UNIVERSITI PUTRA MALAYSIA

EMOTIONAL BURDEN AND ITS EFFECT ON DISEASE CONTROL IN PATIENTS WITH ADULT TYPE 2 DIABETES MELLITUS IN HOSPITAL SERDANG

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EMOTIONAL BURDEN AND ITS EFFECTS ON DISEASE CONTROL IN PATIENTS WITH ADULTS TYPE 2 DIABETES MELLITUS IN HOSPITAL SERDANG

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ABSTRACT

BACKGROUND: In Malaysia, every 1 in 5 adult is having diabetes mellitus. Researches in controlling Type 2 diabetes mellitus (T2DM) were more focus in term of medication, procedure in handling patient and doctor factor. Local data on the patients' emotional factors was scarce.

OBJECTIVE: To study patients' emotional burden and their effect on disease control in adult T2DM in Hospital Serdang.

METHOD: This was a cross-sectional study. Our sampling population was T2DM patients eighteen years old and above attending to Hospital Serdang. Diabetes Distress Scale (DDS) and Patient Health Questionnaire 9 (PHQ) were used to measure distress and depression level respectively. Higher score indicate higher distress and depression. Proforma was used to record patients' HbA1c, blood pressure and LDL level.

RESULT: Most of the respondents were normal in distress level (87.5%) and had minimal depression (48.1%). HbA1c level ($p=0.034$, $r_s=-0.226$) and diastolic blood pressure ($p<0.001$, $r_s=-0.397$) had significant indirect correlation with age of respondents. Chinese had lower diastolic blood pressure compared to Indian. PHQ scores correlated with LDL cholesterol level ($p=0.034$, $r_s=-0.212$). Patients with clinically significant distress (DDS score ≥ 3) were more likely to achieve blood pressure control ($p<0.001$). Patients with more complications and on more medications were associated with higher depression and distress but these associations did not reach statistical significance. There was significant correlation and significant association between distress and depression level ($p<0.001$, $r=0.423$) ($X^2= 4.46$, $p=0.035$).

CONCLUSION: T2DM patients with higher depression and distress levels could have been receiving more medical attention and medicine due to having more complications and could have facilitated them to have lower LDL cholesterol level and achieved BP control. Depression and distress might be of different psychological domains as they showed different association with disease control.

Keyword: *Type 2 diabetes mellitus, emotional burden, distress, depression, disease control, HbA1c level, blood pressure, LDL cholesterol level.*

BEBANAN EMOSI DAN KESANNYA KE ATAS PENGAWALAN PENYAKIT PESAKIT KENCING MANIS JENIS 2 DI HOSPITAL SERDANG

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ABSTRAK

LATAR BELAKANG: Di Malaysia, setiap 1 dalam 5 orang dewasa mempunyai kencing manis. Kajian mengenai pengawalan kencing manis jenis 2 (T2DM) lebih fokus kepada ubat-ubatan, prosedur dalam mengendalikan pesakit dan faktor doktor. Maklumat tempatan mengenai faktor-faktor emosi pesakit adalah terhad.

OBJEKTIF: Untuk mengkaji bebanan emosidan kesannya ke atas pengawalan penyakit pesakit kencing manis jenis 2 di Hospital Serdang.

KAEDAH: Satu kajian keratan rentas.Sampel populasi kami adalah pesakit T2DM berumur lapan belas tahun dan ke atas hadir ke Hospital Serdang. *Diabetes Distress Scale* (DDS) dan *Patient Health Questionnaire* (PHQ) soal selidik telah digunakan untuk mengukur tahap tekanan dan tahap kemurungan pesakit. Skor yang tinggi menunjukkan tahap tekanan dan kemurungan yang tinggi. Proforma telah digunakan untuk mencatat paras HbA1c , tekanan darah dan paras LDL.

KEPUTUSAN: Kebanyakan daripada responden mempunyai tekanan yang normal (87.5%) dan mempunyai kemurungan yang minimum (48.1%). Paras HbA1c ($p = 0.034$, $rs = -0,226$) dan tekanan darah diastolik ($p < 0.001$, $rs = -0,397$) mempunyai hubungan signifikan secara tidak langsung dengan umur responden.Orang cina mempunyai tekanan darah diastolik lebih rendah berbanding dengan orang India. Skor PHQ berkait rapat dengan paras kolesterol LDL ($p = 0.034$, $rs = -0,212$). Pesakit yang mempunyai tahap tekanan yang klinikal (skor DDS $\geq$ 3) lebih cenderung untuk mengawalan tekanan darah ($p < 0.001$). Pesakit yang mempunyai komplikasi yang banyak dan memakan ubat yang bayak mempunyai dikaitkan dengan tahap kemurungan yang tinggi dan tekanan tetapi kaitan ini tidak mencapai statistik yang signifikan. Terdapat hubungan yang signifikan dan yang signifikan di antara tekanan dan tahap kemurungan ($p < 0.001$, $r = 0,423$) ($X2 = 4.46$, $p = 0.035$).

KESIMPULAN: T2DM pesakit tahap kemurungan yang tinggi dan tahap tekanan boleh mendapat perhatian yang lebih, kerana mereka mempunyai komplikasi yang banyak dan boleh menolong mereka mempunyai paras kolesterol LDL yang lebih rendah dan mencapai kawalan BP. Kemurungan dan tekanan mungkin domain psikologi yang berbeza kerana mereka menunjukkan persatuan yang berbeza dengan pengawalan penyakit.

Kata Kunci: *kencing manis Jenis 2 , beban emosi, tekanan, kemurungan, pengawalan penyakit, paras HbA1c, tekanan darah, paras kolesterol LDL.*

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LIST OF ABBREVIATIONS

T2DM Type 2diabetes mellitus

DDS Diabetes Distress Scale

PHQ Patient Health Questionnaire

NMHS National Health and Morbidity Survey

NCD Non-communicable Disease

WHO World Health Organization

CPG Clinical Practice Guideline

LDL Low Density Lipoprotein

HbA1C Glycosylated Hemoglobin

SBP Systolic Blood Pressure

DBP Diastolic Blood Pressure

INTRODUCTION

In recent years, the global disease map has changed from a communicable disease to non-communicable disease (NCD). The recent report by the World Health Organization (WHO) had shown that 65% of the world deaths in 2008 were caused by the non-communicable disease with the majority of the death was from low and middle income country. The deaths by NCD were expected to increase by 15 % globally between 2010 and 2020 (WHO, 2008). In Malaysia, NCD is a common problem, especially diabetes mellitus. Every 1 in 5 Malaysian is diabetic (NHMS 2011). The prevalence of diabetes in Malaysia had increased from 11.2 % in 2006 to 15.2% in 2011 (NHMS 2011).

With the increase in diabetes among Malaysian, other complications will eventually come around. The two main groups of complication are macro vascular and micro vascular. Micro vascular Type 2 diabetes mellitus (T2DM) includes nephropathy, retinopathy, neuropathy, and small vessel vasculopathy. A report from Malaysian Dialysis Registry found that Diabetic Nephropathy (DN) was a major cause of chronic kidney disease (CKD) contributing to 57% of new patients requiring dialysis in 2007 in Malaysia (Malaysian Dialysis Registry of the National Renal Registry). Compared with the recent report, 56% of the new patients required dialysis was from diabetes mellitus patients (Malaysian Dialysis Registry, 2011). Evidence in the University of Malaya Medical Centre also showed that the prevalence of diabetic retinopathy was more than half, which was 51.6% (112 out of 217 patients) (I Tajunisah,2006). Moreover, complication caused by macro vascular diabetes was also a major issue. Increase in the diabetic foot (one of the macro vascular type) among diabetic patient attending Kuala Langat Health Centre from 1999 to 2008 was also another major

concern with an average of 9.9% annually of patients having diabetic foot (Faridah et al, 2009).

Treatment of Type 2 diabetes mellitus in Malaysia follows the Malaysian Clinical Practice Guideline and it has already been used by majority of the Malaysian clinicians. It is mainly composed of oral hypoglycemic agent. Metformin is the preferred choice and other alternative drugs are acceptable. If that does not work, combination of oral hypoglycemic agents is effective in T2DM which are Biguanide, metformin and other insulin secretagogues agents.

Although in Malaysia there are many efforts has been done in reducing and controlling diabetes by the Ministry of Health which includes introducing campaigns, advertisements and special programs, as well as the addition of the Malaysian Clinical Practice Guideline on handling diabetic patients, the prevalence of diabetes in Malaysia is still rising and not getting any better.

1.1 Problem statement

Researches in controlling Type 2 diabetes mellitus were widely done. However, more researches were focus in term of medication doses and regimen, procedure in handling patient and doctor factor. Local data on the emotional factors affecting the controlling of Type 2 diabetes mellitus was scarce.

Therefore the aim of this study was to study patients' emotional burden and their effect on disease control in adult Type 2 diabetes mellitus (T2DM) in Hospital Serdang. Information

obtained from this research hope would be useful to clinicians in optimizing the emotional management of Type 2 diabetes mellitus patient in order to achieve better disease control.

1.2 Objectives

1.2.1 General objective

To study patients' emotional burden and their effect on disease control in adult Type 2 diabetes mellitus (T2DM) in Hospital Serdang.

1.2.2 Specific objectives

- To determine the characteristic of Type 2 diabetes mellitus patients in Hospital Serdang according to
  - ✓ Their socio-demographic profile
  - ✓ Their lifestyle profile
  - ✓ Their distress and depression level
  - ✓ Their disease control based on HbA1c level, blood pressure level and LDL cholesterol level
- To relate socio-demographic profile of Type 2 diabetes mellitus patients in Hospital Serdang with their disease control.
- To relate lifestyle profile of Type 2 diabetes mellitus patients in Hospital Serdang with their disease control.
- To relate distress and depression level of Type 2 diabetes mellitus patients in Hospital Serdang with their disease control.
- To relate number of disease complications of Type 2 diabetes mellitus patients in Hospital Serdang with their distress and depression level.

- To relate number of medications taken by Type 2 diabetes mellitus patients in Hospital Serdang with their distress and depression level.
- To relate distress level with depression level of Type 2 diabetes mellitus patients in Hospital Serdang.

*Disease control refers to the control of patients' HbA1c level (glycemic control), blood pressure level (blood pressure control) and LDL level (cholesterol control).

*Emotional burden includes distress and depression level which were measured by using Diabetes Distress Scale (DDS) and Patient Health Questionnaire (PHQ) score respectively.

1.3 Research hypothesis

There is no association between patients' emotional burden and disease control in patients with adult Type 2 diabetes mellitus. (Null hypothesis)

LITERATURE REVIEW

2.1 Social demography

Malaysian T2DM scene is mainly increasing in the older generation. In 2011 most of the diabetic are from 55 years old and above. 40-55 years showing a quiet high number of prevalence. To compared with the prevalence in 2006, among the age group 50 above show a bit lower. (NHMS 2011 and NHMS 2006)

Male are higher risk than their female counterpart. With 15.5 % of prevalence among male and only 14.6% are from female in 2011. (NHMS 2011 and NHMS 2006)

Among the state of Malaysia, in 2011 Perlis is the highest with 24.8% prevalence of diabetes mellitus, followed by Negeri Sembilan and Kedah with 22.0% and 22.5%. Compared, in 2006 Perlis is not highest but in was Negeri Sembilan which was 15.3%. Even though the states were not same, the worrying number was the increase of about 5%, which show diabetes is not reducing. (NHMS 2011 and NHMS 2006)

In 2011, when it comes to ethnicity Indian dominated above all main ethnicity in Malaysia with nearly 25% (24.9%) are diabetic, followed by the Malay which is 16.9% and the Chinese 13.8%. In 2006 Indian also was highest prevalence of diabetes which was 19.9%. This increase in prevalence between 2006 and 2011 is alarming. (NHMS 2011 and NHMS 2006)

When comparing marital status, divorce/windowed are the highest with 27.2% is the prevalence and only 18.4% among married couple and only 5.5% among people who are single. (NHMS 2011 and NHMS 2006)

Education level also saw a change. Prevalence of about 22% is coming from people who are either have no formal education or having only primary school education. The prevalence of diabetes among the secondary and the higher education is the half of the primary and the no formal education level. (NHMS 2011 and NHMS 2006)

Income status is also important. The finding by the Malaysian health instituted found that majority of the prevalence are low income status (RM 1000 below). People who are income status above RM1000 are around 13-15% prevalence. (NHMS 2011 and NHMS 2006)

2.2 Emotional Distress

All in all, study done Tanzania found that the important of keeping the distress control and in improving social support , which is another important factor in keeping the patient motivation high (Theobald C. E. Mosha and Heri Rashidi, 2009).

Supports it's important for building self-confidence. This study show a good control of diabetes is done if the managing the problem of patient and improving social support (Whittermore et al, 2005).

A cohort study done in Sweden showed that psychological distress is important as it can increase the risk of having T2DM, especially in men. (AK Erikson, 2008). Psychosocial factors also have been found to play an important factor with glycemic control in T2DM and there is association between mood states and glycemic control (Nakahara et al,2006).

Another study also showed the similar result there is association between distresses and glycemic control compared with other factor such as physical activity (L. Fisher, 2010).

A result from a study found there are more significant higher mean in their distress score of patient who has poor glycemic control compare with good glycemic control (Anthonia Ogbera and Adekunle Adeyemi-Doro, 2009).

A study done showed that distress does related with poor glycemic control. 65% of the subject found to be distress and having poor glycemic control (Yasuaki Hayashino et al, 2012).

Another study also showed that distress and poor glycemic are related (Sasi Sekhar TVD, 2013).

Study patient with both distress and depress show worst glycemic control and when depression n depress combined the odd ratio are even higher (K. M. P. van Bastelaar, 2010).

The study done by L Fisher et al in 2010 show there are association between high HbAlc related depressive effect and diabetes distress than anxiety disorders (L. Fisher, 2008).

Randomized control trial done in Holand found that improving the distress of the patient show a better result compared to those who have followed the distress management program (Jenny van Son et al2012).

All in all, the association between depression and glycemic control, diabetes-specific emotional distress appears to be an important mediator. Addressing diabetes-specific emotional problems as part of depression treatment in diabetes patients may help improve glycemic outcomes (K. M. P. van Bastelaar, 2010).

2.3 Depression and Diabetes

Depression is a common mental disorder that presents with depressed mood, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, low energy, and poor concentration (WHO, 2008).

Depression can be defined as persistent prolonged low mood, associated with reduced interest lasting for at least two weeks duration, affecting his/ her social and occupational functioning, regardless of the underlying causal factors (Malaysia Guideline for Management of Depression in Primary Care, 2008). Without treatment, depression has the tendency to assume a chronic course, to recur, and to be associated with increasing disability over time (WHO, 2007).

Depression is twice as prevalent in patients with diabetes compared with those without the disorder, and many people with a diagnosis of diabetes suffer depressive symptoms and distress (Anderson RJ et al., 2001).

A study also done in tertiary care in India show one fourth of the patient is depressed. Patients with long duration of diabetes and on combination of anti-diabetic drugs were significantly associated with depression (K. G. Guruprasad et al 2012)

In study done by Engum et al., (2005) involving 65648 respondents and using Hospital anxiety and Depression (HADS) for screening of depression, revealed 19.0% Type 2 likely to be depressed as compared to non- diabetic population (Engum et al., 2005).

In a study, they concluded that failure to detect and manage depression may compromise the management of diabetes itself (Roberts et al., 2004). Major depression affects approximately one of every five patients with diabetes and severely impairs quality of life and all aspects of functioning. These disorders can lead to poor glycemic control through alterations in neurohormonal and neurotransmitter and through disruption in diabetes self-care (Gavard et al., 1993). Depression may impact on diabetes outcomes by reducing patient adherence with self-care or by reducing the effectiveness of medical care by disrupting doctor–patient communication. Observational studies suggest that depression reduces self-care behaviours which in turn impacts on diabetes outcomes (Piette J et al., 2004). Among adults with diabetes, depression impedes the adoption of effective self-management behaviors (including physical activity, appropriate dietary behavior, foot care, and appropriate self-monitoring of blood glucose behavior) through a decrease in social motivation (Leonard E. Egede et al., 2010).

A meta-analysis study by Mary et al., (2001) revealed that depression was significantly associated with a variety of diabetes complications (Mary et al., 2001). Co-morbidity of depression and diabetes is associated with disease complications and mortality. Depression may also be an important risk factor in developing diabetes (Mezuk B et al., 2008).

A study relating blood pressure and depression in situation show that , high systolic blood pressure in both high arouse and low arouse situation but low depression situation(Dmitry M. Davydov et al, 2012)

On the other hand, study done by M. Papelbaum et al in 2010 show depression has no effect on glycemic control (M. Papelbaum et., 2010).

While a study done relating LDL level and depression showed that people who had already known their LDL level was high had no sign of depression symptom on them (Gunnar Einvik et al 2008).

A local study done in Penang showed that females who were older were depressed (Tahir M Khan et al 2011).

2.4 Lifestyle

Lifestyle modification is one of the major determinants of diabetes control (T.S. Sanal et al.). Lifestyle related risk factors such as obesity, eating behavior, and physical activities are important in the prevention and treatment T2DM (Wing RR et al., 2001). However, this is often the most challenging aspect of care for both patients and healthcare practitioners (Marie Clark, 2002).

Evidences from a few cross-sectional and prospective studies demonstrate the role of obesity and a sedentary lifestyle as major risk factors for the development of T2DM (Tuomilehto J, 1989; Perry IJ, 1995; Harris MI et al., 1998). A study found that a lifestyle intervention including diet and exercise decreased the risk of diabetes by 50% (Eriksson and Lindgarde, 1991) while a study conducted in China reported a 25% risk reduction from either diet, exercise, or the combination of both, compared with a control group (Pan et al., 1997). Results indicate that lifestyle changes can reduce the risk of progression to diabetes by 58% over 4 years in both men and women at high risk of the disease (Tuomilehto et al., 2001).

Studies have shown that these factors can lead to reduction in risk of developing further complications of diabetes mellitus if effectively well controlled. This indicates that for a better control of blood glucose and total cholesterol in diabetics, balanced and healthy diets as well as a good and regular exercise regime are necessary. (Puska P et al., 1983; Salonen JT et al., 1983; Fortmann SP et al., 1995).

When data of smokers versus non-smokers was compared, it was found that the smokers had significantly higher values of TC, LDL-C, VLDL-C and TG than that of non-smokers, both prior to and after intervention (S.M. Deshmukh, 2000).

In the Nurses' Health Study, it is found that the risk of T2DM decreased with the increase of alcohol consumption (ranging from 1.5 to 415 g/day) (Stampfer MJ et al., 1988). After adjustment for confounders, the men who drank more than three drinks per day were found to have a 50% increased risk of developing T2DM. Light to moderate drinking was associated with a decrease in risk of developing type 2 diabetes mellitus in univariate analysis but this effect was lost after adjustment for potential confounders (Kao WH et al.,2001). The US Male Physicians' study which used rarely/never drinkers as the reference group found that light to moderate alcohol intake was associated with a reduced risk of diabetes (Ajani UA et al.,2000).

The largest national study into diabetes prevalence in Australia estimated that 44% of participants with impaired glucose were obese – suggesting that 56% were not – and that 15.9% of those who were obese did not have impaired glucose (Dunstan et al. 2001). Despite the complex causal pathways that lead to diabetes, the disease is increasingly represented in deceptively simple terms. 2000 researchers, commentators and policy-makers in Australia have linked the rise in diabetes directly to the increases in obesity in the same populations (Barr et al. 2006;Colagiuri et al. 2006; Duke, Colagiuri, and Colagiuri 2009; Dunstan et al. 2001; Zimmet 2001). In this framing, overweight and obesity are not symptoms of diabetes but have become a significant contributing factor; diabetes has emerged as an obesity-related

condition of epidemic proportions and the two 'conditions' have been merged into diabesity (Darlene M.N 2013).

The Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study confirmed that, in individuals with diabetes, improved metabolic control (achieved via an intensive self-care regimen that included lifestyle change) was significantly associated with delayed onset and progression of microvascular complications (DCCT, 1993; UKPDS, 1999). From another study in Japan, lifestyle modifications can prevent T2DM among overweight Japanese with impaired fasting glucose levels (Saito, Toshikazu et al., 2011).

2.5 Disease control

Age

Age and glycemic control are related to one another, a study done in India show that age, sex , distress, and BMI is related with poor glycemic control. (Sasi Sekhar TVD,2013)

Increase age is related with the increase Systolic blood pressure level.(Shivananda b. Nayak et al, 2012)

Diabetic patient can also have hypertension. The risk factor which are age,BMI,HbA1c level and education level are found in the study done in Hospital USM.(Salwa Selim Ibrahim Abougalambou and Ayman S. Abougalambou , 2013)

In a local study done, also shows that older age are also prone to get uncontrolled blood pressre. (Boon How Chew et al 2012)

Gender

An international study also found that poor glycemic control does not related to gender. (Ranjita Misraa, Julie Lagerb 2009)

Age and glycemic control are related to one another, a study done in India show that age, sex, distress, and BMI is related with poor glycemic control. (Sasi Sekhar TVD et al,2013)

A study done in Pahang about blood pressure in diabetic patient show that female has higher Systolic Blood Pressure over male.(SMS Azarisman et al 2010)

Ethnicity

A same international study conducted on gender show that Asian have good glycemic control over others.(Ranjita Misraa, Julie Lagerb 2009)

A study done by IS Ismail et al show that the Chinese had better glycemic controlled over the other race. Glycemic controlled is not effected by BMI, gender, education level and household income(IS Ismail et al, 2000)

A study done locally show that Indian are having higher HbA1c level co pared to other race(C Y Hong et al, 2004)

Another study done by Shivananda b. Nayak et al in 2012 show that East Indian had highest Diastolic blood pressure to other race in Trinidad. (Shivananda b. Nayak et al in 2012)

While study done locally show that Chinese and Indian are less likely to have hypertension(C Y Hong et al,2004). Furthermore, a local study done also found that the Malay are likely to have uncontrolled blood pressure.

Disease Controlled

A study done cross seven nation which consist of three develop and 4 undeveloped countries found that patient achieving the WHO goal of all controlled are very low ranging from 1%-12%. (Emmanuela Gakidou et al,2011)

2.6 Conceptual framework

Title: Emotional Burden and Its Effect on Disease Control of Patient with Adult Type 2 Diabetes Mellitus

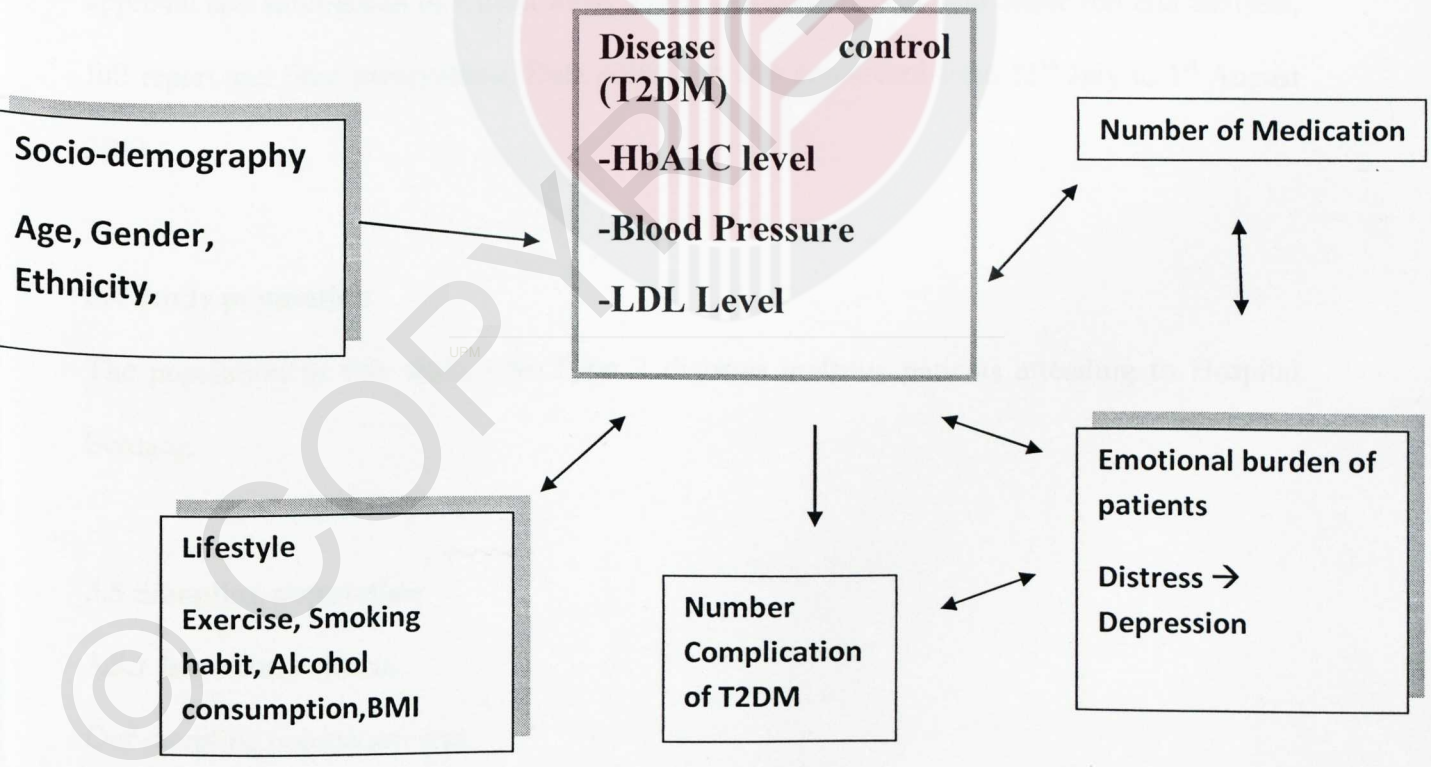

Figure 2.6.1 Conceptual Framework

METHODOLOGY

3.1 Study location

This study was carried out at Diabetes Clinic in Hospital Serdang.

3.2 Type of study

A cross-sectional study design was used to study association between Type 2 diabetes mellitus patients' emotional burden with their disease control.

3.3 Study duration

Our study took around six months duration, from 28th March to 6th September 2013 which consisted of 2 phases. Phase one consisted of proposal preparation, presentation as well as approval and submission of ethical form. Phase two consisted of data collection and analysis, full report and final presentation. Data collection was conducted from 15th July to 1st August 2013.

3.4 Study population

The population in this study was Type 2 diabetes mellitus patients attending to Hospital Serdang.

3.5 Sampling population

3.5.1 Inclusion criteria

Our sampling population was

- Type 2 diabetes mellitus patients with age range 18 years old and above in Hospital Serdang
- Understand Malay or English or Chinese.

3.5.2 Exclusion criteria

- paediatric patients
- pregnant mothers
- patients with Type 1 diabetes mellitus
- patients with memory impairment
- foreigners

3.6 Sampling unit

A type 2 diabetes mellitus patient attending diabetes clinic of Hospital Serdang was the sampling unit of this study.

3.7 Sampling method

We used universal sampling method in this study. Patients attending to diabetes clinic in Hospital Serdang during our research period were invited.

3.8 Sample Size

The sample size was being calculate by :

$$\frac{\left\{Z\left(1-\frac{\alpha}{2}\right)\sqrt{2\overline{P}(1-\overline{P})}+\ Z(1-\beta)\sqrt{P1(1-P1)+\ P2(1-P2)}\right\}^2}{(P1-P2)^2}$$

Comparison between Indian with Malay: (P1=0.249,P2=0.169)

$$=\frac{\{1.96\sqrt{2(0.04)(0.96)}+0.842\sqrt{(0.249)(0751)+(0.169)(0.831)}\}^2}{(0.08)^2}$$

= 164.1544= 165

Comparison between Indian with Chinese: (P1=0.249,P2=0.138)

$$= \frac{\left\{1.96\sqrt{2(0.0555)(0.9445)} + 0.842\sqrt{(0.249)(0.751) + (0.138)(0.862)}\right\}^2}{(0.111)^2}$$

= 98.271= 99

Comparison between Malay with Chinese: (P1=0.169,P2=0.138)

$$= \frac{\left\{1.96\sqrt{2(0.0155)(0.9845)} + 0.842\sqrt{(0.169)(0.831) + (0.138)(0.862)}\right\}^2}{(0.031)^2}$$

= 618.96= 619

Since the number of subject was limited in Hospital Serdang, we used 99 as our sample size.

Thus, the total sample size = n + 20%n

= 99+ 20% (99)

= 118 subjects

Total minimum size of sample in this study was 118 subjects. About 20% non-response rate was added to make sure to cover if the subjects were unavailable or we received incomplete questionnaire. P1 and P2 were taken from NHMS 2011.

3.9 Parameters / variables

3.9.1 Dependent

- Disease control of Type 2 diabetes mellitus patient by parameter HbA1c level, blood pressure level and cholesterol level of patient
- Emotional burden of Type 2 diabetes mellitus patient (*only when compared with number of disease complications and number of medication taken by Type 2 diabetes mellitus patient)

3.9.2 Independent

- Emotional burden of Type 2 diabetes mellitus patient
- Socio-demography profile of Type 2 diabetes mellitus patient
- Lifestyle profile of Type 2 diabetes mellitus patient
- Number of disease complications of Type 2 diabetes mellitus patient
- Number of medication taken by Type 2 diabetes mellitus patient

3.10 Study instrument

Questionnaire and proforma were used as the study instruments for this study. Questionnaire was used to measure patient's related factors such as socio-demography, distress and depression level as well as lifestyle. At the same time, proforma was used to determine the disease control of the respondents, height, weight, number of disease complication and number of medication taken. Height and weight is used to calculated the Body Mass Index(BMI)

3.10.1 Social demography

In this part of questionnaire, we included age, sex, ethnicity, marital status, income status and educational level of patient.

3.10.2 Emotional Distress

The Diabetes Distress Scale (DDS) questionnaire was used to measure the distress level of respondents. It consisted of seventeen items which covered emotional burden distress, physician-related distress, regimen-related distress and diabetes-related interpersonal distress. In each scale we used the Likert Scale from 1(not a problem) to 6(very serious problem) to answer each of the questions ask. Mean score of total DDS score and of every single subscale score were counted. Mean score less than three indicated normal distress level while mean score three or higher indicated distress level which requires clinical attention.

The reliability of the questionnaire was around 0.83. For each subscale, the highest were emotional burden distress and regimen-related distress which were both 0.88, followed by diabetes-related interpersonal distress(0.76) and physician-related distress(0.67) (William H. Polonsky et al., 2005).

3.10.3 Depression and Diabetes

Depression level was measured using the Patient Health Quality 9 questionnaire (PHQ). This questionnaire consisted of 9 items. Every item had 0 (not at all), 1 (several days), 2 (more than half the days) and 3 (nearly every day) as the choices of the answer. Scores of all the 9 items would be added up. Score from 0 to 4 indicated minimal depression, 5 to 9 indicated mild depression, 10 to 14 indicated moderate depression, 15 to 19 indicated moderately severe depression and 20 to 27 indicated severe depression.

This questionnaire had a sensitivity of 88% and specificity of 88% (Kurt Kroenko, et al 2001). It had also been tested in Malaysia. In Malaysia the sensitivity is 87% and specificity of 82% (MS Sherina, B Arroll and F Goodyear-Smith, 2012).

3.10.4 Lifestyle

In lifestyle factor, we included obesity, exercise, smoking habit and alcohol consumption of patient in our questionnaire. Obesity was measured using height and weight recorded in proforma.

3.10.5 Disease control

Proforma was used to record disease control status of patient. Case record form contained table to record patients' HbA1c level, blood pressure level and LDL cholesterol level.

Criteria	**Value which consider achieved target**
Glycemic level	Hb1Ac level < 6.5%
Blood Pressure	≤ 130/80 mmHg
Cholesterol level	LDL cholesterol – ≤ 2-6 mmol/L

Taken from the Malaysian Clinical Practice Guideline (4th Edition) 2009

Patients' height, weight, number of disease complication and number of medication taken were also included in proforma.

3.11 Data collection

Data collection involved respondents who were Type 2 diabetes mellitus patients by means of a cross-sectional data through questionnaire. Researchers provided all the necessary information to the participants before and while administering the questionnaires. All respondents were asked to sign a consent form before participating in this study. After the consent was obtained, respondents needed to answer all the questions. Duration for the respondents to answer was around 20 minutes.

Proforma was used to collect the disease status of the patients and their disease control was examined. Data on obesity, number of disease complication and number of medication taken by respondents were also collected through proforma.

3.12 Data analysis

The data collected was analyzed using SPSS Version 21.0. Descriptive statistics were generated. We used Spearman test to study the correlation between variables, Mann Whitney U test to find the association between quantitative and qualitative variables, Kruskal-wallis test to find the association between quantitative and qualitative variables (more than 2 groups) and chi-square x^2 to find the association between qualitative and qualitative variables.

3.13 Study ethics

Ethics committee approval was obtained from the Medical Research Ethics Committee, Ministry of Health, Malaysia and Ethics Committee Faculty of Medicine and Health Sciences, University Putra Malaysia (UPM). We also obtained permission from Hospital Serdang to carry out data collection for the study.

3.14 Terms definition

Terms (Socio-demography)	Definition
Age	The age is counted from the day the patients were born; date of birth is based on their identification card.
Ethnicity	Ethnicity is determined following the paternal side.
Gender	Gender is identified based on JPN report.

Terms (Lifestyle)	Definition
Smoking habit	Smoking habit was divided into 4 categories : Never, Yes, I have stopped smoking more than 5 years, I have stopped smoking less than 5 years.
Alcohol consumption	Alcohol consumption was divided into 3 categories : Never, Yes, Have stopped drinking. * For the 'Yes' option, respondents were required to state the types of drinks and the amount taken per week in Ounces. *1 Ounces = 30 mls

Obesity	Obesity was determined based on BMI of patient. BMI = weight in kilogram / (height in meter)^2 BMI > 23 is counted as overweight. BMI > 27.5 is counted as obese.
Exercise	Only regular and consistent physical activity was counted as exercise. There were 3 categories : No, I do at most 3 times in a week, I do more than 3 times in a week.

Terms **(Emotional burden)**	**Definition**
Distress	Physical or mental suffering. Distress level was determined using DDS score. Mean score of total DDS score and of every single subscale score were counted. • <3 normal distress level • ≥3 requires clinical attention.
Depression	Being depressed and low spirits Depression level was determined using PHQ-9 score. Scores of all the 9 items would be added up. • 0-4 minimal depression • 5-9 mild depression • 10-14 moderate depression

	• 15-19 moderately severe depression • 20- 27 severe depression.

Terms	Definition
Number of medication	Total number of medication taken by respondents only included current medications taken.
Number of disease complication	Disease complications included five complications which were cerebrovascular disease, ischaemic heart disease, retinopathy, nephropathy and diabetic foot problems. Number of disease complication was counted based on presence of these five complications.

DATA ANALYSIS

4.1 Response Rate

One hundred and eighteen patients were approached and invited to participate, out of 118, 104 respondents responded. This gave an overall response rate of 88.1%.

4.2 Normality Test

Distribution of continuous variable was determined using Kolmogorov-Smirnov normality test. A variable was considered as normally distributed if the value of p (Kolmogorov-Smirnov) was greater than 0.05 and the skewness and kurtosis values were approximate to zero. Table I showed the values of Kolmogorov-Smirnov test and its skewness and kurtosis. It showed that the variables were not normally distributed.

Table I: Normality Test for Continuous Variables

Variable	Kolmogorov-Smirnov	Skewness	Kurtosis
Age	0.195	-0.477	-0.092
HbA1c	0.001	0.846	1.192
Systolic Blood Pressure	0.004	-0.049	0.221
Diastolic Blood Pressure	0.200	0.179	-0.065
LDL Cholesterol	0.000	0.953	1.740

4.3 Descriptive Statistic

4.3.1 Socio-demographic of respondents

Figure 4.1 showed the distribution of age of respondents in this study. Mean of age was 58.6 while standard deviation was 13.03.

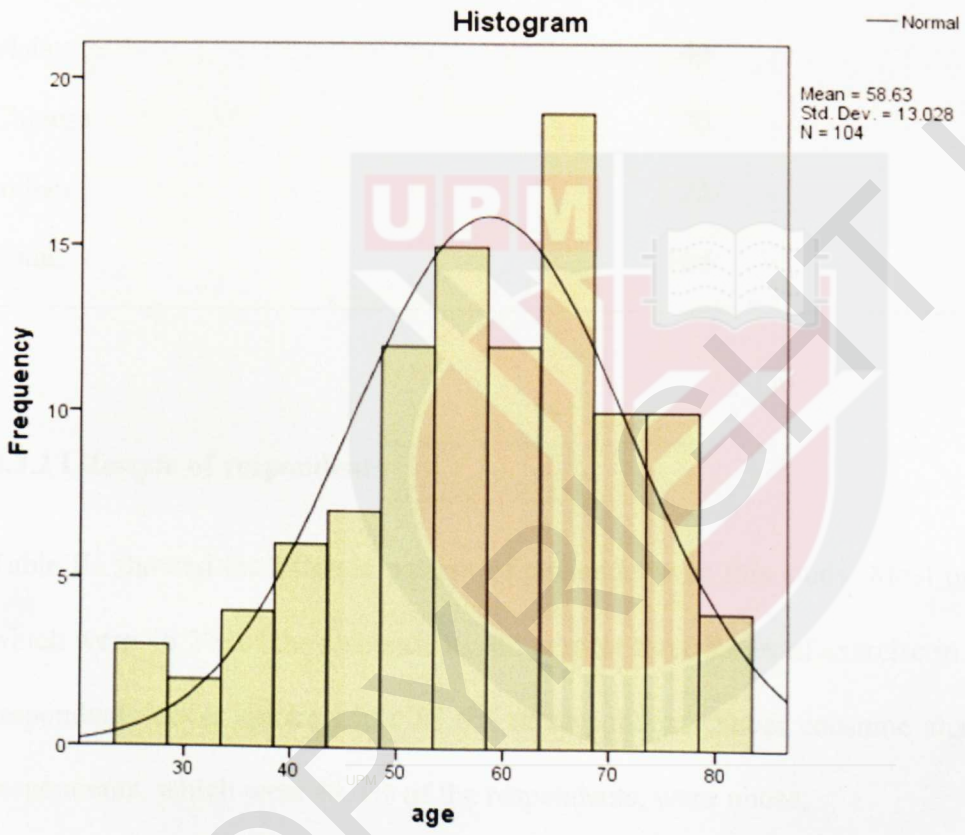

Figure 4.1 Distribution of age of respondents

Table II showed the distribution of gender and ethnicity of respondents in this study. There were 51.9% male and 48.1% female. There were 44.2% Malay, 34.6% Chinese and 21.2% Indian.

Table II Gender and ethnicity of respondents

Factor	Frequency (n)	Percentage (%)

Gender		
Male	54	51.9
Female	50	48.1
Total:	**104**	**100.0**
Ethnicity		
Malay	46	44.2
Chinese	36	34.6
Indian	22	21.2
Total:	**104**	**100.0**

4.3.2 Lifestyle of respondents

Table III showed the lifestyle pattern of respondents in this study. Most of the respondents, which were 46.2% of the respondents, do at most three times of exercise in a week. 76.9% of respondents never smoke while 85.6% of respondents never consume alcohol. Most of the respondents, which were 44.6% of the respondents, were obese.

Table III Lifestyle pattern of respondents

Factor	Frequency (n)	Percentage (%)	Valid Percentage (%)
Exercise			
No	32	30.8	
I do at most 3 times in a week	48	46.2	
I do more than 3 times in a week.	24	23.1	
Total:	**104**	**100.0**	

Smoking habit			
Never	80	76.9	
Yes	10	9.6	
I have stopped smoking more than 5 years	8	7.7	
I have stopped smoking less than 5 years	6	5.8	
Total:	**104**	**100.0**	
Alcohol consumption			
Never	89	85.6	
Yes	9	8.7	
Have stopped drinking	6	5.8	
Total:	**104**	**100.0**	
Obesity			
Normal	16	15.4	17.4
Overweight (BMI>23)	35	33.7	38.0
Obese (BMI>27.5)	41	39.4	44.6
Total:	92	88.5	**100.0**
Missing System	12	11.5	
Total:	**104**	**100.0**	

4.3.3 Distress and depression level among respondents

Table IV showed the central tendency and dispersion of distress and depression level among respondents. It showed that distress score of respondents had the mean around two while depression score had the mean around six. Emotional burden score had the highest mean of around 2.4 while interpersonal distress score had the lowest mean of around 1.5.

Table IV Central tendency and dispersion of distress and depression level among respondents

	Mean DDS score	Mean emotional burden score	Mean physician distress score	Mean regimen distress score	Mean interpersonal distress score	Total PHQ score
Mean	1.9712	2.3846	1.7260	2.0346	1.5032	6.01
Median	1.7941	2.2000	1.0000	1.8000	1.0000	5.00
Mode	1.12	1.00	1.00	1.00	1.00	2
Std. Deviation	0.85672	1.20119	1.16091	0.95955	0.88861	5.613
Variance	0.734	1.443	1.348	0.921	0.790	31.505
Range	4.18	5.00	5.00	4.40	5.00	27
Minimum	1.00	1.00	1.00	1.00	1.00	0
Maximum	5.18	6.00	6.00	5.40	6.00	27

Mean DDS score consists of 1-6marks while total PHQ score consists of 0-27marks.

Table V showed frequency and percentage of DDS result score categories. Most of the respondents which were 87.5% of respondents were normal in level of distress and did not required clinical attention.

Table V Frequency and percentage of DDS result score categories

Categories of DDS result score	Frequency	Percentage
Normal (score<3)	91	87.5
Required clinical attention (score≥3)	13	12.5
Total	**104**	**100.0**

Table VI showed frequency and percentage of PHQ result score categories. 48.1% of the respondents had minimal depression.

Table VI Frequency and percentage of PHQ result score categories

Categories of PHQ result score	Frequency	Percentage
Minimal depression (0-4)	50	48.1
Mild depression (5-9)	30	28.8
Moderate depression (10-14)	17	16.3
Moderately severe depression (15-19)	4	3.8
Severe depression (20-27)	3	2.9
Total	**104**	**100.0**

4.3.4 Disease control among respondents

Table VII showed central tendency and dispersion of parameters of disease control which included HbA1c level, systolic and diastolic blood pressure as well as LDL level.

Table VII Central tendency and dispersion of disease control

		Glycemic control	Blood pressure control		Cholesterol control
		HbA1c	Systolic	Diastolic	LDL
N	Valid	88	104	104	100
	Missing	16	0	0	4
Median		7.2500	141.00	80.00	2.4650
Standard Deviation		2.34223	16.263	11.082	1.01478
Variance		5.486	264.494	122.806	1.030
Range		13.50	86	54	6.25
Minimum		2.40	100	56	0.00
Maximum		15.90	186	110	6.25

Table VIII showed that only one respondent had all three controlled targets of disease treatment. Most respondents which were 38.5% achieved one controlled target of disease control parameters.

Table VIII Frequency and percentage of number of disease control parameters which achieved target

Number of Target Control Achieved	Frequency	Percentage	Valid Percentage
All 3	1	1.0	1.1
2	23	22.1	26.4
1	40	38.5	46.0
None	23	22.1	26.4
Total	87	83.7	100.0
Missing data	17	16.3	
Total	104	100.0	

Three disease treatment targets are HbA1C <6.5%, Blood pressure ≤ 130/80 mmHg and LDL cholesterol ≤ 2.6 mmol/L.

4.4 Association between socio-demographic profile of patients and disease control of Type 2 diabetes mellitus

Age

Table IX showed the association between age and disease control among the respondents. It showed that HbA1c level (p=0.034) had significant poor indirect correlation (r_s=-0.226) with age of respondents. Diastolic blood pressure (p<0.001) had significant fair indirect correlation (r_s=-0.397) with age of respondents. The older patient had the lower HbA1c level and diastolic blood pressure. Systolic blood pressure (p=0.306) and LDL level (p=0.060) were not significantly correlated with age of respondents.

Table IX Correlation between age and disease control

	HbA1c	Systolic Blood Pressure	Diastolic Blood Pressure	LDL
Age				
Spearman's correlation coefficient	-0.226*	0.101	-0.397**	-0.189
p-value	0.034	0.306	0.000	0.060
N	88	104	104	100

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Gender

HbA1c

Table X showed association between gender of respondents and HbA1c level. It showed that there was no significant difference in HbA1c level (p=0.341) among gender.

Table X Comparison of HbA1c level between genders of respondents

HbA1c	N	Mean Rank	Z	P
Male	44	41.91	-0.952	0.341
Female	44	47.09		
Total	88			

Table XI showed association between gender of respondents and control of their HbA1c level. Gender had no significant association with HbA1c control (p=0.237).

Table XI Association between gender and control of HbA1c level

	HbA1c control, n (%)		Total	X^2	p
	<6.5%	>6.5%			
Gender				1.397	0.237
Male	15 (34.1)	29 (65.9)	44 (100.0)		
Female	10 (22.7)	34 (77.3)	44 (100.0)		
Total	25 (28.5)	63 (71.6)	88 (100.0)		

Blood Pressure

Table XII and table XIII showed association between gender of respondents and blood pressure. It showed that there was no significant difference in blood pressure (p=0.345) (p=0.837) among gender.

Table XII Comparison of systolic blood pressure between genders of respondents

Systolic Blood Pressure	N	Mean Rank	Z	P
Male	54	49.81	-0.944	0.345
Female	50	55.40		
Total	104			

Table XIII Comparison of diastolic blood pressure between genders of respondents

Diastolic Blood Pressure	N	Mean Rank	Z	P
Male	54	51.92	-0.205	0.837
Female	50	53.13		
Total	104			

Table XIV showed association between gender of respondents and control of their blood pressure. There was no significant association between gender of respondents and their blood pressure control (p=0.734).

Table XIV Association between gender and control of blood pressure

	Blood pressure control, n (%)		Total	X^2	p
	≤130/80mmHg	>130/80mmHg			
Gender				0.115	0.734
Male	10 (18.5)	44 (81.5)	54 (100.0)		
Female	8 (16.0)	42 (84.0)	50 (100.0)		
Total	18 (17.3)	86 (82.7)	104 (100.0)		

LDL

Table XV showed association between gender of respondents and LDL level. It showed that there was no significant difference in LDL level (p=0.704) among gender.

Table XV Comparison of LDL cholesterol level between genders of respondents

LDL	N	Mean Rank	Z	P
Male	52	49.44	-0.379	0.704
Female	48	51.65		
Total	100			

Table XVI showed association between gender of respondents and control of their LDL level. There was no significant association between gender of respondents and control of LDL level (p=0.754).

Table XVI Association between gender and control of LDL level

	LDL control, n (%)		Total	X^2	P
	≤2.6mmol/L	>2.6mmol/L			
Gender				0.098	0.754
Male	33 (63.5)	19 (36.5)	52 (100.0)		
Female	29 (60.4)	19 (39.6)	48 (100.0)		
Total	62 (62.0)	38 (38.0)	100 (100.0)		

Ethnicity

HbA1c

Table XVII showed association between ethnicity and HbA1c level. It showed no significant difference in HbA1c level among ethnic groups.

Table XVII Comparison of HbA1c level among ethnic groups

Ethnicity	HbA1c			
	N	Mean Rank	X^2	p-value
Malay	40	45.64	3.717	0.156
Chinese	29	37.91		
Indian	19	52.16		
Total	88			

Table XVIII showed association between ethnicity of respondents and control of their HbA1c level. There was no significant association between ethnicity of respondents and control of HbA1c level (p=0.146).

Table XVIII Association between ethnicity and control of HbA1c level

	HbA1c Control, n (%)		Total	X^2	P
	<6.5%	≥6.5%			
Ethnicity				3.843	0.146
Malay	13 (32.5)	27 (67.5)	40 (100.0)		
Chinese	10 (34.5)	19 (65.5)	29 (100.0)		

Indian	2 (10.5)	17 (89.5)	19 (100.0)
Total	25 (28.4)	63 (71.6)	88 (100.0)

Blood Pressure

Table XIX showed association between ethnicity and blood pressure. It showed no significant difference in systolic blood pressure (p=0.351) among ethnic groups. There was significant difference in diastolic blood pressure (p=0.039) among ethnic groups.

Table XIX Comparison of blood pressure among ethnic groups

Ethnicity	Blood Pressure	Systolic			Diastolic		
	N	Mean Rank	X^2	p-value	Mean Rank	X^2	p-value
Malay	46	48.93	2.096	0.351	53.65	6.489	0.039
Chinese	36	58.33			43.78		
Indian	22	50.41			64.36		
Total	104						

Table XX showed all pair-wise comparisons to be not significant except between Chinese and Indian (p=0.007). Chinese had lower diastolic blood pressure compared to Indian.

Table XX Association between ethnicity and diastolic blood pressure

Ethnicity	Diastolic Blood Pressure			
	N	Mean Rank	Z	p-value (2-tailed)
Chinese	36	24.83	-2.696	0.007
Indian	22	37.14		
Total	58			

Table XXI showed association between ethnicity of respondents and control of their blood pressure. There was no significant association between ethnicity of respondents and control of blood pressure (p=0.826).

Table XXI Association between ethnicity and control of blood pressure

	Blood Pressure Control, n (%)		Total	X^2	p
	≤130/80mmHg	>130/80 mmHg			
Ethnicity				0.381	0.826
Malay	9 (19.6)	37 (80.4)	46 (100.0)		
Chinese	6 (16.7)	30 (83.3)	36 (100.0)		
Indian	3 (13.6)	19 (86.4)	22 (100.0)		
Total	18 (17.3)	86 (82.7)	104 (100.0)		

LDL

Table XXII showed association between ethnicity and LDL level. It showed no significant difference in LDL level (p=0.443) among ethnic groups.

Table XXII Comparison of LDL level among ethnic groups

Ethnicity	LDL			
	N	Mean Rank	X^2	p-value
Malay	43	46.88	1.627	0.443
Chinese	36	51.25		
Indian	21	56.62		
Total	100			

Table XXIII showed association between ethnicity of respondents and control of their LDL level. There was no significant association between ethnicity of respondents and control of LDL level (p=0.228).

Table XXIII Association between ethnicity and control of LDL level

	LDL Control, n (%)		Total	X^2	p
	≤2.6mmol/L	>2.6mmol/L			
Ethnicity				2.957	0.228
Malay	30 (69.8)	13 (30.2)	43 (100.0)		
Chinese	22 (61.1)	14 (38.9)	36 (100.0)		
Indian	10 (47.6)	11 (52.4)	21 (100.0)		
Total	62 (62.0)	38 (38.0)	100 (100.0)		

4.5 Association between lifestyle of patient and disease control of Type 2 diabetes mellitus.

HbA1c Level

Table XXIV showed association between lifestyle of respondents and control of their HbA1c level. Table XXIV showed no significant association between exercise activity and control of HbA1c level (p=0.057), between smoking habit and control of HbA1c level (p=0.574) and between alcohol consumption and control of HbA1c level (p=0.310).

Table XXIV Association between lifestyle of respondents and control of their HbA1c level

	HbA1c level, n (%)		Total	X^2	P	Fisher's Exact Test
	<6.5%	≥6.5%				p
Exercise				5.732	0.057	
No	3 (11.1)	24 (88.9)	27 (100.0)			
At most 3 times a week	14 (35.9)	25 (64.1)	39 (100.0)			
More than 3 times a week	8 (36.4)	14 (63.6)	22 (100.0)			
Total	25(28.4)	63(71.6)	88(100.0)			
Smoking						0.574
Never	18 (26.5)	50 (73.5)	68 (100.0)			
	7 (35.0)	13 (65.0)	20 (100.0)			

Smoke			
	25 (28.4)	63 (71.6)	88 (100.0)
Total			
Alcohol Consumption			0.310
	20(26.3)	56 (73.7)	76 (100.0)
Never			
	5 (41.7)	7 (58.3)	12 (100.0)
Drink			
	25 (28.4)	63 (71.6)	88 (100.0)
Total			

Blood Pressure

Table XXV showed association between lifestyle of respondents and control of their blood pressure level. Table XXV showed no significant association between exercise activity and control of blood pressure (p=0.261), between smoking habit and control of blood pressure (p=1.000) and also between alcohol consumption and control of blood pressure (p=1.000).

Table XXV Association between lifestyle of respondents and control of their blood pressure

	Blood pressure, n (%)		Total	X^2	p	Fisher's Exact Test
	≤130/80mmHg	>130/80mmHg				P
Exercise				2.687	0.261	
No	8 (25.0)	24 (75.0)	32 (100.0)			
At most 3 times a week	8 (16.7)	40 (83.3)	48 (100.0)			
More than 3 times a week	2 (8.3)	22 (91.7)	24 (100.0)			
Total	18 (17.3)	86 (82.7)	104 (100.0)			
Smoking						1.000
Never	14 (17.5)	66 (82.5)	80 (100.0)			
Smoke	4 (16.7)	20 (83.3)	24 (100.0)			

Total	18 (17.3)	86 (82.7)	104 (100.0)	
				1.000
Alcohol consumption	16 (18.0)	73 (82.0)	89 (100.0)	
Never	2 (13.3)	13 (86.7)	15 (100.0)	
Drink	18 (17.3)	86 (82.7)	104 (100.0)	
Total				

LDL Cholesterol Level

Table XXVI showed association between lifestyle of respondents and control of their LDL level. Table XXVI showed no significant association between exercise activity and control of LDL level (p=0.344), between smoking habit and control of LDL level (p=1.000) and between alcohol consumption and control of LDL level (p=0.379).

Table XXVI Association between lifestyle of respondents and control of their LDL level

	LDL Level, n (%)		Total	X^2	P	Fisher's Exact Test
	≤2.6mmol/L	>2.6mmol/L				P
Exercise				2.136	0.344	
No	21 (67.7)	10 (32.3)	31 (100.0)			
At most 3 times a week	25 (54.3)	21 (45.7)	46 (100.0)			
More than 3 times a week	16 (69.6)	7 (30.4)	23 (100.0)			
Total	62 (62.0)	38 (38.0)	100 (100.0)			
Smoking						1.000
Never	48 (62.3)	29 (37.7)	77 (100.0)			
Smoke	14 (60.9)	9 (39.1)	23 (100.0)			
Total	62 (62.0)	38 (38.0)	100 (100.0)			

			0.379
Alcohol	55 (64.0)	31 (36.0)	86 (100.0)
Never			
	7 (50.0)	7 (50.0)	14 (100.0)
Drink			
	62 (62.0)	38 (38.0)	100 (100.0)
Total			

Obesity

Table XXVII showed correlation between obesity and disease control of respondents. It showed no significant correlation between obesity with HbA1c level (p=0.711), systolic blood pressure (p=0.301), diastolic blood pressure (p=0.444) and LDL level (p=0.340).

Table XXVII Correlation between BMI and disease control of respondents

	HbA1c level	Systolic blood pressure	Diastolic blood pressure	LDL level
BMI				
Spearman's Correlation Coefficient	0.041	-0.108	0.080	0.101
p-value	0.711	0.301	0.444	0.340
N	82	93	93	91

Table XXVIII showed association between obesity and control of HbA1c level. There was no significant association between obesity and control of HbA1c level (p=0.930).

Table XXVIII Association between obesity and control of HbA1c level

	HbA1c Level, n (%)		Total	X^2	p
	<6.5%	≥6.5%			
Obesity				0.146	0.930
Normal	4 (28.6)	10 (71.4)	14 (100.0)		
Overweight	7 (23.3)	23 (76.7)	30 (100.0)		
Obese	9 (24.3)	28 (75.7)	37 (100.0)		

Total	20 (24.7)	61 (75.3)	81 (100.0)

Table XXIX showed association between obesity and control of blood pressure. There was no significant association between obesity and control of blood pressure (p=0.610).

Table XXIX Association between obesity and control of blood pressure

	Blood pressure, n (%)		**Total**	**X^2**	**P**
	≤130/80mmHg	**>130/80mmHg**			
Obesity				0.989	0.610
Normal	3 (18.8)	13 (81.3)	16 (100.0)		
Overweight	4 (11.4)	31 (88.6)	35 (100.0)		
Obese	8 (19.5)	33 (80.5)	41 (100.0)		
Total	15 (16.3)	77 (83.7)	92 (100.0)		

Table XXX showed association between obesity and control of LDL level. There was no significant association between obesity and control of LDL level (p=0.590).

Table XXX Association between obesity and control of LDL level

	LDL level, n (%)		Total	X^2	P
	≤2.6mmol/L	>2.6mmol/L			
Obesity				1.056	0.590
Normal	10 (62.5)	6 (37.5)	16 (100.0)		
Overweight	19 (55.9)	15 (44.1)	34 (100.0)		
Obese	27 (67.5)	13 (32.5)	40 (100.0)		
Total	56 (62.2)	34 (83.7)	90 (100.0)		

4.6 Association between distress and depression level in Type 2 diabetes mellitus patient and their disease control

Table XXXI showed correlation between distress and depression level and disease control of respondents. Only between depression level and LDL cholesterol level (p=0.034) (r_s=-0.212) showed significant poor correlation. The two variables were inversely related.

Table XXXI Correlation between distress and depression level and disease control of respondents

	HbA1c	Systolic Blood Pressure	Diastolic Blood Pressure	LDL
Total DDS				
Spearman's Correlation Coefficient	0.151	-0.106	-0.056	-0.037
p-value	0.159	0.286	0.570	0.718
N	88	104	104	100
Total PHQ				
Spearman's Correlation Coefficient	-0.085	-0.077	-0.027	-0.212*
p-value	0.431	0.435	0.789	0.034
N	88	104	104	100

*. Correlation is significant at the 0.05 level (2-tailed).

Table XXXII showed association between distress and depression level with control of HbA1c level. There was no significant association between distress (p=0.170) and depression level (p=0.357) with control of HbA1c level.

Table XXXII Association between distress and depression level with control of HbA1c level

	HbA1c Level, n (%)		Total	X^2	P
	<6.5%	≥6.5%			
Distress level				1.880	0.170
< 3	24 (30.8)	54 (69.2)	78 (100.0)		
≥ 3	1 (10.0)	9 (90.0)	10 (100.0)		
Total	25 (28.4)	63 (71.6)	88 (100.0)		
Depression level				0.847	0.357
< 10	18 (26.1)	51 (73.9)	69 (100.0)		
≥ 10	7 (36.8)	12 (63.2)	19 (100.0)		
Total	25 (28.4)	63 (71.6)	88 (100.0)		

DDS= Diabetes Distress Scale, Mean score less than three indicated normal distress level while mean score three or higher indicated distress level which requires clinical attention.

PHQ= Patient Health Questionnaire, Score less than ten indicated minimal to mild depression, score ten and above indicated moderate to severe depression.

Table XXXIII showed association between distress and depression level with control of blood pressure. There was significant association between distress level and control of blood pressure ($p<0.001$) while there was no significant association between depression level and control of blood pressure ($p=0.603$).

Table XXXIII Association between DDS and PHQ scores with control of blood pressure

	Blood Pressure Control, n (%)		Total	X^2	P
	≤130/80mmHg	>130/80mmHg			
DDS Score				13.859	> 0.0001
< 3	11 (12.1)	80 (87.9)	91 (100.0)		
≥ 3	7 (53.8)	6 (46.2)	13 (100.0)		
Total	18 (17.3)	86 (82.7)	104 (100.0)		
				0.271	0.603
PHQ Score					
< 10	13 (16.3)	67 (83.8)	80 (100.0)		
≥ 10	5 (20.8)	19 (79.2)	24 (100.0)		
Total	18 (17.3)	86 (82.7)	104 (100.0)		

DDS= Diabetes Distress Scale, Mean score less than three indicated normal distress level while mean score three or higher indicated distress level which requires clinical attention.

PHQ= Patient Health Questionnaire, Score less than ten indicated minimal to mild depression, score ten and above indicated moderate to severe depression.

Table XXXIV showed association between distress and depression level with control of LDL level. There was no significant association between distress (p=0.323) and depression level (p=0.132) with control of LDL level.

Table XXXIV Association between distress and depression level with control of LDL level

	LDL level, n (%)		Total	X^2	P
	≤2.6mmol/L	>2.6mmol/L			
				0.978	0.323
Distress level					
< 3	53 (60.2)	35 (39.8)	88 (100.0)		
≥ 3	9 (75.0)	3 (25.0)	12 (100.0)		
Total	62 (62.0)	38 (38.0)	100 (100.0)		
Depression level				2.265	0.132
< 10	44 (57.9)	32 (42.1)	76 (100.0)		
≥ 10	18 (75.0)	6 (25.0)	24 (100.0)		
Total	62 (62.0)	38 (38.0)	100 (100.0)		

DDS= Diabetes Distress Scale, Mean score less than three indicated normal distress level while mean score three or higher indicated distress level which requires clinical attention.

PHQ= Patient Health Questionnaire, Score less than ten indicated minimal to mild depression, score ten and above indicated moderate to severe depression.

4.7 Association between disease complications of patient and distress as well as depression level of patient.

Table XXXV showed association between number of complications and grade of distress level of respondents. It showed no significant association between number of complications and grade of distress level of respondents (p=0.109).

Table XXXV Association between number of complications and grade of distress level of respondents

	DDS score, n (%)		Total	Fisher's Exact Test
	Normal (<3)	Need Clinical Attention (≥3)		p-value (2-sided)
Complication Category				0.109
Without Complication and with 1 complication	84 (89.4)	10 (10.6)	94 (100)	
More than 1 complication	7 (70)	3 (30)	10 (100)	
Total	91 (87.5)	13 (12.5)	104 (100)	

Table XXXVI showed association between number of complications and grade of depression level of respondents. It showed no significant association between number of complications and grade of depression level of respondents (p=0.693).

Table XXXVI Association between number of complications and grade of depression level of respondents

	PHQ score, n (%)		Total	Fisher's Exact Test
	Minimal to mild depression (0-9)	Moderate to severe depression (10-27)		p-value (2-sided)
Complication Category				0.693
Without Complication and with 1 complication	73 (77.7)	21 (22.3)	94 (100)	
More than 1 complication	7 (70)	3 (30)	10 (100)	
Total	80 (76.9)	24 (23.1)	104 (100)	

4.8 Association between number of medication taken by patients and their distress as well as depression level

Table XXXVII showed the comparison of respondents' distress and depression level among different categories of number of medications taken. There was no significant difference for distress (p=0.977) and depression level (0.714) in number of medications taken.

Table XXXVII Comparison of respondents' distress and depression level among different categories of number of medications taken.

Number of Medications	Emotional Burden	DDS score			PHQ score		
	N	Mean Rank	X^2	p-value	Mean Rank	X^2	p-value
0-2	5	50.60	0.046	0.977	42.20	0.673	0.714
3-5	27	52.98			50.94		
6 and above	71	51.73			53.09		
Total	103						

There are categories for number of medication, which are 0-2, 3-5 and more than 6 medications taken.

4.9 Association between distress level and depression level of Type 2 diabetes mellitus patients

Table XXXVIII showed the correlation between distress and depression level of respondents. There was significant fair direct correlation between distress and depression level ($p<0.001$, $r=0.423$). After dividing distress score into its subgroup, there was significant fair direct correlation between emotional burden and depression level of respondents ($p<0.001$, $r=0.434$), significant poor direct correlation between physician distress and depression level ($p=0.021$, $r=0.226$), and significant fair direct correlation between regimen distress and depression level ($p=0.001$, $r=0.330$). There was no significant correlation between interpersonal distress and depression level ($p=0.268$).

Table XXXVIII Correlation between distress and depression level of Type 2 diabetes mellitus patients

	Total PHQ Score
Total DDS	
Spearman's Correlation Coefficient	0.423**
p-value	0.000
N	104
Emotional Burden	
Spearman's Correlation Coefficient	0.434**
p-value	0.000
N	104
Physician Distress	

Spearman's Correlation Coefficient	0.226*
p-value	0.021
N	104

Regimen Distress

Spearman's Correlation Coefficient	0.330**
p-value	0.001
N	104

Interpersonal Distress

Spearman's Correlation Coefficient	0.110
p-value	0.268
N	104

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table XXXIX showed the association between distress level and depression level of Type 2 diabetes mellitus patients. It showed significant association between distress and depression level of respondents (p=0.035).

Table XXXIX Association between distress level and depression level of Type 2 diabetes mellitus patients

	Depression Level, n(%)		Total	X^2	p
	Minimal to mild	Moderate to severe			
Distress level				4.457	0.035
Normal	73 (80.2)	18 (19.8)	91 (100.0)		
Requires clinical attention	7 (53.8)	6 (46.2)	13 (100.0)		
Total	80 (76.9)	24 (23.1)	104 (100.0)		

DISCUSSION

The aim of this study was to determine the association between disease control of Type 2 diabetes mellitus patients and 1) their socio-demographic profile, 2) their lifestyle profile and 3) their distress and depression level.

5.1 Association between socio-demographic profile of type 2 diabetes mellitus patient with their disease control

In the study, the mean age of the respondent took part was 58.6 years old, which was expected as many type 2 diabetes mellitus (T2DM) patients are mainly 50 years and above. Our finding was similar with record from National Health and Morbidity Survey 2006 and National Health and Morbidity Survey 2011(NHMS 2006 and NHMS2011), showed that T2DM patient were mainly 50 year and above.

Comparing the gender of the patients involved, they were mainly equal, with 51.9% were male and 49.1% were female. It was expected as the prevalence of diabetes is more in men when compared with their female counterparts (NHMS 2006 and NHMS2011).

Majority of our respondent were Malay which accounted nearly half of our respondents, Chinese was around 34.6% and Indian was one fifth of total amount. This was not presenting the general ethnic distribution of T2DM patients in the Malaysia as majority of the diabetic patients are Indian (NHMS 2006 and NHMS 2011). Even though the ethnicity did not follow the general country distribution, a study done in Federal Territory showed a similar ethnicity distribution. (Ai Theng Cheong et al, 2013). Never the less, it depends on the state which the

location conducted. For example, studies conducted in Hospital University Sains Malaysia show around 85% were Malay, 14% Chinese and 1% are Indian (Salwa Selim Ibrahim Abougalambou and Ayman S. Abougalambou, 2013).

Age

In our finding we found that age had little association with the disease control. Our data found that HbA1c level had significant poor correlation (r_s=-0.226) with age of respondents. These variables were inversely related, that was, as one variable increased the other variable decreased Our previous finding showed a contrasting result with ours. (Sasi Sekhar TVD, 2013). This research found that age did relate with poor glycemic control. Another research done locally in Hospital Universiti Sains Malaysia (HUSM) also had the same result (Salwa Selim Ibrahim Abougalambou and Ayman S. Abougalambou, 2013). Moreover other research found that older patient had lower HbA1C level, the previous studies in China and South Korea showed high HbA1C level had association with older age group (Yi-Ching et al 1997)(Chul-Hee Kim et al 2011).

Diastolic blood pressure ($p<0.001$) had significant fair correlation (r_s=-0.397) with age of respondents. These variables were inversely related, that was, as one variable increased the other variable decreased. When we compared to a study done in HUSM, it was not similar. The study showed that diabetic patients were likely to have high blood pressure. Logistic regression indicated that high blood pressure was positively associated with age in diabetic patients (P = 0.040) (Salwa Selim Ibrahim Abougalambou and Ayman S. Abougalambou, 2013).

On the other hand, systolic blood pressure (p=0.306) had no significant correlation with age. This finding also differs from the study done in Trinidad. They found that systolic blood pressure did increase with age. Increase in age was related with the increase in systolic blood pressure level in diabetic patients (Shivananda b. Nayak et al, 2012).

Lastly, LDL level (p=0.060) are not significantly correlated with age of respondents.

Gender

Comparing gender and disease control, none of disease control gives any significant finding.

The result was similar to a study done before which was an international study found that poor glycemic control did not relate to gender (Ranjita Misraa, Julie Lagerb 2009). However, this finding differed with another study done in India which found that sex was related with poor glycemic control (Sasi Sekhar TVD, 2013).

In our data none could relate sex and blood pressure but a study done in Pahang about blood pressure in diabetic patient showed that female had higher systolic blood pressure over male (SMS Azarisman et al 2010).

Ethnicity

When comparing ethnicity and disease control, there was no association except in the Chinese and Indian diastolic blood pressure.

An international study showed that Asian had good glycemic control over others (Ranjita Misraa, Julie Lagerb 2009). Another study done showed that the Chinese had better glycemic control over the other race (IS Ismail et al, 2000). A study done locally showed that Indian was having higher HbA1c level compared to other races (C Y Hong et al, 2004). However, in our study we could not find any association.

Furthermore, when compared between ethnicity and blood pressure, there was significant finding. We found that there was significant relation between diastolic blood pressure in Indian and Chinese. A study done locally showed that Chinese and Indian were less likely to have hypertension (C Y Hong et al, 2004). However, in our study, we found that Chinese had lower diastolic blood pressure when compared to Indian. This result was a bit similar to a study done by Shivananda b, Nayak et al which found that East Indian in Trinidad were having highest diastolic. Another study done by Shivananda b. Nayak et al in 2012 showed that East Indian had the highest diastolic blood pressure compared to other races in Trinidad.

Disease Control

Disease controls in this study consisted of HbA1c level, blood pressure and LDL cholesterol level. Out of all the respondents, only one of our respondents managed to keep all three disease controls at a target set by the Malaysia Clinical Practice Guideline (CPG). Most only managed to keep to at least one target. Based on the previous study conducted in developed and in developing country, it was also true only small amount of patients achieved all target set. Most were not controlled or at least one was in control (Emmanuela Gakidou et al 2011). Locally conducted study in HUSM, showed a similar result, in the sense, most patients did not achieve the target (M Eid et al 2004).

5.2 Association between lifestyle profile of Type 2 diabetes mellitus patients with their disease control.

In this study, the results showed no significant association between lifestyle profile of Type 2 diabetes mellitus patients with their disease control. Lifestyle profile included exercise activity, smoking habit, alcohol consumption and obesity status of respondents. Disease control included glycemic control, blood pressure control and cholesterol control.

This result was contrasting result to other studies. There were studies which showed association between exercise activity and disease control of patients. A study found that a lifestyle intervention including diet and exercise decreased the risk of diabetes by 50% (Eriksson and Lindgarde, 1991) while a study conducted in China reported a 25% risk reduction from either diet, exercise, or the combination of both, compared with a control group (Pan et al., 1997).

When data of smokers versus non-smokers was compared, it was found that the smokers had significantly higher values of TC, LDL-C, VLDL-C and TG than that of non-smokers. (S.M. Deshmukh, 2000).

In the Nurses' Health Study, it was found that the risk of type 2 diabetes mellitus decreased with the increase of alcohol consumption (ranging from 1.5 to 415 g/day) (Stampfer MJ et al., 1988). However, in The United State Male Physicians' study, it showed that light to moderate alcohol intake was associated with a reduced risk of diabetes (Ajani UA et al., 2000). Another study also showed that light to moderate drinking was associated with a

decrease in risk of developing Type 2 diabetes mellitus in univariate analysis but this effect was lost after adjustment for potential confounders (Kao WH et al., 2001).

In term of obesity, over 2000 researchers, commentators and policy-makers in Australia had linked the rise in diabetes directly to the increases in obesity in the same populations (Barr et al. 2006;Colagiuri et al. 2006; Duke, Colagiuri, and Colagiuri 2009; Dunstan et al. 2001; Zimmet 2001). Another study stated that overweight and obesity were not symptoms of diabetes but had become a significant contributing factor and diabetes had emerged as an obesity-related condition of epidemic proportions (Darlene M.N 2013).

5.3 Association between distress and depression level in Type 2 diabetes mellitus patients and their disease control.

Most respondents, which were 87.5% of respondents were normal in level of distress and did not need clinical attention. Most respondents, 48.1% of the respondents had only minimal depression. Only 12.5% were distress and 6.7% were depressed (moderately severe and severely), which required clinical attention. For distress level, mean score less than three indicated normal distress level while mean score three or higher indicated distress level which requires clinical attention. For depression level, scores of all the 9 items would be added up. Score from 0 to 4 indicated minimal depression, 5 to 9 indicated mild depression, 10 to 14 indicated moderate depression, 15 to 19 indicated moderately severe depression and 20 to 27 indicated severe depression.

In this study, correlation between distress and depression level and disease control of respondents was done. Only between depression level and LDL cholesterol level ($p=0.034$) ($r_s=-0.212$) showed significant poor correlation and the two variables were inversely related. It was not parallel to a study done in China among Type 2 diabetes mellitus patient found that depression was related to high LDL level (Rose Z.W. et al 2013). It was also not parallel to another study done relating LDL level and depression which showed that people who had already known their LDL level was high had no sign of depression system on them (Gunnar Einvik et al., 2008).

The findings in this study showed that there was no significant association between distress level of respondents and their disease control which included glycemic control, blood pressure control and cholesterol control. This result was not parallel with that of a study done in Sweden showed that psychological distress was important as it could increase the risk of having Type 2 diabetes, especially in men (AK Erikson, 2008). There were also studies showed that there was association between distress and poor glycemic control (L. Fisher, 2010; Yasuaki Hayashino et al, 2012; Sasi Sekhar TVD, 2013).

In this study, there was no significant association between depression level of respondents and their glycemic and blood pressure control. It was parallel to a study which showed that depression had no effect on glycemic control (M. Papelbaum et., 2010). However, another study relating blood pressure and depression showed that high systolic blood pressure in both high stress and low stress situation showed low depression (Dmitry M. Davydov et al., 2012).

In addition, a study showed that among adults with diabetes, depression impeded the adoption of effective self-management behaviors (including physical activity, appropriate dietary behavior, foot care, and appropriate self-monitoring of blood glucose behavior) through a decrease in social motivation (Leonard E. Egede et al., 2010). There were also observational studies which suggested that depression reduced self-care behaviour which in turn impacted on diabetes outcomes (Piette J et al., 2004).

5.4 Association between Medication, Complication and Distress and Depression

Complication with Distress and Depression

For association between complication with distress and depression, we could not find any significant relation between them.

However, some previous studies showed the importance of controlling complication. The Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study confirmed that, in individuals with diabetes, improved metabolic control (achieved via an intensive self-care regimen that included lifestyle changes) was significantly associated with delayed onset and progression of micro vascular complications (DCCT, 1993; UKPDS, 1999).

A meta-analysis study by Mary et al., (2001) revealed that depression was significantly associated with a variety of diabetes complications (Mary et al., 2001). Co-morbidity of depression and diabetes was associated with disease complications and mortality. Depression might also be an important risk factor in developing diabetes (Mezuk B et al., 2008).

Number of Medication with Distress and Depression

After running various tests to find any relationship between number medication taken by T2DM patients with distress and depression, we still could not find any significant association.

A study done in India showed a statistically significant result between medicine taken and depression. They found that a combination of drug taken (more than one drug taken) showed depression on diabetes patient (K. G. Guruprasad, et al 2013). A similar kind of study showed if the patients had good compliance with the medicine, they would have good glycemic control (Joanne Hui Min Quah et al 2013).

5.5 Association between Distress and Depression

Our result showed a significant association between distress and depression level of respondents (p=0.035).

The study showed that depression (PHQ) was significantly correlated with distress DDS(r = 0.40, P = 0.001) (L Fisher et al 2010). This finding was also similar in Iran where distress (35%) was very common among diabetic patients (Hamid R. Baradaran et al 2013).

Another study showed that T2DM patients had increased depression. When taking medication like insulin or heavy medication, T2DM patients were a bit depressed but not distress (Molly L. Tanenbaum et al 2013). To our best effort, we could not find any study that relate directly between distress and depression without involving disease control as the dependent variable.

CONCLUSION, RECOMMENDATION, STRENGTH AND LIMITATION

6.1 Conclusion

In term of socio-demographic of respondents, only age and HbA1c level as well as diastolic blood pressure showed significant indirect correlation. Chinese had lower diastolic blood pressure compared to Indian. For lifestyle profile of respondents, it had no significant association with disease control of respondents in any aspect. In term of disease control, only one respondent had all three controlled targets of disease treatment which were HbA1c level lower than 6.5%, blood pressure level less than or equal to 130/80 mmHg and LDL cholesterol less than or equal to 2.6 mmol/L. Most respondents achieved only one controlled target of disease control parameters. Most respondents were normal in level of distress and did not need clinical attention. Most respondents had only minimal depression. There was significant poor indirect correlation between depression level and LDL cholesterol level while other factors showed no significant correlation. There was significant association between distress level and control of blood pressure.T2DM patients with higher depression and distress levels could have been receiving more medical attention and medicine due to having more complications. This could have facilitated them to have lower LDL cholesterol level and achieved BP control. Depression and distress might be of different psychological domains as they showed different association with disease control.

6.2 Recommendation

Our recommendation to others who is interested in doing this study is to increase the number of respondents and location of study. The duration of the study could be increase to more than a month. The right technique of interviewing respondent should be acquired to avoid bias. Lastly, avoid doing this study during fasting month, as it is may give a different result.

Furthermore, mild distress and depression might not be bad. Physician might pay more attention to distress and depression level of T2DM patients but not to be over worried of mild or beneficial distress and depression if this was not related to poor disease control.

6.3 Strength and Limitation

The strengths of this study were that it looked into distress and depression together and was carried out in a diabetes clinic in Hospital Serdang. Our questionnaire included three languages, which were Malay, Chinese and English. Questionnaires with different languages provided convenience to both researchers and respondents when conducting the study.

The sample population was a limitation of this study. Proportion of the respondents which was 44% Malay, 35% Chinese and 21% Indian could not be generalized with the other medical center. Patients were rather homogenous in term of age, disease severity and distress and depression level. At the same time, this study was carried out during fasting month. During fasting month, distress and depression level, disease control of respondents and attitude of respondents when answering questionnaire might have some difference compared to study which has been carried out during normal period.

This study included both questionnaire giving and patients information retrieving from data system of hospital. There were limitations such as many respondents were old and alleged to have blurring vision. It took longer time to complete as interview method was used. When interview method was used, respondents might not answer honestly as our questionnaire

involved some sensitive issues. Some of the respondents were too old and were not able to answer the questionnaire themselves, their family member answered on behalf of them. This might cause some inaccuracy and bias in the data collected from questionnaire. In addition, we could not rule out that respondents might also give answers which were socially desirable. Furthermore, there was also limitation in retrieving secondary data. Some data was incomplete. Some patients did not have the past three months record for the HbA1c level, blood pressure and LDL cholesterol level, therefore the latest record were taken.

However, for the fixed factors such as socio-demography of respondents and disease control like HbA1c level, blood pressure and LDL cholesterol level, there were significant result as expected. This proved that there were sufficient quality of data of HbA1c level, blood pressure and LDL cholesterol level despite the limitations as mentioned above.

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To: "kkroenke@regenstriet.org" <kkroenke@regenstriet.org>
Cc: "kkroenke@iupui.edu" <kkroenke@iupui.edu>
Sent: Thursday, 14 March 2013, 10:50
Subject: Permission to use Patient Health Questionnaire (PHQ-9)

Dear Dr Kroenke,

I am a family physician affiliated with an academic center in Malaysia as below. I am planning a study on the emotional distress and its effect on disease control in patients with Type 2 diabetes mellitus at primary care level using the 17-Item version of the Diabetes Distress Scale (DDS). In order to also assess the possibility of severe depression among the patients, I would like to ask your permission to use the PHQ-9 in my study. I would also ask permission to use the Malay and Chinese version from the respective owner/author.

Anticipate your soonest favorably reply.

Best regards,

DR. CHEW BOON HOW
MD (USM) Mmed Family Medicine (UM)
Senior Medical Lecturer, Family Medicine Specialist
Department of Family Medicine
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia, 43400 UPM Serdang,
Selangor Darul Ehsan, Malaysia
Tel: 603-8947 2520,-2538 Fax: 603-8947 2328
email: chewbh@medic.upm.edu.my
Website: http://profile.upm.edu.my/chewboonhow

Subject:	Re: Diabetes Distress Scale
From:	William Polonsky (whp@behavioraldiabetes.org)
To:	chewboonhow@yahoo.com;
Date:	Thursday, 26 April 2012, 22:11

You are more than welcome to use the DDS.
I have attached:

1. The official English version
2. Our first DDS article
3. A Chinese translation used in a recent study. (Note that they chose to delete two of the DDS items; I would not recommend that you do this).

I am not aware of a Tamil or Malaysian translation of the DDS, but if you do create one, could you please send me a copy so we could share it with others in the future?
Good luck with your research.
Best Regards,
Bill

William H. Polonsky, PhD, CDE
Chief Executive Officer, Behavioral Diabetes Institute
Associate Clinical Professor
University of California, San Diego
whp@behavioraldiabetes.org

Dear William H. Polonsky,

I am named and affiliated as below.

I am interested to study emotional distress among type 2 diabetes patients at the public health clinics in Malaysia using Diabetes Distress Scale (DDS).

Would you be able to advise me in getting permission for using the DDS? Is there any translating works+validation on-going for other languages such as Malay, Chinese and Tamil? These are the three main languages of the three major ethnicity in Malaysia.

Anticipate your reply. Thank you.

DR. CHEW BOON HOW
MD (USM) Mmed Family Medicine (UM)
Senior Medical Lecturer, Family Medicine Specialist
Department of Family Medicine
Faculty of Medicine and Health Sciences
University Putra Malaysia, 43400 UPM Serdang,
Selangor Darul Ehsan, Malaysia

From: Kroenke, Kurt
Sent: Thursday, March 21, 2013 6:11 AM
To: Burgett, Donna F
Subject: FW: Permission to use Patient Health Questionnaire (PHQ-9)

Kurt Kroenke, MD

Professor of Medicine, Indiana University

Research Scientist, VA HSR&D Center for Implementing Evidence-Based Practice

Regenstrief Institute, 5th Floor

1050 Wishard Blvd

Indianapolis, IN 46202

From: chew boonhow [mailto:chewboonhow@yahoo.com]
Sent: Thursday, March 21, 2013 4:06 AM
To: Kroenke, Kurt
Cc: kkroenke@iupui.edu
Subject: Re: Permission to use Patient Health Questionnaire (PHQ-9)

Dear Dr Kroenke,

I am resending my email as below. Hope you could reply me with permission soonest possible.

DR. CHEW BOON HOW

From: chew boonhow <chewboonhow@yahoo.com>

Subject:	RE: Permission to use Patient Health Questionnaire (PHQ-9)
From:	Burgett, Donna F (dfburget@regenstrief.org)
To:	chewboonhow@yahoo.com;
Date:	Thursday, 21 March 2013, 20:07

Hello,

The PHQ is now in public domain and freely available for use. Copies of the PHQ family of measures, including the GAD-7 are available at the website: www.phqscreeners.com. Also, translations, a bibliography, an instruction manual (with scoring information) and other information are also provided on the website.

Kind regards,
Donna

Donna Burgett
Administrative Assistant III
to Kurt Kroenke, MD
Regenstrief Institute, Inc.
1050 Wishard Blvd., RG5
Indianapolis, IN 46202

APPENDIX 3 -- NMRR Approval letter

NATIONAL INSTITUTES OF HEALTH (NIH) RECOMMENDATION FOR THE CONDUCT OF RESEARCH IN THE MINISTRY OF HEALTH MALAYSIA
PENGESAHAN INSTITUSI KEBANGSAAN NEGARA UNTUK MENJALANKAN PENYELIDIKAN DI KEMENTERIAN KESIHATAN

This is an auto-generated document. It is issued by one of the research institute under the National Institutes of Health (NIH). The institutes as follows: Institute for Medical Research (IMR), Institute for Public Health (IPH), Clinical research centre (CRC), Institute for health Management (IHM), Institute for Health System Research (IHSR) and Institute for Health Behavioural Research (IHBR).

Dokumen ini adalah cetakan berkomputer. Borang ini dikeluarkan oleh salah satu institusi dibawah National Institutes of Health (NIH) iaitu Institut Penyelidikan Perubatan (IMR), Institut Kesihatan Umum (IKU), Pusat Penyelidikan Klinikal (CRC), Institut Pengurusan Kesihatan (IPK), Institut Pengurusan Sistem Kesihatan (IPSK) dan Institut Penyelidikan Tingkahlaku Kesihatan (IPTK).

Unique NMRR *[Nombor Pendaftaran]*	NMRR-13-691-16819
Research Title *[Tajuk]*	EMOTIONAL BURDEN AND ITS EFFECT ON DISEASE CONTROL IN PATIENTS WITH ADULT TYPE 2 DIABETES MELLITUS
Protocol Number if *[Nombor Protokol jika ada]*	

#	Investigator Name *[Nama Penyelidikan]*	Institution Name *[Nama Institusi]*
1	CHEW BOON HOW	Serdang Hospital
2	Choo Shze Yee	Serdang Hospital
3	MOHAMMAD ASYRAF BIN YAHYA	Serdang Hospital

I have reviewed the above titled research, and has recommended to MREC* for its decision.

Saya telah menyemak penyelidikan yang bertajuk diatas, dan telah disyorkan untuk MREC bagi keputusannya.

Name of Director *[Nama pengarah]*	Dr Roslinah Ali
NIH Institute (IMR, IPH, CRC, IHM, IHSR, IHBR) *[Nama institusi di bawah NIH]*	Institute for Health Management (IHM)
Signature & Official Stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	22-08-2013

*Final approval is pending MREC decision.

APPENDIX 4 QUESTIONNAIRE

RESPONDENT'S INFORMATION SHEET

Please read the following information carefully and do not hesitate to discuss any questions you may have with the researcher.

STUDY TITLE

Emotional burden and its effect on disease control in patients with adult Type 2 diabetes mellitus

INTRODUCTION

We invite you to take part in this research study on the Emotional Factor in Type 2 Diabetes Mellitus

- Type 2 Diabetes Mellitus is a common problem in Malaysia
- Little research done on the emotional factors on controlling Type 2 diabetes mellitus
- The research conducted here are trying get a much better understanding regarding emotional factors and controlling Type 2 diabetes Mellitus

WHAT WILL YOU HAVE TO DO?

If you decide to take part, you will need to answer all the questions in this questionnaire booklet honestly.

WHO SHOULD NOT ENTER THE STUDY?

If you are the following

- pediatric patients
- pregnant mothers
- patients with type 1diabetes mellitus
- patients with memory impairment
- foreigners

WHAT WILL BE THE BENEFITS OF THE STUDY:

(a) TO YOU AS THE SUBJECT?
To find other factor that can affect the control of type2 diabetes mellitus in Malaysia

(b) TO THE INVESTIGATOR? .
This is then hopefully will help to improve clinicians in controlling patient diabetes problem.

WHAT ARE THE POSSIBLE RISKS?

There are no invasive procedure in this study. You may find the questions in the questionnaires somewhat personal and would need you to recall some information in the past 2 to 4 weeks.

WILL THE INFORMATION THAT YOU PROVIDE AND YOUR IDENTITY REMAIN CONFIDENTIAL?

All your information is confidential and only known to the investigators. No personal information could be identified to any single patient. The questionnaire will be keep in a safe place. All data will be pooled in analyses and presented in the reports.

WHO SHOULD YOU CONTACT IF YOU HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?

If you have any concern please contact us ,

MOHAMMAD ASYRAF BIN YAHYA
D. 2. 6, Kolej 17,
Universiti Putra Malaysia, 43400 UPM Serdang,
Selangor Darul Ehsan, Malaysia
Tel: 0127101310

CHOO SHZE YEE
C. 2. 9, Kolej 17,
Universiti Putra Malaysia, 43400 UPM Serdang,
Selangor Darul Ehsan, Malaysia
Tel: 0164845878

DR. CHEW BOON HOW
Department of Family Medicine
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia, 43400 UPM Serdang,
Selangor Darul Ehsan, Malaysia
Tel: 603-8947 2520,-2538 Fax: 603-8945 0151
email: chewbh@medic.upm.edu.my

CONSENT FORM (RESPONDENT)

RESEARCH TITLE :

Emotional Burden and its Effect on disease control in patients with adult Type 2 diabetes mellitus

RESEARCHER :

MOHAMMAD ASYRAF BIN YAHYA 161378 Tel: 0127101310	CHOO SHZE YEE 161512 Tel: 0164845878

I ..... Identity Card No. .....
address.....
.....hereby voluntarily agree to take part in the clinical research *(clinical study, questionnaire study/ drug trial) specified above.

I have been informed about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as written in the Respondent Information Sheet). I understand that I have the right to withdraw from this clinical research at any time without assigning any reason whatsoever. I also understand that this study is confidential and all information provided with regards to my identity will remain private and confidential.

* delete where necessary

Signature ..... Signature .....
(*Respondent*) (*Witness*)

Date :..... Name :.....

I/C No. :.....

I confirm that I have explained to the respondent the nature and purpose of the above –mentioned clinical research.

Date ..... Signature .....
(Researcher)

1/3: THE 17-ITEM VERSION OF THE DIABETES DISTRESS SCALE

DIRECTIONS: *Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.*

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

No.	Problems	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1.	Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
2.	Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
3.	Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4.	Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5.	Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6.	Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7.	Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
8.	Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

9.	Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10.	Feeling that diabetes controls my life.	1	2	3	4	5	6
11.	Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12.	Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13.	Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14.	Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15.	Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16.	Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17.	Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

For Researcher Use

Total DDS Score	a. Sum of 17 item scores=	b. Divide by: 17	c. Mean item score=
A. Emotional Burden	a. Sum of 5 items **(2, 4, 7, 10, 14)**=	b. Divide by: 5	c. Mean item score=
B. Physician Distress	a. Sum of 4 items **(1, 5, 11, 15)**=	b. Divide by: 4	c. Mean item score=
C. Regimen Distress	a. Sum of 5 items **(6, 8, 3, 12, 16)**=	b. Divide by: 5	c. Mean item score=
D. Interpersonal Distress	a. Sum of 3 items **(9, 13, 17)**=	b. Divide by: 3	c. Mean item score=
To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale.			

2/3: PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use "✔" to indicate your answer)

No.	Problem	Not at all	Several days	More than half the days	Nearly every day
1.	Little interest or pleasure in doing things	0	1	2	3
2.	Feeling down, depressed, or hopeless	0	1	2	3
3.	Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4.	Feeling tired or having little energy	0	1	2	3
5.	Poor appetite or overeating	0	1	2	3
6.	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7.	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8.	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9.	Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
	FOR OFFICE CODING *0* + _____ + _____ + _____ =Total Score: _____				

10.	**If you checked off <u>any</u> problems, how <u>difficult</u> have these problems made it for you to do your work, take care of things at home, or get along with other people?**			
	Not difficult at all ❒	Somewhat difficult ❒	Very difficult ❒	Extremely difficult ❒

3/3: BIODEMOGRAPHY

1. Date: DD/MM/YYYY **2. Age:**

3. Gender (*Please ✓one*): ❒ Female ❒ Male

4. Ethnicity, based on paternal side (*Please ✓one*):
❒ Malay ❒ Chinese ❒ Indian ❒ Aborigines (Orang Asli) ❒ Other_____

5. Do you have a specific religion? (*Please ✓one*):
❒ I do not observe a religion ❒ Islam ❒ Buddhism ❒ Hindu ❒ Sikh ❒ Christian ❒ Roman Catholic ❒ Other_____

6. Marital status (*Please ✓one*):
❒Married ❒ Living with a partner ❒ Divorced ❒ Widowed ❒ Separated ❒ Single

7. Educational level (tick ✓ highest):
❒ Primary ❒ Secondary ❒ Tertiary (college) ❒ Others_____

8. Employment status (*Please ✓one*):
❒ Employed ❒ Unemployed seeking work ❒ Retired ❒ Home manager ❒ Student

9. Family gross income per month (total incomes of both husband and wife in Ringgit Malaysia).
❒ < 2,000 ❒ 2,000-4,999 ❒ 5,000-9,999 ❒10,000-19,999 ❒ > 20,000

10. Do you exercise? (*Please ✓one*)
❒ No ❒ I do at most 3 times in a week ❒ I do more than 3 times in a week

11. Do you smoke? (*Please ✓one*)
❒ Never ❒ I have stopped smoking more than 5 years
❒ Yes ❒ I have stopped smoking less than 5 years

12. Do you drink alcohol? (*Please ✓one*)
❒ Never ❒ I have stopped drinking
❒ Yes. Types of drinks……..
How much? ..... (Ounces/ week) *1 ounce = 30 mls

THANK YOU VERY MUCH FOR PARTICIPATING IN THIS SURVEY

**For Researchers' use only

Emotional Burden and Type 2 Diabetes Mellitus

Patient Code:

Date:

Tick (√) one only where ○ box is provided.
Tick (√) one or more where applicable where □ box is provided.

Section 1: Diabetes Mellitus		
Type of Diabetes:	○ Type 1 ○ Type 2	□ Unknown
Year of Diagnosis: (yyyy)		□ Unknown
Section 2: Clinical Information (within the past three months)		
Weight: (kg)		□ Not Done
Height: (kg)		□ Not Done
Waist Circumference: (cm)		□ Not Done
Blood Pressure: (mmHg)		□ Not Done
HbA1c: (%)		□ Not Done
LDL-C: (mmol/L)		□ Not Done
Section 3: Co-morbidity		
Hypertension	○ No ○ Yes, year of diagnosis:_____	□ Unknown
Dyslipidaemia	○ No ○ Yes, year of diagnosis:_____	□ Unknown
Section 4: Complication		
Cerebrovascular Disease - Stroke / TIA:	○ No	

	O Yes, year of diagnosis:_____	☐ Unknown
Ischaemic Heart Disease:	O No O Yes, year of diagnosis:_____	☐ Unknown
Retinopathy:	O No O Yes, year of diagnosis:_____	☐ Unknown
Nephropathy:	O No O Yes, year of diagnosis:_____	☐ Unknown
Diabetic Foot Problems*:	O No O Yes, year of diagnosis:_____	☐ Unknown
Section 5: Treatment		Total number of medication taken
Diet therapy only	O No O Yes	
Oral Hypoglycaemic Agent	O No O Yes, ▫ Biguanides ▫ Sufonylureas ▫ Alpha glucosidase inhibitor ▫ Thiazolidinediones ▫ Meglitinides ▫ Others, specify:_____	
Insulin	O No O Yes	
Anti-hypertensive Agent	O No	

	O Yes, number of agents:_____	
Lipid-lowering Agent	O No O Yes, number of agents:_____	
Anti-platelet Agent	O No O Yes, number of agents:_____	
Others medication	O No O Yes, number of agents:_____	

*Peripheral Neuropathy, Peripheral Vascular Disease, Foot Deformity, Ulcer (current), Amputation

APPENDIX 5 -- BUDGET

No	**Items**	**Estimated cost**
1.	Printing	RM 50.00
2.	Hard cover	RM 50.00
3.	Photocopy	RM 200.00
4.	Binding	RM 10.00
5.	Transportation and etc	RM 130.00
	Total	**RM 440.00**

APPENDIX 6 -- GANTT CHART

Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Preparation of draft proposal	X	X																						
Submission of draft proposal		D																						
Preparation, submission and presentation of final proposal			X	D																				
Preparation of ethical approval and permission letters to organizations				D	D																			
Data collection and analysis																	X	X	X					
Submission of data analysis and presentation																			D					
Preparation of project report and scientific article																				X	X			
Submission of project report and scientific article																				X	X	X		
Preparation of final presentation																						X	X	
Final presentation																							D	
Correction of final report																							X	X
Submission of final report, scientific article																								D

Attachment 2

JKEUPM Ref No. : FPSK_Mei (13)66

Members of the JKEUPM who reviewed the documents:

Assoc. Prof. Dr. Johnson Stanslas

Date of approval: 24/7/2013

Endorsed at JKEUPM Meeting on **2/8/2013**, attended by:

NAME	DESIGNATION	GENDER	TICK IF PRESENT
Prof. Dr. Norlijah Othman	Paediatrics& Dean, Faculty of Medicine and Health Sciences	Female	√
Prof. Dr Zamberi Sekawi	Medical Microbiologist & Deputy Dean of Research and Internationalization, Faculty of Medicine and Health Sciences	Male	√
Prof. Dato' Dr. Lye Munn Sann	Medical Statistician, Dept of Community Health, Faculty of Medicine and Health Sciences	Male	
Prof. Dr. Tengku AizanAbd Hamid	Gerontologist & Director, Institute of Gerontology	Female	√
Prof. Dr. Lekhraj Rampal	Medical Statistician, Dept of Community Health, Faculty of Medicine and Health Sciences	Male	
Prof. Dr. Elizabeth George	Pathologist, Dept of Pathology, Faculty of Medicine and Health Sciences	Female	√
Prof. Dr. Lim ThiamAun	Anesthesiologist, Dept of Surgery, Faculty of Medicine and Health Sciences	Male	
Prof. Dr. Wan Omar Abdullah	Medical Parasitologist, Dept of Medical Microbiology and Parasitology, Faculty of Medicine and Health Sciences	Male	
Prof. Dr. Patimah Ismail	Professor of Biomedicine, Dept of Biomedical Sciences, Faculty of Medicine and Health Sciences	Female	√
Assoc. Prof. Dr. Johnson Stanslas	Pharmacologist, Dept of Medicine, Faculty of Medicine and Health Sciences	Male	√
Assoc. Prof Dr. Mansor Abu Talib	Assoc. Professor of Guidance and Counselling, Dept of Human Development and Family Studies, Faculty of Human Ecology	Male	
Assoc. Prof. Dr. Noritah Omar (Lay Person)	Assoc. Professor of English Language, Dept of English Language, Faculty of Communication and Modern Languages	Female	√
Dr. RojanahKahar (Lay Person)	Lecturer of Dept of Human Development and Family Studies, Faculty of Human Ecology	Female	√
Tan Sri Dato' Napsiah Omar (Lay Person)	Chairman, National Population and Family Development Board	Female