DEPRESSION AND ITS ASSOCIATED FACTORS AMONG ELDERLY WITH TYPE 2 DIABETES MELLITUS

By

DR AZNIZA BT MUHAMAD RADZI

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTERS OF MEDICINE (FAMILY MEDICINE)

2016

DECLARATION

I hereby declare that the work produced in this thesis is of my own effort except for quotations and summaries which have been duly acknowledge.

30th November 2016

Dr Azniza Bt Muhamad Radzi

PUM0016/10

ACKNOWLEDGEMENT

First and foremost, I would like to thank my supervisors namely Dr Nani Draman and Dr Siti Suhaila Mohd Yusoff, my lecturers and Family Medicine Specialists at Hospital Universiti Sains Malaysia for undivided support from the beginning in making sure this dissertation ends well.

I would like to also giving my sincere appreciation to Head of Department, Department of Family Medicine and all my lecturers in Department of Family Medicine, School of Medical Sciences, Universiti Sains Malaysia for their support and guidance.

My special thanks also go to my mentor and clinical supervisor Dr Habshoh bt Hat, Senior Family Medicine Specialist, Klinik Kesihatan Bandar Sungai Petani for allowing me to run the research in the clinic.

I would like also to give my gratitude to Ms Izyan Hazwani Bt Baharuddin for her invaluable guidance in statistical analysis.

Last but not least, further acknowledgement and gratitude to my wonderful husband, my beloved parents and my adored children for their continuous support, prayers, patience and understanding of the time much spent in finishing this research.

Table of Contents

List of Tables

List of Figures

List of Appendixes

List of Abbreviations

BDI	Beck Depression Inventory
CES-D	Centre of Epidemiological Suides of Depression
DM	Diabetis Mellitus
ECAQ	Elderly Cognitive Assessment Questionnaire
FBS	Fasting Blood Glucose
GDS	Geriatric Depression Scale
KKBSP	Klinik Kesihatan Bandar Sungai Petani
M-GDS-14	Malay version Geriatric Depression Scale 14-item
RBS	Random Blood Glucose

Abstract

English version

Title: Depression and its associated factors among elderly with Type 2 Diabetes Mellitus.

Introduction: The prevalence of Diabetes Mellitus in elderly is escalating. Depression although carries high mortality and morbidity is often under diagnosed and undertreated. Furthermore elderly with diabetes has higher chance to have depression compared to those who are not.

Objectives: To determine the proportion of depression and its associated factors among elderly with Type 2 Diabetes Mellitus in Sungai Petani, Kedah.

Methodology: A cross-sectional study involving 509 elderly with type 2 Diabetes Mellitus age 60 and more. Systematic random sampling 1:3 was applied to elderly patients attended Klinik Kesihatan Bandar, Sungai Petani from November 2015 to January 2016. The inclusion criteria were patients who were diagnosed with Type 2 Diabetes Mellitus. The exclusion criteria were cognitive impairment, ECAQ score 5 and less, presence of organic brain syndrome, presence of severe mental disorder like schizophrenia, patients with mental retardation and patients who either deaf or mute. A self-administered questionnaire and participant's case note were used to obtain the information needed. Malay version of Geriatric Depression Scale (M-GDS-14) was used to assess the depressive symptoms. The data was analyzed using descriptive statistic and multiple logistic regressions.

Results: The median age of the respondents was 65 (8.0) years old. Half of respondents were male (54%) and 236 (46%) were female. Majority of respondent were Malays (63.3%) followed by Indians (27.3%) and Chinese (9.4%). Majority of respondents were married (76.8%), some were widows/divorced (21%) while the remaining were single (2.2%). More

than half were retired (68.2%), 23.4% were never employed and only small numbers of them who were still working (8.4%). Only small number of respondents completed their tertiary education (16.3%), many had completed their secondary schools (39.7%), while the remaining only had their education at primary school level (34.8%) or they did not received formal education (9.2%). Majority of the respondents (67.4%) had household income of less than RM1000. The proportion of depression was 32.2%. Elderly living with children - 1.62(*p*=0.002, 95%CI 0.07, 0.55), Elderly living with spouse, children, in law & grandchildren 1.08(*p*=0.021, 95%CI 1.18, 7.37), diabetic complication 4.68(*p*=0.001, 95%CI 2.63, 8.35) and HbA1c 1.23(*p*=< 0.001, 95%CI 1.09, 1.39) are significantly associated with depression.

Conclusion: Depression is high among elderly with Type 2 Diabetes Mellitus. Living arrangement, diabetic complication and HbA1c were significantly associated with depression.

Abstrak

Bahasa Melayu

Tajuk: Kemurungan dan faktor-faktor berkaitan di kalangan warga tua yang menghidap Diabetes Mellitus Jenis 2.

Pengenalan: prevalen Diabetes Mellitus di kalangan warga emas semakin meningkat. Walaupun kemurungan membawa risiko mortality dan morbidity yang tinggi, ia seringkali tidak dikenalpasti dan tidak dirawat. Tambahan pula, warga emas yang menghidap Diabetes Mellitus mempunyai kemungkinan yang lebih tinggi untuk mendapat kemurungan berbanding dengan mereka yang tidak menghidap Diabetis Mellitus.

Objektif: Mengenalpasti kadar kemurungan dan factor-faktor berkaitan kemurungan di kalangan warga tua menghidap Diabetes Mellitus Jenis 2 yang hadir ke Klinik Kesihatan Bandar Sungai Petani

Metodologi:Ini adalah kajian keratan rentas yang melibatkan 509 warga emas berumur 60 dan ke atas yang menghidap diabetes mellitus. Kaedah persampelan rawak bersistematik 1:3 digunakan untuk memilih peserta di kalangan warga emas yang hadir ke Klinik Kesihatan Bandar Sungai Petani dari November 2015 hingga Januari 2016. Kriteria kemasukan adalah pesakit yang menghidap Diabetes Mellitus Jenis 2, berumur 60 tahun ke atas dan skor ECAQ melebihi 5. Kriteria pengecualian pula ialah warga emas yang mempunyai masalah kognitif dan sakit mental yang teruk seperti skizofrenia dan masalah terencat akal. Borang soal selidik Skala Kemurungan Geriatrik versi Bahasa Malaysia (M-GDS-14) digunakan untuk saringan gejala kemurungan. Data di analasis menggunakan analisis deskriptif dan analisis regresi logistic berganda.

Keputusan: Median umur responden adalah 65 (8.0) tahun. Separuh daripada responden adalah lelaki (53.8%) dan 236 (43.2%) adalah wanita. Majoriti responden adalah Melayu (63.0%) diikuti India (27.6%) dan Cina (9.4%). Majoriti responden berkahwin (76.9%), janda (20.9%) manakala selebihnya adalah tidak berkahwin(2.2%). Lebih daripada separuh merupakan pesara (68.3%), 23.3% tidak pernah bekerja dan hanya sebilangan kecil daripada mereka yang masih bekerja (8.4%). Hanya sebilangan kecil responden menamatkan pendidikan tinggi mereka (16.2%), sebahagian responden mendapat pendidikan sehingga sekolah menengah (39.9%), manakalaselebihnya hanya mendapat pendidikan formal sehingga peringkat sekolah rendah (34.6%) atau tidak bersekolah (9.6%). Majoriti responden (67.5%) mempunyai pendapatan isi rumah kurang daripada RM1000. Peratusan kemurungan adalah 164 (32.1%). Warga emas yang tinggal bersama dengan anak -1,62 (p = 0.002, 95% CI 0.07, 0.55), tinggal bersama dengan pasangan, anak, menantu & cucu 1.08 (p = 0.021, 95% CI 1.18, 7.37), komplikasi diabetes 4.68 (p = 0.001, 95% CI 2.63, 8.35) dan HbA1c 1.23 (p = <0.001, 95% CI 1.09, 1.39) didapati berkait rapat dengan kemurungan.

Kesimpulan: Kadar kemurungan dikalangan warga emas adalah tinggi. Susunan tempat tinggal, komplikasi diabetis dan HbA1c adalah berkait rapat dengan kemurungan.

CHAPTER 1 INTRODUCTION

1.1 ELDERLY POPULATION

1.0 ELDERLY

Ageing Population is a global phenomenon in this new millennium and is poised to become a major issue in developing country. According to the United Nation World Assembly on Ageing held in Vienna, 1982, elderly is defined by age 60 years and above. This has been used as the cut-off and Malaysian policy makers have adopted this demarcation in planning for the senior citizens (1). The elderly population in Malaysia has increased from 5.7 per cent of total population in 1980 to 6.2 per cent in 2000. It is estimated to further increased to 10 per cent of total population in the year of 2020 (2).

The major contribution factors in the ageing of a population are rate of declining fertility ,improvement of health care system as well as standard of living which results in reducing trend of mortality rates (3). Life expectancy at birth among Malaysians has also risen to 72 years for men and 76 years for women in 2011 and there are gains also in the expectation of life at 60 years of age for all ethnic groups (3,4). Aging Health issues in Malaysia can be summarized into three main domain that is physical health, psychosocial health and nutritional problem (5).

It was shown that e. Svethe prevalence of chronic illnesses among elderly was 60.1%ein combination (6). also where in National Health Morbidity Survey 2015 8.3 (8) a

Based on National Health and Morbidity Survey in 2006, prevalence of Diabetes Mellitus in age group 60 to 64 years is 26.2% (7).

1.2 DEPRESSION AND DIABETES MELLITUS

1.1 DEPRESSION

Depression is a commonly occurring, serious, recurrent disorder with the lifetime prevalence of Major Depressive Disorder range from 8 to 16% (12). It is projected that depression, will be among the major causes of worldwide disability by the year 2020 (13). The prevalence of depression among adult in Malaysia was found to ranges from 8% to 12% regardless of geographical differences of the study setting (14). While Sherina et al reported the prevalence of depression among adult women in Malaysia as 8.6% ,recent study bt Siti et al found the prevalence of depression among adult in an urban city in Selangor was 10.3% (15,16) .

According to DSM V, criteria for Major Depressive Disorder (MDD) include five or more of the following symptoms that have been present during the same 2-week period and represent the change from previous functioning and at least one of the symptoms is either depressed mood or loss of interest or pleasure.

The symptoms include:

1. Depressed mood most of the day, nearly everyday
2. Markedly diminished interest or pleasure in all or almost all activities most of the day, nearly every day.
3. Significant weight loss when not dieting or weight gain or decrease or increase in appetite nearly every day
4. Insomnia or hypersomnia nearly every day.
5. Psychomotor agitation or retardation nearly every day.
6. Fatigue or loss of energy nearly every day.
7. Feeling worthlessness or excessive or inappropriate guilt.

8. Diminished ability to think or to concentrate.
9. Recurrent thought of death, recurrent suicidal ideation without specific plan for committing suicide.

The symptoms caused clinically significant distress or impairment in social, occupational or other aspect of functioning and it is not due to direct psychological effect or substance or general medical condition (17).

Chronic diseases cause a lot of stress. As a result, depression is a common comorbidity in a patient with chronic diseases., . 15.6% ofbetween chronic diseases andis attributable to depression vice versa (18).

According to Moussavi et al, the prevalence of depression is significantly higher in patients with chronic medical illness compared to patients who do not have it. He revealed that 9.3% of diabetes patients have comorbid depression (19). A meta-analysis looking at the prevalence of comorbid depression in adult with diabetes showed the lifetime prevalence and odds of depression is significantly higher in diabetes compared to non-diabetic group (20).

In Malaysia, the prevalence of depression in adult with Type 2 Diabetes Mellitus was 11.5% as reported by Kaur et al. Whereas, higher prevalence rate was found among diabetes patient attending out-patient clinic in a district hospital in northern Malaysia which is 22% (21,22). Older adults who have depression are at higher risk of suicide compared to other age group and most of these suicidal patient were experiencing the first episode of Major Depression Disorder (23).

Therefore it is important to detect depression in elderly especially those who have comorbid physical illness.

However, the detection of depression in elderly is challenging. because the symptoms are usually overlapped with physical illness and sometimes is atypical (25). Symptoms suggestive of depression in elderly include psychomotor retardation, poor concentration, constipation, poor perceived health, prominent anxiety symptoms, cognitive deficits and prominent somatic symptoms. They are less complaint of sadness compared to younger adult (26).

.The co-existence of both depression and chronic diseases worsen the illness outcome and quality of life and reduce compliance to the treatment regime. A meta-analysis looking at the prevalence of comorbid depression in adult with diabetes showed the lifetime prevalence and odds of depression is significantly higher in diabetes compared to non-diabetic group (22). In Malaysia, the prevalence of depression in adult with Type 2 Diabetes Mellitus was 11.5% as reported by Kaur et al. Whereas, higher prevalence rate was found among diabetes patient attending out-patient clinic in a district hospital in northern Malaysia which is 22% (23,24) .

3depressionICHAPTER 2 LITERATURE REVIEW

2.1 DEPRESSION IN ELDERLY WITH TYPE 2 DIABETES MELLITUS

According to a study by Sherina et al, 60.1% of the elderly reported having chronic illness and from this about 25% of this group are Diabetic either alone or combined with other comorbidity such as Hypertension, Ischemic Heart Disease and Gouty Arthritis (6). Similar finding was found in National Health and Morbidity Survey III in 2006, the prevalence of Diabetes Mellitus in elderly age more than 60 years was 26.2% (7). Although prevalence of depression among elderly in community was 7.6% seems to be lower than the general population, it was reported higher prevalence among elderly attending primary care clinic, ranging from 13.9 to 18% (17–19). Older adults who have depression have higher risk of suicide compared to other age group and most of these suicidal patient were experiencing the first episode of Major Depression Disorder (20). In general, the prevalence of depression was significantly higher in elderly patients with comorbid medical conditions as compared to the general community (10). .According to Moussavi et al, the prevalence of depression is significantly higher in patients with chronic medical illness compared to patient who do not have it and it revealed that 9.3% of diabetes patients have comorbid depression (25).

e Other study in Hong Kong found that 26% of elderly with diabetic had depression (31).The odds of major depression are 1.6 greater among elderly with Diabetes Mellitus than among those without diabetes and the diagnosed annual prevalence of major depression among elderly with diabetes was 2.85% compared to elderly without diabetes (32).

The ELDER (Evaluation Long-term Diabetes Self-management Among Elder Rural Adults) diabetes study that was done in North Carolina found that 15.8% of the sample had depressive symptoms and older people with diabetes and concurrent depression are less likely

to adhere to self-management thus increasing their risks of getting complications of the disease (33,34). Data from the Hispanic Established Population for the Epidemiologic Study of the Elderly Survey showed the overall rate of high levels of depressive symptoms among those with Diabetes Mellitus was significantly higher compared to those without diabetes. Presence of concomitant depression in elderly with diabetes was associated with higher health burden than is seen among diabetic without depression (35).

Presence of concomitant depression in elderly with diabetes was associated with higher health burden than is seen among diabetic without depression (35). It is also associated with higher risks of increase morbidity and mortality and higher risk of micro vascular and macro vascular complication (36).

Depression in elderly with diabetes is associated with higher risks of increase morbidity and mortality. Diabetic patient with depression were significantly associated with higher risk of micro vascular and macro vascular complication (30). Therefore it is important to screen for depression in elderly especially those who have comorbid physical illness.

Having said that, the detection of depression in elderly is pretty much challenging. It is because the symptoms are usually overlapped with physical illness and sometimes is atypical (32).Symptoms suggestive of depression in elderly include psychomotor retardation, poor concentration, constipation, poor perceived health, prominent anxiety symptoms, cognitive deficits and prominent somatic symptoms. They are less complaint of sadness compared to younger adult (33). 2.2 SCREENING FOR DEPRESSION IN ELDERLY

USPSTF recommendations encouraged physician to screen for depression in adult patients attending clinics. Evidence supported screening for depression followed by appropriate intervention by the staff does improve the depression outcomes. Evidence also showed no potential harm risks of screening for depression in adult (23,39).

The screening is simple to do, does not require extensive training and able to detect depression in elderly. Some of the self-reporting questionnaires can be quickly completed and scored. Some other interviewer-administered questionnaires that are time consuming may be necessary when patients are cognitively impaired. Persons scoring above the established cut-off level should be interviewed for further assessment and evaluation based on the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM 5). There are several screening measures that can be used to screen depression in elderly. It is important to consider the level of cognitive impairment as cognitive impairment may affect the understanding and interpretation of the questions asked in the questionnaires. The available screening tools are as below:

2.2.1 Geriatric Depression Scale

The Geriatric Depression Scale (GDS) is an instrument that was developed to screen for depressive symptoms among older people. The GDS can be self-administered or presented as an interview. The question have yes/no format to make it easier for the elderly to answer (40).

The original GDS has 30-item, however shorter version with 15-item have been suggested to reduce problem in completing the scale arising from fatigue or concentration difficulties. It was presented by Sheikh and Yesavage (1986) base on the items correlate best to the depressive symptoms. The GDS 15 was equally successful as the 30-item version in differentiating between those with and without depression among people age 55 years and over and living in the community (41). Conradsson et al also reported that GDS 15 have an overall usefulness for assessing the depressive symptoms among very old people with Mini Mental State Examination (MMSE) score of 10 or more (42).

Teh then translated the GDS 15 to Malay language and validated, living out item 9, due to its non-discriminatory value against clinical diagnosis of depression, making it 14-item scale.

Malay language Geriatric Depression Scale 14-item (M-GDS-14) is validated to be used in elderly patient as self-administered questionnaire (Cronbach's alpha 0.84, test-retest validity 0.84) and concurrent validity with Montgomery-Asberg Depression Rating Scale (MADRS) (Spearman's rho 0.68). the M-GDS-14 detected all clinically significant depression at the score of 5/6 with the sensitivity of 95.5% and specificity of 84.2% (43).

Geriatric Depression Scale (GDS) is currently the preferred instrument to be used in elderly with intact cognitive function whereas for cognitively impaired elderly, Cornell Scale for Depression in Dementia is more suitable (44,45). Several studies that look into prevalence of depression in Malaysia also used Geriatric Depression Scale (M-GDS-14) (28,46). Therefore, M-GDS-14 was chosen as the screening tool for this study because this questionnaire has been validated and suitable to be used in study population. This questionnaire is relatively simple, short and takes about 10 minutes to be filled by the participants, making it practical for use in the clinic.

2.2.2 Beck Depression Inventory (BDI)

Beck Depression Inventory (BDI) was first introduced in 1961 by Beck et al. It was derived from clinical observation about the symptoms and the attitudes displayed by the depressed patients. These attitudes and the symptoms were consolidated into 21 items and scaled 0 to 3 for each item. Higher values correspond to higher depressive symptomatology. Since then, it has been revised and upgraded to BDI-IA, BDI-II and BDI-PC to make it better suited for the use in the population. It has become one of the most widely instrument used for measuring the severity of depression in psychiatric patients (47–49). BDI also has been shown to be comparable to the Geriatric Depression Scale in the effectiveness for assessing the severity of depression in elderly (50). It was initially designed to be clinician-administered but most

often it is self-administered (47,49). BDI was then translated and validated into Malay language to suite it used in the Malay population (51). However, this questionnaire was not used in this study. It is because majority of study on depression among elderly in Malaysia used Geriatric Depression Scale and very few study used BDI.

2.2.3 Center for Epidemiological Studies Depression Scale (CES-D)

The CES-D is a 20-item, self-reported measure which assesses the number and frequency of depressive symptoms that a person experienced in the past one week. The items emphasize on the affective component, depressed mood. Scores range from 0-60, with higher scores indicating more symptoms of depression (52). A CES-D (10-item) version was then developed and found to be comparable to those reported for the original CES-D. it was proven to be excellent properties for use as a screening instrument for the identification of major depression in older adults (53,54). CES-D also has been proved to be a reliable instrument for identifying depressive symptoms in diabetic patients in Singapore (55). It has been translated and validated in Malay language and was proved to be reliable (56,57). However the used in the geriatric population still need to be further studied.

2.2.4 Cornell Scale for Depression in Dementia

Cornell Scale for Depression in Dementia is a 19-item instrument specifically designed for rating of symptoms of depression in demented patients. It is more appropriate than self-reported instrument for cognitively impaired patients. However, it should be administered by the clinician to the primary care-giver and require more times (58).

2.3 ASSOCIATED FACTORS FOR DEPRESSION IN DIABETES MELLITUS

2.3.1 Socio-demographic Factors

Depression in diabetes was found to be significantly associated with gender, ethnicity, educational level, marital status and current job status. Kaur et al has found that sex, ethnicity and educational level are predictors of depression in people with diabetes (21). Many studies have shown female are more common to have depression compared to male (27,28,46). While some study found Indian ethnicity had higher rate of depression, other studies found the difference among race were not significant (21,29,33). Marital status is significantly associated with depression in elderly where by being single or divorce do confer the risk of being depressed (21,27,28,46). Unemployment and low educational level also was considerably associated with depression among elderly (33,59). However, a study on prevalence of depression among elderly Chinese with diabetes showed that diabetes alone is significantly related to depression even after controlling for age, gender, marital status and education (31).

2.3.2 Family Dynamic Factors

2.3.2.1 Living Arrangement

Living arrangement also has important role in developing depression among elderly, more so if they have chronic illness such as diabetes. Studies have shown there was higher percentage of elderly who lives alone or live with other than family members to have depressive symptoms compared to those who live with family (27,29,46). A study in Korea also reported that elderly who are living without spouse in a nuclear family or living alone are more likely to have depression compare to elderly living with their spouse (60,61).

2.3.3 Medical /Health Factors

2.3.3.1 Duration of Diabetes

In adult with diabetes, duration of less than 2 years of diagnosis is significant predictors of depression (21). However, majority of the elderly was diagnosed to have diabetes for more than 10 years and longer duration of diabetes has been shown to be associated with depression in elderly with diabetes (33,62).

2.3.3.2 Control of Diabetes (HbA1c)

Studies have linked the association between depression and diabetes self-care. High level of depressive symptoms was inversely associated with being physically active and following healthful eating plan (34). Patients with major depression were more likely to lack of self-care activities and more sedentary than non-depressed patients (62). The percentage of days in oral hypoglycaemic therapy interruptions was shown to be significantly associated with depressive symptoms severity (37).

In a study by Fisher et al, only diabetes distress was found to be associated with diabetes control and there were no significant relationship between Major Depressive Disorder or depressive symptoms with glycaemic control although in his earlier study, it has been shown that high depressive affect also linked with high HbA1c (63,64). Other studies also showed that there were significant longitudinal relationship between depression and glycaemic control as measured by HbA1c and that the depression is associated with persistently higher HbA1c level over 4 year follow up (65). Prior cross-sectional study by Lustman et al demonstrated that depression in diabetes patient was significantly associated with hyperglycaemia (66).

2.3.3.3 Comorbidities and Diabetes complications

Comorbidities and presence of diabetic complications also has significant association with depression. There were higher rates of depression among those who have chronic conditions (33). The influence of diabetes on depression are explained by multiple comorbid conditions related to diabetes and mainly attributable to vascular complications (31). Fisher et al also found that high comorbidities were consistently and independently related to greater persistence of depressive symptoms in patients with diabetes (64).

2.4 JUSTIFICATION AND RATIONAL OF THE STUDY

To date, the local data that are available is the prevalence of depression and associated factors among elderly in general population and the prevalence of depression among adult with diabetes. There are limited local data on the prevalence of depression among elderly with Type 2 Diabetes Mellitus. This gap of data is an actuation that a study need to be conducted to look into depression among diabetic elderly and how does depression associated with glycaemic control. With the information from the study, it will help the physician and family medicine specialist in detecting early depression in elderly, so we can treat and manage early.

CHAPTER 3 OBJECTIVES

3.1 GENERAL OBJECTIVES

To determine the proportion of depression and its associated factors among elderly with Type 2 Diabetes Mellitus attending Klinik Kesihatan Bandar Sungai Petani.

3.2 SPECIFIC OBJECTIVES

1. To determine the proportion of depression in elderly with Type 2 Diabetes Mellitus attending Klinik Kesihatan Bandar Sungai Petani
2. To determine the associated factors with depression among elderly with Type 2 Diabetes Mellitus attending Klinik Kesihatan Bandar Sungai Petani.
    i. Sociodemographic factors
        a. Gender
        b. Marital status
        c. Level of education
        d. Level of income
    ii. Family dynamic factors
        a. Living arrangement
    iii. Medical/Health factors
        a. Duration of diabetes
        b. HbA1c
        c. Comorbidities
        d. Diabetes complications

CHAPTER 4 METHODOLOGY

4.1 STUDY AREA/BACKGROUND

The study was conducted in Klinik Kesihatan Bandar Sungai Petani (KKBSP). KKBSP is situated in the centre of Sungai Petani. Klinik Kesihatan Bandar Sungai Petani covers almost 100,000 population and run by 120 staffs including 1 Family Medicine Specialist and 25 medical officers. According to National Diabetes Registry, the registered number of Diabetes patients who undergo follow up for their treatment in KKBSP are 8900 patients, encompasses half of the total diabetic patients registered in District of Kuala Muda. Therefore, Klinik Kesihatan Bandar Sungai Petani is chosen to be the place to conduct this study.

4.2 STUDY DESIGN

This study was a cross-sectional study.

4.3 POPULATION SAMPLE

4.3.1 REFERRENCE POPULATION

Elderly patients with Type 2 Diabetes Mellitus in Kuala Muda district

4.3.2 SOURCE POPULATION

Elderly patients with Type 2 Diabetes Mellitus attending Klinik Kesihatan Bandar Sungai Petani.

4.3.3 STUDY POPULATION

The elderly patients with Type 2 Diabetes Mellitus attending Klinik Kesihatan Bandar Sungai Petani from 1st November 2015 to 31st January 2016.

4.4 INCLUSION CRITERIA

1. Patients who is diagnosed with Type 2 Diabetes Mellitus.
2. Age 60 years and above
3. ECAQ score more than 5

4.5 EXCLUSION CRITERIA

1. Presence of organic brain syndrome
2. Presence of severe mental disorder like schizophrenia
3. Patients with mental retardation
4. Subjects who either deaf, mute

4.6 SAMPLE SIZE CALCULATION

Sample size to determine the proportion of depression among elderly with type 2 Diabetes Mellitus in Klinik Kesihatan Bandar Sungai Petani was calculated using a single proportion formula. Sample size for the associated factors is calculated using 2 proportion formula. Sample size calculation was calculated for each study specific objectives and the biggest amongst the sample size was chosen.

Objective 1: To determine the proportion of depression in elderly with Type 2 Diabetes Mellitus attending Klinik Kesihatan Bandar Sungai Petani.

Calculation of sample size was using Single Proportion formula. Based on the estimated prevalence from previous study of 15.8% (16) the calculated sample size is 217 (including a possible 20% of drop-out rate of 37), with confidence level of 95% and power of 80%.

$n = (z/\Delta)^2 p(1-p)$

n = minimum required sample size

z = value of standard normal distribution. The level of confidence is 95%; therefore z value is taken as 1.96

Δ =absolute precision = 0.05

p = is the prevalence of depression among elderly with Type2 Diabetes Mellitus ()

=0.16

$n = (1.96/0.05)^2 \times 0.16(1-0.16)$

20% drop out rate of = 181 + 36.2

= 217

Objective 2:

The sample size for categorical was calculated using two proportions formula (by PS software). The calculations of sample size were as follows:

Categorical Variables (33)

Table 1: Sample size calculation for categorical variables

Variables	**p1**	**p2**	**minimum sample size (n)**	**n+20% non respond rate**
Gender	0.2	0.1	219	272
Marital status	0.19	0.12	446	535
Educational status	0.21	0.09	154	184

Numerical variable

Table 2: Sample size calculation for numerical variable

Variables	**σ**	**δ**	**minimum sample size (n)**	**n+20% non respond rate**
HbA1c	1.41	0.4	392	470

The biggest sample size belongs to marital status 535. Therefore, in this study the sample size will be taken as 535.

4.7 SAMPLING METHOD

Systematic random sampling (1:3) was applied in the sampling frame. The required sample size was 535 subjects for three months duration. Therefore the total number of patients required for a month was 177. Thus, the total number of patients required per week was 44. Study was done for 3 days per week, therefore total number of patients requires to be interviewed per day was 14. Based on the attendance list, the average number of elderly patient with Type 2 Diabetes Mellitus who come for follow up at the clinic is about 50 patients per day.

4.8 RESEARCH TOOLS

4.8.1 Personal Information Data

This questions was prepared to get information on general background of the patients. It has 18 items which inquire personal bio data (identification, gender, age and race), marital status and living arrangement, educational level, occupation, total income and sources, and diabetes status (Duration of Diabetes, HbA1c levels, presence of co-morbidities/chronic diseases and diabetic complications).

4.8.2 Geriatric Depression Scale (M-GDS-14)

M-GDS-14 is the Malay version of Geriatric Depression Scale which was based on the Geriatric Depression Scale (GDS). The GDS has been recommended by the Royal College of Physicians, British Geriatric Society and The Royal College of General Practitioners as a suitable scale to screen for depression in elderly. The shorter version of GDS 15-item scale was validated against the 30-item scale and it is recommended to be used in primary care (41,67).

The GDS 15 was translated to Malay language and validated, living out item 9, due to its non-discriminatory value against clinical diagnosis of depression, making it 14-item scale.M-GDS-14 is validated to be used in elderly patient as self-administered questionnaire (Cronbach's alpha 0.84, test-retest validity 0.84) and concurrent validity with MADRS (Spearman's rho 0.68). The M-GDS-14 detected all clinically significant depression at the score of 5 with the sensitivity of 95.5% and specificity of 84.2% (43).

Subjects with the score of five and more will be in the depression group, while those with score of less than five will belong to the non-depression group. Those patients who were detected to have clinically significant depression were referred to the attending medical officer/family medicine specialist/ psychiatrist for further evaluation and treatment as needed.

4.8.3 Participant's Case Note

Patients' case notes were used to obtain detail information of patient's data regarding presence of comorbidities/chronic disease and also HbA1c level within latest six month.

4.8.4 Elderly Cognitive Assessment Questionaire (ECAQ)

Elderly Cognitive Assessment Questionnaire is a quantitative assessment of cognitive impairment among elderly. It has 10-item questionnaires assessing memory, orientation and memory recall. It has sensitivity of 85.3%, specificity 91.5% and positive predictive value 82.5%. Each item with a correct response carries one mark. Score of 5 or less indicates cognitive impairment (68).

4.9 DATA COLLECTION PROCEDURE

Total duration of data collection was three months from November 2015 to January 2016. Participants only answer the questionnaire once. After registration, patients were screened for inclusion and exclusion of criteria. Those who were eligible were invited to participate in the study with the informed consent. They were selected using systematic random sampling whereby 1 in 3 patients were chosen. If a patient refused to participate, the next patient was selected. Patients care was delivered indifferently even if he/she refused to involve in the study. Consented participants were given patient information sheet that explained about the research. After the patient signed the informed consent form, he/she was given the set of questionnaire to be answered (assisted self-guided). The researcher stayed beside the respondent to help if there were any questions or inquiry. The remaining information needed was completed by referring to patients' case notes. Participants who were detected to have score five and more will be referred to the Medical Officer for further evaluation and assessment and they were treated accordingly.

Duration of involvement of participant in this study was about 15 minutes (to answer the questionnaire).

4.10 OPERATIONAL DEFINITIONS

1. Elderly

   Age 60 years and above (1).

2. Type 2 Diabetes Mellitus

   DM was defined as self-report of physician diagnosis and the diagnosis was done using Malaysian Clinical Practice Guideline of Diabetes Mellitus by using one abnormal fasting blood sugar (FBS) or Random Blood Sugar (RBS) for symptomatic

and two abnormal FBS/RBS for asymptomatic patient with value for FBS ≥ 7.0 mmol/L and RBS ≥ 11.0 mmol/L.

3. Depression

   It was defined as symptoms meeting established clinical threshold criteria for depression as measured by validated questionnaires or standardized psychiatric interview. Screening for depression in this study using Geriatric Depression Scale (Malay language) M-GDS-14 and cut off point to label the respondent as depression is 5 and above (43)

4. Comorbidities

   Presence of one or more of chronic illness other than DM.

5. Diabetic complications

   Presence of one or more complications of DM such as retinopathy, nephropathy, neuropathy, dermopathy, diabetic foot and erectile dysfunction.

4.11 STATISTICAL ANALYSIS

Data entry and analyses were performed by using Statistical Package for the Social Sciences (SPSS) Statistic version 22 for descriptive analysis and multiple logistic regression. Respondent who did not complete the questionnaire were included in the descriptive analysis for socio demographic data but were excluded in the proportion of depression and multiple logistic regression. The numerical variable was expressed in median and interquartile ratio (IQR) for age. Whereby, HbA1c and duration of Diabetes Mellitus were expressed in mean and standard deviation (SD). As for categorical variables, frequency and percentage were calculated. Variable with p-value less than 0.05 in the Simple Logistic Regression and thought to be important risk factors of depression were entered into the Multiple Logistic Regression. The forward and backward method was used to predict the associated variables

for depression. The presence of interaction was assessed prior to determining the model. The dependent variable is depression. The independent variables are gender, marital status, level of education, level of income, living arrangement, duration of diabetes, HbA1c, comorbidities and diabetic complications.

4.12 ETHICAL APPROVAL

The proposal of this study was presented to Department of Family Medicine and Ethics Committee of University of Science Malaysia. Ethical approval was received on 9th September 2015 USM/JEPeM/15010026 (Appendix I). This study was registered with National Medical Research Register (NMRR) and received the approval on 29th October 2015 NMRR-15-1243-24003 (IIR) (Appendix II).