**Dr Badariah Ahmad**
Approved:	**From: 13 July 2012** **To: 13 July 2017**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research**.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Dr Anuar Zaini Mdzain, Dr Kia Fatt Quek

[redacted]

Appendix 3 Explanatory Statement (*Borang Pemberitahuan*).

MONASH University

SULIT

BORANG PEMBERITAHUAN

Tajuk: Malaysian Diabetes And Research Lifelong Lifestyle Intervention Study Group (**MY DARLLING**): The impact of knowledge on diabetes and metabolic control and intervention of self care skills in diabetes management

Nama Doktor: Badariah Ahmad

Alamat dan nombor telefon:
Jeffrey Cheah School of Medicine and Health Sciences,
Monash University Sunway campus,
Jalan Lagoon Selatan, 46150 Bandar Sunway,
[redacted]

Kepada partisipan,

Anda dijemput untuk menyertai kajian ini. Keputusan untuk menyertai kajian ialah keputusan anda sepenuhnya. Anda dinasihatkan supaya membaca semua maklumat berkenaan tujuan kajian, tanggungjawab sebagai partisipan, ganjaran serta risiko sebelum anda bersetuju menandatangani borang ini. Sekiranya anda tidak faham maklumat dalam borang pemberitahuan keizinan ini, sila tanya kepada doktor atau jururawat, dan mereka boleh terangkan kepada anda.

SEKIRANYA ANDA TIDAK BERSETUJU MENGAMBIL BAHAGIAN DALAM KAJIAN INI, INI TIDAK AKAN MENJEJASKAN LANGSUNG RAWATAN YANG ANDA TERIMA DI KLINIK INI.

Tujuan

Tujuan utama kajian ialah untuk mengetahui sekiranya ujian cucuk jari dirumah atau *self-monitoring blood glucose* (SMBG) ialah cara yang berjaya untuk pesakit Diabetis Jenis 2 memantau paras gula. SMBG ialah ujian darah yang boleh anda lakukan sendiri dirumah dengan mencucuk jari. Ujian SMBG ini boleh memberi maklumat tentang paras gula anda sebelum dan selepas makan. Ujian ini juga boleh memberi maklumat sekiranya paras gula anda terlampau rendah (hipoglisaemia) atau terlampau tinggi (hiperglisaemia); kedua-dua keadaan ini boleh memudaratkan kesihatan anda. Adalah penting untuk mengawal paras gula supaya ia berada dalam julat yang ideal, untuk mengelakkan daripada komplikasi diabetes seperti hilang penglihatan (buta), amputasi, sakit jantung, strok dan sakit buah pinggang. Sepanjang tempoh kajian, selain daripada melakukan

ujian cucuk jari (SMBG), anda masih dibawah jagaan doktor diabetis anda sendiri. Anda juga masih perlu makan ubat diabetis yang telah ditentukan oleh doktor.

Prosedur Kajian
Kajian ini akan mengambil masa selama 18 bulan. Terdapat lebih kurang 160 partisipan dari Kuala Lumpur dan Johor Bahru. Anda telah dijemput untuk menyertai kajian ini disebabkan oleh kawalan paras gula anda kurang memuaskan (HbA1C ≥8%) mengikut ujian darah anda yang terkini. Kajian ini mempunyai beberapa bahagian yang akan dijelaskan dibawah.

Sekiranya anda bersetuju untuk memasuki kajian ini, anda akan dipilih secara rawak melalui sistem komputer kepada 2 kumpulan. Walaubagaimanapun, anda telah bersetuju unutk menyertai kajian, anda tidak boleh memilih kumpulan anda. Pemilihan hanya boleh ditentukan oleh sistem komputer untuk pastikan semua partisipan mendapat peluang yang sama memasuki kedua-dua kumpulan. Sekiranya anda dipilih untuk memasuki kumpulan pertama, anda akan membuat ujian cucuk jari pada 6 bulan pertama. Sekiranya anda dipilih untuk memasuki kumpulan kedua, anda akan membuat ujian cucuk jari pada 6 bulan kemudian. Walaupun anda dalam kumpulan pertama atau kedua, anda tetapkan akan menjalani intervensi untuk kajian iaitu melakukan ujian cucuk jari selama 6 bulan.

Temujanji Pertama - Bahagian Satu kajian memerlukan anda datang ke klinik ini untuk mengikuti satu ceramah berkenaan dengan diabetis and penjagaan diri dalam diabetis. Ceramah ini akan mengambil masa 1-1.5 jam. Anda dikehendaki mengambil satu ujian pendek sebelum dan selepas ceramah untuk mengetahui sekiranya anda memahami ceramah tersebut. Pada perjumpaan pertama ini juga, sekiranya anda bersetuju, doktor atau jururawat akan mengambil tekanan darah, berat badan, tinggi dan ukur-lilit pinggang anda sebagai rekod sebelum anda menyertai kajian ini. Perjumpaan pertama ini akan mengambil masa lebih kurang 2 jam.

Temujanji Kedua - Bahagian Dua kajian memerlukan anda datang ke klinik untuk menghadiri sesi video latihan ujian cucuk jari atau SMBG. Semasa sesi video latihan, doktor akan memberi penerangan tentang kepentingan SMBG serta cara yang betul untuk menggunakan alat glukometer. Glukometer ialah alat yang boleh membaca paras gula anda. Doktor atau jururawat juga akan memerhatikan cara anda menggunakan alat glukometer dan cara anda mencucuk jari semasa sesi latihan ini.
Diakhir sesi latihan SMBG, anda akan diberi **"pek permulaan glukometer"** yang mengandungi sebuah glukometer, jarum, kepingan/strip glukosa, buku log dan beg bimbit kecil untuk dibawa balik. Pek permulaan ini adalah percuma dan boleh digunakan sepanjang tempoh kajian.Sesi latihan akan mengambil masa lebih kurang 90 minit.

Kumpulan Pertama: Jika anda dipilih oleh komputer untuk masuk dalam Kumpulan Pertama, anda akan disuruh membuat ujian cucuk jari selama **6 bulan pertama** (selepas perjumpaan kedua di klinik).

Kumpulan Kedua: Jika anda dipilih oleh komputer untuk masuk dalam Kumpulan Kedua, anda akan disuruh membuat ujian cucuk jari selama **6 bulan kemudian** (selepas perjumpaan kedua di klinik).

Bahagian Tiga – Ujian cucuk jari di rumah (SMBG)
Ujian cucuk jari dirumah ialah intipati kajian ini. Jika anda sudah bersetuju untuk memasuki kajian ini, penyelidik kajian sangat memerlukan kerjasama anda untuk mengikut jadual SMBG yang telah ditentukan. Pendek kata, anda akan disuruh melakukan ujian cucuk jari sebelum dan 2 jam selepas makan selama 6 bulan. Anda dikehendaki melakukan ujian cucuk jari *selepas makan* lebih *banyak* kali daripada ujian cucuk jari sebelum makan. Dengan cara ini, anda boleh mengenalpasti jenis makanan yang boleh memberi kesan pada paras gula anda.

Rajah 1. Jadual ujian cucuk jari selama 6 bulan

Tempoh 6 bulan	**Kekerapan ujian cucuk jari (Total = 114)**
6 minggu pertama	8 kali seminggu 3 X sebelum makan 5X selepas makan
6 minggu kedua	5 kali seminggu 2 X sebelum makan 3X selepas makan
6 minggu ketiga	3 kali seminggu 1X sebelum makan 2X selepas makan
6 minggu keempat	3 kali seminggu 1X sebelum makan 2X selepas makan

Pemantauan Telefon
Anda akan dihubungi melalui telefon oleh doktor ataupun jururawat dalam masa bekerja (8pg–6ptg) sebanyak beberapa kali selama tempoh 18 bulan. Sekiranya anda mempunyai masa yang khusus untuk menerima panggilan telefon, pihak penyelidik boleh membuat panggilan bersesuaian dengan masa anda. Semasa pemantauan telefon, anda akan ditanya beberapa soalan berkenaan rawatan diabetes. Soalan yang diajukan adalah berasaskan ceramah yang telah anda ikuti pada permulaan kajian. Anda dinasihatkan supaya menjawab semua soalan sebaik mungkin.

Temujanji yang seterusnya untuk ujian darah HbA1C
Pada penghujung bulan ke-6, ke-12 dan ke-18 anda akan dipanggil balik ke klinik untuk ujian darah; HbA1C untuk mengetahui kawalan paras gula anda.

Aktiviti-aktiviti yang disuruh buat sekiranya anda setuju untuk memasuki kajian ini

Sekiranya anda bersetuju untuk memasuki kajian ini, kami ingin mengingatkan supaya anda dapat (i) hadir mengikuti 2 ceramah yang telah disediakan (ii) meneliti jadual ujian cucuk jari yang telah disediakan serta memfikirkan bagaimana anda boleh menyesuaikan ujian cucuk jari ini dengan aktiviti harian anda selama 6 bulan (iii) anda boleh dihubungi melalui telefon selama 18 bulan untuk pemantauan telefon (iv) merekodkan segala simptom hipoglisaemia yang anda mungkin rasa (cth mengggigil, berpeluh, mahu pitam dll) dan paras gula semasa anda diserang hipoglisaemia di dalam buku log anda dan juga paras gula anda semasa mengalami simptom hipoglisaemia itu (cth. berapa rendah paras gula?)

Potensi Risiko dan Kesan Sampingan

Dalam kajian ini, anda dikehendaki mengikut jadual ujian cucuk jari. Sepanjang tempoh 6 bulan kajian, dan terutamanya dalam 6 minggu pertama, dimana anda dikehendaki mencucuk jari setiap hari, anda akan merasa sedikit sakit. Tetapi, jika anda mengikut teknik yang betul seperti yang ditunjukkan dalam demonstrasi video SMBG, dan memilih tempat yang sesuai untuk mencucuk jarum, sakit ialah minimal. Kedua, anda mungkin mendapati yang dengan pengawalan gula yang baik, anda mungkin perlu turunkan dosej insulin anda. Walaubagaimanapun, jika anda kurang pasti, anda boleh bertanya dengan doktor anda. Ketiga anda mungkin akan mengalami kesan sampingan hipoglisaemia yang boleh berlaku kepada semua pesakit diabetis. Anda perlu mengambil langkah untuk mencegahnya seperti makan mengikut masa yang ditetapkan. Selain daripada sakit melakukan ujian cucuk jari dan hipoglisaemia, kajian ini tiada risiko atau kesan sampingan yang lain. Sepanjang tempoh kajian, selain daripada melakukan ujian cucuk jari (SMBG), anda masih dibawah jagaan doktor diabetis anda sendiri. Anda juga masih perlu makan ubat diabetis yang telah telah ditentukan oleh doktor.

Potensi Ganjaran

Dengan melakukan ujian SMBG dirumah, anda dapat mengetahui paras gula sepanjang hari. Ini boleh membantu anda untuk membuat keputusan yang bijak tentang makanan/diet yang diambil, kegiatan fizikal yang anda buat, serta suntikan insulin dan ubat diabetes yang anda ambil. Anda dapat maklumat mengenai rawatan diabetes dan mengetahui bagaimana paras gula anda boleh berubah sepanjang hari. Disamping itu, dengan mempunyai alat glukometer, ia memberi peluang kepada anda untuk memantau paras gula anda sepanjang hari dan memberi semangat atau motivasi kepada diri anda untuk mengambil inisiatif dalam mengawal penyakit diabetes. Maklumat berkenaan SMBG boleh bantu anda mengawal cara hidup anda dan rawatan diabetes.

Kompensasi kepada Anda

Anda akan mendapat kompensasi sebanyak tiga kali, dalam bentuk RM 10 bagi setiap temujanji. Anda juga akan menerima "pek permulaan glukometer" yang mengandungi sebuah glukometer, jarum, kepingan/strip glukosa, buku log dan beg bimbit kecil (berharga RM 465 per pak). Anda boleh menyimpan mesin glukometer ini selepas kajian tamat, untuk membantu anda mengawal paras gula anda.

Penyertaaan secara sukarela/ Tarik diri
Penyertaan anda adalah secara sukarela. Anda bebas menarik balik persetujuan dan berhenti dari menyertai kajian ini pada bila-bila masa tanpa sebarang penalti atau kerugian ganjaran. Penarikan diri daripada kajian ini, tidak akan menjejaskan langsung rawatan yang anda sedia terima di klinik kesihatan anda.

Maklumat Sulit
Semua maklumat peribadi akan dirahsiakan. Sekiranya keputusan kajian diterbitkan, nama anda akan dirahsiakan.

Penyimpanan Data/Maklumat
Semua data yang dikumpulkan akan disimpan mengikut peraturan Monash University, dalam kawasan universiti, didalam peti berkunci selama 5 tahun.

Nombor untuk berhubung

Sekiranya anda mempunyai apa-apa pertanyaan berkenaan dengan kajian diatas atau ingin membuat aduan berkaitan dengan kajian ini, sila hubungi:	Sekiranya anda mempunyai apa-apa pertanyaan berkenaan dengan cara kajian ini dikendalikan atau ingin tahu tentang hak anda sebagai seorang partisispan, sila hubungi:
Dr Badariah Ahmad, Jeffrey Cheah School of Medicine and Health Sciences, Monash University Sunway campus, [redacted]	Dr S Asmaliza Ismail NIH Secretariat, Ministry of Health Malaysia [redacted]

Appendix 4 Informed Consent *(Borang Keizinan).*

MONASH University

BORANG KEIZINAN

Tajuk: Malaysian Diabetes And Research Lifelong Lifestyle Intervention Study Group (**MY DARLLING**): The impact of knowledge on diabetes and metabolic control and intervention of self-care skills in diabetes management

☐ Saya dengan sukarela menyertai kajian Malaysian Diabetes and Research Lifelong Lifestyle Intervention Study Group (**MY DARLLING**): The impact of knowledge on diabetes and metabolic control and intervention of self-care skills in diabetes management.

☐ Saya faham yang saya dijemput untuk mengambil bahagian didalam aktiviti kajian dibawah selama 18 bulan: (Sila tandakan)

Aktiviti Kajian	Ya	Tidak
a) Menghadiri dua ceramah diabetis yang akan diadakan di klinik pesakit luar pada hari yang telah disetujui.		
b) Melakukan ujian cucuk jari dirumah untuk bacaan paras gula mengikut jadual yang telah ditentukan dalam borang pemberitahuan selama 6 bulan.		
c) Untuk merekodkan semua bacaan gula dalam buku log yang telah disediakan selama 6 bulan.		
d) Membenarkan tekanan darah, berat, ketinggian badan dan ukur lilit pinggang diambil ketika hadir untuk temujanji pertama.		
e) Untuk menjawab semua soalan yang diajukan kepada saya melalui pemantauan telefon selama 18 bulan.		

☐ Saya telah membaca maklumat dalam borang ini mengenai kajian diatas. Semua soalan saya berkenaan dengan kajian ini telah dijawab. Saya faham yang saya bebas untuk menarik diri dari kajian ini pada bila-bila masa sahaja.

☐ Saya faham yang semua maklumat yang saya berikan ialah sulit, dan tiada sebarang maklumat pun yang boleh digunakan untuk mempaparkan identiti seseorang individu kepada mana-mana pihak.

☐ Saya beri keizinan untuk menerbitkan kesemua maklumat dan jawapan saya berkenaan dengan pemahaman diabetes semasa tempoh kajian ini kepada kakitangan penyelidikan dari Monash University, Institutional Review Board Independent Ethics Committee (IRB/IEC) serta badan-badan lain yang berkaitan dengan kajian ini.

□ Saya faham yang semua data yang dikumpulkan akan disimpan ditempat yang selamat dan hanya boleh di akses oleh kumpulan penyelidik. Saya juga faham yang maklumat ini akan dimusnahkan selepas tempoh 5 tahun dan tidak digunakan untuk kajian akan datang kecuali dengan keizinan saya.

□ Saya faham dan terima salinan borang pemberitahuan yang telah saya tandatangani dan bertarikh.

□ Dengan menandatangani borang ini, saya tidak akan memansuhkan sebarang hak saya sebagai seorang peserta dalam kajian ini.

_____ _____
(Tandatangan Peserta) Tarikh

_____
(Nama Peserta)

No IC baru : _____

Nombor telefon: _____

Appendix 5 Ethics Approval from Selangor Health State Department for two extra clinical sites.

JABATAN KESIHATAN NEGERI SELANGOR
TINGKAT 9,10,11 & 17 WISMA SUNWAYMAS,
JALAN PERSIARAN KAYANGAN,SEKSYEN 9,
40100 SHAH ALAM,
SELANGOR DARUL EHSAN.
[redacted]

QUALITY SYSTEM SIRIM
STANDARDS MALAYSIA
MS ISO/IEC GUIDE 62:1999
QS 0212/1999 CB 01
Certified to ISO 9001:2008
Cert. No. AR 3856

Ruj Tuan:
Ruj Kami : JKNS/KA/Q-712/04-01 Jld.7 (26)
Tarikh : 25 Mac 2013

Dr Badariah Ahmad
Tan Sri Jeffrey Cheah School Of Medicine,
Monash University Sunway Campus,
Jalan Lagoon Selatan,
[redacted]

Puan,

ADDENDUM KEPADA KAJIAN NMRR-10-1131-7882:- "MALAYSIAN DIABETES AND RESEARCH ON LIFEFONG LIFESTYLE INTERVENTION STUDY GROUP (MY DARLING)"

Dengan hormatnya merujuk perkara di atas dan surat permohonan daripada Puan yang bertarikh 14Februari 2013 adalah berkaitan.

2. Sukacita dimaklumkan bahawa Bahagian Kesihatan Awam, Jabatan Kesihatan Negeri Selangor tiada halangan untuk pelaksanaan kajian tersebut di Klinik Kesihatan Kelana Jaya dan Klinik Kesihatan Shah Alam, PKD Petaling sekiranya pihak Puan memenuhi perkara berikut :

i. Membentangkan hasil kajian kepada kami setelah kajian selesai.

ii. Memberikan se salinan hasil kajian kepada kami untuk bahan bacaan dan rujukan pegawai-pegawai di jabatan ini.

iii. Sebarang penerbitan, diseminasi atau sebarang hasil kajian penyelidikan tersebut sama ada melalui penulisan, pengiklanan, pembentangan atau untuk ke media perlu mendapat kelulusan Ketua Pengarah Kesihatan Malaysia terlebih dahulu.

3. Selain daripada itu, pihak Puan perlu berbincang tentang kajian terlebih dahulu dengan Pegawai Kesihatan Daerah Petaling di talian 03-78045333.

4. Untuk sebarang pertanyaan atau maklumat lanjut, sila hubungi Dr. Ismawati Ismail, Unit Kualiti (Kesihatan Awam), Jabatan Kesihatan Negeri Selangor ditalian 03-51237331/51237338.

Kerjasama dan perhatian Puan adalah dihargai dan didahului dengan ucapan terima kasih.

Sekian.

"BERKHIDMAT UNTUK NEGARA"

"PENYAYANG, KERJA BERPASUKAN DAN PROFESIONALISMA ADALAH BUDAYA KERJA KITA"

Saya yang menurut perintah,

[redacted]

(DR. HJ. ZAINUDIN BIN ABDUL WAHAB, NO.MPM: 25033)
Timbalan Pengarah Kesihatan Negeri (Kesihatan Awam)
b/p Pengarah Kesihatan Negeri,
Jabatan Kesihatan Negeri Selangor

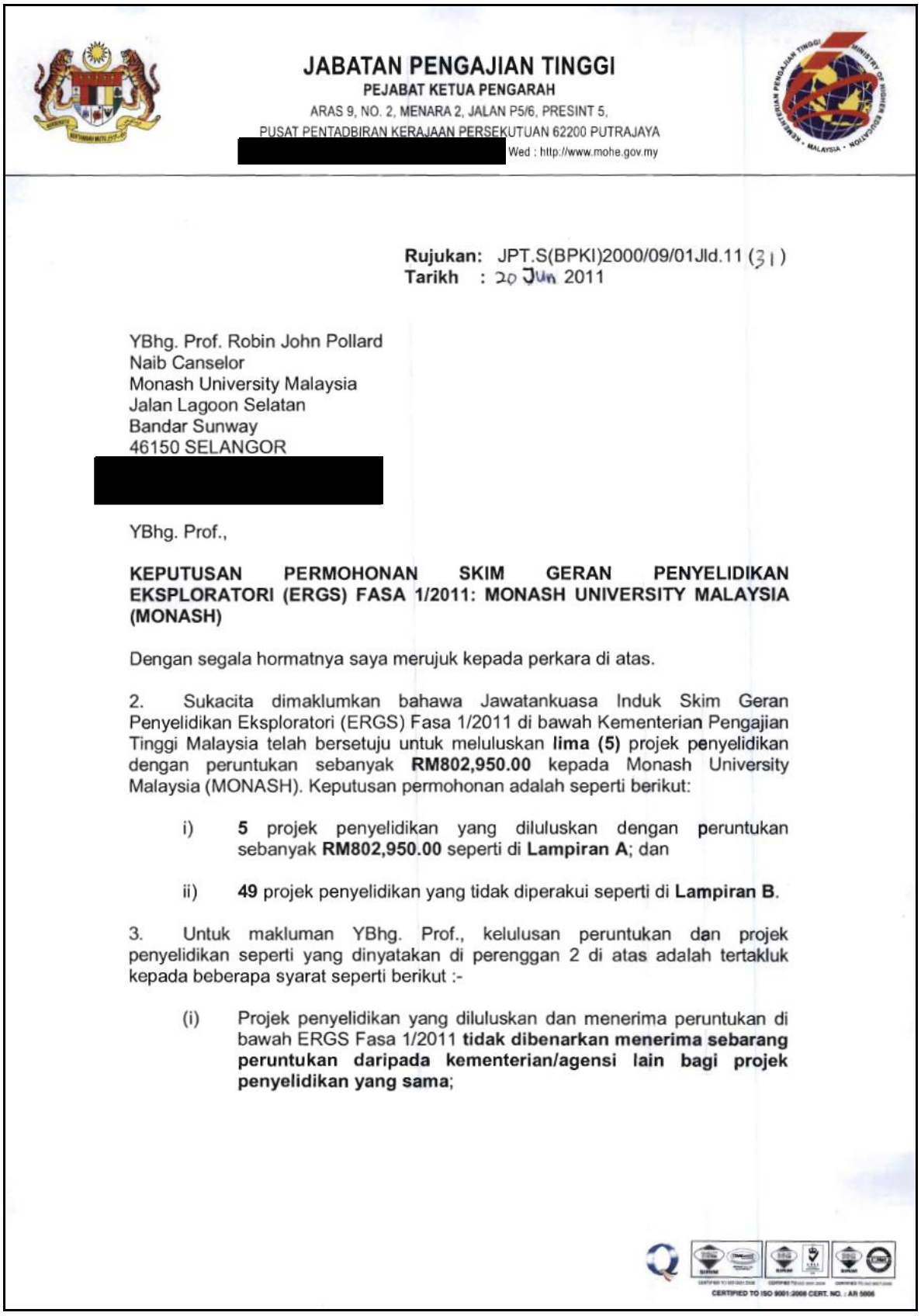
Dr. Isma (Unit Kualiti)

s.k

Pengarah Kesihatan Negeri,
Jabatan Kesihatan Negeri Selangor

Pegawai Kesihatan Daerah,
Pejabat Kesihatan Daerah Petaling

Appendix 6 Funding Approval from Ministry of Higher Education, Malaysia.



JABATAN PENGAJIAN TINGGI
PEJABAT KETUA PENGARAH
ARAS 9, NO. 2, MENARA 2, JALAN P5/6, PRESINT 5,
PUSAT PENTADBIRAN KERAJAAN PERSEKUTUAN 62200 PUTRAJAYA
[redacted] Wed : http://www.mohe.gov.my

Rujukan: JPT.S(BPKI)2000/09/01Jld.11 (31)
Tarikh : 20 Jun 2011

YBhg. Prof. Robin John Pollard
Naib Canselor
Monash University Malaysia
Jalan Lagoon Selatan
Bandar Sunway
46150 SELANGOR
[redacted]

YBhg. Prof.,

KEPUTUSAN PERMOHONAN SKIM GERAN PENYELIDIKAN EKSPLORATORI (ERGS) FASA 1/2011: MONASH UNIVERSITY MALAYSIA (MONASH)

Dengan segala hormatnya saya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Jawatankuasa Induk Skim Geran Penyelidikan Eksploratori (ERGS) Fasa 1/2011 di bawah Kementerian Pengajian Tinggi Malaysia telah bersetuju untuk meluluskan **lima (5)** projek penyelidikan dengan peruntukan sebanyak **RM802,950.00** kepada Monash University Malaysia (MONASH). Keputusan permohonan adalah seperti berikut:

i) **5** projek penyelidikan yang diluluskan dengan peruntukan sebanyak **RM802,950.00** seperti di **Lampiran A**; dan

ii) **49** projek penyelidikan yang tidak diperakui seperti di **Lampiran B**.

3. Untuk makluman YBhg. Prof., kelulusan peruntukan dan projek penyelidikan seperti yang dinyatakan di perenggan 2 di atas adalah tertakluk kepada beberapa syarat seperti berikut :-

(i) Projek penyelidikan yang diluluskan dan menerima peruntukan di bawah ERGS Fasa 1/2011 **tidak dibenarkan menerima sebarang peruntukan daripada kementerian/agensi lain bagi projek penyelidikan yang sama**;

CERTIFIED TO ISO 9001:2008 CERT. NO. : AR 5006

Sekiranya syarat seperti di perenggan 3(i) **tidak dipatuhi**, pihak Kementerian memohon kerjasama Pusat Pengurusan Penyelidikan IPT untuk **menarik balik** kelulusan peruntukan ERGS Fasa 1/2011 bagi projek penyelidikan tersebut.

4. Peruntukan ERGS Fasa 1/2011 akan disalurkan kepada Bendahari MONASH setelah selesai beberapa proses kewangan di peringkat Kementerian. Pihak MONASH juga digalakkan memulakan terlebih dahulu projek penyelidikan yang telah diluluskan di bawah ERGS Fasa 1/2011.

5. Perkara yang dinyatakan di atas dipanjangkan untuk makluman dan tindakan YBhg. Prof. jua.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

[redacted]

(DATO' PROF. DR. RUJHAN BIN MUSTAFA)
Ketua Pengarah
Jabatan Pengajian Tinggi
Kementerian Pengajian Tinggi

s.k.:

Setiausaha Bahagian
Bahagian Pembangunan
Kementerian Pengajian Tinggi Malaysia

Pengarah
Pusat Pengurusan Penyelidikan
Monash University Malaysia
[redacted]

Bendahari
Monash University Malaysia

Appendix 7.1 Sample telephone contact question.

Nama: _____

Kad Pengenalan: _____

Tarikh: _____

1) **Apakah jenis makanan yang bertukar menjadi gula selepas melalui proses penghadaman?**
   a) Karbohidrat
   b) Vitamin
   c) Lemak

2) **Apakah hormon yang menurunkan paras gula dalam darah selepas makan?**
   a) Insulin
   b) Glukagon
   c) Adrenalin

3) **Berikut adalah amalan hidup yang cegas/aktif :**
   a) Kebiasaan meletak kereta di tempat yang paling dekat bila pergi membeli belah di pusat membeli-belah
   b) Kebiasaan menggunakan lif bila mengangkat barang-barang
   c) Kebiasaan memanjat tangga beberapa kali bila mengangkat barang-barang

4) **Pemakanan sihat termasuk:**
   a) Kurangkan makan buah-buahan
   b) Kurangkan makan garam
   c) Kurangkan makanan sayur-sayuran

5) **Simptom Diabetes termasuk:**
   a) Rasa haus
   b) Kurang kencing pada malam hari
   c) Kurang kencing pada siang hari

6) **Sebelum ujian cucuk jari, anda mesti memeriksa tarikh luput kerana jalur glukosa yang melebihi tarikh luput:**
   a) Boleh digunakan pada masa yang akan datang
   b) Memberi bacaan yang tepat
   c) Memberi bacaan yang kurang tepat

Appendix 7.2 Sample telephone contact question.

Nama: _____

Kad Pengenalan: _____

Tarikh: _____

1) **Apa langkah-langkah yang boleh anda ambil untuk melambatkan komplikasi diabetes?**
a) Menghadiri pemeriksaan mata setahun sekali
b) Menghadiri pemeriksaan mata sekali dalam 2.5 tahun
c) Menghadiri pemeriksaan mata sekali dalam 5 tahun

2) **Apakah kelenjar yang rosak dalam diabetes?**
a) Kelenjar tairoid
b) Kelenjar air liur
c) Kelenjar pankreas

3) **Pemakanan sihat termasuk:**
a) Lebihkan makan sayur-sayuran
b) Lebihkan makan makanan berkanji
c) Lebihkan makan garam

4) **Simptom hipoglisaemia termasuk:**
a) Rasa haus
b) Rasa penat
c) Banyak kencing pada malam hari

5) **Dalam diabetes, "darah manis" atau hiperglisaemia boleh merosakkan semua salur darah dalam badan. Apakah komplikasi diabetes yang sering didapati?**
a) Hilang ingatan
b) Hilang pendengaran
c) Hilang penglihatan

6) **Apa yang perlu anda buat selepas sahaja habis melakukan ujian cucuk jari:**
a) Terus rekodkan bacaan gula dalam buku catatan setiap kali lepas ujian cucuk jari
b) Rekodkan bacaan gula dalam buku catatan seminggu sekali
c) Rekodkan bacaan gula dalam buku catatan sebulan sekali

Appendix 7.3 Sample telephone contact question.

Nama: _____

Kad Pengenalan: _____

Tarikh: _____

1) **Apakah paras gula yang dianggap normal SELEPAS makan?**
a) 10-12 mmol/l
b) 8-10 mmol/l
c) 6-8 mmol/l

2) **Manfaat senaman:**
a) Rendahkan paras kolestrol dalam darah
b) Tinggikan tekanan darah
c) Tambahkan obesiti

3) **Dalam diabetes, "darah manis" atau hiperglisaemia boleh merosakkan semua salur darah dalam badan. Apakah organ yang boleh dirosakkan oleh diabetes?**
a) Paru-paru
b) Hidung
c) Jantung

4) **Pemakanan sihat termasuk:**
a) Lebihkan makan lemak ikan (*cth omega 3)*
b) Lebihkan makan lemak tepu
c) Lebihkan makan lemak *trans*

5) **Simptom Diabetes termasuk:**
a) Batu karang dalam air kencing
b) Gula dalam air kencing
c) Garam dalam air kencing

6) **Apakah ikon atau tanda di skrin glukometer yang menunjukkan mesin glukometer sudah sedia untuk digunakan?**
a) Gula
b) Jari
c) Darah

Appendix 7.4 Sample telephone contact question.

Nama: _____

Kad Pengenalan: _____

Tarikh: _____

Sila jawab semua soalan dibawah. Bulatkan jawapan yang betul.

1) Penjagaan kaki penting dalam diabetes. Apa yang patut dibuat untuk penjagaan kaki anda?

a) Tidak memakai kasut apabila berjalan keluar rumah
b) Pastikan celah-celah jari kaki sentiasa kering
c) Merawat luka atau ulser dikaki dengan sendiri

2) Apa langkah-langkah yang boleh anda ambil untuk mengelakkan atau melambatkan komplikasi diabetes?

a) Menghadiri pemeriksaan mata sekali dalam 5 tahun
b) Jika gemuk atau sangat gemuk, turunkan berat badan sebanyak 5-10%
c) Mengabaikan luka/ulser di kaki yang lambat pulih

3) Apa langkah-langkah yang boleh anda ambil untuk mengelakkan atau melambatkan komplikasi diabetes?

a) Tidak bersenam
b) Bersenam sekali seminggu selama 30-45 minit
c) Bersenam lima kali seminggu selama 30-45 minit

4) Dalam diabetes, "darah manis" atau hiperglisaemia boleh merosakkan semua salur darah dalam badan. Apakah organ yang boleh dirosakkan oleh diabetes?

a) Lidah
b) Otak
c) Hidung

5) Apa yang menyebabkan "darah manis" atau dikalangan pesakit diabetes?

a) Kelenjar pankreas kurang menghasilkan insulin
b) Hati kurang menghasilkan gula
c) Sel lemak boleh menyerap gula

6) Yang mana boleh meninggikan paras gula anda?

a) Tidak makan ubat diabetes
b) Melakukan senaman
c) Terlupa untuk makan

Appendix 7.5 Sample telephone contact question.

Nama: _____

Kad Pengenalan: _____

Tarikh: _____

Sila jawab semua soalan dibawah. Bulatkan jawapan yang betul.

1) **Penjagaan kaki penting dalam diabetes. Apa yang patut dibuat untuk penjagaan kaki anda?**
a) Tidak memakai kasut apabila berjalan keluar rumah
b) Pastikan celah-celah jari kaki sentiasa kering
c) Basuh kaki anda seminggu sekali

2) **Dalam diabetes, "darah manis" atau hiperglisaemia boleh merosakkan semua salur darah dalam badan. Apakah komplikasi diabetes yang sering didapati?**
a) Dialisis buah pinggang
b) Transplantasi hati
c) Transplantasi lutut

3) **Faktor yang mana akan MENINGGIKAN risikomendapat diabetes?**
a) Makan gula dengan banyak
b) Makan sayur dengan banyak
c) Makan kalsium dengan banyak

4) **Manfaat senaman:**
a) Rendahkan paras gula dalam darah
b) Tambahkan sakit sendi
c) Tinggikan paras kolestrol dalam darah

5) **Apa yang menyebabkan "darah manis" atau hiperglisaemia dikalangan pesakit diabetes?**
a) Sel lemak tak boleh menyerap gula dari salur darah
b) Tisu otot boleh menyerap gula dari dalur darah
c) Kelenjar pankreas menghasilkan insulin seperti normal

6) **Yang mana boleh meninggikan paras gula anda?**
a) Makanan berkarbohidrat
b) Banyak melakukan senaman
c) Mengambil ubat diabetes

Appendix 7.6 Sample telephone contact question.

Nama : _____

Kad Pengenalan: _____

Tarikh: _____

Sila jawab semua soalan dibawah. Bulatkan jawapan yang betul.

1) Penjagaan kaki penting dalam diabetes. Apa yang patut dibuat untuk penjagaan kaki anda?

a) Abaikan sebarang luka atau ulser di kaki
b) Tidak memakai kasut apabila berjalan keluar rumah
c) Selalu menyapu krim/pelembab pada kaki dan buku lali anda

2) Apa langkah-langkah yang boleh anda ambil untuk mengelakkan atau melambatkan komplikasi diabetes? Jika anda gemuk atau sangat gemuk:-

a) turunkan berat badan anda sebanyak 1-2%
b) turunkan berat badan anda sebanyak 5-10%
c) turunkan berat badan anda sebanyak 20%

3) Apa langkah-langkah yang boleh anda ambil untuk mengelakkan atau melambatkan komplikasi diabetes?

a) Jika masih merokok, berhenti dengan segera
b) Tidak bersenam
c) Menghadiri pemeriksaan mata sekali dalam 5 tahun

4) Dalam diabetes, "darah manis" atau hiperglisaemia boleh menjejaskan semua salur darah dalam badan. Apakah organ yang boleh dirosakkan oleh diabetes?

a) Paru-paru
b) Pundi kencing
c) Buah pinggang

5) Apa yang menyebabkan "darah manis" atau hiperglisaemia dikalangan pesakit diabetes?

a) Sel lemak boleh menyerap gula dari salur darah
b) Tisu otot boleh menyerap gula dari salur darah
c) Pankreas kurang menghasilkan insulin

6) Berikut adalah pemakanan yang sihat

a) Banyakkan makan gula
b) Banyakkan makan sayur-sayuran
c) Banyakkan makan kalsium

Appendix 8.1 Behavioural Questionnaire at Baseline *(Malay)*.

Nama: _____

Kad Pengenalan: _____

Tarikh: _____

Sila jawab semua soalan di bawah.

1.1) Pada pendapat anda, berbanding dengan pesakit diabetis lain, apakah kemungkinan yang paras gula anda sebelum makan (puasa) ialah <7.0mmol/l?

Kemungkinan Sangat rendah	Kemungkinan Rendah	Kemungkinan Baik	Kemungkinan Tinggi	Kemungkinan Sangat tinggi

1.2) Pada pendapat anda, berbanding dengan pesakit diabetis lain, apakah kemungkinan yang paras gula anda selepas makan ialah > 10.0mmol/l?

Kemungkinan Sangat rendah	Kemungkinan Rendah	Kemungkinan Baik	Kemungkinan Tinggi	Kemungkinan Sangat Tinggi

Dari aspek peribadi, apa yang boleh berubah jika anda melakukan ujian cucuk jari secara lazim (regular)?

2.1) Kesihatan saya akan meningkat.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

2.2) Peluang untuk melambatkan komplikasi penyakit diabetis (contoh sakit jantung, sakit strok, kerosakkan buah pinggang) saya akan meningkat.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

3.1) Dalam tempoh dua minggu akan datang, saya akan membuat perancangan yang teliti tentang *bagaimana* saya akan melakukan ujian cucuk jari.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

3.2) Dalam tempoh dua minggu akan datang, saya akan membuat perancangan yang teliti tentang *bila* saya akan melakukan ujian cucuk jari.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

3.3) Dalam tempoh dua minggu akan datang, saya akan membuat perancangan yang teliti tentang *dimana* saya akan melakukan ujian cucuk jari.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

Appendix 8.2 Behavioural Questionnaire at Baseline (English).

A. Risk perception for getting normal blood sugar level or an out-of-range blood sugar

1) Compared to other diabetes patients how do you estimate the likelihood that you will have a fasting blood sugar of <7.0mmol/l?

Poor	Fair	Good	Very Good	Excellent

2) Compared to other diabetes patients how do you estimate the likelihood that you will have a fasting blood sugar of > 10.0mmol/l?

Poor	Fair	Good	Very Good	Excellent

B. Outcome expectancy for general health and prevention of diabetes complications

1) What would be the personal consequences for you, if you adopt regular blood sugar monitoring?

a) My well-being will be increased.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

b) My chance of reducing or delaying diabetes complications will increase.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

C. Self-efficacy in performing self monitoring blood sugar (SMBG)

1) Within the coming two weeks, I will make detail plans regarding how I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

2) Within the coming two weeks, I will make detail plans regarding when I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

3) Within the coming two weeks, I will make detail plans regarding where I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

4) Within the coming two weeks, I will make detail plans regarding how often I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

Appendix 9.1 Behavioural Questionnaire at 3 months *(Malay)*.

A. Self-efficacy in performing self monitoring blood sugar (SMBG)

1) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *bagaimana* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

2) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *bila* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

3) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *dimana* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

4) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *berapa kerap* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

Appendix 9.2 Behavioural Questionnaire at 3 months (English)

A. Self-efficacy in performing self monitoring blood sugar (SMBG)

1) In the past two weeks, I have made detail plans regarding how I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

2) In the past two weeks, I have made detail plans regarding when I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

3) In the past two weeks, I have made detail plans regarding where I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

4) In the past two weeks, I have made detail plans regarding how often I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

Appendix 10.1 Behavioural Questionnaire at 6 months *(Malay)*.

A. Self-efficacy in performing self monitoring blood sugar (SMBG)

1) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *bagaimana* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

2) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *bila* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

3) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *dimana* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

4) Semenjak dua minggu lepas, saya telah membuat perancangan yang teliti tentang *berapa kerap* saya akan melakukan ujian cucuk jari saya.

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

B. Maintenance Self-efficacy

1) Bagaimana pastinya anda, bahawa ujian cucuk jari secara tetap akan terus anda lakukan, walaupun anda sibuk dengan hal-hal lain?

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

C. Recovery Self-efficacy

1) Sekiranya anda telah berhenti melakukan ujian cucuk jari selama *3 bulan*, adakah anda boleh kembali melakukan ujian cucuk jari secara tetap selepas itu?

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

2) Sekiranya anda telah berhenti melakukan ujian cucuk jari lebih dari *6 bulan,* adakah anda boleh kembali melakukan ujian cucuk jari secara tetap selepas itu?

Sangat tidak bersetuju	Tidak Setuju	Tidak pasti	Setuju	Sangat Setuju

Appendix 10.1 Behavioural Questionnaire at 6 months (English).

A. Self-efficacy in performing self monitoring blood sugar (SMBG)

1) In the past two weeks, I have made detail plans regarding how I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

2) In the past two weeks, I have made detail plans regarding when I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

3) In the past two weeks, I have made detail plans regarding where I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

4) In the past two weeks, I have made detail plans regarding how often I am going to monitor my blood sugar?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

B. Maintenance Self-efficacy

1) How certain are you that you can continue to monitor your blood sugar regularly, even if you are occupied by other events in your life?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

C. Recovery Self-efficacy

1) Are you able to return to regular blood sugar monitoring if you happen to give it up for three months?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

2) Are you able to return to regular blood sugar monitoring if you happen to give it up over 6 months?

Strongly disagree	Disagree	Undecided	Agree	Strongly agree

Appendix 11 Publication 1.

Ahmad et al. BMC Endocrine Disorders 2014, 14:31
http://www.biomedcentral.com/1472-6823/14/31

BMC Endocrine Disorders

RESEARCH ARTICLE Open Access

A pilot study: the development of a culturally tailored Malaysian Diabetes Education Module (MY-DEMO) based on the Health Belief Model

Badariah Ahmad*, Amutha Ramadas, Quek Kia Fatt and Anuar Zaini Md Zain

Abstract

Background: Diabetes education and self-care remains the cornerstone of diabetes management. There are many structured diabetes modules available in the United Kingdom, Europe and United States of America. Contrastingly, few structured and validated diabetes modules are available in Malaysia. This pilot study aims to develop and validate diabetes education material suitable and tailored for a multicultural society like Malaysia.

Methods: The theoretical framework of this module was founded from the Health Belief Model (HBM). The participants were assessed using 6-item pre- and post-test questionnaires that measured some of the known HBM constructs namely cues to action, perceived severity and perceived benefit. Data was analysed using PASW Statistics 18.0.

Results: The pre- and post-test questionnaires were administered to 88 participants (31 males). In general, there was a significant increase in the total score in post-test (97.34 ± 6.13%) compared to pre-test (92.80 ± 12.83%) ($p < 0.05$) and a significant increase in excellent score (>85%) at post-test (84.1%) compared to pre-test (70.5%) ($p < 0.05$). There was an improvement in post-test score in 4 of 6 items tested. The remaining 2 items which measured the *perceived severity* and *cues to action* had poorer post-test score.

Conclusions: The preliminary results from this pilot study suggest contextualised content material embedded within MY DEMO maybe suitable for integration with the existing diabetes education programmes. This was the first known validated diabetes education programme available in the Malay language.

Keywords: Self-efficacy, Validation, Education, Module, Knowledge, Health-belief model

Background

Diabetes education and self-care in diabetes remains the cornerstone of diabetes management [1,2]. Norris *et al.* observed that diabetes self-management education (DSME) have evolved over the past four decades from primarily didactic interventions into the collaborative and theoretically based "empowerment" models [3].

In the United Kingdom, several structured diabetes education programmes were developed in an effort to provide better diabetes care. For instance, diabetes education of self-management for on-going and newly diagnosed (DESMOND) type 2 diabetes patients [4] and expert patient education versus routine treatment (X-PERT) [5] and dose adjustment for normal eating (DAFNE) for type 1 diabetes patients [6] were developed and implemented. Contrastingly, evidences of theoretically based diabetes education programmes are scanty in Malaysia.

Due to explosion of diabetes in Malaysia [7-10], an executive decision made by various policymakers to increased resource centres (e.g. one-stop diabetes centre) in primary care settings and hospitals to improve diabetes care delivery [11]. Worryingly, despite the multiple-pronged efforts, glycaemic control in Malaysia remained suboptimal [12-19].

The aim of this pilot study was to review existing diabetes education programmes both in Malaysia and abroad and consequently develop a culturally suitable diabetes education module based on the Health Belief Model.

* Correspondence: badariah.ahmad@monash.edu
Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia, Jalan Lagoon Selatan, Bandar Sunway, 47500 Petaling Jaya, Malaysia

Methods

Needs assessment for a contextualised Malaysian Diabetes Education Module (MY DEMO) in Malay

Evidence on structured diabetes education study in Malaysia has been scarce. A recent study by Tan *et al.* using a structured education programme based on self-efficacy theoretical framework succeeded in short term improvement of glycated haemoglobin, three self-care practices and diabetes knowledge in a cohort of poorly controlled diabetes patients [20].

The American Association of Diabetes Educators (AADE) defined the seven essential self-care behaviours for successful and effective diabetes self-management [21]. These 7 self-care behaviours (AADE7™) include healthy eating, being active, monitoring, taking medication, problem solving, healthy coping and reducing risks. Majority of these essential self-care components were embedded within MY DEMO (Figure 1).

Recent evidences had shown that culturally tailored packages were useful in helping diabetes patients in managing their diabetes. These packages included information that was easy to convey, with appealing visual teaching tools and that were interactive and effective in delivering diabetes education to high risks indigenous groups [22,23]. Vincent *et al.* opined that specific cultural modifications such as incorporation of dietary preferences and cultural beliefs, delivery in mother tongue language and using bilingual nurses and dieticians can enhanced diabetes self-management and result in improved glycaemic control [24].

Figure 1 The important aspects highlighted in the MY DEMO.

Theoretical background

While it is well known that knowledge alone did not always predict behaviour change or glycaemic control [25], health behaviour theories would generally include basic knowledge as a necessary element of health behaviour change and outcomes [26]. Many health models developed in the past five decades had tried to describe, predict, explain and ultimately change health behaviours. Most of the well-known health behaviour models have their roots in the field of psychology; Health Belief Model (HBM) by Rosenstock [27]; Social Cognitive Theory (SCT) by Bandura [28]; Transtheoretical Model (TTM) by Prochaska and DiClemente [29] and more recently Health Action Process Approach (HAPA) by Schwarzer [30]. MY DEMO was developed based on HBM and made clear attempts to measure some of the constructs such as cues to action, perceived benefit and perceived severity. In addition, the other three constructs such as perceived susceptibility, perceived barriers and self-efficacy were integrated into MY DEMO.

Development of MY DEMO

Culturally tailored components in MY DEMO development

Malaysia is a multicultural country and the Malays, Chinese and Indians form the fabric of the society. Although *Malay* language is widely spoken, Mandarin and Tamil are frequently used too. The first key concept the author wanted to highlight was the common misnomer used to describe diabetes. It is well known that diabetes is due to the dysfunctional sugar metabolism due to the lack of insulin and/or insulin resistance leading to hyperglycaemia. There was an emphasis to educate participants on the importance of the term "sweet blood" (*darah manis* in Malay) rather than "sweet urine". This was to make participants aware that the issue in diabetes is hyperglycaemia and not glycosuria - which usually presents later when the diabetes complications had ensued. The terminology "sweet urine" is a common reference for diabetes patients and general population in Malaysia (i.e. *kencing manis* in *Malay*, *inippu neer* in *Tamil* and *tang-niow* in *Mandarin*), as most people associate the diabetes condition with glycosuria and not hyperglycaemia. Glycosuria (*kencing manis*) was highlighted as a side-effect of a declining kidney function and hence the importance of early detection of hyperglycaemia (*darah manis*) in diabetes diagnosis. Other core topics such as patho-physiology of diabetes, the recognition of diabetes symptoms and signs, complications and prevention of diabetes were also emphasized using simple *Malay* language. Visual and colorful diagrams were employed to illustrate the complex and essential concepts which can lead to insulin resistance.

Simple analogies were also used to enhance understanding of the role of insulin by explaining how the insulin "key" can open the cell "door" and help normalize blood sugar level in the body. In addition, the authors likened the "national road transport system" as an equivalent to a vascular system in the body which can be damaged due to prolonged and uncontrolled hyperglycaemia. The diabetes complications such macro-vascular and micro-vascular diseases were clearly illustrated using visual aids such photographs, anatomical diagrams and animations. The HBM constructs such as perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy were embedded in the module during the development of MY DEMO. Finally, other key messages emphasised in MY DEMO were healthy lifestyle modifications including balance diet and regular exercise. Popular local physical activities (i.e. *tai chi, qi gong, yoga,* brisk walking) were also mentioned to incorporate active lifestyle into daily activities.

Delivery of MY DEMO

Every effort was made to ensure that content could be easily followed by participants. Some of the key elements of plain language defined by Kandula *et al.* are; a) delivering important information first b) breaking complex information into understandable chunks c) using simple language and d) defining technical terms were adopted during MY DEMO delivery [31]. The delivery of MY DEMO was through a one-hour didactic lecture followed by another hour of dialogue session to the group participants. In total, MY DEMO talk was delivered thrice by the same author (BA). Different types of format were used during MY DEMO delivery to address different types of learning styles that may be employed by participants [32,33]. For example, the author used visual illustrations, audio animations and peer discussion to engage the participants during the session. Later, a group discussion ensued to address any other questions or issues related to the diabetes lecture.

Research tools

Development of pre- and post-questionnaires for the diabetes module

The module was evaluated in this pilot study using pre- and post-test questionnaire. The initial step of item generation garnered a large pool of questions (18 items and 37 sub-items). Consequently, all the items were examined for face and content validity by a panel of experts and non-experts from the faculty. The panellists consisted of two endocrinologists, two general practitioners and two basic scientists who are fluent in both the English and *Malay* language. Based on their expertise and background knowledge on diabetes, the panellists were asked to first scan through the questions for face validity. Consequently, the panellist were asked to rank the questions according to the level of difficulty by the help of a Likert-scale of easy, moderate, difficult or not suitable as part of the content validity exercise.

Generally the questions were divided into sections; (a) general diabetes information (eg. signs and symptoms, risk factors, pathophysiology, diabetes complications, hypoglycaemia) and (b) self-care practices (healthy eating, exercise, foot care, self-monitoring blood glucose). Briefly, easy-type questions consisted of basic information about pathophysiology of diabetes (i.e. insulin hormone deficiency) and common diabetes complications (i.e. blindness and kidney failure). Examples of moderate-type questions are like benefits of exercise on blood sugar and cholesterol, types of food that convert to glucose and normal level of fasting and 2 hours post prandial sugars. Difficult-type questions tested complex issues like pathophysiology of diabetes, insulin resistance and lack of glucose absorption. In addition, the panellists also commented on the suitability of the language and ensured that the questions phrased were jargon-free and using simple *Malay* language. Items deemed unsuitable were removed from the pool of questions. Finally, six items (2 ranked easy; 3 ranked moderate; 1 ranked difficult) were selected and used in the pre- and post-test questionnaires (Table 1).

Briefly, four items tested the general knowledge of diabetes section (Q1, Q3, Q4 and Q6) and two items tested the self-care practices section (Q2 and Q5). All the HBM constructs embedded within these items and were measured subsequently in the pre- and post-questionnaires. Participants had five to ten minutes to read and complete the pre and post questionnaires before submitting them. Each question had three options and only one correct answer.

The participants had to answer all questions. Failure to select any one or selecting more than one option was considered incorrect and no marks given. The score is categorised as the following: 74.99% or below as failure to understand the content, 75–79.99% as pass, 80–84.99% as good and ≥85% of above as excellent.

Evaluation tool and process

The participants were asked to evaluate the objectives and content material of MY DEMO (e.g. physiology of body, definition, signs and symptoms, complications and prevention of diabetes and identification of hypoglycaemia symptoms). A 4-item Likert-scale was developed for participants to select if the items (mentioned above) were (i) very useful (ii) useful (iii) less useful and (iv) not at all useful.

Study sample

The sample size calculation, which was carried out using GPower software [34] was based on improvement in

Table 1 Measurement of Health Belief Model constructs and ranking system for the 6 items used in pre- and post-test questionnaire

Section	Questions 3 options (1 correct answer)	Item code	Difficulty index	Construct
	What types of food will be converted to glucose once it has been digested?	Q1	Easy	Cues to action
	• ***Carbohydrate***			
	• *Vitamin*			
	• *Fat*			
	After eating a meal, what hormone is responsible to reduce blood sugar level?	Q3	Moderate	Cues to action
	• ***Insulin***			
	• *Glucagon*			
	• *Adrenaline*			
	In diabetes, "sweet blood" or hyperglycaemia can affect all the blood vessels in the body. Which is a common diabetes complication?	Q4	Moderate	Perceived severity
	• ***Kidney dialysis***			
	• *Liver transplant*			
	• *Knee transplant*			
	What factor leads to "sweet blood" in diabetes patients?	Difficult		Cues to action
	• *Fat cells able to absorb sugar*			
	• *Muscle tissues able to absorb sugar*			
	• ***Pancreas gland produce less insulin***			
	Foot-care is important in diabetes. What should you do to look after your feet?	Q2	Easy	Perceived benefit
	• *Do not wear any shoes when walking outdoors*			
	• ***Keep the spaces between your toes dry***			
	• *Treat any foot ulcer or wound by yourself*			
	Benefits of exercise	Q5	Moderate	Perceived benefit
	• ***Increase insulin sensitivity***			
	• *Increase blood sugar*			
	• *Increase blood pressure*			

diabetes knowledge score in the intervention group as reported by Vincent et al. [24]. From the literature review, the baseline value for mean diabetes knowledge score was 15.11 with standard deviation (sd) 2.6. Post intervention has shown that the mean diabetes knowledge score has increased to 16.89 with sd 3.3. A sample size of 72 was required to detect this mean and sd difference at significance (α) 0.05 and power (1-β) = 0.80 (80%).

Convenience sampling was used in this pilot study from two government organisations and a private industrial sector in three states (Selangor, Kuala Lumpur and Johor) in Peninsular Malaysia. Two weeks prior to the arranged date, all potential participants received an in-house e-mail to inform them about the MY DEMO talk from their respective organisations. An in-house e-mail was administered to increase the dissemination of news regarding the scheduled talk. In addition, a reminder e-mail was circulated a few days before the talk to ensure as many staff could attend the talk. Of note, the author could only get verbal feedback from the respective human resource departments regarding the number of interested parties who might be coming on the scheduled day. Nevertheless, some participants attended the talk on the day itself after hearing from their work colleagues and others could not attend due to competing work commitments. Consequently following the recruitment exercise, ninety-one Malaysian adults (18 years and above) with minimum secondary (O-Level equivalent) level education and conversant in the *Malay* language, were recruited to evaluate the diabetes education package. The participants were predominantly Malays (96.6%). All participants gave their consent to attend the module and agreed to complete the pre – and post-test questionnaires. This study received ethics approval from the Ministry of Health, Malaysia.

Statistical analysis

Mean and standard deviation were calculated for continuous variables, while frequency tables were constructed for categorical variables. Paired *t*-test was used to determine the mean differences of scores, while chi-

square or Fisher's Exact test was used to determine the association between categorical variables. All statistical analyses were performed with IBM® PASW® Statistics 17.0. The significance level was set at p = 0.05.

Results

Comparison of pre and post-test results

Eighty-eight participants (response rate = 96.7%) completed both pre- and post-test questionnaires, while all participants (n = 91) completed the process evaluation questionnaire. Table 2 presents the responses given by the participants to all the items. There was an increase in correct answers to all items related to perceived benefits, and two items related to cues to action. The increase in number of correct answers for item Q1 at post-test was significant ($p < 0.01$). There is a slight decrease in correct answers to item Q4, which measured the perceived severity. Item Q6, which was ranked as difficult, had the lowest number of correct answers in post-test (93.2%).

Results in Table 2 also presents the differences between pre- and post-test scores. There was a significant increase in the total score in post-test (97.34 ± 6.13%) compared to pre-test (92.80 ± 12.83%) ($p < 0.01$). There was an increase in number of participants who obtained excellent score (>85%) at post-test (84.1%) compared to pre-test (70.5%), while there were decreases in those scoring fair (50–69.99%) and good (70–84.99%). Notably, there were no very poor or poor scores in both the pre-test and post-test questionnaire.

Discussion

Implications of MY DEMO results

The items selected in the pre and post-test questionnaire were to emphasised important issues regarding the application of diabetes knowledge in optimising care in diabetes patients. Although only some of the HBM constructs were selected in the pilot project, in future intervention study, other constructs such as perceived susceptibility, perceived barriers and self-efficacy will be considered too [27].

In the questionnaire, the authors chose to highlight three items related to cues to action in order to provide "how-to" or applied information and promote awareness about diabetes. For example, item Q1 (cues to action) pertaining types of food eaten was considered as basic knowledge. There was no issue with this item and all participants scored significantly higher post-test. The significantly higher score amongst the excellent category also confirmed majority of participants benefited from MY DEMO.

Contrastingly, the results of item Q3 pertaining role of insulin hormone and item Q6 pertaining pathophysiology of diabetes showed a decline in the score. The reported knowledge gap in these two areas should be given due consideration by the authors when implementing future intervention study. In addition, the low score for this item (Q6) was somewhat expected as this item was ranked as a "difficult" question by the panel of experts during item generation. However, as part of an assessment mechanism of MY DEMO, the authors had decided to include at least one "difficult" question in each assessment item module.

Item Q4 measured perceived severity showed a reduction in post–test score. The aim of item Q4 was to prompt patients *vis-a-vis* the pitfall of sustained "sweet blood" and the damage it can cause to the circulatory system leading to micro- and macro-vascular damage. Again, this negative finding is relevant to the authors as it identified some of the gaps in participant's understanding of diabetes complications and should be address when delivering MY DEMO in future intervention study.

There were no difficulties with the two items (Q2 and Q5) which measured perceived benefits of diabetes self-care practices such as foot care and exercise. Item Q2

Table 2 Correct responses at pre- and post-test

Construct (HBM)	Item's code		Pre-test	Post-test	P value
Perceived benefit	Q5	Correct	83 (94.3)	88 (100.0)	n/a
Perceived benefit	Q2	Correct	71 (80.7)	85 (96.6)	0.479
Cues to action	Q1	Correct	84 (95.5)	86 (97.7)	0.002*
	Q3	Correct	88 (100.0)	87 (98.9)	n/a
	Q6	Correct	76 (86.4)	82 (93.2)	0.188
Perceived severity	Q4	Correct	87 (98.9)	86 (97.7)	1.000
Total score		Mean ± SD	92.80 ± 12.83	97.35 ± 6.13	0.004*
Category of score, n (%)		Excellent (>85%)	62 (70.5)	74 (84.1)	0.005*
		Good (80–84.99%)	17 (19.3)	14 (15.9)	
		Pass (75 – 79.99%)	9 (10.2)	0 (0.0)	

*Significant at $p < 0.01$.

that emphasised on foot care was selected as it defined simple actions that can be taken by patients in order to prevent common diabetes complications such as infection and amputation. Furthermore, item Q5 focused on the benefits of physical activity on the body's glucose metabolism and blood pressure control, which is essential in optimising diabetes control. Nevertheless, the authors opined that these items are important aspects of diabetes management and should be reinforced in the module and tested in the questionnaire to ensure participants understanding.

The authors also acknowledged a small discrepancy between those who completed the evaluation questionnaires (n = 91) compared to those who completed the pre- and post-test questionnaires (n = 88). This small discrepancy (3.3%) occurred because three of the participants did not complete the post-test questionnaires. Although the authors tried to make contact with the participants, *via* the Human Resource departments, the effort was not fruitful and the questionnaires remain incomplete. However, given the high response rate (96.7%) the authors posit that this small discrepancy is not significant.

Inconsistent health outcomes from past diabetes education programme studies

Previous literature review on diabetes self-management education has found short-term (<6 months) positive effects on knowledge, dietary habits and glycaemic control. A meta-analysis has shown a decrease in HbA1C of 0.8% at immediate follow up and 0.3% at 4 months or longer follow-up. Hence, the benefit of self-management education on glycated haemoglobin had been shown to decrease between 1 and 3 months and not sustained for long term [35]. However, the recent X-PERT programme succeeded in showing sustained improvement for glycaemic control and other secondary outcomes such as body weight, BMI and waist circumference, reduction of diabetes medication, knowledge of diabetes, self-empowerment and self-management skills at 14 months [5]. Remarkably, although, the DESMOND study succeeded in showing improvement in weight loss, smoking cessation and positive improvement in beliefs about illness at one year it did not show sustained improvement in glycated haemoglobin [4].

A further 3-year post intervention DESMOND study also failed to show sustained improvement in biomedical and lifestyles outcomes, although some changes to illness beliefs were sustained [36]. Contrastingly, a long-term Italian study - rethink organisation to improve education and outcomes (ROMEO) had shown favourable clinical, cognitive and psychological outcomes following a 4-year study of a continuous diabetes education programme [37].

Other potential primary outcomes to measure a diabetes education programme

There had been some criticisms about the limited short-term improvement in glycaemic outcome in many diabetes education programmes [4,6]. Hence the role of glycated haemoglobin as the primary outcome to measure the effectiveness of a diabetes education intervention programme have been questioned. Cooper *et al.* argued there were other issues that may also be important to the diabetes patients. He posited the success of diabetes education should be regarded as having wide benefits, and should not be judged only by standard clinically based endpoints [38].

The authors are aware of some of these challenges and must identify the gaps early on in the development and implementation of a diabetes education programme. Hence, a point of consideration in our future intervention study is to adopt a multi-approach intervention like the use of teaching videos and regular telephone consultations. The authors will also include other primary outcomes such as self-efficacy, compliance and motivation in addition to glycated haemoglobin in an attempt to measure the wider benefit of the effectiveness of the programme.

Strengths and limitations

To our knowledge, ours was the first study to validate a diabetes education module in the *Malay* language. The content of MY DEMO was contextualised to emphasis important messages and hopefully facilitates transfer of knowledge by using familiar keywords, common analogies and concepts. The delivery of MY DEMO was kept standardised with minimal variation, as the main author was also the sole presenter during these sessions.

However, the authors would like to highlight the limitation of convenience sampling used in this pilot study. Firstly, participants were from the public rather than known diabetes patients. This decision was partly because of the ease of delivering MY DEMO in a timely manner. However, demographic characteristics of the participants showed majority were Malays and conversant in the *Malay* language and the sample is representative of future cohort of patients. Thirdly, participants must have at least secondary level education in order to follow the basic content of MY DEMO. The same inclusion criteria of literacy will be built-in for future intervention study. Hence, it is reasonable to surmise the results of this pilot study can be generalised with the cohort of diabetes patients in future intervention study.

Conclusions

The results of the pilot study suggest that MY DEMO would be suitable as part of a diabetes management strategy particularly in the aspect of patient education.

This was the first known diabetes education programme in the *Malay* language that had attempted to use the health belief model as its framework and measure its outcomes using the known constructs. The preliminary result is positive and suggests that MY DEMO might be beneficial as part of or in addition to the existing diabetes education programme.

Abbreviations

MY DEMO: Malaysian Diabetes Education Module; HBM: Health-belief Model; DESMOND: Diabetes Education of Self-Management for ON-going and Newly Diagnosed (for type 2 diabetes patients); DAFNE: Dose adjustment for normal eating (for type 1 diabetes patients); X-PERT: EXpert Patient Education versus Routine Treatment; AADE: American Association of Diabetes Educators; ROMEO: Rethink Organisation to improve Education and Outcomes.

Competing interest

The authors declare that they have no competing interests.

Authors' contribution

BA is the main author of the research paper. She has made substantial contributions to development and validation of the diabetes education module (MY DEMO), conception and design of the study and acquisition, analysis and interpretation of data. AR has contributed towards the validation of the research tools (e.g. questionnaires), analysis and interpretation of data. QKF has contributed in the design of the study, determination of sample size and validation of the research tools (e.g. questionnaires), analysis and interpretation of data. AZ has contributed in the overall concept of the study design, development of the diabetes education module and interpretation of data. All authors read and approved the final manuscript.

Authors' information

BA is a Senior Lecturer and currently pursuing her PhD is Diabetes Education. Her doctoral topic is looking at the impact of education and self-management skills in optimising diabetes management.
AR is a Lecturer and recently completed her doctoral in Public Health. She is a trained nutritionist and clinical researcher.
QKF is an Associate Professor in Community Health and Medical Statistician.
AZ is a Professor of Endocrinology axnd the Head of the Jeffrey Cheah School of Medicine and Health Sciences, Sunway campus.

Acknowledgements

We would like to thank all the participants who agreed to take part this study.
We would like to thank the Human Resources Department in the respective agencies (Malaysian Productivity Centre (MPC), Malaysian Industrial Development Agency (MIDA) and Syarikat Faiza Sdn Bhd) for facilitating the attendance of their staff to the diabetes talk.
Part of this work was supported by the national grant received by the corresponding author from the Ministry of Higher Education (MOHE) of Malaysia.

Received: 8 June 2013 Accepted: 27 March 2014
Published: 8 April 2014

References

1. Mensing C, Boucher J, Cypress M, Weinger K, Mulcahy K, Barta P, Hosey G, Kopher W, Lamb B, Mangan M, Norman J, Tanja J, Yauk L, Wisdom K, Adams C: **National standards for Diabetes Self-Management Education.** *Diabetes Care* 2003, **26**(Suppl 1):149–156.
2. Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC: **Patient empowerment: results of a randomized controlled trial.** *Diabetes Care* 1995, **18**:943–949.
3. Norris SL, Engelgau MM, Venkat Narayan KM: **Effectiveness of Self-Management Training in Type 2 Diabetes: a systematic review of randomised controlled trials.** *Diabetes Care* 2001, **24**:561–587.
4. Davies MJ, Heller S, Skinner TC, Campbell MJ, Carey ME, Dallosso HM, Daly H, Doherty Y, Eaton S, Fox C, Oliver L, Rantell K, Rayman G, Khunti K: **Effectiveness of the diabetes education for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial.** *Brit Med J* 2008, **336**:491–495.
5. Deakin TA, Cade JE, Williams R, Greenwood DC: **Structured patient education: the Diabetes X-PERT Programme makes a difference.** *Diabetic Med* 2006, **23**:944–954.
6. DAFNE Study Group: **Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial.** *Brit Med J* 2002, **325**:746–751.
7. Wan Nazaimoon WM: **Results of the Metabolic Syndrome Study of Malaysia (MSSM) 2007–8.** In *Malaysian Endocrine and Metabolic Society Annual Congress*; 2010.
8. West KM, Kalbfleisch JM: **Glucose tolerance, nutrition and diabetes in Uruguay, Venezuela, Malaya and East Pakistan.** *Diabetes* 1996, **15**:9–18.
9. Bakri R: *Diabetes Mellitus*. Malaysia: Ministry of Health; 1996.
10. Letchuman GR, Wan NAzaimoon WM, Wan Mohamad WB, Chandran LR, Tee GH, Jamaiyah H, Isa MR, Zanariah H, Fatanah I, Ahmad Fauzi Y: **Prevalence of Diabetes in the Malaysian National Health Morbidity Survey III 2006.** *Med J Malaysia* 2010, **65**:173–179.
11. Ming YT, Magarey J: **Self Care Practices of Malaysian adults with diabetes and suboptimal glycaemic control.** *Patient Educ and Couns* 2008, **72**:252–267.
12. Wan Nazaimoon WM, Kamarul IM, Amir SMK, Aziz Al-Safi I, Ikram SI, Khalid BA, Nor Azmi K, Nor Azwany Y, Norlaila M, Osman A, Siti Hamida MI, Wan Mohamad WB: **Prevalence of overweight and obesity among adult Malaysians: an update.** *Asia Pac J Clin Nutr* 2011, **20**:35–41.
13. Ahmad B, Khalid BA, Zaini A, Hussain NA, Quek KF: **Influencing factors of glycaemic control in patients attending different types of urban health care settings in Malaysia.** *Diabetes Res Clin Pract* 2011, **93**:e12–e14.
14. Mafawzy M: **Diabetes control and complications in private primary healthcare in Malaysia.** *Med J Malaysia* 2005, **60**:212–217.
15. Lim TO, Lim YN S: *13th Report of the Malaysian Dialysis & Transplant Registry*. Kuala Lumpur: NRR; 2005.
16. Mimi O, Teng C, Chia Y: **The prevalance of diabetic peripheral neuropathy in an outpatient setting.** *Med J Malaysia* 2003, **58**:533–538.
17. Chuang LM, Tsai ST, Huang BY, Tai TY, Diabcare-Asia Study Group: **The status of diabetes control in Asia - a cross sectional survey of 24317 patients with diabetes mellitus in 1998.** *Diabetes Med* 2002, **19**:978–985.
18. Ismail IS, Nazaimoon W, Mohammad W, Letchuman R, Singaraveloo M, Hew FL, Shuguna C, Khalid BA: **Ethnicity and glycaemic control are major determinants of dyslipidaemia in Malaysia.** *Diabetes Med* 2001, **18**:501–508.
19. Ismail IS, Wan Nazaimoon WM, Wan Mohammad WB, Letchuman R, Singaraveloo M, Pendek R, Faridah I, Rasat R, Sheriff IH, Khalid BA: **Socioeconomic determinants of glycaemic control in young diabetic patients in Peninsular Malaysia.** *Diabetes Res Clin Pract* 2000, **47**:57–69.
20. Tan MY, Magarey JM, Chee SS, Lee LF, Tan MH: **A brief structured education programme enhances self-care practices and improves glycaemic control in Malaysians with poorly controlled diabetes.** *Health Educ Res* 2011, **26**:896–907 21.
21. AADE Position Statement: **AADE7TM Self-care Behaviours.** *Diabetes Educ* 2008, **34**:445–450.
22. Look MA, Baumhofer NK, Ng-Osorio J, Furubayashi JK, Kimata C: **Diabetes training of community health workers serving Native Hawaiians and Pacific People.** *Diabetes Educ* 2008, **34**:834–840.
23. Fatupaito MPT, Lilomalava R: **Pacific diabetes self-management group education programme in Pacific churches.** *Diabetes Res Clin Pract* 2008, **79**(Suppl 1):27.
24. Vincent D, Pasvogel A, Barrera L: **A feasibility study of a culturally tailored diabetes intervention for Mexican Americans.** *Biol Res Nurs* 2007, **9**:130–141.
25. Ve C, Boore JR: **Knowledge and diabetes self-management.** *Patient Educ and Couns* 1996, **29**:99–108.
26. Glanz K, Lewis FM, Rimer BK: *The Health Belief Model. Health behaviour and health education: theory, research and practice*. San Francisco: Jossey Bass; 2008.
27. Rosenstock IM, Stecher VJ, Becker MH: **Social learning theory and health belief model.** *Health Edu Quarterly* 1988, **15**:175–183.

28. Bandura A: **Self-efficacy: toward a unifying theory of behaviour change.** *Psychol Rev* 1977, **84**:191–215.
29. Prochaska JO, DiClemente CC: **Stages and processes of self-change in smoking: toward an intergrative model of change.** *J Consult Clin Psychol* 1983, **51**:390–395.
30. Schwarzer R: **Self-efficacy in the adoption and maintenance of health behaviours: theoretical approaches and a new model.** In *Self-efficacy: Thought Control of Action*. Edited by Schwarzer R. Washington DC: Hemisphere; 1992.
31. Kandula NR, Nsiah-Kumi PA, Makoul G, Sager J, Zei CP, Glass S, Stephens Q, Baker DW: **The relationship between health literacy and knowledge improvement after a multimedia type 2 diabetes education program.** *Patient Educ Couns* 2009, **75**:321–327.
32. Kolb DA: *Experiential Learning: Experience as the Source of Learning and Development*. Eaglewood Cliffs: Prentice-Hall; 1984.
33. Felder R: **Are Learning Styles Invalid? (Hint: No!).** In *On-Course Newsletter*; 2010. Available from: http://oncourseworkshop.com/life-long-learning/learning-styles-invalid-hint/.
34. Faul F, Erdfelder E, Lang A-G, Buchner A: **G*Power 3: A flexible statistical power analysis for the social, behavioral, and biomedical sciences.** *Behav Res Methods* 2007, **39**:175–191.
35. Norris SL, Lau J, Smith SJ, Schmidt CH, Engelgau MM: **Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycaemic control.** *Diabetes Care* 2002, **25**:1159–1171.
36. Khunti K, Gray LJ, Skinner T, Carey ME, Realf K, Dallosso H, Fisher H, Campbell M, Heller S, Davies MJ: **Effectiveness of a diabetes education and self-management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care.** *Brit Med J* 2012, **344**:e2333.
37. Trento M, Gamba S, Gentile L, Grassi G, Miselli V, Morone G, Passera P, Tonutti L, Tomalino M, Bondonio P, Cavallo F, Porta M: **Rethink Organisation to iMprove Education and Outcomes (ROMEO): a multicenter randomised trial of lifestyle intervention by group care to manage type 2 diabetes.** *Diabetes Care* 2010, **33**:745–747.
38. Cooper H, Booth K, Gill G: **A trial of empowerment-based education in type 2 diabetes – Global rather than glycaemic benefits.** *Diabetes Res Clin Pract* 2008, **82**:165–171.

doi:10.1186/1472-6823-14-31
Cite this article as: Ahmad *et al.*: A pilot study: the development of a culturally tailored Malaysian Diabetes Education Module (MY-DEMO) based on the Health Belief Model. *BMC Endocrine Disorders* 2014 **14**:31.

Appendix 12 Publication 2.

Diabetes & Metabolic Syndrome: Clinical Research & Reviews 11S (2017) S901–S906

Contents lists available at ScienceDirect

Diabetes & Metabolic Syndrome: Clinical Research & Reviews

journal homepage: www.elsevier.com/locate/dsx

Original Article

Type 2 diabetes patients are more amenable to change following a contextualised diabetes education programme in Malaysia

Badariah Ahmad*, Anuar Zaini Md Zain, Quek Kia Fatt

Jeffrey Cheah School of Medicine & Health Sciences, Monash University Malaysia, Jalan Lagoon Selatan, Bandar Sunway, 47500, Selangor D.E. Malaysia

ARTICLE INFO

Article history:
Received 6 June 2017
Accepted 1 July 2017

Keywords:
Ambulatory
Structured diabetes education
Contextualised
Suboptimum glycaemic control
Telehealth
Type 2 diabetes mellitus

ABSTRACT

The aim of the study is to determine the impact of diabetes education on patients' glycaemic control. A prospective 18-month intervention study was conducted at four ambulatory diabetes centres. Poorly controlled type 2 diabetes patients attended an hour of structured diabetes education at their respective diabetes centres. A month post-intervention patients were contacted through telephone and followed up for 18 months. Anthropometric measurements and socio-demographic details were collected during the first visit. HbA1C blood test for each patient was taken at beginning and end of study. Patients' diabetes knowledge showed 80% obtained Excellent or Very Good score. The Telephone Contact (TC) retention rate was 75.52% at 18 months. There was a significant improvement ($p = 0.001$) in patients' glycaemic control with a reduction in HbA1C of ≥1% from baseline. Diabetes education intervention contributed positively to significant glycaemic improvement and should be embedded within a structured diabetes care delivery system.

1. Background

The global prevalence of Type 2 diabetes is 8.3% [1] According to International Diabetes Federation (IDF), Malaysia is one of the top ten diabetes hotspots in the Western Pacific region with a diabetes prevalence of 10.9% [2]. The continual ascent of diabetes prevalence amongst Malaysian adult population age ≥30 years from 0.65% in 1960 to 14.9% in 2006 as per reported in the National Health Morbidity and Mortality Survey is a grim indication for the healthcare system [3].

Cognisant of the increase in diabetes prevalence an emphasis was placed on capacity building of healthcare givers especially in the area of diabetes management from as early 3 decades ago. Realising the importance of diabetes education and self-care in diabetes management, a concerted effort was made by Ministry of Health (MOH) Malaysia, affiliated government hospitals and non-governmental organisations to trained nurses and medical assistants to become diabetes educators [4]. Although diabetes educators in Malaysia are still modest in numbers, the effort is a positive step towards better diabetes management [5].

In addition, the framework of diabetes management care was established in the mid-90s to ensure annual diabetes care screening (ie. diabetes foot care, eye examination and electrocardiogram) became an integral part of diabetes ambulatory clinics [4] as well development and successive revision of the Malaysian Clinical Practice Guidelines (CPG) for Type 2 Diabetes Mellitus [6].

On the contrary, there was a lack of emphasis in the development of a structured diabetes education programme for patients in Malaysia. Compared to United Kingdom (UK) which in 2005 initiated an effort to fund, regulate and ensure quality of diabetes education [7], Malaysia have not carefully considered this education process and how it can be embedded and audited within our healthcare delivery system.

Briefly a structured education programme should include key criteria such as a clear underlying philosophy, a written curriculum, trained educators, a quality assurance system which can be applied to process, content and delivery and importantly an audit process of the programme [7]. Consequently, over the past 15 years many diabetes education programmes were funded, developed, implemented and vigorously evaluated in the United Kingdom [7–11].

In the recent Malaysian DiabCare 2013 audit, 19 tertiary care government hospitals reported very high screening rates especially for urinalysis (97.8%), fundal examinations (93.3%) and foot

Abbreviations: TC, telephone contact; HbA1C, glycated haemoglobin C; MOH, Ministry of Health; MY-DEMO, Malaysian Diabetes Education Module; WC, waist circumference; BMI, body mass index; DKS, diabetes knowledge score.

* Corresponding author.
E-mail addresses: badariah.ahmad@monash.edu (B. Ahmad), anuar.zaini@monash.edu (A.Z. Md Zain), quek.kia.fatt@monash.edu (Q.K. Fatt).

http://dx.doi.org/10.1016/j.dsx.2017.07.013
1871-4021/

examination (97.1%) with an astounding 90% of patients going through all three examinations within the last 12 months [12]. Unfortunately, we have not seen the same rigour for the implementation and evaluation of quality diabetes education. By ensuring a smooth process for diabetes education to patients overall glycaemic control may begin improve and diabetes-related complications reduced.

The authors endeavour to examine the potential gaps from the point of view of delivery, structure and timing of diabetes education in Malaysia. The premise of the study was to deliver a specifically contextualised diabetes education module to poorly controlled type 2 diabetes patients (≥8.0 mmol/L) [6] regardless of the chronicity of their disease.

Hence, the aim was to educate all poorly controlled diabetes patients with an education module that was tailor-made for the locality and language of majority of the patients. Since patients were recruited from government-run four ambulatory health care centres, the method and frequency of delivery were tailored to the practicality of a busy centre.

2. Materials and methods

2.1. Clinical settings and inclusion & exclusion criteria

The four health care settings were located in Peninsular Malaysia. The inclusion criteria included patients; (i) who were conversant in *Bahasa Melayu* (ii) with adequate literacy and numeracy (iii) accessible via mobile phone or fixed phone line. Exclusion criteria included (i) pregnancy (ii) malignancy.

2.2. Sample size

Briefly, to estimate appropriate sample size, several systematic reviews were appraised. *Welschen* et al. included six randomised controlled trials on SMBG in non-insulin treated patients in their systematic review [13]. The review showed the overall effect of SMBG on HbA1C was statistically significant, with a reduction of 0.39% in HbA1C compared to control groups. On the basis of a previous randomized control trial a sample size was calculated (with a power of 80% and alpha 0.05, 2-tailed) for a reduction of HbA1C of 1.0% ± 1.08% for treatment group and reduction of HbA1C of 0.54% ± 1.4% for control group. The sample size required is 118 per group. After taking into consideration attrition rate of 20%, the total number of patient required is 284.

2.3. Recruitment process & modifications

Initially eligible patients were approached and recruited from "one-stop diabetes centres" in 2 ambulatory clinical sites by nurses. The recruited patients (n = 443) were invited to attend Module I. Approximately a third of patients (28.8%; n = 128) did not turn up for Module I despite multiple calls.

Consequently, minor modifications were done to address the issue of high attrition rates. Multiple face-to-face (19) briefing sessions (from November 2013 till June 2015) were provided at the 3 clinical sites. Albeit this extra step was resource-intensive, the retention rate improved from 57.19% in 2012 to 81.25% in 2013 and 2015.

2.4. Intervention tools

The development and validation of the diabetes education tool and the questionnaires had been described elsewhere by Ahmad et al. [14], Succinctly, Malaysian Diabetes Education Module (MY-DEMO) was the first ever contextualised module which was developed in *Bahasa Melayu* or *Malay* language. The theoretical framework of the module was based on the Health Belief Model (HBM) and several key components were embedded to enhance patient's understanding of their own condition within MY DEMO.

2.5. Validation process for diabetes knowledge questionnaires (DKQs) used for telephone contact (TC)

The pool of questions (n = 128) used for the TC follow up was based on the set of questions validated from authors' previous work [14]. Concisely, for each TC session between 4 and 5 items tested on general knowledge of diabetes and another 1–2 items tested on self-care practices. The questions were based on the content from the education module. The HBM constructs such as perceived benefit, perceived severity and cues to action were embedded within these TC questions.

2.6. First visit

Anthropometry measurements such as weight, height, waist circumference (WC) and body mass index (BMI) and blood pressure were measured during the first visit. Patients were barefooted and in light clothing when measurements were taken. Height was measured using a portable body meter and weight was measured using digital weighing scale. The height and weight of patients were used to calculate the BMI. The WC was measured using non-elastic tape measure. Blood pressure was measured using automatic blood pressure monitor. The most recent (≤3 months) HbA1C result of patients' were obtained from their medical record. Socio-demographic details such as age, gender, ethnicity, education levels, and duration of disease were also recorded.

2.7. Diabetes education intervention session (MY DEMO)

All patients attended the diabetes education module for approximately 60 min. As mentioned earlier, the education module was contextualised to suit the locality and language of patients. Although it would have been ideal to deliver serial education sessions, such as previous works [7–10,15] the authors deliberated to present a concise 60-min module. The succinct session tailored the needs and availability of space and time, for both patients and busy clinical settings.

In addition, the author (BA) solely delivered all the sessions (n = 23). Hence, the programme was high fidelity and any variations were minimised. The X-PERT study was also delivered by a single experienced educator to established diabetes patients.[9] All sessions were delivered over a staggered period of time (3.5 years) from 2012 to 2015 while patients were being recruited.

2.8. Telephone contact (TC) follow-Up

Approximately a month post intervention, each patient was contacted by BA and questioned on several aspects of the diabetes module. Each TC session took approximately 15 min to complete. The patients were asked 6 questions and each question had 3 options (ie. a, b, c). Patients were encouraged to answer all the six questions. Feedback was given at end of TC if patients had answered incorrectly. In total, each patient was asked 168 questions and received a minimum of 28 TC for 18 months.

2.9. End visit

Patients returned to their ambulatory health care clinics to have their final HbA1C blood test at the end of 18 months.

2.10. Statistical analysis

Mean and standard deviation were calculated for continuous variables, while frequency tables were constructed for categorical variables. Paired *t*-test was used to determine the mean difference for the primary outcome HbA1C. Multiple linear regression test was employed to determine which factor(s) contributed to the improvement of diabetes control. The data analysis was performed using IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. $p < 0.05$ was taken as the level of significance.

3. Results

3.1. Socio-demographic

443 patients were recruited from the four ambulatory health care settings. There were 237 males (53.5%) and 206 females (46.5%). The ethnicity distribution consisted of Malays (71.8%), Indians (23.9%) and Chinese (4.3%). An overwhelming majority (82.4%) of patients were overweight and obese. Among male and female patients abdominal obesity was 86.4% and 90.8% respectively (Tables 1).

3.2. Retention rate

The attrition rate post recruitment was 35.44% and consequently 286 patients attended and received the diabetes education intervention. All of the patients who dropped out post recruitment were loss to follow-up. These patients (n = 157) failed to attend the diabetes education module despite numerous telephone contacts.

The majority of patients who received the intervention were middle-age (64%), received secondary level education (54.9%) and had medium-term duration of disease (60.5%). Of note, as the premise of our study was to include all poorly controlled diabetes patients to receive education regardless of the chronicity of the disease, the distribution of disease duration was not equally matched and those with shorter disease duration was relatively small in percentage (7.9%) compared to medium and long term duration. At 18 months, 216 patients completed the study and retention rate was 75.52%. Subsequent data use for analysis will be derived from the final cohort of n = 216. Some of the reasons for attrition were; death; transfer to another state/city; pregnancy; malignancy; needle phobia; illiteracy; loss to telephone follow-up.

3.3. Primary outcome of HbA1C using paired t-test

HbA1C at the start showed the following results; mean± sd (10.06% ± 1.44%). Out of the 216 patients, n = 26 patients had HbA1C ≥ 12.0%.

HbA1C at the end showed the following results; mean ± sd (8.82% ± 1.81%). Out of the 216 patients, n = 13 patients had HbA1C ≥ 12.0%.

The mean reduction of HbA1C from baseline was 1.24% ($p < 0.001$). The primary outcome both showed statistical and clinical significant improvement in the overall blood glucose control (Table 2).

Table 2
Primary outcome showing reduction of HbA1C from baseline.

HbA1C	Pre Intervention	Post Intervention	p value
Mean	10.06	8.82	0.001*
SD	1.44	1.81	
Median	9.80	8.50	

Table 1
Social and Metabolic demographic of the study patients.

Social and Metabolic Demographics	Patients Characteristics	Numbers (n = 216)	Percentages (100%)
Gender	Male	118	54.6
	Female	98	45.4
Ethnicity	Malay	161	74.5
	Indian	45	20.8
	Chinese	10	4.6
Age groups	Young (<40 yrs)	10	4.6
	Middle-age (40–59 yrs)	134	62.0
	Elderly (≥60 yrs)	72	33.3
Education Level	Primary and Lower	26	12.0
	Secondary	112	51.9
	Tertiary and Higher	78	36.1
Duration of Disease	Short (<2 years)	17	7.9
	Medium (2–5 years; 5–10 years)	130	60.2
	Long (10–20 years; >20 years)	69	31.9
Body Mass Index (kg/m^2)[a]	<18.5 (Underweight)	2	0.9
	18.5–22.9 (Normal)	18	8.3
	23.0–27.4 (Pre-obese)	65	30.1
	27.5–34.9 (Obese I)	113	52.3
	35.0–39.9 (Obese II)	12	5.6
	≥40 (Obese III)	6	2.8
Waist circumference[b]	Male <90 cm	16/118	13.6
	Male ≥90 cm	102/118	86.4
	Female <80 cm	9/98	9.2
	Female ≥80 cm	89/98	90.8

[a] Classification of BMI in accordance to the Malaysian CPG for Obesity 2003 which differs from WHO classification of BMI.
[b] Classification of Waist Circumference in accordance to the Malaysian CPG for Type 2 Diabetes 2009.

3.4. Diabetes knowledge score (DKS) from 18 months telephone contact follow up

In total 168 questions were asked to each of the patients (n = 216) throughout the 18 months. The lowest and highest DKS was 44/168 (26.19%) and 167/168 (99.40%) respectively. The DKS were classified into five categories; Excellent (90–100%); Very good (80–89.99%); Good (60–79.99%); Unsatisfactory (30–59.99%); Poor (0–29.99%). Approximately 80% of patients scored excellent (33.8%) or Very Good (45.8%). Conversely, 7.0% patients scored Unsatisfactory (6.5%) or Poor (0.5%). In addition, correlation between total knowledge scores and reduction of HbA1C were not statistically significant ($p = 0.611$) (Fig. 1).

3.5. Significant predictors of glycaemic control amongst poorly controlled diabetes patients using multiple linear regression tests

The result of the multiple linear regression test showed the only significant predictor of glycaemic control was the short duration of disease ($p < 0.004$). The other factors such as patients' age, ethnicity, education level, waist circumference, medium and long term duration of disease as well as patients' knowledge score (ie. a month post-intervention) were not significant. However, due to the small sample size (7.9%) of recently diagnosed diabetes patients when compared to the entire cohort this result should be interpreted with some caution.

4. Discussion

4.1. Strength

Our results confirmed education positively impact patients' sugar control. The reduction of HbA1C by 1.24% from baseline is statistically and clinically significant, especially among poorly controlled diabetes patients who have higher risks of developing diabetes-related complications. Established landmark studies have shown for every 1% reduction of HbA1C, there is a reduction in both micro- (37%) and macro- vascular (14%) complications and death from diabetes (21%) [16–18].

Our results showed majority of patients (79.6%) scored very well in their DKS throughout the entire 18 months of telephone follow-up. Approximately a third of the patients (33.8%) scored above 90% for all 168 questions. Almost half of the patients (45.8%) scored Very Good category (80–90%). These encouragingly high knowledge scores (≥80%) were achieved and accompanied by high retention rate (75.52%) among the study patients. The authors opined the education programme was well received and importantly the knowledge retained by patients remained elevated 18 months post intervention.

The authors were cognisant of the single face-to-face education intervention method. Hence it was important to have a telephone follow-up post intervention to record their knowledge retention. The authors strongly believe the high frequency of TC ($n \leq 28$) was a contributing factor to the excellent retention rate and DKS among patients. Previous study had shown that frequent contacts between patients and physicians can increase patients' compliance, help them achieve good glycaemic control and reduce diabetes-related complications [19].

Although patients were contacted through telephone and meetings were not face-to-face, the positive trend supports results of other diabetes tele-health studies [20,21]. In an era where most healthcare systems are resource constrained [22], it is worthwhile to consider telephone follow-up as an adjunct platform to reinforce patients' knowledge.

4.2. Limitations

Firstly, it was not a randomised control study. One of the key reasons was to test the diabetes education tool *per se* rather than the cohort of patients. Consequently, it was important to implement and evaluate the education intervention tool equally to the entire cohort of patients. Next, the high reduction of HbA1C (1.24%) might be contributed to the higher baseline of Hb1AC amongst the diabetes patients. Finally, we did not attempt to change the treatment regime nor report the change of treatment in patients as we had wanted to emulate real-world scenario of patient management. The authors argue regardless of patients' treatment regime; the aim of the study was to see the impact of education and telephone contact follow-up have on patients' control of sugar, knowledge and motivation to continue within the

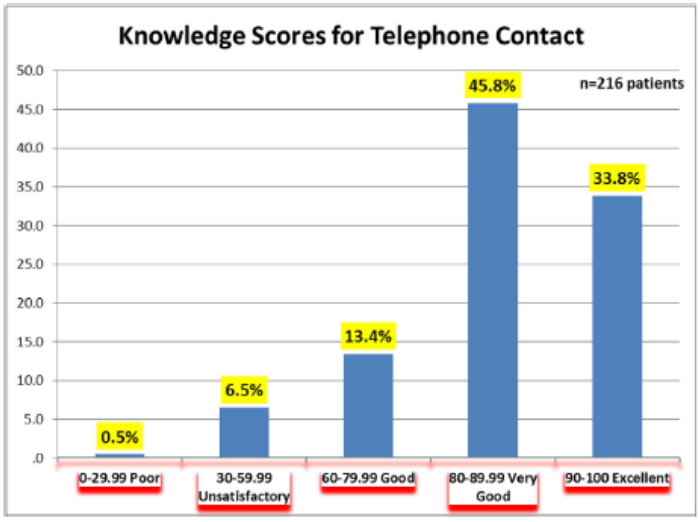


Fig. 1. Diabetes Knowledge Score (DKS) among patients.

study. The relatively high retention rate (almost 70%) after 18 months indicates the programme is engaging for patients to remain and benefit from it.

4.3. Recommendations

The authors recommend two affirmative steps to complement the existing diabetes delivery framework by carefully considering (i) the delivery of an appropriate and culturally contextualised education module which is suitable for Malaysian patients (ii) the time frame for diabetes education to occur simultaneously with the annual screening programme.

Further studies are needed within the local context, to identify the most suitable timing for education to be delivered. Although our results suggest the most significant predictor for glycaemic control was short duration of disease, our sample size for this group was too small to make affirmative recommendations. Intuitively, it does seem like the best time to educate patients would be during early days of diagnosis but more research are needed. In a previous study, Chew et al. found there was more young type 2 diabetes patients with shorter duration of disease attending ambulatory compared to hospital care settings [23]. Given these patient profiling it makes real sense to optimise the resources at this level of care.

Ultimately, diabetes is a chronic disease and patients need lifelong education as a cornerstone for their management. Our results suggest that an appropriately designed diabetes education module when delivered to poorly controlled diabetes patients showed a large improvement in their glycaemic control, which will ultimately control and minimise the risk of diabetes-related complications.

4.4. Below optimum glycaemic target

Despite encouraging reports in DiabCare 2013 study [12], there were no improvements in the glycaemic control and prevalence of diabetes-related complications when compared with the earlier DiabCare 2008 study [24]. The majority of patients (73.0%) had suboptimal HbA1C measurements >7.0% (>53 mmol/mol). One of the best outcomes reported by the DiabCare 2013, were the overwhelmingly high screening rates with a vast 90% of patients undergoing all three examinations (eye, ECG, foot) within the last 12 months [12].

These high rates are very impressive, but the big questions seem to be (i) Why did it not translate to a reduction of prevalence of diabetes related complications? (ii) Why high screening rates failed to translate to better clinical control? (iii) What is the missing link between successful diabetes audits and an overall suboptimal control amongst diabetes patients?

5. Conclusions

Our study showed that significant improvement in glycaemic control can be achieved after patients received diabetes education. A recent literature review on structured diabetes education programme in Malaysia has not yielded very much, indicating an obvious gap. Disappointingly, there has been none of the large scale theory-based diabetes education programmes like the ones in UK and Europe.

The handful of small-size education studies done locally signals a clarion call for more research on this front [5,25,26]. Patient education is an essential and critical component of diabetes management [4]. However to date, there has been limited effort in delivering structured diabetes education program and consequently measuring patients' understanding of their condition in a more formalised manner.

Indeed the extremely high screening rates reported by Diabcare 2013 [12] must have adopted an assiduous operating procedure which would be worthwhile replicating to ensure diabetes education programme received similar robust attention. As challenging as it is, the authors strongly suggest a contextualised diabetes education programme to be embedded as part of a diabetes checklist screening programme. What would be beneficial to explore in the future would be to determine the change in physical and mental health as well as diabetes-related complications among knowledgeable patients.

Declaration of conflict of interest

The authors of this article would like to declare that they have no conflicting interest throughout the process of conducting and writing this research article.

Ethics approval

The study was approved by Ethical Committee of National Institute Health (NIH), Ministry of Health (MOH) Malaysia. The study is registered under National Malaysian Medical Research (NMMR). NMMR no: 10-1131-7882. All patients gave their informed consent to participate in the study.

Funding

The study was fully funded by the Ministry of Higher Education (MOHE) of Malaysia from the period of 2011 for 3 years.

Authors' contributions

Badariah Ahmad (BA) is the primary author of this manuscript and also the Primary Investigator of the study. Anuar Zaini Md Zain (AZ) provided overall guidance and constructive comments for this article and participated in editing the manuscript. Quek Kia Fatt (QKF) provided statistical support and was instrumental in data analysis of the study and participated in editing the manuscript. All authors read and approved the final manuscript.

Acknowledgements

The authors would like to thank all the patients who agreed to participate in the study.

References

[1] Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. IDF Diabetes Atlas: Global estimates of the prevalence of diabetes for 2013 and projections for 2035. Diabetes Res Clin Pract 2014;103:137–49.
[2] Chan JC, Cho NH, Tajima N, Shaw J. IDF diabetes atlas. diabetes in the western pacific region: past, present and future. Diabetes Res Clin Pract 2014;103:244–55.
[3] Letchuman GR, Nazaimoon WM, Chandran LR, Tee GH, Jamiyah H, Isa MR, et al. Prevalence of diabetes in the malaysian national health morbidity survey III 2006. Med J Malaysia 2010;65(September (3)):173–9.
[4] Umma DS, Hayati KS, Suriani I, Rampal L. Diabetes Educators' competencies in facilitating self-management among diabetic patients at government heath care centres: a concept paper. Int J Public Health Clin Sci 2014;1:210–9.
[5] Tan Ming Yeong, Magarey Judy. Self-care practices in Malaysian adults with diabetes. Patient Educ Counsel 2008;72:252–67.
[6] Ministry of Health Malaysia. Clinical Practice Guidelines (CPG) on Management of Type 2 Diabetes Mellitus (T2DM). 4th ed. Putrajaya: Ministry of Health Malaysia; 2009.
[7] Loveman E, Frampton GK, Clegg J. The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review. Health Technol Assess 2008;12:7–45.
[8] Davies MJ, Heller S, Skinner TC, Campbell MJ, Carey ME, Dallosso HM. *et al*: Effectiveness of the diabetes education for ongoing and newly diagnosed

(DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. Br Med J 2008;336:491–5.
[9] Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the Diabetes X-PERT Programme makes a difference. Diabet Med 2006;23:944–54.
[10] Study Group DAFNE. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. Br Med J 2002;325:746–51.
[11] Cooper H, Booth K, Gill G. Using combined research methods for exploring diabetes patient education. Patient Educ Counsel 2003;51(1):45–52.
[12] Mohamed Mafauzy, Hussein Zanariah, Nazeri Avideh, Chan Siew Peng. A cross-sectional study of hospital based diabetes delivery and prevention of diabetes related complications in Malaysia. Med J Malaysia 2016;71(4):177–85.
[13] Welschen LM, Bloemendal E, Nijpels G. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. Diabetes Care 2005;28:1510–7.
[14] Ahmad B, Ramadas A, Quek KF, Md Zain A Zaini. A pilot study: the development of a culturally tailored Malaysian diabetes education module (MY-DEMO) based on the health belief model. BMC Endocr Disord 2014. http://www.biomedcentral.com/1472-6823/14/31.
[15] Trento M, Gamba S, Gentile L, Grassi G, Miselli V. Morone G, et al. Rethink Organisation to iMprove Education and Outcomes (ROMEO): A multicentre randomised trial of lifestyle intervention by group care to manage type 2 diabetes. Diabetes Care 2010;33(4):745–7.
[16] UKPDS Group. UK Prospective Diabetes Study Group 33: Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk complications in patients with type 2 diabetes. Lancet 1998;352:837–53.
[17] Nathan DM, Cleary PA, Backlund JY, Genuth SM, Lachin JM, Orchard TJ, et al. The diabetes control and complication trial/epidemiology of diabetes intervention and complications (DCCT/EDIC) study research group. intensive diabetes and cardiovascular treatment in patients with type 1 diabetes. N Engl J Med 2005;353:2643–53.
[18] Holman RH, Paul SK, Bethel MA, Matthews DR, Neil HAW, UKPDS Group, et al. 10 year follow-up of intensive glucose control in type 2 diabetes. N Engl J Med 2008;359:1577–89.
[19] Glasgow RE, Eakin EG, Toobert DJ. How generalizable are the results of diabetes self-management research: the impact of participation and attrition. Diabetes Educ 1996;22:573–85.
[20] Nesari M, Zakermoghadam M, Rajab A, Bassampour S, Faghihzadeh S. Effect of telephone follow-up on adherence to a diabetes therapeutic regimen. Jpn J Nurs Sci 2010;7:121–8.
[21] Sacco WP, Morrison AD, Malone JI. A brief, regular, proactive telephone coaching intervention for diabetes: rationale, description and preliminary results. J Diabetes Complications 2004;18:113–8.
[22] Su Dejun, Zhou Junmin, Kelly Megan S, Michaud Tzeyu L, Siahpush Mohammad, Wilson Fernando, et al. Does telemedicine improve treatment outcomes for diabetes? A meta-analysis of results from 55 randomised controlled trials. Diabetes Res Clin Pract 2016;116:136–48.
[23] Chew BH, Shariff-Ghazali S, Lee PY, Cheong AT, Mastura I, Haniff J, et al. Type 2 diabetes mellitus profile, diseases control and complications at four public health facilities: a cross-sectional study based on the audit diabetes control and management (ADCM) registry 2009. Med J Malaysia 2013;68:397–404.
[24] Mafauzy MZ, Chan SP. The status of diabetes control in Malaysia: results of DiabCare 2008. Med J Malaysia 2011;66(3):175–81.
[25] Tan MY, Magarey JM, Chee SS, Lee LF, Tan MH. A Brief structured programme enchances self-care practices and improves glycaemic control in Malaysians with poorly controlled diabetes. Health Educ Res 2011, doi:http://dx.doi.org/10.1093/her/cyr047.
[26] Sazlina Shariff-Ghazali, Browning Collete Joy, Yasin Shajahan. Effectiveness of personalised feedback alone or combined with peer support to improve physical activity in sedentary older Malays with type 2 diabetes: a randomised controlled trial. Front Public Health 2015, doi:http://dx.doi.org/10.3389/fpubh.2015.00178.