PSYCHOSOCIAL ASSOCIATED FACTORS FOR GLYCAEMIC CONTROL AMONG TYPE TWO DIABETES MELLITUS PATIENTS IN KUALA TERENGGANU

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ABSTRACT

PSYCHOSOCIAL ASSOCIATED FACTORS FOR GLYCAEMIC CONTROL AMONG TYPE TWO DIABETES MELLITUS (T2DM) PATIENTS IN KUALA TERENGGANU

Background: Prevalence of poor glycaemic control is significantly increased in Malaysia**.** There are multiple factors influencing the glycaemic control including psychosocial factors. Achieving good glycaemic control requires patients to follow a treatment regime, which involve lifelong behavioural changes, life regulation through lifestyle changes and self-management skills. This is where psychosocial factors play a role in the management of diabetes despite good medications prescribed to them.

Objective: To determine the psychosocial factors associated with glycaemic control among type 2 diabetes mellitus (T2DM) patients in Kuala Terengganu.

Methodology: A cross-sectional study involving 338 patients with T2DM attending two selected out-patient health clinics with highest prevalence of poor glycaemic control in Kuala Terengganu from December 2014 to June 2015. Systematic random sampling, 1:15 interval was applied. A self-administered questionnaire consists of socio-demographic background, social support score, Malay version of DASS-21 for psychological factors and Malaysian version of Medication Adherence Score (MalMAS) has been distributed to respondents.

Medical background of patients were completed by the researcher. The data were analysed using descriptive statistic and logistic regression.

Results: The mean age was 60.9 (±SD 10.3). 76% (257) patients has uncontrolled diabetes with mean HbA_{1c} of 8.55% (±SD 1.95). The median social support score was 22.0 (17.0, 28.0). Through multivariable analysis using multiple logistic regression test, this study showed unemployed and pensioner patients with type 2 diabetes mellitus have protective association to have poor glycaemic control by 0.46 (p=0.035) and 0.28 (p=0.001) times respectively. Patients who perceived diabetes had interfered with their activity of daily living have 3.18 times (p=0.024) the odds to have poor glycaemic control and a patient with an increase of 1 social support score has 7% higher risk (p=0.001) to have poor glycaemic control.

Conclusion: Psychosocial associated factors which were employment status, patients' perceived diabetes had interfered with their activity of daily living, and the social support score has significant influence on the outcome of diabetes control.

Key words: diabetes control, glycaemic status, psychosocial factors

ABSTRAK

FAKTOR PSIKOSOSIAL BERKAITAN KAWALAN PARAS GULA DI KALANGAN PESAKIT DIABETES MELLITUS JENIS DUA (T2DM) DI KUALA TERENGGANU

Latarbelakang: Prevalens kawalan paras gula teruk semakin meningkat di Malaysia. Terdapat pelbagai faktor yang mempengaruhi kawalan paras gula termasuk faktor psikososial. Bagi mencapai kawalan paras gula yang baik, pesakit perlu mematuhi pelan rawatan yang melibatkan perubahan tingkah laku secara berterusan, peraturan hidup melalui perubahan gaya hidup dan kemahiran pengurusan diri. Ini kerana psikososial memainkan peranan dalam pengurusan diabetes walaupun ubat-ubatan yang baik telah diberikan kepada mereka.

Objektif: Untuk menentukan faktor-faktor psikososial yang berkaitan dengan kawalan paras gula di kalangan pesakit kencing manis jenis 2 (T2DM) di Kuala Terengganu.

Metodologi: Sebuah kajian keratan rentas yang melibatkan 338 pesakit kencing manis jenis dua (T2DM), yang menghadiri dua buah klinik pesakit luar terpilih disebabkan tahap kawalan glisemik teruk di Kuala Terengganu dari Disember 2014 hingga Jun 2015. Persampelan rawak sistematik, dengan kadar 1:15 telah digunakan. Satu soal selidik isi-sendiri yang mengandungi soalan berkaitan latarbelakang sosio-demografi, skor sokongan sosial, DASS-21 untuk menilai

faktor-faktor psikologi dan skor kepatuhan ubat versi Malaysia (MalMAS) telah digunakan. Data dianalisa menggunakan statistik deskriptif dan regresi logistik.

Keputusan: Umur min adalah 60.9 (+ SD 10.3) tahun. 76.0% (257) pesakit mempunyai kawalan diabetes yang teruk dengan min HbA_{1c} 8.55% (± SD 1.95). Markah median sokongan sosial ialah 22.0 (17.0, 28.0). Melalui analisa Regresi Logistik Pelbagai, kajian ini menunjukkan bahawa pesakit yang menganggur dan pesara adalah faktor yang melindungi pesakit daripada kawalan glisemik yang teruk, masing-masing sebanyak 0.46 (p = 0.035) dan 0.28 (p = 0.001) kali. Pesakit yang menganggap diabetes mengganggu aktiviti hidup harian mereka mempunyai 3.18 kali (p = 0.024) kemungkinan untuk mempunyai kawalan glisemik teruk dan pesakit dengan peningkatan sebanyak 1 skor sokongan sosial adalah 7% (p = 0.001) lebih berisiko untuk mempunyai kawalan glisemik teruk.

Kesimpulan: Faktor-faktor psikososial faktor yang berkaitan seperti status pekerjaan, persepsi pesakit bahawa diabetes mengganggu aktiviti hidup mereka setiap hari, dan skor sokongan sosial mempunyai pengaruh yang besar ke atas kawalan diabetes.

Kata kunci: kawalan diabetes, status paras gula, faktor-faktor psikososial

CHAPTER ONE: INTRODUCTION

Diabetes is a chronic and debilitating disease, making it a major public health concern. This applies not only in Malaysia but also worldwide. The prevalence of diabetes continues to rise in Malaysia. From the third National Health and Morbidity Survey (NHMS III) in 2006 [1], the prevalence of diabetes in persons aged 18 years old or more was 11.6%, while in 2015 NHMS survey, the prevalence increased further up to 17.5% [2]. World Health Organization (WHO) also estimates that more than 180 million people worldwide have diabetes. This number is likely to double by 2030 without urgent action [3].

Problems occur when not only the prevalence of diabetes has increased but the prevalence of patients with poor glycaemic control also shows the similar pattern. Many have studied the multiple factors influencing the glycaemic control of diabetes patients. This is important as patients with near normal glycaemic will develop complications later than patients with uncontrolled or poor controlled glycaemic. Cardiovascular disease (CVD) events is relatively more likely to happen in patients with type two diabetes. In the Framingham Heart Study, diabetes predisposed subjects to all of the major atherosclerotic diseases and coronary heart disease (CHD) was the most common and most lethal among all the atherosclerotic diseases [4].

Achieving good glycaemic control requires patients to follow a treatment regime, which involve lifelong behavioural changes, life regulation through lifestyle changes and self-management skills. This is where psychosocial factors play a role in the management of diabetes. Once people had been diagnosed as having diabetes, it will affect them psychologically and socially. At the same time

his psychosocial background will also affect the disease outcome including glycaemic control, diabetes complications and the quality of life.

In Malaysia our government has provided a very good pharmacological and non-pharmacological management for diabetes patients. However the percentage of patients with poor glycaemic control is still very high up to almost 80% of all diabetes patients [5]. This problem give rise to many more debilitating health problems and complications including cardiovascular events, renal failure and visual problems. We are hoping that our study will help in evaluating how psychosocial associated factors influence the glycaemic control in type two diabetes patients especially those who have proper primary care follow up. In primary care, we are the first responder to all diabetes patients and we are close to the community. This study give us an overview of the psychosocial associated factors among our population thus we can cater with the problems or factors encountered to help the patients achieving good glycaemic control.

CHAPTER TWO: LITERATURE REVIEW

2.1 Diabetes

Diabetes is a common chronic disorder not only in Malaysia but also worldwide. There is chronic hyperglycaemic together with other metabolic abnormalities in a person who newly been diagnosed as diabetes. Diabetes is a cardiovascular disease equivalent risk factor for coronary heart disease and currently there is no known cure. The person can only controlled the disease to lead a healthy and productive life. So, the aim of diabetes management is directed at reducing micro- and macro-vascular complications by targeting a better glycaemic control in each person with diabetes.

The type two diabetes results from a progressive insulin secretory defect on the background of insulin resistance [6]. It is the commonest form of diabetes mellitus resulting from a combination of genetic and environmental factors [7]. In developing countries, the highest prevalence of type two diabetes mellitus occurs among the upper socio-economic group [8]. Asians aged 40–64 years had five times higher prevalence of diabetes as compared to Europeans, as shown in an article reported by Mather and Keen, 1985 and Zargar et al., 2000 [7, 9].

The current epidemic of diabetes is principally due to increasing prevalence of type two diabetes, although type one diabetes prevalence rates are also rising [10]. More than 30 million people are already diagnosed with diabetes in the Asian Pacific Region and the number is estimated to double by 2025 [10]. Diabetes prevalence rates already exceed 8% in 12 countries and areas within this Region [10]. In Malaysia, the fourth National Health and Morbidity survey (NHMS 2011) has been completed and the results are worrying.

Despite aggressive health awareness campaigns, about one in five Malaysians over 30 are having diabetes (6% up from 2006) [11].

2.2 Glycaemic control

In real time, there are a growing number of people diagnosed with diabetes each single day [12]. This situation does not mean anything except for more health burden to healthcare provider and also human population. So, adequate blood glucose control is vital in diabetes management to prevent complications which may worsen their future life [12].

Prediction of poor glycaemic control from patient characteristics among patients with diabetes in general practice is hardly possible [13]. In other words, we need more objective measurements to assess glycaemic control. There are two primary techniques available for healthcare providers and patients to assess the effectiveness of the management plan on glycaemic control, i.e. self-monitoring of blood glucose (SMBG) or interstitial glucose, and glycosylated haemoglobin (HbA_{1c}) levels [6]. Goudswaard et al., 2004, in their study suggested that, in daily diabetes care in addition to measurements of HbA_{1c}, measuring of fasting blood glucose (FBG) is useful to assess glycaemic control [13]. The FBG is actually a part of SMBG itself.

2.2.1 Glycosylated Haemoglobin (HbA_{1c})

The most recent glycaemic goal recommended by the American Diabetes Association (ADA) 2016, selected on the basis of practicality and the projected reduction in complications over time, is ‘in general’ or for many non-pregnant adults, an HbA_{1c} level of <7% [6, 14]. For ‘the individual patient’, the HbA_{1c} should

be ‘as close to normal (<6%) as possible without significant hypoglycaemic’ [14]. More stringent HbA_{1c} goals might reasonably suggested by the providers for selected individual patients, if hypoglycaemic or other adverse effects of treatment can be avoided [6].

On the other hand, the glycaemic goal set by the European Union-International Diabetes Federation (IDF) is a HbA_{1c} level <6.5% [14]. The ADA consensus is that an HbA_{1c} of ≥7% should serve as a call to action to initiate or change therapy, with the goal of achieving an HbA_{1c} level as close to the non-diabetes range as possible or, at a minimum, decreasing the HbA_{1c} to <7% [14]. Lowering HbA_{1c} to below or around 7% has been shown to reduce micro-vascular complications of diabetes, and if implemented soon after the diagnosis of diabetes is associated with long-term reduction in macro-vascular disease [6].

DiabCare Malaysia 2008 results showed deteriorating glycaemic control with mean HbA_{1c} of 8.66±2.09% with only 22% of the patients achieving ADA target of <7% [5, 6]. The variables with significant effects on glycaemic control were ethnicity, age and duration of diabetes mellitus [15].

2.2.2 Self-Monitoring Blood Glucose (SMBG)

Another way in assessing glycaemic control is by using the self-monitoring blood glucose (SMBG). The SMBG is a component of effective therapy as shown in many major clinical trials of insulin-treated patients [6]. Evaluation of individual response to therapy and assessment of glycaemic targets achievement can be done using SMBG. Ideally, hypoglycaemic prevention, adjustments of medications, medical nutrition therapy (MNT), and physical activity can successfully be practice based on the results of SMBG [6] as it is especially

important for insulin-treated patients. This is because the purpose of SMBG is to monitor for and prevent asymptomatic hypoglycaemic and hyperglycaemic. The target glucose level during SMBG are; pre-prandial of 4.4-7.0mmol/L and postprandial of 4.4-8.5mmol/L [16].

2.3 Psychosocial associated factors influencing glycaemic control

According to Marie O'Toole, 2003, psychosocial is defined as pertaining to or involving both psychic and social aspects [17]. It is also defined by Segen in 2006 as an adjective referring to a person's psychological development in, and interaction with, a social environment [18]. While Jacqueline, 2001 defined psychosocial as a term referring to the mind's ability to, consciously or unconsciously, adjust and relate the body to its social environment [19].

In 2003, Ando and Ando mentioned in their study that psychosocial factors were considered to be involved in glycaemic control and in adherence to initial treatment in diabetes patients [20]. Research into the psychosocial correlates of glycaemic control in youth with insulin-dependent diabetes has been variable in outcome [21]. Patterns of psychosocial relationships with glycaemic control within diabetes persons have been a recent area of inquiry [21].

It is reasonable to include assessment of the patient's psychological and social situation as an ongoing part of the medical management of diabetes [6]. The ADA Standard Care 2016 recommends for psychosocial screening and evaluation during follow-up should include the patients' attitudes about the illness, their expectations for medical management and outcomes, their affect/mood, their quality of life (general and diabetes-related), the resources

(financial, social, and emotional), and the psychiatric history [6]. The psychological problems that should be evaluated are depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when self-management is poor [6]. A systematic review and meta-analysis showed that psychosocial interventions modestly but significantly improved HbA_{1c} (standardized mean difference −0.29%) and mental health outcomes [6].

Psychosocial factors such as stressful life events, maturity of the adolescent, individual psychological adjustment and stability of the family may be associated with metabolic control [22].

2.3.1 Psychological factors

Diabetes is recognized as one of the most emotionally and behaviourally demanding chronic illnesses, yet most patients seem to adapt to and cope reasonably well with the disease and report a satisfactory quality of life [23]. Inter-relationship of diabetes and its psychological impact is to be recognized at different stages of disease which includes of initial response at diagnosis, restriction of daily life pattern, burden of chronic disease and apprehension of complications and likely disability [24]. This can bring in feeling of being different in one's life from the peers, loss of spontaneity and family concern in each and every activity of the person [24].

Psychological refers to an adjective of or relating to psychology, or arising from the mind or emotions, or influencing or intended to influence the mind or emotions [17]. Gale defined psychosocial as a term pertaining to the mind, its mental processes, and its emotional makeup [17].

Diabetes patients in the poorly controlled glycaemic group tended to be less able to cope under stress compared to those in the well-controlled glycaemic group tended to be extroverted [20]. Moreover, glucose concentrations in patients with type two diabetes were significantly increased when stress is experienced in the postprandial period [25]. It also caused a significantly delayed decrease of glucose concentrations, hence rendering the patients to worse glycaemic control [25].

Type two diabetes is associated with increased risk of depression with the relative risk (RR) of 1.15 (95% CI 1.02–1.30) [26]. Roy and Lloyd, 2012, in their systematic review found that people with T2DM have almost double the risk of depression compared to those without diabetes. Men experienced a lower prevalence of depression than women with diabetes and also women without diabetes [27]. Even though the exact direction of this relationship remains unclear, the authors concluded that reviewed studies provide support for a modest relationship between diabetes and depressive symptoms [27-30].

It is widely recognized that patients with type two diabetes may be at increased risk of negative effects on health due to stress. The elevation of glucose levels resulted from the experience of stress was associated with the release of counter regulatory hormones and energy mobilization [31]. In addition, diabetes control can be indirectly disrupted by stress through effects on diet, exercise, and other self-care behaviours. Several studies have demonstrated a relationship of stress to glycaemic control in samples of patients with type two diabetes [32-34].

Peyrot et.al concluded in his study in 1999 that better glycaemic control was seen in better self-controlling persons and worse glycaemic control among

emotional persons (because of differences in stress) [35]. There was more variance in glycaemic control was seen with variability of psychosocial factors [35]. Transient worse glycaemic control was associated with stress and regimen non-adherence, while better chronic glycaemic control was associated with stable psychosocial reasons (i.e., education, being married and positive coping styles [35]. Thus evaluation of psychosocial factors is very important in T2DM as majority of T2DM with stress demonstrate a positive association with daytime blood glucose level [36].

2.3.2 Social aspects

Younger patients (age group < 50 years) had significantly higher mean A_{1c} than elderly patients [15]. Duration of diabetes had a clear influence on glycaemic level [15]. Patients with recently diagnosed diabetes (duration of disease < 5 years) had the best glycaemic control [15]. Older adults (>65–70 years) often have a higher atherosclerotic disease burden, reduced renal function, and more co-morbidities [37-39]. The younger, healthier individuals may have more ambitious glycaemic targets compared to elderly with long-standing or more complicated disease [39, 40]. If lower targets cannot be achieved with simple interventions, an HbA_{1c} of <7.5–8.0% (<58–64 mmol/mol) may be acceptable, transitioning upward as age increases and capacity for self-care, cognitive, psychological and economic status, and support systems decline [39].

Type two diabetes mellitus patients with poor glycaemic control had lower mean quality score using the 36-Item Short Form Health Survey (SF-36) scores in physical functioning, general health, social functioning and mental health, and

the SF-36 scores in these patients were also lower than the SF-36 norms of the Malaysian population [41]. Ando and Ando, 2003 study showed that glycaemic control was significantly affected by the respondents' level of physical activity, their educational status, and the dose of oral hypoglycaemic agents taken by the respondents [20]. Adaptation to diabetes and other aspects of health-related quality of life were associated with the quality of marriage among insulin-treated adults with diabetes [42]. Further study need to be done to show that marital adjustment, the impact of couples-focused interventions on adaptation, and adherence may relate to glycaemic control [42].

From a study done by Ayele et al., 2012, we can conclude that in order to intensify own self care practice, the education background of the patients with diabetes should be evaluated [43]. The study also showed that performance of self-care was poorer among higher income patients [43]. The constraints that limited their ability to good control of diabetes were the ethnicity, the cultural and financial beliefs [12]. A study done by Delamater et al., 1991, showed black youths with type 1 diabetes mellitus are in poorer metabolic control than white youths [44]. A literature also done in United States reveals that barriers to achieve good glycaemic controls may be inherent (e.g.; genetic, cultural, and language/communication) or acquired (e.g.; those associated with changes in lifestyle and socioeconomic factors) [45].

2.4 Methods of assessment/ Measurement tools and instruments

There are various methods used in previous studies on psychosocial factors and glycaemic control. The following are the methods used to assess psychological alone, social alone and psychosocial in combination.

2.4.1 Assessment of psychological factors

In this study, the psychological factors that we look at were on depression, anxiety and stress that may influence the glycaemic control of the patients. As we all know, diabetes and depression are two major non-communicable diseases that are expected to increase to epidemic level in several developing countries. Depression was found to negatively effect on diabetes patients, which may effect on their behaviours such as healthy eating or blood glucose testing and monitoring. Stress negatively effect on diabetes control and management such as regularly monitoring blood glucose level, planning for healthy meals, and timing of medications (including insulin) on time which are difficult to be controlled during stress [46].

2.4.1 (a) Depression, Anxiety and Stress Scale (DASS)

The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress [47, 48]. It was constructed not just as a scale to measure emotional states, but to further the process of defining, understanding, and measuring the ubiquitous and clinically significant emotional states usually described as depression, anxiety and stress [48, 49].

The Depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, and lack of interest/involvement, anhedonia, and inertia [48-50]. The Anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect [48-50]. The Stress scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient [48-50]. Subjects are asked to use 4-point severity/frequency scales to rate the extent to which they have experienced each state over the past week. Scores for Depression, Anxiety and Stress are calculated by summing the scores for the relevant items [48].

Ramli et al. has translated The Depression Anxiety Stress Scales 21 items (DASS-21) into Malay version in 2007. This DASS-21 which is modified to shorter version from the original version of DASS 42 items [48], also have been translated in various languages and validated in different populations [51]. It is not a diagnostic questionnaire but rather as a severity measurement (dimensional rather than a categorical) [52]. DASS is suitable to be used in any clinical or non-clinical settings [49, 51]. The questionnaire is easy and simple to administer to general population without any special training is needed [51]. Researchers would be able to assess levels of depression, anxiety and stress at the same time by only using this questionnaire [51]. As none of question in DASS-21 items mentioned any aspects on certain culture or religion thus it is said that almost all 21 items in this questionnaire are relatively cultural free [51].

The shortened version of the DASS (DASS-21) was selected in preference to the full-scale version of the DASS (DASS-42) for this study because, in contrast to the DASS-42, the factor-analytic studies that have directly

compared the two questionnaire in clinical populations suggest that the DASS-21 is associated with a cleaner factor structure relative to the DASS-42 (Antony et al., 1998; Clara et al., 2001). The relative superiority of the DASS-21 compared with the full-length DASS may be attributable to the fact that three items have consistently been shown to reduce the discriminant validity of the measure [51].

Furthermore, less time consumed to answer the short version compared to full version. This DASS-21 questionnaire was translated into various languages all over the world and Ramli et al. translated and validated it into Malay version in 2007 [51]. This Malay version of DASS-21 was also been used to evaluate psychological impact of chronic diseases among Malaysian as part of screening program in Malaysia.

Chronic disease and disease duration were significantly associated with the three disturbances (depression, anxiety and stress), while employment status was associated with anxiety and depression [53]. Logistic regression analysis in Almawi et al., 2008 study showed that anxiety, depression, and stress were associated with T2DM after adjusting for all variables, while age was the only significant variable associated with stress [53]. Almawi et al. used DASS-21 as the measurement tools.

This DASS-21 was used in our study because it is conveniently accepted by the Ministry of Health Malaysia, to be used as assessment of psychological impact of chronic disease/s. it also is superior compared to other tools in assessing psychological factors affecting chronic disease patients particularly those who had diabetes mellitus.

2.4.1 (b) Beck Depression Inventory (BDI)

BDI is an assessment used to evaluate depression based on patients own symptoms [54]. It was derived from clinical observation about the symptoms and the attitudes displayed by the depressed patients or reported by depressive patients him/herself [54]. It was first introduced in 1961 by Beck et al. These attitudes and the symptoms were consolidated into 21 items and scaled 0 to 3 for each item. Higher values correspond to higher depressive symptomatology. Since then, it has been revised and upgraded to BDI-IA, BDI-II and BDI-PC to make it better suited for the use in the population. It has become one of the most widely instrument used for measuring the severity of depression in psychiatric patients. It was initially designed to be clinician-administered but most often it is self-administered (48,50). BDI was then translated and validated into Malay language to suite its used in the Malay population (52). However, this questionnaire was not used in this study. It is because it only cater depressive aspects while in this study other psychological factors also needed to be assess.

2.4.1 (c) Trier Social Stress Test (TSST)

In a study to compare the effect of acute psychosocial stress on glucose concentrations in the fasting state and following food intake in patients with type 1 diabetes, Psychological stress test (Trier Social Stress Test) had been used. All subjects were exposed to standardized moderate psychosocial stress by means of the Trier Social Stress Test (TSST) [55]. In brief, the TSST consists of a 5-min preparation task, a 5-min speech task where subjects have to introduce themselves and apply for a job, and a 5-min mental arithmetic task in front of an audience consisting of at least two members in white coats [55]. To enhance

stress, the session is videotaped, and the audience is trained to appear emotionally neutral [55]. At the beginning of the stress test, subjects are informed that during their performance, nonverbal communication is particularly looked at and analysed post hoc by means of the tape [55]. TSST is not the tool of choice as it require a proper place for videotaping session.

2.4.1 (d) Hospital Anxiety Depression Scale (HADS)

Gois et al., 2012 done a study on vulnerability to stress, anxiety and depressive symptoms and metabolic control in Type two diabetes and they used two scales to examine on the three symptoms which are the hospital anxiety depression scale (HADS) and he 23 questions to assess vulnerability to stress (23QVS).

The HADS is a self-report scale. It was designed to detect depressive and anxiety symptoms, and has 14 questions, seven on anxiety and seven on depression having only an answer to each question along a 0 to 3 points scale [56]. Final score ranges from 0 to 21 points for each sub-scale and a higher score means the presence of increased anxious or depression symptoms [56].

2.4.2 Assessment for Social Factors

Diabetes Care Profile (DCP)

A study which examines diabetes attitude differences by treatment modality (insulin vs. no insulin), race/ethnicity, and the interaction of these two variables for people with type two diabetes using diabetes care profile (DCP), an instrument that assesses psychosocial factors related to diabetes. The respondents in that study were divided into four patient categories (two ethnicities by two treatment modalities). The result showed treatment modality had a significant effect on 6 of the 16 DCP scales (Control, Social and Personal Factors, Positive Attitude, Negative Attitude, Self-Care Ability, and Exercise Barriers) [57]. Ethnicity was a significant effect for three scales (Control, Support, and Support Attitudes) [57]. The interaction of race/ethnicity and treatment modality was a significant effect for two related attitude scales (Positive Attitude and Negative Attitude) [57].

One section in DCP questionnaire, which is section V, social support was adapted for use in our study. This section has four main questions with sub items to evaluate social support. We adapted question number two (Q2) which consist of six questions asking about type of help and support that the patients get from their family and friends. The first question (Q1) is to determine what type of help and support that the diabetes patients want from their family and friends. Q3 is regarding the patients feeling about how family and friends care about them and their diabetes. And Q4 assessing who is the most care person in the diabetes patients' life. So, the other three questions were not included as according to the researchers from the Diabetes Research and Training Centre, the scores for all

four questions were able to be counted separately and the results were able to stand on its own.

2.4.3 Assessment on medication adherence

Although various methods and assessment tools have been used, there is still no gold standard to assess medication adherence [58]. In Malaysia, Chua et al. 2013, developed and validated a questionnaire for medication adherence assessment called Malaysian Medication Adherence Scale (MalMAS).

The MalMAS consists of one domain with 8 items and it was compared to the 8-item Morisky Medication Adherence Scale (MMAS-8) during the development of the MalMAS [58]. The face and content validity of the MALMAS was established via an expert panel. The MalMAS was found to be a more reliable questionnaire with the Cronbach's alpha value of 0.689 as compared to the MMAS-8 which was 0.504. All items in the MalMAS showed no significant difference in the test-retest analysis, indicating that the MalMAS has achieved stable reliability [58].

MalMAS was used for assessment of medication adherence not only for diabetes patients but also to patients with chronic illnesses.

2.5 Rationale of the study/ Research justification

Maintaining satisfactory metabolic control, retaining minimal complications caused by diabetes mellitus and improving the patients' quality of life are the main goals in diabetes care [59]. As we all know diabetes is one of chronic debilitating disease acquired in our Malaysian population. By assessing the psychosocial associated factors, we can further influence our Malaysian healthcare providers and patients to have better informed knowledge on these issue and later on can make changes for better glycaemic control for better future life.

There are multiple factors contributing to the glycaemic control of a diabetes patient. It includes bio-psycho-social-spiritual aspect of the patient himself. However in this study, only psychosocial factors will be evaluated because both pharmacological and non-pharmacological management had been the main intervention in daily practice while the spiritual aspect is mainly from the patients themselves. Although psychosocial factors have been examined among diabetes patients in previous studies, studies that examine comprehensively in psychological and social aspects among individuals with type two diabetes are currently unavailable especially in Kuala Terengganu. Previous studies mostly only explore one or two different factors.

Furthermore, most of the studies examined the psychosocial factors among type one diabetes patients. Only few researchers studied on type two diabetes patients. This is because patients with type one diabetes were mostly children. And their glycaemic control can be sustained or exacerbated by the inappropriate views of "significant others" whether relatives or friends [24] compared to patients with type two diabetes who are mostly adults. Children with

type one diabetes also mainly been managed in tertiary hospitals with paediatricians or endocrinologists. Only few of them were managed in primary care setting with Family Medicine Specialists. So for better view in managing type two diabetes which mostly been managed by primary care team, the psychosocial factors which may influence glycaemic control need to be evaluated.

It is important to have better level of glycaemic to reduce severe diabetes complications which later on will increase our nation expenses. Patients' quality of life also will be affected. Before these entire hazard come to life, we have to avoid them by taking appropriate action through research and studies exploring the possible causes of poor glycaemic in diabetes patients. Our study tried to evaluate the psychosocial associated factors for poor glycaemic control among those with type two diabetes.

There are so many things that our government has implemented to our health system including many more potent and latest medications to lower the glycaemic level in diabetes patients. However with only medications but without proper psychosocial support to these patients, the glycaemic status of them would not be better. Here, in this study psychosocial factors which could possibly influence glycaemic level will be examined comprehensively. It is to help our health care providers and also the patients to get better view of dealing with glycaemic status then proper and better management can be implemented.

The outcome of this study is hoped to help us, health care providers, in managing patients with type two diabetes mellitus better and improve the national health status in future as we are heading towards developed country and the diabetes patients would have better quality of life in the coming days.

2.6 Conceptual framework

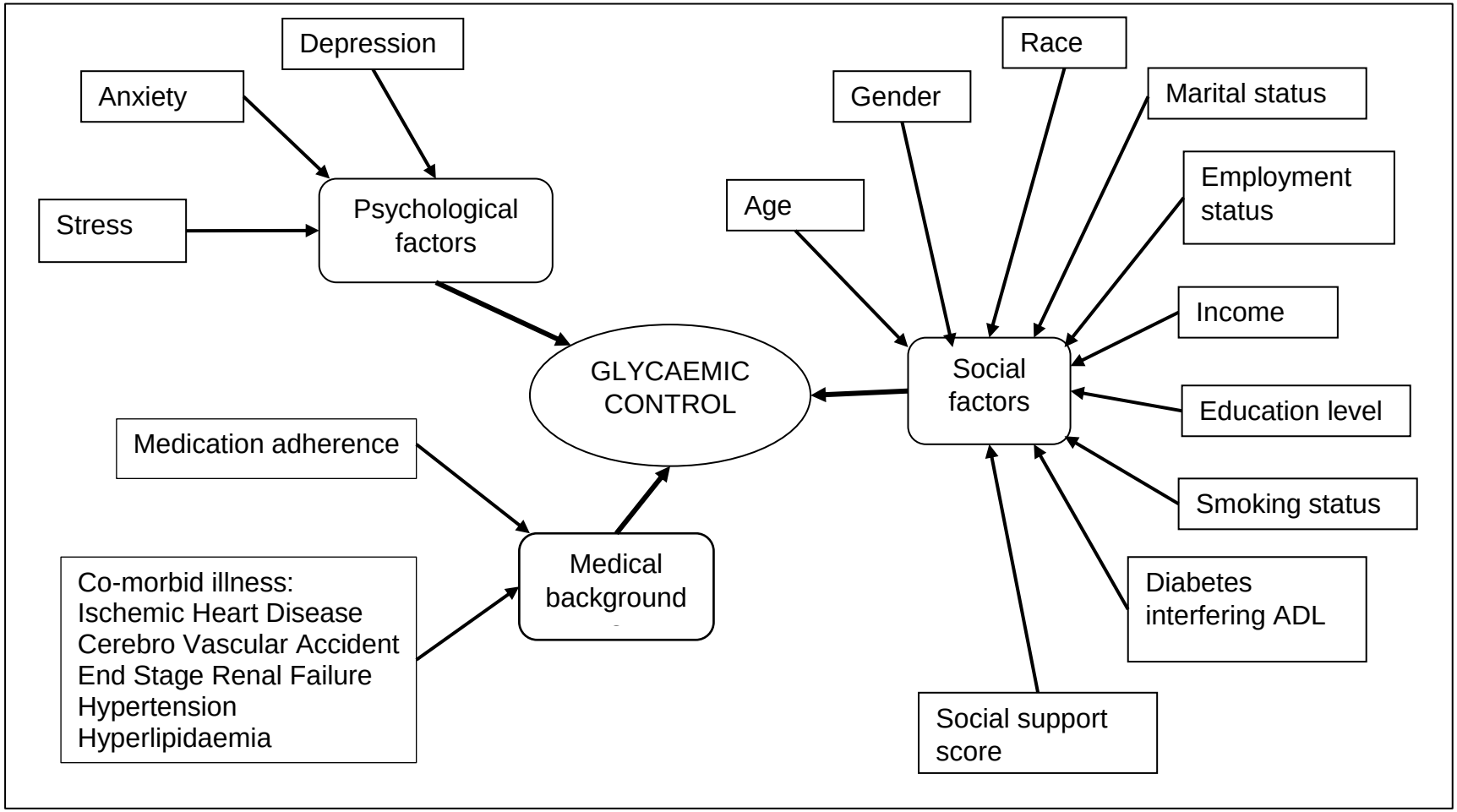

Figure 1: Conceptual framework

CHAPTER THREE: OBJECTIVES AND RESEARCH HYPOTHESIS

3.1 Objectives

3.1.1 General objective

To determine the prevalence of poor glycaemic control and its psychosocial associated factors among type two diabetes mellitus patients in Kuala Terengganu.

3.1.2 Specific objective

1) To determine the prevalence of poor glycaemic control among diabetes mellitus patients in Kuala Terengganu.
2) To identify the psychosocial associated factors for poor glycaemic control in type two diabetes mellitus patients in Kuala Terengganu.

3.2 Research Questions

1) What is the prevalence of poor glycaemic control among type two diabetes mellitus patients in Kuala Terengganu?
2) What are the psychosocial associated factors, which contribute to poor glycaemic control among type two diabetes mellitus patients in Kuala Terengganu?

3.3 Research hypothesis

Psychosocial associated factors are significantly associated with poor glycaemic control among type two diabetes mellitus patients in Kuala Terengganu.

CHAPTER FOUR: METHODOLOGY

4.1 Study design, Operational Area and Timeline:

This study is a cross sectional study conducted from December 2014 to June 2015 at outpatient health clinics in Kuala Terengganu. There are five outpatient health clinics in Kuala Terengganu. In this study, two clinics were chosen as they had the highest T2DM patients with poor glycaemic control [60-62], which were Klinik Kesihatan Batu Rakit (KKBR) and Klinik Kesihatan Seberang Takir (KKST). The average attendance of T2DM to the clinics is 50-80 patients per day.

4.2 Reference Population

The reference population was all type two diabetes mellitus (T2DM) patients attending outpatient health clinics in Kuala Terengganu.

4.2.1 Source Population

The source population was all T2DM patients attending Klinik Kesihatan Batu Rakit (KKBR) and Klinik Kesihatan Seberang Takir (KKST) from December 2014 to June 2015.

4.2.2 Sampling Frame:

All T2DM patients attending Klinik Kesihatan Batu Rakit (KKBR) and Klinik Kesihatan Seberang Takir (KKST) from December 2014 to June 2015 who fulfil the inclusion and exclusion criteria as below:

4.2.2 (a) Inclusion criteria:

1. Adult patients with T2DM aged 18 and above.
2. Duration of illness equal or more than five years [15, 63]
3. Able to understand and read either Malay or English language.
4. Able to read and write or has accompany (e.g.; relatives, caretaker, friend, etc.) to answer on questionnaire form if indicated.

4.2.2 (b) Exclusion criteria:

1. Patients having acute, severe illness or life-threatening conditions during visit which are acute coronary syndrome, hypertensive urgencies, acute stroke, acute asthmatic attack, acute heart or renal failure.
2. Type one diabetes mellitus.
3. Patients already diagnosed as having any psychotic illness such as schizophrenia. This information was obtained from patients' record book.

4.3 Sample size calculation

The sample size calculation for objective 1 was obtained using the single proportion formula while for objective 2, based on comparing two proportions using Power and Sample size (PS) software.

Based on the study done by Mafauzy, Hussein and Chan in 2008, the proportion of poor glycaemic control among type two diabetes patients was 78% [5]. We used this proportion in the calculation for sample size for objective 1.

Objective 1: To determine the prevalence of poor glycaemic control among T2DM patients in Kuala Terengganu.

By using the single proportion formula, the confidence interval was set at 95% and 5% precision, the calculated sample size was:

$N = (Z/\Delta)^2 P(1-P)$

n = required sample size

Z = 1.96 (as level of confidence was set at 95%)

Δ = precision was 0.05

P = proportion of poor glycaemic control among type two diabetes patients was 0.78 [5]

So,

$N = (1.96/0.05)^2 0.78 (1-0.78)$

$= 264$