Effectiveness of *Diabetes Conversation Map*™ on insulin acceptance among insulin refusal patients of Type 2 Diabetes Mellitus

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BMI   Body Mass Index

NCD   Non-communicable disease

NHMS   National Health and Morbidity Survey

SD   Standard Deviation

USM   Universiti Sains Malaysia

WHO   World Health Organization

DCM   Diabetes Conversation Map

T2DM   Type 2 Diabetes Mellitus

PIR   Psychological insulin resistance

KRK   Klinik Rawatan Keluarga Universiti Sains Malaysia Hospital

ABSTRAK

Keberkesanan *Diabetes Conversation Map™* dalam penerimaan rawatan insulin di kalangan pesakit diabetis jenis 2 yang menolak rawatan insulin.

Latar Belakang: Pendidikan kesihatan merupakan komponen penting di dalam perawatan pesakit diabetis. Ia boleh diberikan sama ada secara berkumpulan atau pun individu. Bagi klinik kesihatan yang agak sibuk, pendidikan kesihatan secara berkumpulan dilihat lebih praktikal untuk dilaksanakan. Namun demikian, kebanyakan klinik kesihatan pada masa kini dilihat masih kurang mempraktiskan pendidikan kesihatan secara berkumpulan. Baru-baru ini, pihak "International Diabetic Federation" telah telah mengambil inisiatif dengan memperkenalkan *Diabetes Conversation Map (DCM)* iaitu modul pendidikan kesihatan yang dikendalikan secara berkumpulan. Modul ini telah digunakan di beberapa negara termasuk Malaysia. Modul ini telah dialih bahasa ke bahasa melayu. Ini menyebabkan penggunaannya semakin meluas. Walaubagaimanapun, keberkesanan penggunaan modul ini masih tidak diketahui di negara kita.

Objektif: Untuk mengetahui peratusan pesakit yang bersetuju menerima insulin di antara kumpulan intervensi iaitu yang diberikan pendidikan kesihatan menggunakan DCM dengan kumpulan kawalan iaitu yang diberikan pendidikan secara individu mengikut modul standard dan faktor-faktor berkaitannya di kalangan pesakit diabetes jenis 2 yang tidak terkawal yang menolak rawatan insulin yang menghadiri klinik rawatan keluarga HUSM.

Kaedah: Sejumlah 88 pesakit yang menghidap diabetes mellitus jenis 2 dan mempunyai Hba1c 8 % dan keatas yang datang ke klinik rawatan keluarga Hospital USM telah terlibat dengan penyelidikan ini. Mereka dibahagikan secara terkawal kepada dua kumpulan iaitu kumpulan

intervensi iaitu yang menerima pendidikan kesihatan secara berkumpulan menggunakan DCM manakala kumpulan terkawal adalah yang menerima pendidikan secara individu mengikut modul standard. Selepas sesi intervensi, pesakit akan ditemubual oleh penyelidik untuk mengetahui penerimaan mereka terhadap permulaan insulin. Analisa regresi logistik telah dilakukan untuk mencari faktor-faktor yang berkaitan dengan penerimaan insulin.

Keputusan: Kadar responden adalah 97.7%. Kumpulan intervensi menunjukkan penerimaan insulin yang lebih tinggi berbanding dengan kumpulan kawalan (86% berbanding 11%, $p < 0.001$). Daripada analisis regresi logisik berganda, didapati faktor yang berkaitan dengan penerimaan insulin adalah sejarah pesakit yang menpunyai ahli keluarga yang menggunakan insulin (AOR: 6.96; 95% CI: 2.30, 21.03; p=0.001).

Kesimpulan: Pendidikan kesihatan secara berkumpulan menggunakan Diabetic Conversation MAP (DCM) menunjukkan penerimaan yang signifikan untuk memulakan insulin berbanding dengan pendidikan standard secara individu. Penggunaan insulin dikalangan ahli keluarga pesakit merupakan faktor berkaitan yang signifikan terhadap penerimaan insulin. Dengan ini, DCM disarankan untuk digunakan secara meluas di pusat kesihatan primer bagi membantu pesakit yang tidak mahu menerima rawatan insulin pada awalnya untuk memerima rawatan insulin bagi memastikan tahap kencing manis pesakit berada dalam keadaan terkawal.

Kata kunci: diabetes mellitus jenis ke 2; Diabetic Conversation Map; pendidikan kesihatan berkumpulan; pendidikan secara individu; insulin;

ABSTRACT

Effectiveness of *Diabetes Conversation Map*™ on insulin acceptance among Type 2 Diabetes Mellitus insulin refusal patients.

Background: Diabetes education is a very crucial aspect of management for a diabetic patient. Educations can be delivered either by group or individual. For busy health centres, group education is the most practical approach in the setting. However, in most of the public hospital setting, the group-based diabetes education is still not yet well established. In recent years, group-based diabetes education using the diabetes conversation maps (DCM) endorsed by the International Diabetes Federation has been popularised ever since the complete set was translated into malay language. However, the effectiveness of this diabetes conversation map is still not known in our country.

Objectives: To compare the percentage of insulin acceptance between the intervention group (those who receive DCM education) and control group (those who receive standard counselling) and associated factors of insulin acceptance among uncontrolled type 2 diabetic patients, who refused insulin initiation attending Klinik Rawatan Keluarga HUSM.

Methodology: An interventional study was carried out where a total of 88 Type 2 diabetic adults from Klinik Rawatan Keluarga, HUSM with glycosylated haemoglobin (HbA_{1c}) concentrations of 8% and or more and refused insulin treatment were randomised into intervention(those who receive DCM education) and control groups(those who receive standard individual education). Post sessions, participants were reviewed by the investigator to find out their acceptance towards insulin initiation. Logistic regression was done to look at the factors associated with the insulin acceptance.

Results: The response rate was 97.7%. There was a significant difference in insulin acceptance between the intervention group education using DCM as compared to the control group using standard individual education module (86% vs 11%, $p < 0.001$). There was a significant association between history of relatives use insulin and insulin acceptance (AOR: 6.96; 95% CI: 2.30, 21.03; $p=0.001$).

Conclusion: Group education using Diabetes Conversation Map (DCM) is effective in increasing insulin acceptance among patient who initially refused insulin treatment. We recommend using DCM in primary care centres for diabetic patients who had difficulties in accepting insulin. Having relative that use insulin is a significant associated factor among patient who accepts insulin.

Keyword: type 2 diabetes; acceptance; insulin; group education; individual education

CHAPTER 1: INTRODUCTION

1.1 Overview of Diabetes Mellitus

Diabetes Mellitus is a very common chronic disease and a condition that is so far no known cure has been found. It has a considerable impact on the life of each individual patient and community at large as well health and economic burden to the country (MOH, 2015). It is a metabolic disorder that is characterised by high glucose levels in the blood that causing many metabolic disorders. In many instances, this condition is due to the insulin resistance whereby the insulin produced did not function as effectively as it should be. The insulin resistance will lead to insulin deficiency eventually.

Another important factor is increasing production of glucose by the liver (MOH, 2015). Not enough insulin or the inability of the body to respond will leads to high levels of blood glucose, or hyperglycemia, which is the main problem in diabetes (Forbes and Cooper, 2013). Hyperglycemia, if left untreated over the long term, will cause damage to many body organs, leading to the development of serious health complications such as myocardial infarction, stroke, kidney failure, an eye disease that can lead to blindness.

1.2 Prevalence of Diabetes Mellitus Worldwide and Malaysia

Diabetes Mellitus is well recognised as an important global health problem. The incidence of diabetes, as well as the prevalence, are escalating more so in developing and newly industrialised countries. In Malaysia, according to a survey done, National Health and Morbidity Survey (NHMS) 2015, the prevalence of diabetes mellitus (known and undiagnosed) among adults between 20 to 79 years old was 17.5% compared to study done in 2011 where the figure was 15.2% (2.6 million) ((NHMS), 2015) . According to US Centres for disease control and prevention

estimates that one in three people in the United States may develop diabetes in the year 2050 (Seaquist, 2014). However the latest facts from International Diabetes Federation, it is estimated that 1 in 11 adults has diabetes and the prevalence of Diabetes in Malaysia in 2017 is 17.9 (Federation, 2017). This shows a rise in the number of diabetes patients and optimisation of the treatment is important in reducing global health expenditure in future.

1.3 Uncontrolled Diabetes

1.3.1 Definition of Uncontrolled Diabetes

Clinically uncontrolled diabetes is defined base on their Hba1c level. We know that poor glycaemic controlled give rise to complications. Therefore good glycaemic control is crucial in preventing diabetic morbidity and mortality. The level of HbA1c gives an indication of the level of glycaemic control of diabetic patients during the previous two to three month duration (Jeffcoate, 2004). According to the American Diabetes Association (ADA), they recommended a HbA1c goal of less than 7 % while according to the American Association of Clinical Endocrinology, they recommended HbA1c of less than 6.5% to be considered in optimal control (Association, 2017; endocrinology, 2015) . According to a study, the Diabetes Expert Panel and Committee of Performance Measurement (CPM) have concluded that HbA1c > 9% is an indicator of poor diabetes controlled (Quality and (NCQA). 2009).

In Malaysia, as stated in the clinical practised guideline on management of type 2 Diabetes Mellitus, a patient who are not approaching targets of Hba1c<6.5% after three to six month of optimal treatment involving combination therapy of oral medication, insulin should be initiated as soon as possible. It also stated after insulin has been started, it is advisable to repeat back Hba1c at 3-4 month later.

Certain changes in HbA1c levels and the HbA1c level at a different point in time will possibly give different implications to the patient and managing clinician. In a study, where the association between HbA1c and complications were explored, the risks to get the complications increased significantly in which with every 1 % increment level of HbA1c, there is an increased risk of 38% in macrovascular event, a 40 % increased risk in microvascular event and a 38 % increased risk in death (all p <0.0001) (Zoungas *et al.*, 2012).

1.3.2 Prevalence of Uncontrolled Diabetes

According to National Diabetes Registry in Malaysia, in 2012, 23.8% of diabetic patient achieved the target of HbA1c < 6.5% while mean HbA1c in that year was 8.1% comparing in 2015 only 22% of people with T2DM achieved HbA1c target of < 7% ((NHMS), 2015). This shows that the number of uncontrolled diabetes in Malaysia are quite high. Based on a study conducted at the Waianae Coast Comprehensive Health Centre (WCCHC) which serves a medically underserved, predominantly Native Hawaiian community on O'ahu found out that more than 38% of their diabetic patients had poorly controlled diabetes (HbA1c >10%) (Ko, 2013). Moreover, a study done in Urban District of Karachi in Pakistan, prevalence of uncontrolled diabetes mellitus among diabetes patients with hbA1c>9% was found to be 38.9% (Siddiqui *et al.*). While a study in south-eastern Iran shows that more than 60% of diagnosed diabetic cases had impaired HbA1c at first diagnosed (Najafipour *et al.*, 2015).

1.3.3 Complications of uncontrolled diabetes

As we know, diabetes itself lead to complications. Uncontrolled diabetes may lead to early complications involving microvascular such as neuropathy, nephropathy and retinopathy and macrovascular complications such as stroke, peripheral arterial disease and coronary artery disease. An epidemiological analysis of the UKPDS data noted that with every single point

reduction in HbA1c level, there was a decrease in the risk involving microvascular complications by 35% reduction (Fong *et al.*, 2003). These complications will subsequently affect the patient's quality of life. Quality of life is actually a multidimensional concept pointing to a person's whole well-being, which includes psychological, social, and physical health status (Bowling *et al.*, 2003).

1.3.4 Management of uncontrolled diabetes

Generally, management of uncontrolled diabetes should involve all aspects which include educations, counselling and medications. Literature ha**s** shown that counselling plays an important role in diabetes management (Dworatzek *et al.*, 2013). According to Malaysia Guidelines, the content of the education given should consist of exercise, diet, medication and complications including acute and chronic, self-monitoring blood glucose, foot care, the hazard of smoking, and psychosocial approach to diabetes (MOH, 2015). Other than that, the most important treatment in an uncontrolled diabetic patients is insulin commencement. Based on our Malaysia Guidelines, it is stated that those diabetic patients who have HbA1c of 8% or more should be started on insulin in ensuring good glycaemic control (MOH, 2015).

Lagging on starting insulin or delayed in insulin initiation for uncontrolled diabetic patient have been found in the various study (Goodall *et al.*, 2009; Nichols *et al.*, 2007; Rubino *et al.*, 2007).Studies that are mention above have concluded that most of the diabetic patients who delayed in starting insulin treatment are those who have poor perception towards insulin and this is mainly because due to lack of knowledge of insulin itself (Polonsky *et al.*, 2005; Wong *et al.*, 2011).

Various educations tools have been developed in enhancing knowledge to improve outcomes of diabetes. Diabetes conversation map (DCM) is one the tool that had been developed

many years ago. Each DCM have its own focus topic. In Malaysia, DCM have been introduced since year 2000. The Ministry of Health of Malaysia has conducted the training courses on using DCM for diabetes nurse educators since the year 2004 and is estimated that around 900 diabetes nurse educators have been trained fully on DCM and had been practising it in both primary care and hospital-based diabetes care. The impact or effectiveness of the DCM is yet to be known.

1.4 Rationale of study

Insulin is the ultimate treatment of choice in T2DM patients. However insulin refusal rate among T2DM is very high. We were trying to find alternative method of education on this issues and noted that DCM is available and already been used in Diabetes Centre HUSM and Klinik Rawatan Keluarga HUSM, however we yet do not know the effectiveness of this tool in managing T2DM patient especially in those who refuse insulin therapy. In this study, we are using DCM on topic initiation insulin treatment as an education tool to increase the knowledge and change the perception towards insulin therapy among T2DM insulin refusal patients. As we are using the DCM on topic initiation insulin treatment and the DCM mainly focus on insulin therapy facts so our primary objective is to see the acceptance on insulin therapy after been educate using the DCM. We also try to figure out associated factors of insulin acceptance among these patients, thus we will try to overcome this factors if it is significant in managing their disease.

1.5 Scope of study

This study is done among uncontrolled T2DM at Klinik Rawatan Keluarga, University Sains Malaysia. This hospital is located in North East Malaysia with tertiary settings. The aim of the study is to look for the effectiveness of the DCM as an education tool in enhancing type 2 diabetic patient who refuse insulin to accept insulin.

CHAPTER 2: LITERATURE REVIEW

2.1 Education in Diabetes Mellitus management

Education to patient is part of diabetes mellitus management. According to clinical practise guideline of Canadian Diabetes Association, nutrition therapy and education play an important role in the treatment of diabetes as it can help in reducing glycated haemoglobin (HbA1c) by 1.0% to 2.0% (Dworatzek *et al.*, 2013). In another study, showed that education to diabetic patient give an improvement in the metabolic control (Gallegos *et al.*, 2006).

Based on a study by Dr.Sachmechi and his team, they compared HbA1c 6 months after diabetes and dietician education in 2 groups and it reveals that among patients who saw the diabetes educators and dietician, the mean HbA1c was reduced significantly by 1.02%, from 8.47% to 7.46% with P value < 0.01 while comparing to control group who did not see the diabetes educators or dietician, the mean HbA1c was also reduced by 0.59%, from 7.8% to 7.24% with P value< 0.01) (DiabetesInControl.com, 2010). This shows that with education to diabetic patients, the Hba1c improve much better compared to without education given. Overall, according to Rurik et all, all glycaemic parameters improved after education in diabetic patients (Rurik *et al.*, 2010)

As we know, the diabetes education is very important in improving clinical outcomes. It should be given to all diabetic patients regardless of treatment or medications they are on. Diabetes education should be delivered by a team of educators. Based on Malaysian guidelines on managing type 2 diabetes mellitus, educators can be anyone who is working in the diabetic clinic which includes dietician, health education officer, nurses, doctors and others. Reinforcement in education, may give the best improvements especially in patient outcomes.

However, any educators will need to have more time and more resources to fulfil the needs of a properly structured educational programme to be run smoothly. One study by Loveman et al found out that diabetes education needs to have a clear programme in the setting (Loveman *et al.*, 2008).

There are established Diabetes Resource Centres in most of the government hospitals where trained diabetes nurse educators are able to deliver patient-centered diabetes education to inpatients and also outpatients. Educations can be delivered either by group or individual education. Patient education constitutes an important tool for a better diabetes control and prevents the diabetes complications which indirectly reduce the costs of treatment (Rickheim *et al.*, 2002). There is not enough evidence at this period of time of what type of education methods are the more effective in improving clinical outcomes for diabetic patients.

Education in a group has been characterised as an alternative to individual education for diabetic patients management in the sense of cost-effective (Mensing and Norris, 2003). Multiple studies have addressed out that group education among diabetic patient was equally effective compared to individual education at improving diabetes control (Rickheim *et al.*, 2002; Trento *et al.*, 2004). A systemic review of 11 studies has concluded that group education for the diabetic patient is effective in reducing the HbA1c level, increase knowledge about diabetes, reducing blood pressure systolic levels and reducing body weight comparing to individual education. (Deakin *et al.*, 2005).

 Furthermore, a recent meta-analysis study of 21 studies has shown that group education gives an improvement in HbA1c level in six months compared to individual education with P-value 0.001, while in 12 months the P value 0.001 and within 2 years the P-value < 0.001. The same study also resulted in significant changes of blood glucose level in 12 months with a P-value

< 0.001 and improvement in diabetes knowledge in 6 months was also noted increase with P – value < 0.001 (Steinsbekk *et al.*, 2012).

A study by Hwee et al. supported that, where in the study they compared individual and group education and they found out that there were fewer acute complications and some improvements in the diabetes care management in laboratory claims for at least two HbA1c (glycated hemoglobin) tests, one lipid test and one optometry or ophthalmology claim for a retinal screening examination were done for the participants (Hwee *et al.*, 2014).

2.2 Diabetes Conversation Map (DCM)

Diabetes conversation map are an education tools for facilitated group education and are designed to engage patients in making changes in behaviour in ensuring good health (Belton, 2008). DCM are developed by Healthy Interactions in collaboration with the International Diabetes Federation (IDF) and are sponsored by Lilly Diabetes. Different DCM versions have been developed worldwide in cooperation with national and international diabetes associations (IDF and the Canadian, American, and U.K. diabetes associations) to reflect differences in culture and background (Belton, 2008; Reaney *et al.*, 2013)

DCM is actually a table top visual tools which size about 3 feet by 5 feet and it is designed to be used for small interactive groups which usually involve three to ten people. The participants in the group will learn about the main topic that is discuss in the DCM. There are many various topic available which include; the basic knowledge about diabetes, living with diabetes disease, healthy eating in diabetes, how to stay active in diabetes, how to self-monitor blood glucose level, common diabetes complications, diabetes in pregnancy, diabetes in ramadan and starting insulin treatment.

The first development of the DCM was noted in Canada in the year 2004 where during that time, a conversation map was used in the management of business organizations and it was observed and they felt that it could be used in health education especially for diabetes patient (Belton, 2008). A team of health educators that were chosen by the Canadian Diabetes Association try to work with the Healthy Interactions group company to develop the DCM. Two DCM topics were developed, one called starting your journey and the other called continuing your journey. They had organised few pilot study in different parts of the country and the results were very positive and the DCM were officially introduced in the year 2005 to Canadian diabetes educators. They noted that the Canadian diabetes educators need to undergone training on how to use the DCM. This was because the educators actually need to act as the facilitator who plays an important role in the discussion and they might require a different set of skills in ensuring the education been delivered successfully (Belton, 2008).

Another DCM was produced by Merck® in collaboration with the American Diabetes Association (ADA) in the year 2006 in the US. The US DCM consists of five different topics. The first DCM gave an overview of diabetes, the second DCM discusses on healthy eating, the third DCM highlights on the importance of blood glucose level monitoring and the fourth DCM describes the natural progression of diabetes and complications while the fifth DCM provides on pregnancy with diabetes.

The Eli Lilly ® Company had launched the DCM in the year 2008, in partnership with Healthy Interactions. The DCM topics consist of living with diabetes, how diabetes works, healthy eating and keeping active, starting insulin treatment, diabetes in Ramadan and caring of your foot (Interactions, 2015) . The DCM that was launched consists of a visual table top with size about 3 feet by 5 feet together with the "myth" and "fact" cards on the specific topic chosen for the

discussion. Example of the content of the cards on the topic starting insulin treatment were what insulin is, benefits on insulin, types of insulin, blood glucose target and etc. Benefits of insulin. The prior participants' knowledge and attitudes regarding diabetes are explored by using question and discussion cards. The facilitator will guide the participants throughout the discussion. The facilitator that had been trained will read the cards out to stimulate an interactive participant discussion. The myths regarding diabetes are read aloud then the topics are discussed in the group and then the true fact will be presented in a clear, proper and concise way. During the first year after it was launch, the DCM had been successfully distributed to 68 countries across the world in 31 different languages including malay language that is used for this study (Interactions, 2015).

In 2010, the similar DCM by Eli Lily® were introduced in Sub-Saharan Africa. The training for educators on the usage of the DCM had been done in Nigeria, in August 2010. After the training had been done, the DCM were equally distributed to all district of the country and slowly it was being introduced into education programs involving diabetes. A study on the usage of the DCM in their environment was done . Among Nigerian, the level of acceptance on DCM usage was high especially in the northern regions area, where the muslims actually lay the conversation map on the floor and they will sit together around it during the learning educational sessions(Chinenye and Young, 2013).

In Malaysia, DCM were introduced in the early 2008 by Eli Lilly® Company (Interactions, 2015). Recently, in year 2012, the complete set was translated into malay language. Since then, it has been used throughout the country. From a study done in Malaysia, they mention that the Ministry of Health of Malaysia has conducted the training courses on using DCM for diabetes nurse educators and is estimated that around 900 diabetes nurse educators have been trained fully on the DCM and had been practising it in both primary care and hospital-based diabetes care

(Hussein *et al.*, 2015) . In ensuring good impact of DCM, the Eli Lilly ® Company have also done training for facilitator of DCM throughout the country.

In University Sains Malaysia Hospital (HUSM), the DCM were used since year 2012. It was use in Diabetes centre and Klinik Rawatan Keluarga. The DCM that were available were in malay language and the topics were living with diabetes, how diabetes works, healthy eating in diabetes, starting insulin treatment and ramadan with diabetes. Adequate training had been done by the Eli Lilly® Company to the diabetes educator in HUSM .

Training is needed for a diabetes educator to become a facilitator for DCM group education. In a survey that was conducted among the earliest educators that had experience on using the DCM, one of them had reported that to act as a facilitator compared to an educator that she was used to be is not an easy task. She also informs that she found it is hard to just listen to the participants during the sessions as the participants go through the DCM and had to prevent herself from giving out the correct answer about the queries immediately. A few numbers of other educators also reported negative experiences using the DCM. These restrictions include reluctance or unwilling to open up to the discussion by some participants, lack of space and occasionally there were personality clashes among the participants (Belton, 2008).

In another study name IDEA study, they mention that it is important to train the educators as facilitator before or prior using the DCM for group education (Fernandes *et al.*, 2010). Facilitators with inadequate training may deliver less effective consultation which will reduce the effectiveness of the DCM. This was noted in a study, where they found that patients who went for group education using DCM had poor glucose control compared to individual education and from that they have concluded that there were possible lack of training of the facilitator in the study that have effect the result (Sperl-Hillen *et al.*, 2011).

2.2.1 Impact of DCM

A study which was name as an IDEA study which is (Interactive Dialogue to Educate and Activate) was done aiming to investigate the effectiveness of the DCM as an important tool for education in diabetes compared with individual education or usual care and it have resulted in improvement in diabetes self-care management in DCM group (Fernandes *et al.*, 2010).

Another study was done in Italy showed that diabetic patient who attended a course using DCM group education had an improvement in HbA1c and body mass index (BMI) comparing to individual education (Ciardullo *et al.*, 2010). While in another study, where they compared DCM to the American Association of Diabetes Educators curriculum, they found out that blood glucose level improved in group education using DCM compared to the usual curriculum (Zheng *et al.*, 2014).

One recent study among T2DM patient using DCM in group discussion resulted in significant improvement in diabetes knowledge for the DCM group comparing to regular care (Penalba *et al.*, 2014).

However, there was a study done among spanish and germany comparing DCM group education and standard care where in their study they concluded that clinical outcomes such as Hba1c and lipid level were noted to be improved in six months within both groups (Reaney *et al.*, 2013). Besides that study, there was another study done showed that individual education resulted in better improvement of glucose control level compared to DCM (Sperl-Hillen et al., 2011).

Based on the research findings mention above, both group and individual education for diabetic patients have a positive impact in clinical outcomes; but, a group education seems to be

able to provide care to a large number of people with T2DM together and approximately able to reduce human resources requirements.

For busy health centres, group education is the most practical approach in the setting (Mash *et al.*, 2008). Even though in most of the public hospital setting, the group-based diabetes education is not yet well established, however in our country, group-based diabetes education using the DCM endorsed by the International Diabetes Federation has been used widely throughout the country ever since the complete set was translated into malay version (Hussein *et al.*, 2015).

However, although many groups and individual educational materials are available, the relationship or interactions between patient and healthcare provider is recognised to have a positive influence on patient understanding, knowledge and adherence to treatment (Stewart, 1995).

Basically, all diabetes education should include all aspects of knowledge that should be delivered to the patient. Based on Malaysia guideline on management of type 2 diabetes mellitus, the content of education given should consist of exercise, diet, medication and complications including acute and chronic, self-monitoring blood glucose, foot care, the hazard of smoking, and psychosocial approach to diabetes (MOH, 2015). As for this study, the education will be more focus on medication, particularly on insulin initiation using the DCM.

2.3 Insulin

2.3.1 Insulin initiation

Achieving good glycaemic targets in T2DM patients has been a great challenge for both healthcare providers and patients. Many studies done have revealed that nearly one-third to one-half of diabetic patients worldwide succeed in achieving HbA1c level less than 7% (53 mmol∕mol) (Steinberg *et al.*, 2008; Tong *et al.*, 2008). The management of the diabetes disease is

complicated by the progressing nature of the disease as β cell function will decline, oral hypoglycemic medications alone are usually inadequate in maintaining good glycaemic control and insulin treatment is usually required at this stage.

Early use of insulin therapy in the management of uncontrolled diabetes has been recommended in preventing and reducing the long-term diabetes complications (Vinik, 2007; Westphal and Palumbo, 2006). According to Malaysia guideline on management of type 2 diabetes mellitus, all diabetic patient who have Hba1c $\geq$8% should be started on insulin therapy(MOH, 2015).

However, delay in starting insulin therapy is common worldwide (Goodall *et al.*, 2009; Nichols *et al.*, 2007; Rubino *et al.*, 2007). It is estimated that 50% of poorly control diabetic patients did not start insulin therapy at the proper time and the starting insulin was noted to be three to five years after the failure of oral hypoglycemic medications (Nichols *et al.*, 2007; Rubino *et al.*, 2007). From Karel Kostev et all, in a primary care practices in three European countries (Germany, France, UK), a patient with T2DM who had already been diagnosed to have macrovascular or microvascular complications, they were more likely to have insulin initiated (Kostev and Rathmann, 2013).

Standard treatment guidelines recommend that physicians should augment their patient's oral hypoglycemic medication with insulin injections after ensuring optimal adherence towards oral treatment. There was a study done in Cape Town city noted that barriers towards insulin initiation therapy include reduce knowledge about insulin among doctor, reduce experience with the use of insulin, lack of guidelines on how to prescribed insulin therapy, language barriers among patients and afraid that insulin will cause hypoglycemia to the patient. In the same study, the doctors also addressed their own opinions on what they thought patient barriers to be. They

concluded that misunderstanding about insulin therapy, the concerns about unable to comply to the medication given, reduce in the understanding of the diabetes disease, a favour to use traditional herbs, afraid or fear to use injections and the last poor socio-economic status. The same study also identified barrier in the system where they found that lack of time, inadequate continuity of care and financial constraints. However, in the study, they acknowledged that the important or major limitation involving the patients' perceptions were not elicited (Haque *et al.*, 2005).

Lagging in starting insulin by physicians was supported by Muharrem AK et al, where almost half of the physicians in the study felt they were incompetent in starting insulin treatment and dosage adjustment. About 40.2 % of the participants also felt incompetent in adjusting and maintaining insulin dosage (Ak *et al.*, 2015). Training programme on insulin initiation that was organised in the study of Jeremy Dale at all, reveal that general practitioner who voluntarily attended the training programme and applies it as everyday practice for the poorly controlled diabetic patient, the impact on glycaemic control is not worsening over 3 years (Dale *et al.*, 2010).

In clinical practice, initiating insulin therapy is commonly met with reluctance. One of a study conducted in United State of America(USA) revealed that 33% of insulin-naıve T2DM patients were not willing to start insulin treatment despite their uncontrolled diabetes (Larkin *et al.*, 2007), while there was another study done amongst bangladeshi stated that out of that 42.5% of patients with T2DM were not willing to start insulin treatment at the beginning but later they accepted insulin as their treatment, while 20.3% refuse to be started on insulin even after repeated counselling (Khan *et al.*, 2008) .

Refusal towards insulin treatment is a complicated problem, and patients commonly have barriers in starting insulin. Apparently, many studies exploring perception and attitudes towards insulin treatment have been carried out among non-Asian patient populations. There is insufficient

information about the prevalence of insulin refusal among Asian patient populations and their perceptions towards insulin treatment. This was covered by a study done in Singapore where the results revealed a high prevalence of insulin refusal in their study population (70.6%).

While, according to Polonsky et all, data showed that less than 20% of diabetic patients are truly not willing to start insulin treatment despite counselling given (Polonsky *et al.*, 2005).Conclusion on insulin refusal has been noted to be a significant problem in Asian with T2DM (Wong *et al.*, 2011). Overall, there are multiple factors contributing to delayed insulin initiation which it may be either from the patient, doctor or the system itself.

2.3.2 Factors associated with insulin refusal

Multiple barriers or factors have been noted contributing to patient non-acceptance to insulin. One of the studies reviewed that, fear of injections and needles and belief that insulin therapy would create difficulty for them to fulfil responsibilities at work and home (Woudenberg *et al.*, 2012). While in another study, barriers noted were the perception that needed for insulin treatment in their diabetes was an indicator that their condition is serious and deteriorating. Another perception of thought that insulin treatment will lead to early age death was also one of the barriers to starting insulin. Other than that, fears of hypoglycaemia, weight gain, poor perception of benefits in improving glycaemic controlled and concern over frequent injections(Wong *et al.*, 2011). From one study, they found out that a lack of adequate information relating to insulin appears to be the major factor behind diabetic patients' refusal of insulin treatment. The fact that patients consider insulin treatment as a final solution to diabetes disease could be related to resistance to the initiation of insulin therapy (Ak *et al.*, 2015).

A comparison study was conducted between "acceptors" and "refusers" of insulin treatment in primary care clinics in Singapore. The RETHINK (Reconsider Therapy with insulin

knowledge) study revealed that acceptors had less concern about insulin injection compared to refusers. Another important barrier noted to initiate insulin was an idea of the significant pain would occur with the injections (Tan *et al.*, 2003).

In a study in Cape Town, doctors also inform regarding their opinions on what they think the patient barrier could be. They included of having the wrong idea about insulin, the concern about unable to comply to insulin, lack of knowledge in diabetes, a favour to use traditional herbs compare to normal medications, afraid of injections and poor socio-economic status (Haque *et al.*, 2005).

The term "psychological insulin resistance" has been introduced. They refer it to a negative attitude towards insulin treatment which will contribute to unnecessarily prolong delays in starting insulin (Polonsky *et al.*, 2005). In this issue involving of psychological resistance, the DAWN (Diabetes Attitudes, Wishes and Needs) study was conducted, in which a big number of the psychosocial survey was undertaken involving 5 000 diabetic patients and 4 000 healthcare workers throughout 13 countries. This study resulted that healthcare workers delayed the starting insulin treatment until they considered it necessary to the patient (Alberti, 2002).

All attitudes belief should be sought out and corrected. A study done at Public Health clinic in Malaysia concluded all the attitude belief about insulin therapy among patient resistance insulin and insulin acceptance. Among the barriers found were the feeling of personal failure if they were to be start on insulin therapy, 64.9% of patient-reported this as a factor making them resistant from taking insulin. However, the statistical analysis showed p-value was not significant $p<0.006$. Injecting is embarrassing (64.9%) and injecting insulin is painful (60.5%) were significantly deterring the patient from using insulin with a p-value of <0.001. Other significant factors suc as fear of problematic hypoglycemia, lack of fairness, restrictiveness and don't have a

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regular time for a regular dose of insulin were the barriers identified. Interestingly,there was also barrier such as feeling like a drug addict if they were to be treat with insulin therapy and 37.6% of patient reporting this (Nur Azmiah *et al.*, 2011).

2.3.3 Factors associated with insulin acceptance

Not many studies have been done to see factors associated with insulin acceptance. According to the previous PIR studies, they noticed that the insulin-naïve T2DM patients who were more ready to accept insulin initiation were males. This study was done in Singapore where males were more ready to be started on insulin treatment (OR 2.0, CI 1.2–3.4) (Wong *et al.*, 2011).There was no explanations given on this in the study.

Furthermore, in the same study, they also revealed an important associated factor between educational level and willingness to accept insulin. They found that patients with tertiary education were more prepared to accept insulin treatment than patients in primary or secondary school education (OR3.3, CI 1.8–6.1). A plausible explanation is given in this study where they found presence of differences in the perceptions of insulin between the educational groups which possible influencing their willingness in accepting insulin therapy.

Moreover, they also explain that usually, patients with lower levels of education will easily accept insulin therapy and commonly less fear to a daily lifestyle, responsibilities and inability to inject insulin properly. However, in their study, the significant differences in perceptions of insulin, suggest that participants with lower levels of education were more concerned with their lifestyle changes and technical aspects of the insulin treatment and cause them to refuse insulin therapy (Wong *et al.*, 2011).

In addition to gender and educational level, having relative use insulin is one of an important associated factor for insulin acceptance. As we know family history is a well-known associated factor for a diabetic patient. Family histories include inherited genetic susceptibilities and shared environments. This actually includes cultural factors such as preferences, idea and values, and perceptions and behavioural factors including diet and physical activity. A study that has been conducted found out that those who have insulin-using relatives and more diabetes-related complications are noted to be factors influencing them for insulin acceptance (Morris *et al.*, 2005; Woudenberg *et al.*, 2012). In other words, we can say that having a history among the family members with chronic disease might influence their relative behaviour and perception towards the disease.

There was a study done among African American adults where in the study they found that having a positive family history of diabetes increased awareness about risk factors in diabetes and engaging them in better health behaviors among participants (Baptiste-Roberts., 2007). This was explained by possible of having the family history of chronic disease will influence their concerns and belief about the disease and its complications. Another study done on insulin acceptance resulted that those who accept insulin initiation was influenced by their perceptions about diabetes and insulin (Guimarães *et al.*, 2010).

As we know, insulin is the most efficient therapy to lower down the blood glucose level and, due to its' progressive nature of T2DM, many people with T2DM will subsequently require insulin therapy to attain and sustain adequate glucose control. Unfortunately, as we discussed above, in clinical practice, starting insulin treatment is commonly delayed in many patients with T2DM who actually would cater more benefit from such treatment. The uncontrolled glycemic burden and not receiving insulin treatment appropriately will lead the diabetic patient to have a

higher risk of macrovascular and microvascular complications. Indeed, in IMPROVE study they found that poor glycemic control and high rates of vascular complications were observed at baseline in 51,286 diabetic patients that were enrolled in the study, where in the study they assessed the safety and effectiveness of biphasic insulin aspart 70/30 in diabetic patients who required insulin treatment (Valensi *et al.*, 2008). The belief and their concern about complications of uncontrolled diabetes and probable side effects of other treatment regime had influenced them in accepting insulin among the participants. Their strong belief in benefits of insulin and its' effectiveness was due to having a good knowledge regarding diabetes and insulin and also having their own self experience. Doctors' assessment and empathy support also helped them in accepting insulin treatment. These factors indirectly allayed their negative thought, concerns and beliefs about diabetes and insulin, which were their initial barriers towards insulin acceptance. (Hassan *et al.*, 2013).

Those who were revealed to have more positive perceptions towards insulin treatment in the sense of its effectiveness in improving their glycaemic control and general health and also preventing diabetes complications were more ready to accept insulin (Morris *et al.*, 2005; Woudenberg *et al.*, 2012). Knowing that insulin is beneficial is an important factor for a diabetic patient to accept insulin treatment (Guimarães *et al.*, 2010; Morris *et al.*, 2005). The expectation and understanding among diabetic patients that good glycaemic control will improve their health and well-being will also increase their perception towards insulin treatment (Guimarães *et al.*, 2010; Nair *et al.*, 2007). A study done among Pakistani revealed that the insulin perception was higher in patients with a higher monthly income (p < 0.001) (Saleem *et al.*, 2016).

From a study by Morris et al. (2005), the patient with T2DM recognised insulin as a 'friend' or 'foe'. This recognition will influence their acceptance towards insulin therapy. The experiences

of using insulin gave them the rationale about the benefits of the insulin and subsequently influence them in accepting insulin as 'a friend'. The experiences increase their confidence towards using insulin by knowing that they were able to inject themselves and adjust the insulin dosage themselves. This allowed demonstration of insulin therapy efficacy when better glycaemic control and well-being were achieved, thus indirectly validate their perception towards insulin benefits (Morris *et al.*, 2005).
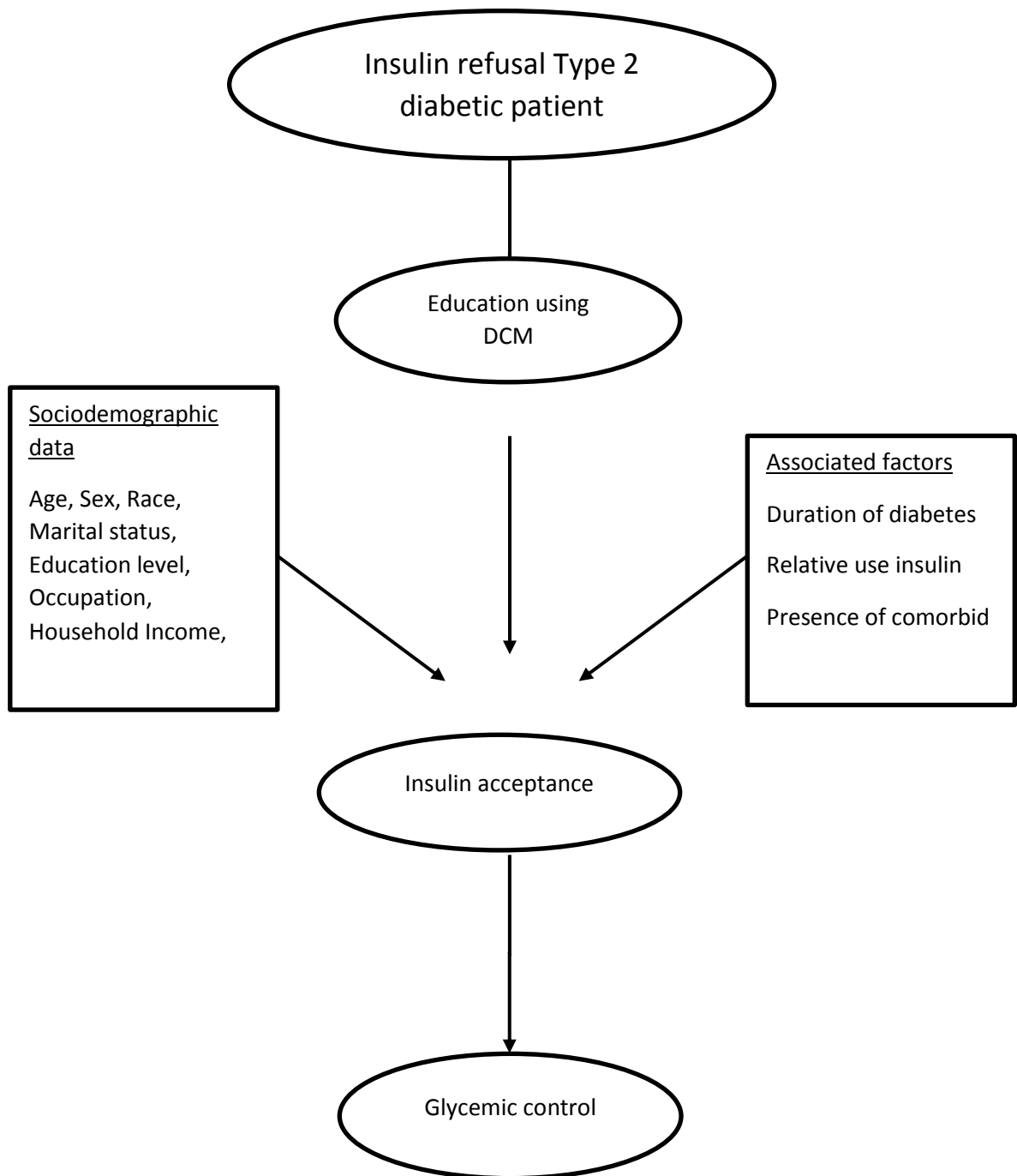
2.4 Conceptual framework

Figure 2. 1: Conceptual Framework

CHAPTER 3: OBJECTIVES & HYPOTHESIS

3.1 Research Question

The study will investigate the following research questions:

1. What is the percentage of insulin acceptance between those receiving group education using DCM comparing to standard individual education among insulin refusal?

2. What are the associated factors for their acceptance of insulin?

3.2 General Objective:

To compare the percentage of insulin acceptance between the intervention group (those who receive DCM education) and control group (those who receive standard individual education) and the associated factor of insulin acceptance among insulin refusal attending Klinik Rawatan Keluarga HUSM.

3.3 Specific objectives

1.   To compare the percentage of insulin acceptance between intervention (those who receive DCM education) and control group (those who receive standard individual education).

2.   To determine the associated factor of insulin acceptance among insulin refusal.

3.4 Research Hypothesis

The percentage of insulin acceptance is higher in those receiving group education using DCM compared to those receiving standard individual education. Socio-demographic, having relative of use insulin and having comorbidities are significant associated factors of insulin acceptance.

CHAPTER 4: METHODOLOGY

This study consist of two phases. Phase one which to study objective one was done in randomize control trial design whereas in phase two to study objective two was done in cross sectional study design.

4.1 Phase one Study

4.1.1 Study Design

This is a prospective, parallel group and open randomised control trial.

The participants were assigned into 2 groups via computer-generated block randomisation.1 group will receive a group education using DCM (intervention group) while the other group will receive standard individual education (control group).

4.1.2 Population and Sample

4.1.2.1- Reference population

The reference of the population is the uncontrolled T2DM patient in Kota Bharu

4.1.2.2- Source population

Uncontrolled T2DM patients attending Klinik Rawatan Keluarga ,HUSM, Kubang Kerian, Kota Bharu, Kelantan

4.1.2.3- Study population

Uncontrolled T2DM patient who refused insulin treatment attending Klinik Rawatan Keluarga, HUSM, Kubang Kerian, Kota Bharu, Kelantan