UNIVERSITI PUTRA MALAYSIA

FACTORS ASSOCIATED WITH GLYCEMIC CONTROL AMONG PATIENTS WITH DIABETES ATTENDING OPHTHALMOLOGY CLINIC, HOSPITAL SERDANG.

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By

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A project submitted as a partial fulfilment of the requirement for Bachelor of Science (Dietetics) degree from the Faculty of Medicine and Health Sciences, Universiti Putra Malaysia

The project titled “Factors Associated with Glycemic Control Among Patients with Diabetes Attending Ophthalmology Clinic, Hospital Serdang” was prepared by Muhammad Harith Bin Zakaria and submitted to the Faculty of Medicine and Health Sciences as a partial fulfilment of the requirement for Bachelor of Science (Dietetics) degree from the Faculty of Medicine and Health Sciences, Universiti Putra Malaysia.

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Date: _____

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ACKNOWLEDGEMENT

First and foremost, I am eternally grateful to God for giving me the strength and energy to complete this study. I am also very thankful for every single person who has helped me directly and indirectly throughout the course of this study, especially to Assoc. Prof. Dr. Barakatun Nisak binti Mohd Yusof who has supervised me and for being a reliable guidance and helped me steer the direction of this study towards a better path. To Dr. Noor `Aniah binti Azmi from the Ophthalmology Department of Hospital Serdang, thank you for your time and help in providing a platform for me to acquire useful resources for this study. To my outstanding study partner, Nur Ain binti Izudin, I can never thank you enough for your endless moral support and always being my best motivator in the completion of this study. To my dearest friends in the dietetics program, thank you for putting up with me, answering my questions, and pushing me to continue my work. I would also be nowhere near the finish of this study without my family's support. Although not mentioned in detail, this study would not have been possible without all the participants and the authorities that have approved the initiation of this study, and I wish to thank every single one of them for believing in me.

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FACTORS ASSOCIATED WITH GLYCEMIC CONTROL AMONG PATIENTS WITH DIABETES ATTENDING OPHTHALMOLOGY CLINIC, HOSPITAL SERDANG.

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Abstract

Most patients who attend ophthalmology clinics have diabetes, and it is one of the factors that contribute to progression of ocular diseases like diabetic retinopathy. Inoptimal glycemic control may contribute to progress of diabetic retinopathy. Therefore, this cross-sectional study aimed to determine factors associated with glycemic control among patients with diabetes attending an ophthalmology clinic. Patients with confirmed diagnosis of diabetes and attended ophthalmology clinic of Hospital Serdang were recruited. Sociodemographic characteristics, nutritional status, medical profile, and dietary adherence were obtained through a questionnaire, 2-day 24-hour diet recall, medical records, and revised Summary of Diabetes Self-Care Activities (SDSCA) questionnaire. A total of 65 patients with T2DM aged 39 to 78 years old participated in this study. Most of them were overweight with average BMI of 27.9 ± 4.8 kg/m^2. They did not take the recommended amount of energy, protein, and fiber from their diet. About 46.2% of them had diabetes for more than 10 years, and 83.1% had comorbidities. Almost half of the patients had diabetic retinopathy. The proportion of patients who had good dietary adherence and optimal glycemic control was only 6.4% and 12.3% respectively. Overall, 87.7% of patients with diabetes who attended ophthalmology clinic did not have optimal glycemic control. There were significant associations of duration of diabetes, presence of comorbidities, and stage of diabetic retinopathy with glycemic control. Interventions should be uniquely tailored for each patient and more emphasis should be put on the factors that were associated with glycemic control.

FAKTOR-FAKTOR BERKAIT DENGAN KAWALAN GLISEMIK DALAM KALANGAN PESAKIT DIABETES MENGHADIRI KLINIK OFTALMOLOGI, HOSPITAL SERDANG

Oleh

MUHAMMAD HARITH BIN ZAKARIA

Abstrak

Kebanyakan pesakit yang menghadiri klinik oftalmologi adalah penghidap diabetes, dan ia menjadi salah satu faktor penyumbang kepada penyakit retinopati diabetik. Kawalan glisemik ternyata mempengaruhi tahap retinopati diabetik, jadi pesakit yang menghadiri klinik oftalmologi dianggap mempunyai kawalan glisemik yang tidak optimum. Kajian ini bertujuan untuk menentukan hubungkait antara faktor sosiodemografi, status pemakanan, latar belakang perubatan, dan pematuhan pemakanan dengan kawalan glisemik dalam kalangan pesakit diabetes yang menghadiri klinik oftalmologi. Kajian keratan rentas ini melibatkan pesakit diabetes yang telah menghadiri klinik oftalmologi di Hospital Serdang. Faktor sosiodemografi, status pemakanan, latar belakang perubatan, dan pematuhan pemakanan telah diambilkira dari boring soal selidik, sejarah pemakanan dalam tempoh 24 jam dari 2 hari yang lepas, rekod perubatan, dan soal selidik Ringkasan Aktiviti Penjagaan Diri Pesakit Diabetes. Kajian ini telah disertai oleh 65 pesakit diabetes yang menghadiri klinik oftalmologi di Hospital Serdang berumur dalam lingkungan 39 hingga 78 tahun. Kebanyakan mereka mempunyai berat badan berlebihan dan secara purata Indeks Jisim Tubuh mereka adalah 27.9 ± 4.8 kg/m^2. Rata-rata mereka tidak mengikut jumlah saranan pengambilan tenaga, protein, dan serat daripada pemakanan mereka. Sebanyak 46.2% daripada mereka telah menghdiap diabetes melebihi 10 tahun, dan 83.1% mempunyai penyakit lain juga. Hampir separuh daripada mereka menghidap penyakit retinopati diabetik. Jumlah pesakit yang mempunyai pematuhan pemakanan yang elok hanyalah 6.4%, manakala yang mempunyai kawalan glisemik yang optimum hanya 12.3% sahaja. Kesimpulannya, sebanyak 87.7% pesakit diabetes yang menghadiri klinik oftalmologi tidak mempunyai kawalan glisemik yang optimum. Juga, faktor-faktor yang berkait dengan kawalan glisemik termasuklah tempoh menghidap diabetes, menghidap penyakit selain diabetes, dan tahap retinopati diabetik. Jadi, lebih penekanan patut diletakkan pada faktor-faktor yang mempengaruhi kawalan glisemik dalam merawat pesakit diabetes.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Research background

Diabetes is a group of metabolic diseases (commonly known like type 1 and type 2 diabetes) which are all marked by hyperglycemia resulting from impaired insulin secretion, insulin action or both, and if chronic it can lead to long-term damage, dysfunction, and failure of organs, mostly targeting the eyes, kidneys, nerves, heart, and blood vessels. Type 2 diabetes is due to a progressive loss of insulin secretion on top of having insulin resistance, and it is the most common type of diabetes accounting up to 95% and type 1 diabetes is due to β-cell destruction, usually leading to absolute insulin deficiency which comes in less at only 5-10% of all diabetes cases (American Diabetes Association, 2018).

Glycated haemoglobin (HbA1c) level is an important marker in monitoring glycemic control among patients with diabetes. Most studies and health authorities recommend HbA1c level of 6.5% as the cut-off point for optimal diabetes control (Florkowski, 2013; Fonseca, Inzucchi, & Ferrannini, 2009). One of the most common complications of diabetes is diabetic retinopathy (DR) which remains a leading cause of visual loss in adults, and it can be diagnosed into two main stages: non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR) accordingly by clinical manifestations of vascular abnormalities in the eye's retina (Wang & Lo, 2018).

There are several factors that might be associated with glycemic control which include sociodemographic characteristics, nutritional status, medical profile, and dietary adherence (Haghighatpanah, Nejad, Haghighatpanah, Thunga, & Mallayasamy, 2018; Raj et al., 2018).

Sociodemographic characteristics include age, sex, ethnicity, educational level, and monthly household income. Poor glycemic control is associated with aging (Chang & Halter, 2003). According to the National Health and Morbidity Survey 2015 Volume II, ethnicity shows an association with glycemic control, with the Indian population having the highest prevalence of diabetes (22.1%) among the other ethnicities in Malaysia: Malays (14.6%), Chinese (12.0%), Other Bumiputras (10.7%), and others (7.4%) (Bakar et al., 2015).

Nutritional status includes Body Mass Index (BMI) that is also associated with glycemic control, in which with increased BMI, there are more complications of diabetes (Gray, Picone, Sloan, & Yashkin, 2015). Dietary intake for instance, plays a significant role in glycemic control (Forouhi, Misra, Mohan, Taylor, & Yancy, 2018).

Also, medical profile has been associated with glycemic control. Use of medications shows an association with glycemic control depending on the complexity of the regimen (Ayele, Tegegn, Ayele, & Ayalew, 2019). Presence of comorbidities is also associated with poor glycemic control. Occurrence of cardiovascular disease is common in patients with diabetes (Luijks et al., 2015).

Dietary adherence can be defined as the extent to which a person's behaviour in following a diet corresponds with the agreed recommendation by a healthcare provider (García-Pérez, Alvarez, Dilla, Gil-Guillén, & Orozco-Beltrán, 2013). An effective therapy for controlling blood glucose is good dietary adherence (Jaworski, Panczyk, Cedro, & Kucharska, 2018).

1.2 Problem statement

According to Malaysia's National Health and Morbidity Survery (NHMS) 2019, prevalence of diabetes among adults rose from 13.4% in 2015 to 18.3% in 2019, indicating that there is a significant amount of people with potentially blinding diabetic retinopathy, a disease that is present in most patients attending an ophthalmology clinic (Goh, Omar, & Yusoff, 2010).

However, there is a limited number of studies in Malaysia regarding the factors associated with glycemic control among patients with diabetes attending ophthalmology clinic. One of the studies conducted among patients with diabetes in primary care setting in East Malaysia confirm that the factors associated with diabetic retinopathy are duration of diabetes, body mass index and visual loss (Mallika et al., 2011).

Studies regarding status of glycemic control specifically among patients with diabetes attending ophthalmology clinics in Malaysia are minimal. A study done among patients with diabetic retinopathy in a Malaysian tertiary teaching hospital, an eye disease common among patients with diabetes who attend an ophthalmology clinic, has shown that glycemic control among most of these patients were suboptimal (HbA1c more than 8.0%) (Huri, Huey, Mustafa, Mohamad, & Kamalden, 2018). However, only one study is not sufficient to be conclusive of the overall population in Malaysia. Other than that, studies from Greece and Malaysia have found that glycemic control in terms of HbA1c level plays a significant role in the progression of diabetic retinopathy (Chatziralli, 2018; Mohamed, Gillies, & Wong, 2007). Patients with diabetes who attended ophthalmology clinics already have or suspected to have ocular diseases that might have progressed due to an inoptimal glycemic control, therefore their status of glycemic control should be studied on to reveal the cruciality in managing them. A study in ophthalmology clinic setting using cut-off point of HbA1c >9.49% to indicate inoptimal glycemic control shows that the patients have high mean HbA1c level (Higgins, Khan, & Pearce, 2007). However, in Malaysia, the cut-off point is more stringent. The HbA1c >6.5% indicating inoptimal glycemic control (Kamaruddin, Omar, & Sukor, 2015). The variance might reveal a huge margin of patients with inoptimal glycemic control.

Dietary adherence also affects glycemic control. However, there are limited studies that have identified the association of dietary adherence with glycemic control. In one of the studies, it

is found that among diabetic patients treated by private general practitioners in Kelantan, Malaysia, showed unsatisfactory results with only 37.4% adhering to the prescribed diet (Mafauzy, 2005). Another study proves that a good dietary adherence results in better glycemic control (Marinho et al., 2018). Nonetheless, both studies were not conducted among patients attending ophthalmology clinic.

Therefore, this study aims to determine the association of sociodemographic characteristics, nutritional status, medical profile, and dietary adherence with glycemic control among patients with diabetes attending an ophthalmology clinic. The following research questions were investigated:

1. What are the sociodemographic characteristics, nutritional status, medical profile, and dietary adherence of patients with diabetes attending ophthalmology clinic of Hospital Serdang?
2. What is the glycemic control status of patients with diabetes attending ophthalmology clinic of Hospital Serdang?
3. What is the association of sociodemographic characteristics, nutritional status, medical profile, and dietary adherence with glycemic control of patients with diabetes attending ophthalmology clinic of Hospital Serdang?

1.3 Significance of this study

This study provided data to the glycemic control status of patients with diabetes attending ophthalmology clinic in Malaysia. This study served as baseline data on the factors associated with glycemic control among patients with diabetes attending an ophthalmology clinic. This knowledge is useful in improving the management of patients with diabetes attending ophthalmology clinics to achieve improved glycemic control.

Also, this study filled the gaps of the limited evidence on the association between dietary adherence and glycemic control among patients with diabetes attending ophthalmology clinic in Malaysia. It is important for healthcare providers to understand the patient's practices in following a diet that influences their glycemic control, so that better strategies can be constructed to correct the dietary practices towards an improved glycemic control.

1.4 Objectives

1.4.1 General objective

To determine factors associated with glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

1.4.2 Specific objectives

1. To determine sociodemographic characteristics, nutritional status, medical profile, and dietary adherence among patients with diabetes attending ophthalmology clinic of Hospital Serdang.
2. To determine glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.
3. To determine association of sociodemographic characteristics, nutritional status, medical profile, and dietary adherence with glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

1.5 Hypotheses

1. There is an association between sociodemographic characteristics and glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

2. There is an association between nutritional status and glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

3. There is an association between medical profile and glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

4. There is an association between dietary adherence and glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

1.6 Conceptual framework

The first independent variable was sociodemographic characteristics, which assesses the respondent's background (age, sex, ethnicity, educational level, and monthly household income). Age, among the other sociodemographic factors is significantly associated with glycemic control (Nanayakkara et al., 2018).

Next, nutritional status (BMI and dietary intake which includes total energy, carbohydrate, protein, fiber and vitamin A intake). Having a higher BMI increases the chances of having poorer glycemic control (Bae, Lage, Mo, Nelson, & Hoogwerf, 2016).

Thirdly, medical profile (random blood glucose, fasting blood glucose, number of medications used, duration of diabetes, stage of diabetic retinopathy, presence of comorbidities). Number and type of comorbidities affect glycemic control negatively in the long run (Luijks et al., 2015).

The final independent variable was dietary adherence. Dietary adherence is crucial in maintaining glycemic control at the optimal level (Habib & M. Durrani, 2018). However, a local Malaysian study has shown that dietary adherence is relatively low among patients with diabetes (Tan, Juliana, & Sakinah, 2011).

Figure 1.0 shows the conceptual framework for this study. Four main independent variables and one dependent variable were chosen in this study. The dependent variable was glycemic control indicated by level of glycated haemoglobin (HbA1c).

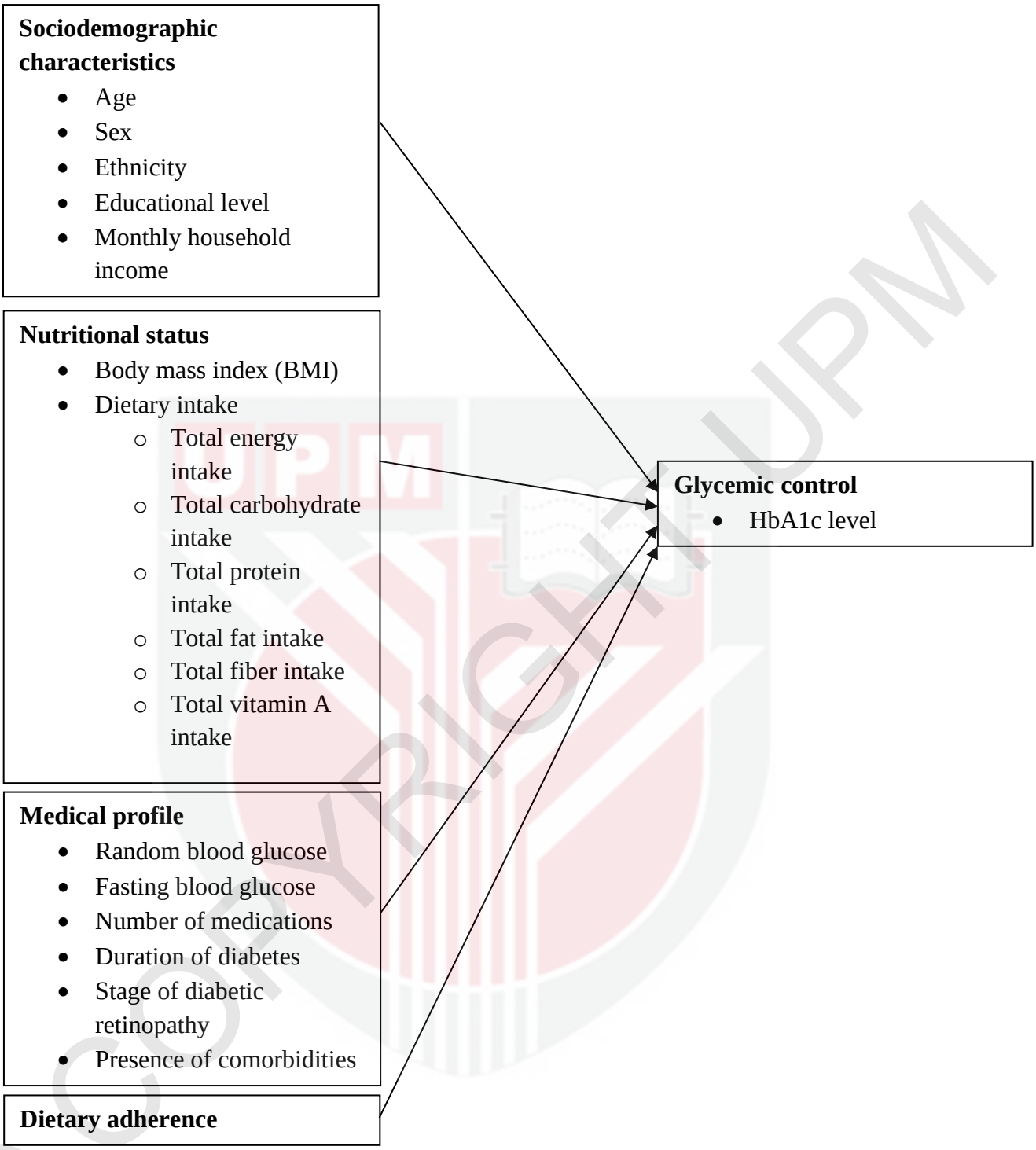


Figure 1.0. Conceptual framework of this study

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview of diabetes mellitus

Diabetes mellitus (DM) is one of the most common diseases in the world with increasing prevalence. It is a group of metabolic diseases characterized by hyperglycemia or increased blood sugar level due to impaired insulin secretion, insulin action, or both (American Diabetes Association, 2013). Long-term increased blood glucose level is associated with damage, dysfunction, and failure of different organs especially the eyes, kidneys, nerves, heart, and blood vessels (American Diabetes Association, 2013). There are some pathogenic processes involved in the development of diabetes which include autoimmune destruction of the β-cells of the pancreas with consequent insulin deficiency, and abnormalities that causes insulin insensitivity or resistance by the target tissues, in which the impairment of insulin secretion and defects in insulin action that frequently coexist in the same patient but it is unclear which is the primary cause of the hyperglycemia, as it can be due to one of them or both (American Diabetes Association, 2013). Diabetes is a major public health concern in Malaysia since it increased up to 18.3% among adults in 2019 (NHMS 2019).

One of the most common complications associated with diabetes mellitus is microvascular disease including diabetic retinopathy (DR). DR is the leading cause of blindness in older adults (Goh et al., 2010; Huri et al., 2018; Wang & Lo, 2018). Among DM patients, it is estimated that 93 million of them have DR, 17 million have proliferative diabetic retinopathy (PDR), and 21 million have diabetic macular edema (DME) globally. A systematic review from 35 worldwide population-based studies have found that the prevalence of DR was 34.6%, PDR was 7%, and DME was 6.8% among DM patients (Yau et al., 2012). This trend occurs especially among working adults in industrialized nations causing them to have severe loss of

vision and visual impairment due to changes and abnormalities occurring in the retina (Safi, Qvist, Kumar, Batumalaie, & Ismail, 2014).

From ophthalmology perspective, 29.2% of patients with T2DM who underwent first time eye screening were found to have retinopathy in a study conducted in tertiary medical centre in Kuala Lumpur (Tajunisah, Wong, Tan, Rokiah, & Reddy, 2011). While another study conducted in ophthalmic unit of a tertiary health care institute in India found that prevalence of diabetic retinopathy was 29.0% among patients with diabetes (Fazili et al., 2019).

2.2 Overview of glycemic control

Glycemic control is the main concern and set as a target for nutrition management in patients with diabetes. Glycemic control is an important factor for the presence and progression of other diseases. Poor glycemic control is prevalent among patients with diabetes in Malaysia (Firouzi, Barakatun-Nisak, & Azmi, 2015). A study has found that glycemic control is associated with reduction in the incidence of major cardiovascular events, while another study has shown that glycemic control remains as a major factor in the worsening of DR (Chatziralli, 2018; Mannucci, Dicembrini, Lauria, & Pozzilli, 2013).

This shows how important glycemic control is among patients with diabetes. Glycemic control can be monitored by referring to glycated haemoglobin (HbA1c) level. According to the Malaysian Clinical Practice Guideline, HbA1c cut-off value for type 2 diabetes mellitus patients in 2015 is ≤6.5% which is considered as good glycemic control and >6.5% as poor glycemic control (Kamaruddin et al., 2015).

HbA1c indicates average blood glucose level for approximately the last 120-day lifespan of the red blood cell, but it represents more of the blood glucose level in the past one month (Tahara & Shima, 1995). Besides, HbA1c tests are more convenient as it does not require the

patient to fast or require any specific diet prior to the test (Borch-Johnsen & Colagiuri, 2009). HbA1c is also very stable and it does not undergo much change in the collection tube that could alter the result prior to its analysis (Florkowski, 2013).

2.3 Factors associated with glycemic control

2.3.1 Sociodemographic characteristics

In a few studies among type 2 diabetes mellitus patients, it is found that age is significantly associated with glycemic control (Nanayakkara et al., 2018; Paul, Ittyachen, Mathew, & Velusamy, 2016). Another Asian study also found that age is significantly associated with glycemic control, along with sex of the subjects (Haghighatpanah et al., 2018). However, in another study among adults with diabetes, age and sex, was found to be not significantly associated with glycemic control along with monthly household income, but educational level is significant since health literacy in diabetes care is related to educational level (Fiseha, Alemayehu, Kassahun, Adamu, & Gebreweld, 2018).

2.3.2 Nutritional status

Several studies agree that having excess weight contribute to higher risk of death, and this was linked to the progression of various diseases including diabetes (Adams et al., 2006; Flegal, Graubard, Williamson, & Gail, 2007). According to a study in the United States of America, body mass index (BMI) is an indicator for excess weight based on a person's height and it was found that BMI plays an important role in the development of diabetes complications (Gray et al., 2015).

In T2DM patients, it was found that body mass index (BMI) is significantly associated with glycemic control (Benoit, Fleming, Philis-Tsimikas, & Ji, 2005). However, in an Indian study, it was found that BMI did not correlate significantly with glycemic control (Paul et al., 2016).

In another Indian study, it was found that BMI has significant association with glycemic control (A Kakade, R Mohanty, & Rai, 2018).

In terms of dietary intake, a Japanese study involving 229 patients with T2DM revealed that total energy intake was significantly associated with glycemic control (Haimoto, Watanabe, Komeda, & Wakai, 2018). Two other studies; one in America and another one in Korea also found the same significant association between total energy intake with glycemic control. However, the latter found that each proportion of macronutrients like carbohydrate, protein, and fat are not closely related to glycemic control (Kang & Kim, 2012; Xu et al., 2007).

On the contrary, total carbohydrate intake was found to be significantly associated with glycemic control in a study among Indonesians, and a study in Japan had the same findings (Haimoto et al., 2018; Wiradarma, Bardosono, & Soebardi, 2018). As for protein intake, there is a positive association with glycemic control among patients with T2DM in Japan (Haimoto et al., 2018). However, two other studies found the association between total protein intake and glycemic control, but with controversial findings on the direction of association (Hakeem, Shiraz, Riaz, Fawwad, & Basit, 2018; Woo, Park, Woo, & Choue, 2010). A study conducted among elderly Korean patients with T2DM has revealed that lower fat intake is significantly associated with higher HbA1c level (Woo et al., 2010). However, another study conducted among American Indians has revealed that higher fat intake is associated with poorer glycemic control (Xu et al., 2007). This trend is also supported by another study done in Japan in which there is a negative association between total fat intake with glycemic control (Haimoto et al., 2018). So, there are varying findings regarding the direction of dietary intake with glycemic control.

2.3.3 Medical profile

According to a study regarding diabetes, fasting plasma glucose was found to be better correlated with HbA1c level than postprandial plasma glucose (Khan, 2001). Another study also found that fasting plasma glucose is significantly associated with glycemic control. Next, the use of medications is also significantly associated with glycemic control as shown by several studies (Ayele et al., 2019; Benoit et al., 2005; Fiseha et al., 2018; Haghighatpanah et al., 2018). Furthermore, a study by Ayele et al. (2019) has shown that a higher medication regimen complexity resulted in poorer glycemic control. One study however, has revealed that medications used is not significantly associated with glycemic control (Paul et al., 2016).

A study has revealed that type of diabetes was not significantly associated with glycemic control (Fiseha et al., 2018). However, the duration of diabetes itself was shown to be significantly associated with glycemic control (Benoit et al., 2005; Fiseha et al., 2018; Haghighatpanah et al., 2018) A study revealed that the outcome of glycemic control in terms of HbA1c is correlated with duration of diabetes in which a 5% reduction in the odds of achieving target glycemic control happens with an increase of a year in duration of diabetes (Ahmad, Islahudin, & Paraidathathu, 2014). Other than that, in a local study, it was found that the severity of diabetic retinopathy was not significantly associated with glycemic control (Huri et al., 2018). On the contrary, an Iranian study has shown that severity of diabetic retinopathy is strongly associated with HbA1c level (Rasoulinejad, Hajian-Tilaki, & Mehdipour, 2015). Other than that, several studies have shown the same findings in which presence of comorbidities is significantly associated with glycemic control (Bae et al., 2016; Haghighatpanah et al., 2018; Luijks et al., 2015). Although, one study has found that presence of comorbidities is not significantly associated with glycemic control (Paul et al., 2016).

2.3.4 Dietary adherence

Dietary adherence can be defined as the extent to which a person's behaviour in following a diet corresponds with the agreed recommendation by a healthcare provider (García-Pérez et al., 2013). Dietary adherence plays an important role in determining glycemic control. Dietary adherence was found to be inversely associated with glycemic control in terms of HbA1c level (Gomes et al., 2018; Habib & M. Durrani, 2018; Khattab, Khader, Al-Khawaldeh, & Ajlouni, 2010). Patients who did not comply to the specific diet recommendation provided by dietitians showed significantly higher HbA1c levels (Khattab et al., 2010). Another study showed that the patients who adhered to the diet regimen prescribed had better glycemic control (Gomes et al., 2018). Several studies have revealed the same findings in which dietary adherence is significantly associated with glycemic control (A Kakade et al., 2018; Raj et al., 2018; Wiradarma et al., 2018).

A study conducted in Hospital Universiti Sains Malaysia have used the adapted Summary of Diabetes Self-Care Activities (SDSCA) questionnaire to assess dietary adherence although it showed that dietary adherence was found not to be significantly associated with glycemic control (Tan et al., 2011). The original SDSCA questionnaire consisted of several items that assessed medication adherence, foot care, blood glucose monitoring, diet, and exercise (Marinho et al., 2018). The revised SDSCA questionnaire was validated and found to be reliable by a local study conducted in nine hospitals across Malaysia (Jalaludin, Fuziah, Hong, Mohamad Adam, & Jamaiyah, 2012).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a cross-sectional study with the aim to determine factors associated with glycemic control among patients with diabetes attending ophthalmology clinic of Hospital Serdang.

3.2 Study location

This study was carried out among patients with diabetes in ophthalmology clinic at Hospital Serdang. Hospital Serdang is in the district of Sepang, Selangor (Department of Survey and Mapping Malaysia, 2015). Hospital Serdang is adjacent to South Kajang Valley Expressway and Faculty of Medicine and Health Sciences UPM is in its west. It also provides services for almost 570,000 residents from Serdang, Putrajaya, Kajang and Bangi. Hospital Serdang was launched in 2006 with a total of 620 beds, 34 departments and units (Portal Rasmi Hospital Serdang, 2015). The ophthalmology department in Hospital Serdang is an international and local reference regarding eye disease. This department is also known for its expertise in specialist oculoplastic. Services provided by the department include General Eye Specialist Clinic, Oculoplastic Clinic, Ophthalmology Emergency Clinic, Diabetic Retinopathy Clinic etc. (Portal Rasmi Hospital Serdang, 2015).

3.2 Sampling and subject selection

3.2.1 Sampling population

Sampling population of this study were patients with diabetes that attend ophthalmology clinic of Hospital Serdang.

3.2.2 Sampling method

The sampling method was based on purposive sampling in ophthalmology clinic of Hospital Serdang during the study period from January 2020 to March 2020.

3.2.3 Selection criteria

Selection of respondent was based on several inclusion and exclusion criteria which were identified based on medical records in ophthalmology clinic Hospital Serdang. Respondents were included in this study if they were (a) diagnosed with T1DM or T2DM; (b) Malaysian; (c) above the age of 18. Respondents were excluded if they (a) had complete loss of vision.

Summary of inclusion and exclusion criteria:

Patients were included if:

1. Above the age of 18
2. Malaysian
3. Diagnosed with T1DM or T2DM

Patients were excluded if:

a) Had complete loss of vision

3.2.4 Sample size determination

Sample size for testing hypothesis on the correlation between independent and dependent variables was calculated using formula by Cole, (1997):

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2}{d^{*2}/(1-d^{*2})} + 5$$

n = sample size
$z_{1-\alpha/2}$ = z score for significance level at 5% = 1.96
$z_{1-\beta}$ = z score for power set at 80% = 0.842
d* = correlation

Due to the Covid-19 pandemic, data collection had to be stopped abruptly, and a smaller sample size had to be used which was 50. After adjusting for 20% non-response rate, the sample size required in this study was 60.

Table 3.1. Summary of sample size calculation using formula by Cole, (1997)

Variables	**Correlation, d***	**Sample size, n**
Dietary adherence and HbA1c level (Habib & M. Durrani, 2018)	r = -0.355	$n = \frac{(1.96+0.84)^2}{(-0.355)^2/(1-(-0.355)^2)} + 5$ = 59
Total protein intake and HbA1c level (Woo et al., 2010)	r = -0.338	$n = \frac{(1.96+0.84)^2}{(-0.338)^2/(1-(-0.338)^2)} + 5$ = 66
Total fat intake and HbA1c level (Woo et al., 2010)	r = -0.385	$n = \frac{(1.96+0.84)^2}{(-0.385)^2/(1-(-0.385)^2)} + 5$ = 50

3.3 Measures

3.3.1 Sociodemographic characteristics

Respondents were interviewed by investigators in which they were assessed on age, sex, ethnicity, educational level, and monthly household income. Educational level was divided into four categories which were no formal education, primary, secondary, and tertiary. Monthly household income was categorized into less than RM2000, RM2000-RM4999, RM5000-

RM9999, and more than RM10,000. According to Department of Statistics Malaysia in 2019, the income threshold for B40 or low-income group was RM4849 while M40 or middle-income group was between RM4850 to RM10,959, and T20 or high-income group was more than RM10,960.

3.3.2 Nutritional status

Nutritional status had two main sections which were BMI and dietary intake. The first section required the respondents' weight and height from patients via interview or medical record and it was used to obtain BMI calculated using formula of weight (in kilogram) divided by height squared (in meter) (WHO, 2016) and then classified as shown in Table 3.2.

Table 3.2. Body Mass Index (BMI) classification based on adult population

Indication	Values
Underweight	<18.5 kg/m^2
Normal	18.5-24.9 kg/m^2
Overweight	25.0-29.9 kg/m^2
Obese (Class I)	30.0-34.9 kg/m^2
Obese (Class II)	35.0-39.9 kg/m^2
Obese (Class III)	≥40.0 kg/m^2

Source: WHO (2016)

Dietary intake was assessed using a 2-day 24-hour diet recall (one day represent weekday and one day represents weekend). The average of patient's total energy, carbohydrate, protein, fat, fiber, and vitamin A intake for two days was calculated. The intake value was reported in kcal for energy, percentage for macronutrients, and grams for fiber and vitamin A. Energy intake of respondents and vitamin A intake were compared with RNI 2017 that also categorised recommendations for energy intake based on age (Ministry of Health (MOH), 2017) while distribution of macronutrients and fiber were compared with reference range according to Clinical Practice Guidelines for Management of Type 2 Diabetes Mellitus 2015 as shown in Table 3.3 (Kamaruddin et al., 2015).

Table 3.3. Recommended nutrient intake

Nutrient	Reference range
Energy (kcal)[1]	
≥ 18-29 years old	1960-2520 kcal (male), 1610-2080 kcal (female)
30-59 years old	1920-2470 kcal (male), 1660-2130 kcal (female)
≥ 60 years old	1780-2280 kcal (male), 1550-1990 kcal (female)
Carbohydrate (%)[2]	45-60% of total energy intake
Protein (%)[2]	15-20% of total energy intake
Fat (%)[2]	25-35% of total energy intake
Fiber[2]	20-30g/day
Vitamin A[1]	600 μg/day

Source: [1]RN1 2017; [2]CPG for Management of T2DM 2015

3.3.3 Medical profile

The following components were extracted from interview with patients and their medical records which included random blood glucose, fasting blood glucose, number of medications, duration of diabetes, stage of diabetic retinopathy, and presence of comorbidities. The values of random blood glucose and fasting blood glucose obtained were compared with the normal values (Table 3.4) (Clinical Practice Guidelines for Management of T2DM 2015).

Table 3.4. Normal values of biochemical data components

Biochemical data	Normal reading
Fasting blood glucose level	4.4-7.0 mmol/L
Random blood glucose level	4.4-8.5 mmol/L

Source: Clinical Practice Guideline for Management of T2DM 2015

Number of medications used was divided into two categories which are 5 medications and less, or more than 5 medications used, in which the term 'polypharmacy' is indicated by taking more than 5 medications at a particular time (Anonim, 2000). Duration of diabetes was divided into three categories which are less than 5 years, 5 to 10 years, and more than 10 years. There was an increase of 20% of vascular deaths with every 5-year increment since diabetes diagnosis, in which poorer glycemic control was associated with twice the mortality risk than better control (Alegre-Díaz et al., 2018). The presence of comorbidities was categorized into yes or no while the stage of diabetic retinopathy was defined by an ophthalmologist into 6 stages: no DR, mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, proliferative DR (PDR), and advanced diabetic eye disease (ADED).

3.3.4 Dietary adherence

Dietary adherence was assessed using adapted Summary of Diabetes Self-Care Activities (SDSCA) questionnaire (Tan et al., 2011). This questionnaire consisted of seven items. The items assessed how many days in a week the respondents practised each of the self-care behaviours and was measured by an eight-point scale ranging from 0 to 7 days with 0 being no practice at all, while 7 indicating daily practice and is the optimum score. The overall dietary adherence of respondents was defined as the mean number of days per week for all the 7 items. Higher score indicates better dietary adherence except for item number 4 (eat high fat foods such as red meat or full-fat dairy products) which was reversely scored. Score of more than 4 days per week is considered as good dietary adherence while poor adherence is indicated by score of less than 5 days per week. Overall dietary adherence was calculated as mean of the total score from the 7 items. SDSCA measure was used in a few local studies among patients with diabetes and it has been validated as well for its Malay version (Jalaludin et al., 2012; Yee, Said, & Manaf, 2018).

3.3.5 Glycemic control

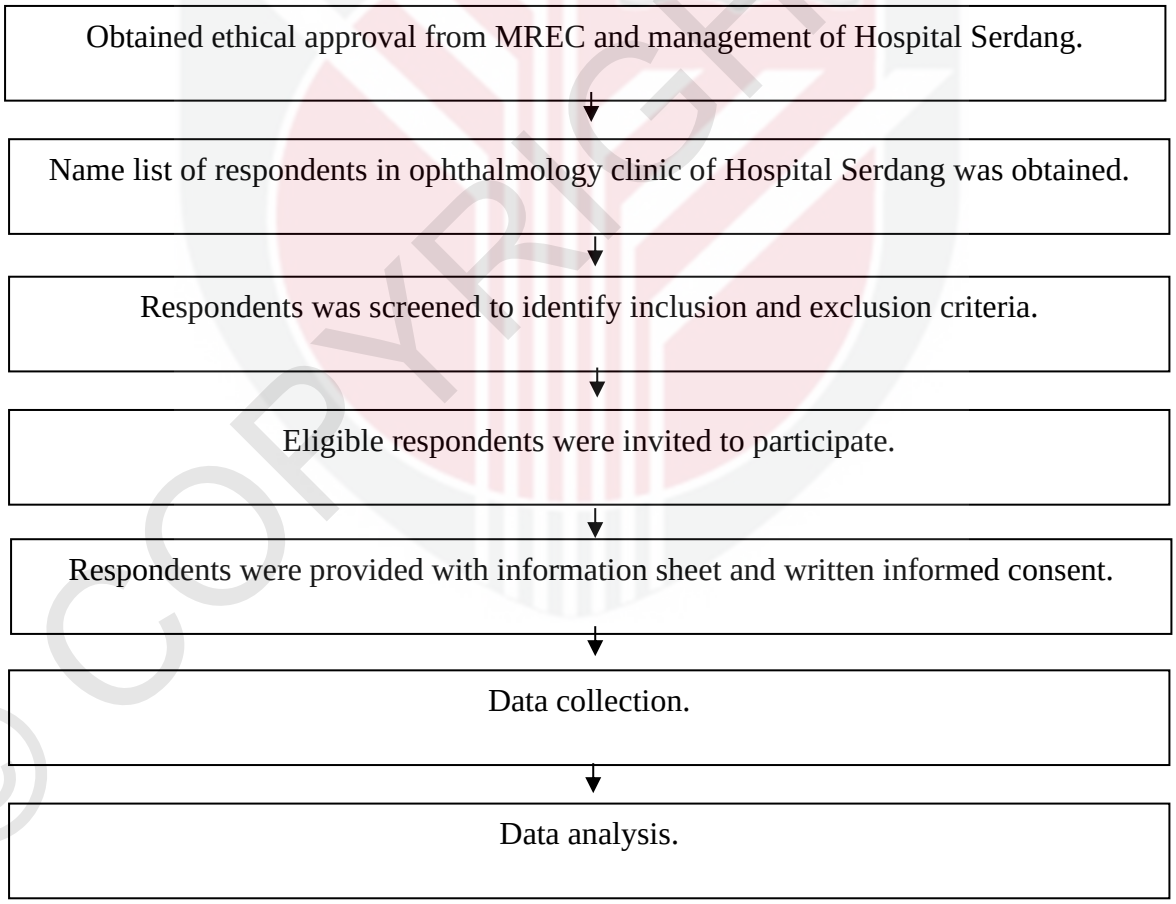
Glycated haemoglobin (HbA1c) level was used as an indicator of glycemic control in this study. This data was obtained from the latest HbA1c reading from respondent's medical records. HbA1c level was compared to the cut-off value recommended by the Malaysian Clinical Practice Guidelines for T2DM 2015 which is ≤6.5% considered as good glycemic control and >6.5% as poor glycemic control (Ministry of Health Malaysia, 2015).

3.4 Study procedures

Prior to the study, ethical approval was obtained from Medical Research and Ethics Committee and relevant authorities of Hospital Serdang. Data collection was proceeded after approval from them. The name list of patients with diabetes in the ophthalmology clinic of Hospital Serdang was obtained and patients were screened to identify those who fulfil the study inclusion criteria. Purposive sampling method was used.

Patients that were selected gave their informed consent before participating in this study. The process of data collection was done within 2 months. Data analysis was done once all the required data were obtained.

Figure 3.1. The flow of study procedures



3.4.1 Pre-testing

Prior to the study, the questionnaire was pre-tested on 8 patients. The duration of data collection was recorded, in which 30 minutes were needed for each patient. Any clarification regarding the questionnaire and instructions was acknowledged. Feedback was obtained from the patients regarding any problem from the process and feasibility of the questionnaire. The subjects from pre-testing were excluded from the actual data collection of this study.

3.5 Data analysis

Data collected was analysed using IBM SPSS Statistics version 22. Significant level was set at p-value < 0.05. Normality of data collected was tested using Exploratory Data Analysis. Descriptive data was analysed using univariate analysis. The results for categorical variables were presented as frequency and percentage. For normally distributed continuous variables, results were presented as mean and standard deviation. For continuous variables that are not normally distributed, results were presented as median and interquartile range. Pearson-product moment correlation coefficients was used to measure the association between continuous variables that are normally distributed. Spearman's Rank-Order test was used to test the association between continuous variables that are not normally distributed. The strength of Pearson's correlation was interpreted based on Rule of Thumb of Cohen's criteria 1988 in which weak association for r is around 0.10, medium for r is around 0.30, and strong for r is 0.50 and higher. Chi-square test was used to find the association between two categorical variables and Fisher's exact test was used when condition of Chi-square test was violated.

CHAPTER FOUR

4.0 RESULTS

4.1 Screening and recruitment of respondents

Figure 4.1 shows the process of screening and recruitment of respondents. A total of 110 respondents were approached. Then, a total of 82 out of 110 respondents were eligible to participate in this study while the other 28 respondents were excluded because they did not have diabetes (n=26) or had other ocular disease and appointment (n=2). Out of 82 eligible respondents, 5 of them refused to participate, leaving only 77 respondents to participate. However, only 65 (84.4%) out of 77 respondents had complete data that was included in the data analysis.

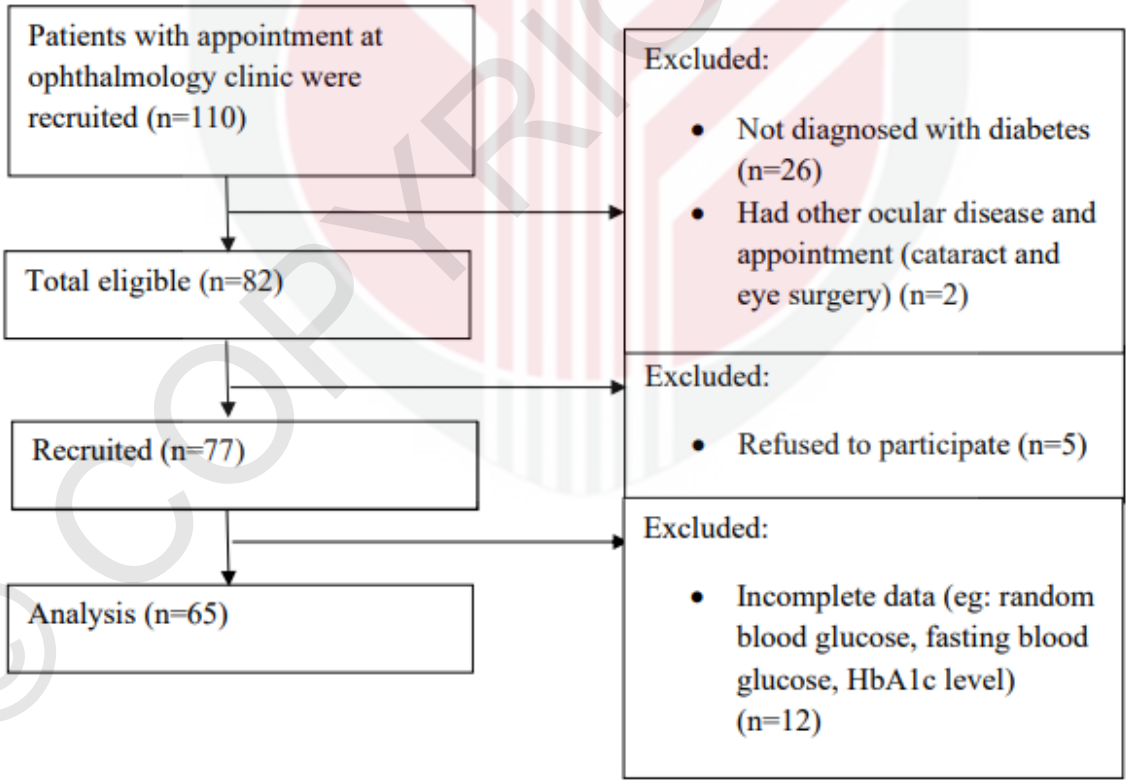


Figure 4.1. Flow diagram of respondents screening and recruitment

4.2 Sociodemographic characteristics of respondents

Table 4.1 shows the sociodemographic characteristics of respondents. There were slightly more males than females. In terms of ethnicity, Malays make up the majority (75.4%) of the respondents followed by Indian (20.0%) and Chinese (4.6%). Half of the respondents attained secondary education (50.4%) while the other half is attended primary schools (24.6%). About half of the respondents had monthly household income between RM2000-RM4999 while approximately 30% of the respondents had monthly household income of less than RM2000 and 1 out of 5 of the respondents' income were above RM5000.

Table 4.1. Sociodemographic characteristics of respondents (n=65)

Sociodemographic characteristics	Frequency (n)	Percentage (%)	Mean ± SD
Age			61.42 ± 8.3
Sex			
Male	37	56.9	
Female	28	43.1	
Ethnicity			
Malay	49	75.4	
Indian	13	20.0	
Chinese	3	4.6	
Educational level			
No formal education	1	1.5	
Primary	16	24.6	
Secondary	33	50.8	
Tertiary	15	23.1	
Monthly household income (RM)			2890 ± 1665
<2000	19	29.2	
2000-4999	34	52.3	
5000-9999	11	16.9	
≥10000	1	1.5	

4.3 Nutritional status of respondents

4.3.1 BMI of respondents

The average BMI of respondents was 27.9 (kg/m^2) which was in the overweight category (Table 4.2).

Table 4.2. BMI of respondents (n=65)

Anthropometry	Mean ± SD
Weight (kg)	71.3 ± 13.2
Height (m)	1.60 ± 0.1
BMI (kg/m^2)	27.9 ± 4.8

As for the BMI classification, 75.4% of them had excess weight. More than half were either overweight (52.3%) or obese (23.1%).

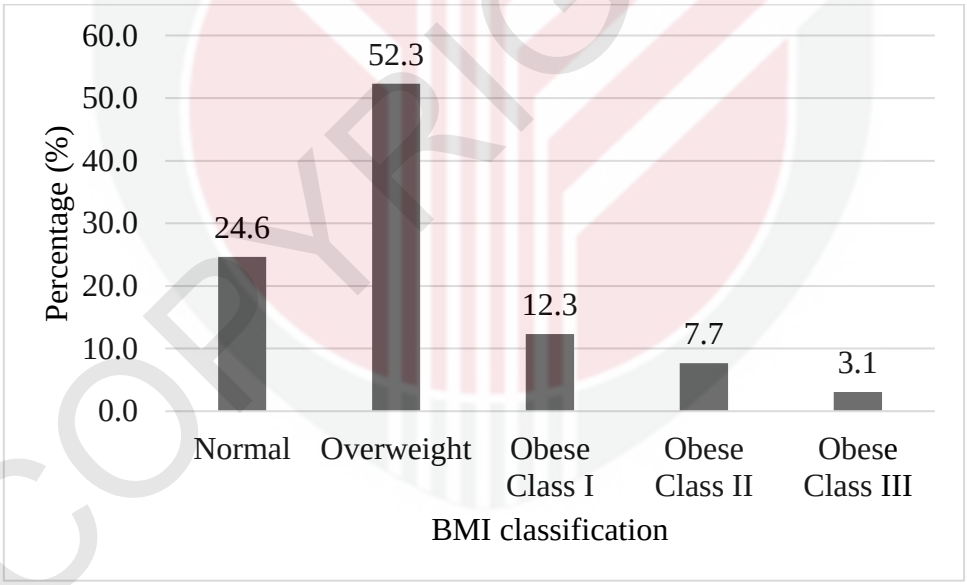


Figure 4.2. BMI classification of respondents (n=65)

4.3.2 Dietary intake of respondents

Table 4.3 shows respondents aged 30-59 years' mean energy intake was higher by 198 kcal than the elderly (60 years and above) respondents' mean energy intake. Male respondents

reported lower energy intake than the national recommendation and lower than the females' energy intake. On average, the elderly female respondents took the recommended amount of energy from their diet while the mean energy intake of female respondents aged 30-59 years exceeded the recommended amount.

Table 4.3. Energy intake of respondents based on age group (n=65)

Energy intake (kcal)	Mean ± SD			Recommended intake
	Male (n=38)	Female (n=27)	Total (n=65)	
Adults aged 30-59 years	1724 ± 439.4	2205 ± 1011.4	1909 ± 735.5	1920-2470 kcal (male), 1660-2130 kcal (female)
Adults aged ≥60 years	1660 ± 487.5	1769 ± 563.4	1711 ± 519.7	1780-2280 kcal (male), 1550-1990 kcal (female)

In table 4.4, the respondents' mean dietary intake of fat (30.8 ± 11.6 %) and median dietary intake of carbohydrate (55.2 ± 10.4 %) were within the recommended amount while the mean dietary intake of protein (14.1 ± 3.7 %) and fiber (8.7 ± 7.4 g) were below the recommended amount. In contrast, the mean dietary intake of vitamin A (1344 ± 840.9 μg) of the respondents were more than double the recommended intake.

Table 4.4. Dietary intake of respondents (n=65)

Dietary intake	Mean ± SD	Recommended intake
Carbohydrate (%)*	55.2 ± 10.4	45-60% of total energy intake
Protein (%)	14.1 ± 3.7	15-20% of total energy intake
Fat (%)	30.8 ± 11.6	25-35% of total energy intake
Fiber (g)	8.7 ± 7.4	20-30g/day
Vitamin A (μg)	1344 ± 840.9	600 μg/day

*Data presented in median ± SD due to data not normally distributed.

4.4 Medical profile of respondents

Based on Table 4.5, 30.8% of the respondents received more than 5 medications. Other than that, most of the respondents (46.2%) had diabetes for more than 10 years, which is almost the same percentage (43.1%) as respondents that had diabetes for 5 to 10 years. Majority (83.1%) of the respondents had other diseases like hypertension, cardiovascular disease, dyslipidaemia, and chronic kidney disease.

Table 4.5. Medical profile of respondents (n=65)

Medical profile	Frequency (n)	Percentage (%)	Mean ± SD
Number of medications			4 ± 2
≤ 5 medications	45	69.2	
> 5 medications	20	30.8	
Duration of diabetes (years)			12 ± 8
< 5	7	10.7	
5-10	28	43.1	
> 10	30	46.2	
Presence of comorbidities			
Yes	54	83.1	
No	11	16.9	

About half of the respondents did not have diabetic retinopathy (DR) in any of their eyes while the other half consisted of mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, PDR and advanced diabetic eye disease (ADED) in both eyes. The number of respondents having cases of NPDR decreases as the severity of NPDR increases, and the number of cases increase again at PDR stage (Figure 4.3).

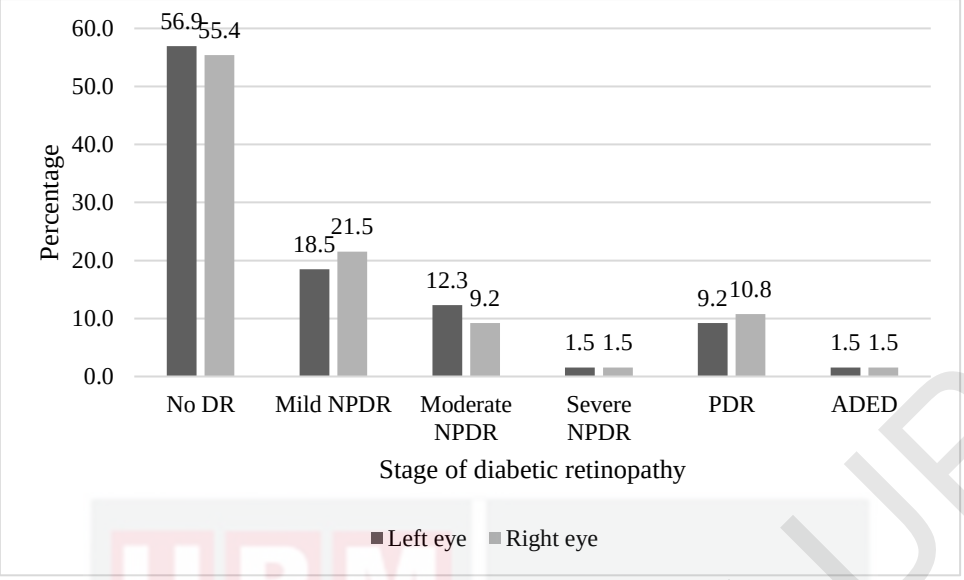


Figure 4.3. Stage of diabetic retinopathy of respondents (n=65)

4.4.1 Biochemical data of respondents

The random blood glucose was within its normal range although it is exactly at the upper limit of the normal range, while fasting blood glucose was relatively far above the normal range (Table 4.6).

Table 4.6. Biochemical data of respondents (n=65)

Biochemical data (mmol/L)	Mean ± SD	Normal range (mmol/L)
Fasting blood glucose	8.3 ± 3.4	4.4-7.0
Random blood glucose	8.5 ± 3.1	4.4-8.5

4.5 Dietary adherence of respondents

Table 4.7 shows the dietary adherence of respondents as measured by SDSCA questionnaire. The optimum score for each item is 7. The overall dietary adherence rate was 3.3 ± 0.9 days per week, reflecting that only 6.2% of the respondents were able to have overall good adherence where good adherence is defined as being able to perform dietary self-care behaviours for 5 and more days per week. Item number 1 (followed a healthful eating plan) had the highest mean score of 4.1 ± 2.2 days per week while item number 7 (reduce the number of calories you eat to lose weight) had the lowest mean score which is 0.7 ± 1.5 days per week.

Table 4.7. Dietary adherence of respondents (n=65)

Items	Mean ± SD	Frequency (%)	
		Good adherence	Poor adherence
1. Followed a healthful eating plan	4.1 ± 2.2	26 (40)	39 (60)
2. Followed your eating plan	3.5 ± 2.0	13 (20)	52 (80)
3. Eat 5 or more servings of fruits and vegetables	4.0 ± 2.0	22 (33.8)	43 (66.2)
4. Eat high fat foods such as red meat or full-fat dairy products	3.4 ± 1.9	17 (26.2)	48 (73.8)
5. Eat very few sweets	3.4 ± 2.4	24 (36.9)	41 (63.1)
6. Eat lots of food high in dietary fiber such as vegetables or oats	3.0 ± 2.3	26 (40)	39 (60)
7. Reduce the number of calories you eat to lose weight	0.7 ± 1.5	3 (4.6)	62 (95.4)
Overall dietary adherence	3.3 ± 0.9	4 (6.2)	61 (93.8)

4.6 Glycemic control of respondents

On average, glycemic control of respondents was inoptimal, meaning that their mean HbA1c level of 8.0% was above 6.5% as set by the Malaysian Clinical Practice Guideline for T2DM patients 2015 (Table 4.8).

Table 4.8. Glycemic control of respondents (n=65)

Glycemic control	Mean ± SD	Target value
HbA1c level (%)	8.0 ± 1.8	≤ 6.5%

The total respondents who had good glycemic control was only 12.3% (Figure 4.4).

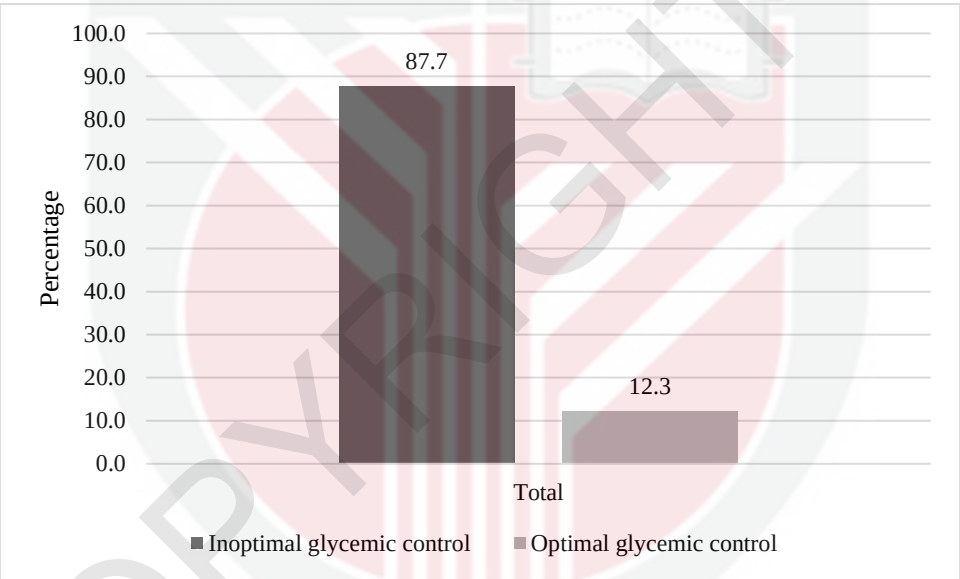


Figure 4.4. Percentage of respondents achieving inoptimal (HbA1c >6.5%) and optimal (HbA1c ≤6.5%) glycemic control (n=65)

4.7 Factors associated with glycemic control of respondents

4.7.1 Association of sociodemographic characteristics with glycemic control

Table 4.9 shows the association of sociodemographic characteristics with glycemic control using Fisher's exact test, Pearson's correlation, and Chi-square test. There was no significant association of sociodemographic characteristics with glycemic control.

Table 4.9. Association of sociodemographic characteristics with glycemic control (n=65)

Sociodemographic characteristics	HbA1c level		
	***r*-value**	**χ^2**	***p*-value[a]**
Age	-0.095		0.535[b]
Sex		0.116	0.734[c]
Ethnicity			1.000
Educational level			0.603
Monthly household income			0.5913

[a] Fisher's exact test
[b] Pearson's correlation
[c] Chi-square test

4.7.2 Association of nutritional status with glycemic control

Table 4.10 shows the association of BMI with glycemic control using Pearson's correlation. There was no significant association of BMI with glycemic control.

Table 4.10 Association of BMI with glycemic control (n=65)

Anthropometry measurements	HbA1c level	
	***r*- value**	***p*- value[b]**
BMI	-0.116	0.449

[b] Pearson's correlation

Whereas Table 4.11 shows the association of dietary intake with glycemic control using Pearson's correlation and Spearman's rank-order test. There was no significant association of dietary intake with glycemic control.

Table 4.11 Association of dietary intake with glycemic control (n=65)

Dietary intake	HbA1c level	
	***r*- value**	***p*- value[b]**
Energy (kcal)	0.111	0.468
Carbohydrate (%)	0.059	0.702[d]
Protein (%)	-0.238	0.115
Fat (%)	0.110	0.470
Fibre (g)	-0.001	0.997
Vitamin A (μg)	-0.024	0.877

[b] Pearson's correlation
[d] Spearman's rank-order test

4.7.3 Association of medical profile with glycemic control

As for the association of medical profile with glycemic control shown in Table 4.12, Pearson's correlation showed a significant association of duration of diabetes with glycemic control (r= 0.430, p= 0.003), suggesting that the longer the respondent had diabetes, the higher the HbA1c level which means a more inoptimal glycemic control. The Chi-square test also showed a significant association of presence of comorbidities with glycemic control (χ^2 (1, 65) = 4.055, p= 0.044). Meanwhile, the Spearman's rank-order test showed a significant association of stage

of diabetic retinopathy with glycemic control, for left eye and right eye, *r*= 0.383, *p*= 0.009 and *r*= 0.368, *p*=0.013 respectively, indicating that as diabetic retinopathy progresses to worse stages, glycemic control of respondents were also more inoptimal.

Table 4.12. Association of medical profile with glycemic control (n=65)

Medical profile	**HbA1c level**		
	***r*- value**	**χ^2**	***p*- value[b]**
Number of medications	0.279		0.063
Duration of diabetes	0.430		**0.003***
Presence of comorbidities		4.055	**0.044[c*]**
Stage of diabetic retinopathy (left eye)	0.383		**0.009[d*]**
Stage of diabetic retinopathy (right eye)	0.368		**0.013[d*]**

[b] Pearson's correlation
[c] Chi-square test
[d] Spearman's rank-order test
* Significant level p<0.05

As for biochemical data, Pearson's correlation was used and showed that there was no significant association between fasting blood glucose and random blood glucose with glycemic control as shown in Table 4.13.

Table 4.13. Association of biochemical data and glycemic control (n=65)

Biochemical data	**HbA1c**	
	***r*- value**	***p*- value[b]**
Fasting blood glucose	0.108	0.489
Random blood glucose	0.181	0.251

[b] Pearson's correlation

4.7.4 Association of dietary adherence with glycemic control

Dietary adherence also showed no significant association with glycemic control as stated in Table 4.14 using Pearson's correlation.

Table 4.14. Association of each items of dietary adherence (SDSCA items) and glycemic control (n=65)

Items	HbA1c level	
	***r*- value**	***p*- value[b]**
1. Followed a healthful eating plan	-0.091	0.550
2. Followed your eating plan	-0.244	0.106
3. Eat 5 or more servings of fruits and vegetables	0.055	0.721
4. Eat high fat foods such as red meat or full-fat dairy products	0.075	0.625
5. Eat very few sweets	0.173	0.254
6. Eat lots of food high in dietary fibre such as vegetables or oats	0.041	0.788
7. Reduce the number of calories you eat to lose weight	-0.072	0.639
Overall dietary adherence	0.001	0.995

[b] Pearson's correlation

CHAPTER FIVE

5.0 DISCUSSION

5.1 Screening and recruitment

The response rate of this study was 84.4% which is relatively higher than other studies. Although there are varying response rates from other studies with similar settings, the quality of a study should not be judged by the response rate itself (Morton, Bandara, Robinson, & Atatoa Carr, 2012). The required data was collected by interviewing the respondents and questions were asked by the interviewer since most of the respondents were elderly and had deteriorated vision. Average time for each respondent to complete the interview was 30 minutes.

5.2 Sociodemographic characteristics of respondents

The average age of respondents in this study was 61 years old which is within the range of mean age of respondents: 56 years and 63 years respectively in two local studies involving patients with diabetes at primary health clinics (Ahmad et al., 2014; Huri et al., 2018). As for sex, another study in Malaysia had more male respondents (52.4%) than female respondents too (Tan et al., 2011). This study involved a bigger proportion of Malays compared to Indian and Chinese, which was similar with another study in Kedah. The study had 80% Malay respondents (Syed Soffian et al., 2019). Other than that, majority of respondents in this study received education up to secondary level, another common finding as with two other local studies in Hospital Universiti Sains Malaysia and Hospital Serdang (Tan et al., 2011; Tiew, Chan, Lye, & Loke, 2014). The proportion of respondents who received monthly household income of less than RM3000 was a half in another study, which is about the same proportion

as the respondents in this study. The income threshold for low income group or B40 group in 2019 was RM4898, meaning that most of the respondents in this study were categorised in the low income group (Department of Statistics Malaysia, 2019).

5.3 Nutritional status of respondents

An old study in 49 private clinics across Peninsular Malaysia revealed that the mean BMI of its respondents was 26.4 kg/m^2 while a more recent study in Hospital Serdang showed higher mean of 29.8 kg/m^2 (Mafauzy, 2005; Tiew et al., 2014). Mean BMI of respondents in this study was within that range. Most of the respondents in this study were overweight, which was also found in two other studies conducted at Universiti Malaya Medical Center and Hospital Universiti Sains Malaysia (Huri et al., 2018; Tan et al., 2011).

As for the mean energy intake, lower mean (1648 kcal) for all the respondents was reported in another local study as compared to 1909 kcal in this study, but its female respondents reported lower energy intake than their male counterparts which was different from this study's findings (Firouzi et al., 2015). In a Japanese study among patients with diabetes and similar age range, the total mean energy intake was closer to this study's which was 1737 kcal (Horikawa et al., 2014). Similar finding was found for carbohydrate intake in which another study also reported mean energy from carbohydrate of 55.7% from total energy (Firouzi et al., 2015). Majority of respondents in a neighbouring country's study accounted 45-60% of their total energy intake from carbohydrate too (Wiradarma et al., 2018). Protein and fiber intake of the respondents in this study was lower than two other studies in Malaysia and Japan which reported 16.5% and 15.7% for protein energy, and 10.6 g and 14.7 g of dietary fiber intake respectively, whereas the average fat intake of respondents in this study was higher than those studies (Firouzi et al., 2015; Horikawa et al., 2014). Mean vitamin A intake of respondents in this study was higher than another local study, with a difference of more than 500 μg (Firouzi et al., 2015). Dietary

intake of vitamin A was found to be a lot higher than the recommended amount and it could be because vitamin A is naturally high in several foods. For example, half cup of carrots or spinach is already exceeding 600 μg of vitamin A (Reboul, 2013).

5.4 Medical profile of respondents

Most respondents in this study had diabetes for more than 10 years, which is similar with another study's findings involving patients with diabetes who had diabetic retinopathy in Universiti Malaya Medical Center (Huri et al., 2018). Proportion of respondents who did not have polypharmacy in this study was smaller than those who had polypharmacy, which was contrasting with another study involving Saudi Arabian outpatients with diabetes (Alwhaibi et al., 2018). Majority (83.1%) of respondents in this study reported having diagnosed comorbidities, although another local study reported higher prevalence of 90.6% (Tan et al., 2011). The trend of proportions for the stages of diabetic retinopathy (DR) are almost similar with another local study except that it did not involve any subjects without DR (Huri et al., 2018). Next, there was an almost similar finding with another local study which reported the average fasting blood glucose of 8 mmol/L (Tan et al., 2011).

5.5 Dietary adherence of respondents

The average number of days per week of practising good dietary behaviours reported were almost similar with another study in Hospital Universiti Sains Malaysia using the same tool, except for item 7 in which the other study has a higher average score of 3.9 days (Tan et al., 2011). Item 7 had the lowest score and it could be due to the respondents not having any intention to lose their weight since most of them reported feeling comfortable with their current weight. Another study in United Arab Emirates found lower mean number of days per week that patients exhibited good diet behaviour which was 2.9 days (Abduelkarem & Sackville, 2009). Proportions are comparable with another local study except for items 5 and 6 in which

the other study showed higher percentage of good adherence although it was only slightly higher than the percentage of poor adherence, and item 7 where the proportions are almost equal, plus, the other study also showed a huge deviation between the percentage of poor adherence (83.6%) and good adherence (16.4%) for the overall score (Tan et al., 2011).

5.6 Glycemic control of respondents

A local study using same cut-off point for HbA1c level showed slightly higher proportion of optimal glycemic control of 15.6% (Syed Soffian et al., 2019) while another study showed double the amount (32.8%) but it was due to a less stringent HbA1c cut-off point of 8.0% (Tan et al., 2011). Huri et al. (2018) found an almost similar mean HbA1c level of 8.1% while a more recent study revealed 8.4% (Syed Soffian et al., 2019). This study has showed lower proportion of patients who achieved optimal glycemic control than those studies.

5.7 Factors associated with glycemic control

5.7.1 Association of sociodemographic characteristics with glycemic control

Similar findings were found in another local study in which age and sex was not significantly associated with glycemic control (Huri et al., 2018) whereas educational level was also not significantly associated with glycemic control in a study by Ahmad et al. (2014). Younger, female, and Indian patients generally had less optimal glycemic control as recently discovered by Syed Soffian et al. (2019). However, this study might have not been able to show any significant association due to the small number of ethnicities other than Malay and most of the patients were above 50 years old, meaning that there were not enough younger patients. Lower educational level was also associated with less optimal glycemic control (Khattab et al., 2010), this finding was supported by another study which also added that poverty was significantly associated with glycemic control (Houle et al., 2016).

5.7.2 Association of nutritional status with glycemic control

BMI was found to be not significantly associated with glycemic control in several other Southeast Asian studies including Malaysia and Indonesia (Ahmad et al., 2014; Syed Soffian et al., 2019; Wiradarma et al., 2018). A study among Jordanian patients with T2DM showed that patients with higher BMI had less optimal glycemic control (Khattab et al., 2010), thus contradicting with this study's findings. A possible reason would be that obese patients are metabolically healthier, in which they have different development and severity of insulin resistance and inflammation as discussed by German professors specializing in diabetes (Stefan, Häring, Hu, & Schulze, 2013), or it could simply be that the more overweight patients are more concerned about controlling their blood glucose levels.

As for the dietary intake; energy, protein, fat, and fiber were not significantly associated with glycemic control which was found in an Indonesian study (Wiradarma et al., 2018) while a Malaysian study found that only fiber was not significantly associated with glycemic control but it could have been due to the insufficient proportion of participants who took the recommended amount of fiber since most of them were inadequate (Firouzi et al., 2015). Although not significant, the association test results suggest that as energy, carbohydrate, and fat intake increased, the HbA1c level also increased indicating a less optimal glycemic control. Whereas when the protein, fiber, and vitamin A intake increased, the glycemic control was more optimal. Two Asian studies concluded that high carbohydrate intake was more prominent among those with less optimal glycemic control (Haimoto et al., 2018; Wiradarma et al., 2018), this relates to the total energy intake since carbohydrate contributes most of the energy and are known to affect blood glucose levels significantly compared to other macronutrients.

5.7.3 Association of medical profile with glycemic control

There were not many studies in Malaysia with similar settings that reported on polypharmacy however, Huri et al (2018) found that the number of antidiabetic agents taken by patients was not significantly associated with glycemic control. Another Asian study reported that the number of oral anti-diabetic drugs prescribed at discharge was significantly associated with glycemic control (Haghighatpanah et al., 2018). Although not significant, this study showed the direction of which as the number of medications taken increased, the glycemic control was less optimal. This could be explained by the increased regimen complexity that made the patients less adhere to the prescribed drugs, especially those that control blood glucose level and thus manifesting as inoptimal glycemic control (Dobrică et al., 2019).

The duration of diabetes was found to be significantly associated with glycemic control and this was similar with two other Asian studies that found longer duration of diabetes was associated with less optimal glycemic control (Khattab et al., 2010; Syed Soffian et al., 2019). A possible reason would be that those patients have a reduced insulin secretion or excessive insulin resistance that progresses with time (Haghighatpanah et al., 2018).

Presence of comorbidities was also found to be significantly associated with glycemic control and this was in line with the findings of an Indian study that found patients with no comorbidities had significantly better glycemic control (Haghighatpanah et al., 2018). The number and type of comorbidities impacts glycemic control differently and it is not a simple sum of diseases, but it is due to specific types of disease that impacts diabetes negatively (Luijks et al., 2015). Plus, elderly patients with comorbidities have higher chance of their diabetes being inappropriately managed (Haghighatpanah et al., 2018).

Other than that, stage of diabetic retinopathy (for both eyes) were also found to be significantly associated with glycemic control. Glycemic control is an important factor for the presence and

progression diabetic retinopathy (Chatziralli et al., 2010). This study suggests that patients with less optimal glycemic control had a more progressed diabetic retinopathy. However, another local study did not find significant association of stage of diabetic retinopathy with glycemic control, but the study shows that majority of T2DM patients with diabetic retinopathy did not achieve targeted glycemic control except for mild NPDR (Huri et al., 2018).

Fasting blood glucose was not significantly associated with glycemic control, and there is a study suggesting that there might be a physiologic basis for the inconsistency between blood glucose and HbA1c level (Cohen & Lindsell, 2012). However, the results show that as fasting blood glucose and random blood glucose level increased, the HbA1c level also increased, indicating less optimal glycemic control although significance was not achieved. Another explanation would be that patients who had longer duration of diabetes have a wide glycemic variability, meaning that their blood glucose level fluctuates drastically throughout the day and it could lead to inconsistency between reading of blood glucose levels with HbA1c level (Juarez et al., 2012).

5.7.4 Association of dietary adherence with glycemic control

Dietary adherence was not significantly associated with glycemic control, and this was also reported in a study conducted in Hospital Universiti Sains Malaysia in which none of the adapted SDSCA items were significantly associated with HbA1c level (Tan et al., 2011). A study in Indonesia however, found that dietary adherence was significantly associated with glycemic control but it did not use the same tool to measure dietary adherence (Wiradarma et al., 2018). Some of the items have a debatable direction of association like for item three (3) Eat 5 or more servings of fruits and vegetables, item five (5) Eat very few sweets, and item six (6) Eat lots of food high in dietary fiber such as vegetables or oats, in which the more these good dietary habits were practised, the less optimal the glycemic control. Consumption of

sweet foods increases HbA1c level, while eating fresh fruits could have a protective effect on glycemic control (Sadiya & Mnla, 2019), thus contradicting with the findings of this study. However, the respondents could also have overreported their good dietary habits. The same study by Sadiya & Mnla (2019) also reported no significant associations of HbA1c level with individual food groups like meat, vegetables, and dairy products. Another study stated that better adherence to a healthy diet regimen leads to better glycemic control (Gomes et al., 2018). Although the degree of direction is not prominent, this study suggests that patients who follow a healthier diet had better glycemic control.

CHAPTER SIX

6.0 CONCLUSION, STRENGTH, LIMITATION, AND RECOMMENDATION

6.1 Conclusion

This study included 65 patients with diabetes who attended ophthalmology clinic of Hospital Serdang. Most of them were above 50 years old, slightly more males, and majority were Malays. Half of the respondents were educated formally up to secondary level, and most of them were low to middle-class in terms of monthly household income.

Most of them were overweight and did not consume the general recommended intake of energy from their diet, males consumed less energy from their diet than females. Protein and fiber intake were inadequate for most respondents, while intake of carbohydrate, fat, and vitamin A were within the recommended amount.

Majority of respondents were diagnosed with diabetes for more than 10 years and had comorbidities, with hypertension being the most prevalent comorbidity. One-third of the respondents had polypharmacy. About half of the respondents were not diagnosed with diabetic retinopathy. As for the other half, the number of respondents decreased as severity of NPDR increases but number of respondents increased again at PDR. On average, respondents had higher than normal blood glucose levels.

As for dietary adherence, respondents practised good dietary habits for 3 to 4 days per week on average. Only 6.2% of the respondents had overall good dietary adherence.

Glycemic control in terms of HbA1c level showed that on average, the respondents had higher HbA1c level than the target value set by Clinical Practice Guidelines for Management of T2DM 2015 and 87.7% of the respondents had inoptimal glycemic control.

There were significant associations of duration of diabetes, presence of comorbidities, and stage of diabetic retinopathy with glycemic control. Interventions should be uniquely tailored for each patient and more emphasis should be put on the factors that were associated with glycemic control. Further investigations must be done to help patients achieve better glycemic control, especially among those who are older and have had diabetes for a longer time.

6.2 Strengths of this study

This study has determined the sociodemographic characteristics, nutritional status, medical profile, and dietary adherence of patients with diabetes attending ophthalmology clinic. Also, status of glycemic control specifically among patients with diabetes attending ophthalmology clinic in Malaysia has been determined in this study.

6.3 Limitations of this study

The method of assessing the respondents' dietary intake might not be highly accurate since a 2-day 24-hour diet recall was used in which the respondents might have underreported their dietary intake, plus a lot of them had difficulties recalling what they ate. Next, the sample size of this study was quite small since data collection had to be halted due to the Covid-19 pandemic, but it did reach the minimal sample size of 60 after adjusting for 20% non-response rate. Besides that, the findings of this study cannot be used to generalize the whole Malaysian population with diabetes that attend ophthalmology clinics since it was done in only one clinic and the sociodemographic characteristics that could influence the findings of the study might be different elsewhere. On top of that, this study was a cross-sectional study, meaning that a cause-and-effect relationship cannot be determined.

6.4 Recommendations from this study

Food diary or food frequency questionnaire would gain more accurate results since it helps the respondents note down what they ate and guide them through writing down what they ate without putting too much effort on recalling. Apart from that, a multi-site study should be done to gain a larger sample size and better representation of the whole Malaysian population with diabetes that attend ophthalmology clinics. Additionally, a longitudinal study with larger sample size would provide better insight on causal relationships between the variables.

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APPENDICES

APPENDICES 1

STUDY QUESTIONNAIRE

APPENDIX *(QUESTIONNAIRE)*

Nombor Rujukan/
Reference Number:

FAKULTI PERUBATAN DAN SAINS KESIHATAN

JABATAN PEMAKANAN DAN DIETETIK

BORANG SOAL SELIDIK

QUESTIONNAIRE

Tajuk Kajian/*Research Question*:

FAKTOR-FAKTOR BERKAIT DENGAN PENGAWALAN GLISEMIK DALAM KALANGAN PESAKIT DIABETES DI KLINIK OFTALMOLOGI, HOSPITAL SERDANG

FACTORS ASSOCIATED WITH GLYCEMIC CONTROL AMONG PATIENTS WITH DIABETES ATTENDING OPHTHALMOGY CLINIC, HOSPITAL SERDANG

Penyelidik/ *Researcher* : Muhammad Harith Bin Zakaria (194395)

Program/ *Program* : B. Sc. (Dietetics)

Penyelia/ *Supervisor* : Prof. Madya Dr. Barakatun Nisak Mohd Yusof

Tarikh/ *Date* : 10 Februari 2020

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BAHAGIAN A / *SECTION A: SOCIODEMOGRAPHIC CHARACTERISTICS*

Sila isi maklumat pada tempat kosong atau tanda (✓) pada pilihan yang paling sesuai dengan anda.

Please fill in the blank or tick (✓) the answers that best applies to you.

No	Maklumat/*Information*	Catatan/ *Remarks*
1.	Umur *Age*	…….. Tahun/ *Years old*
2.	Jantina *Sex*	❑ Lelaki/ *Male* ❑ Perempuan/ *Female*
3.	Kaum *Ethnicity*	❑ Melayu/ *Malay* ❑ Cina/ *Chinese* ❑ India/ *Indian* ❑ Lain-lain/ *Others* Sila nyatakan/ *Please specify*: ……
4.	Tahap Pendidikan *Education level*	❑ Tidak bersekolah/ *No education* ❑ Sekolah rendah/ *Primary level* ❑ Sekolah menengah/ *Secondary level* ❑ Pra-universiti/ *Pre-university* ❑ Universiti/*University*

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5.	Status perkahwinan *Marital Status*	❑ Bujang/ *Single* ❑ Berkahwin/ *Married* ❑ Bercerai/ *Divorced* ❑ Balu/*Widow* atau/*or* Duda/*Widower*
6.	Pekerjaan *occupation*	Sila nyatakan/ *Please specify*: .....
7.	Pendapatan bulanan isi rumah *Monthly household income*	Sila nyatakan/ *Please specify*: RM ……..
8.	Sumber pendapatan *Source of income*	❑ Gaji/ *Salary* ❑ Wang pencen/ *Pension fund* ❑ KWSP/ *Provident fund* ❑ Bantuan amal/ *Charity aid* ❑ Duit poket/ *Pocket money* ❑ Lain-lain/ *Others* Sila nyatakan/ *Please specify*: .....
9.	Tempat tinggal *Living area*	❑ Bandar/ *Urban* ❑ Luar bandar/ *Rural* ❑ Lain-lain/ *Others* Sila nyatakan/ *Please specify*: .....

BAHAGIAN B / *SECTION B: MEDICAL BACKGROUND*

Bahagian ini akan **DIISI OLEH PENYELIDIK** dengan merujuk kepada rekod perubatan anda dan sesi temu bual.

*This section is **TO BE FILLED BY RESEARCHER** by referring to your medical record and interview session.*

No.	**Maklumat Perubatan / *Medical Information***	**Catatan/ *Remarks***
1.	Tempoh durasi diabetes *Duration of diabetes*	Sila nyatakan/ *Please specify*: .....
2.	Penggunaan insulin *Insulin use*	☐ Ya/ *Yes* ☐ Tidak/ *No*
3.	Komorbiditi *Comorbidities*	☐ Darah tinggi / *Hypertension* ☐ Sakit jantung / *Cardiovascular disease* ☐ Penyakit hati/ *Liver disease* ☐ Sakit Buah Pinggang/ *Kidney Disease* ☐ Lain-lain / *Others* Sila nyatakan/ *Please specify*: .....
7.	Sejarah keluarga *Family history*	☐ Diabetes/ *Diabetes* ☐ Dislipidemia / *Dyslipidemia* ☐ Darah tinggi / *Hypertension* ☐ Lain-lain / *Others* Sila nyatakan/ *Please specify*: .....

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<table>
<tr><td>8.</td><td>Tahun diagnosis
Year of diagnosis</td><td>Penyakit / Diseases</td><td>Tahun / Year</td><td>Rawatan / Treatment</td></tr>
<tr><td></td><td></td><td>❑ Diabetes/ Diabetes
❑ Darah tinggi / Hypertension
❑ Sakit jantung / Cardiovascular disease
❑ Lain-lain / Others
Sila nyatakan/ Please specify:
.....</td><td></td><td></td></tr>
<tr><td>9.</td><td>Number of medications
Jumlah ubat-ubatan</td><td colspan="3">Sila nyatakan/ Please specify: .....</td></tr>
<tr><td>10.</td><td>Tahap diabetic retinopati
Stages of Diabetic Retinopathy</td><td colspan="3"></td></tr>
</table>

BAHAGIAN C / *SECTION C: ANTHROPOMETRIC MEASUREMENTS*

Bahagian ini akan **DIISI OLEH PENYELIDIK** dengan merujuk kepada rekod perubatan anda dan sesi temu duga.

*This section is **TO BE FILLED BY RESEARCHER** by referring to your medical record and interview session.*

No.	**Maklumat/ *Information***	**Bacaan pertama / *First reading***	**Bacaan kedua / *Second reading***	**Purata / *Average***
1.	Bacaan antropometri *Anthropometry measurements*			
	-Berat semasa / *Current weight* -Tinggi / *Height* -BMI	.....kg .....m .....kg/m^2	.....kg .....m .....kg/m^2	.....kg .....m .....kg/m^2

BAHAGIAN D / *SECTION D: BIOCHEMICAL DATA*

Bahagian ini akan **DIISI OLEH PENYELIDIK** dengan merujuk kepada rekod perubatan anda.

*This section is **TO BE FILLED BY RESEARCHER** by referring to your medical record.*

Data biokimia / *Biochemical data*	**Bacaan / *Reading***	**Bacaan normal / *Normal value***
-Random blood glucose level (RBG)	.....mmol/L	
-Fasting blood glucose level (FBG)	.....mmol/L	
-HbA1C	.....%	

BAHAGIAN E / *SECTION E: DIETARY INTAKE*

A) Sejarah pemakanan / *Diet history*

Arahan:

1. Dalam bahagian ini, responden diminta untuk menyatakan kebiasaan makanan yang diambil selama 2 hari, iaitu **satu hari mewakili hari bekerja** dan **satu hari mewakili hujung minggu.**
2. Responden diminta untuk menyenaraikan kebiasaan makanan yang diambil pada setiap hari.
3. Responden diminta untuk menerangkan saiz hidangan makanan yang diambil.

Instruction:

1. *In this section, the respondents need to state the usual food intake for 2 days which is* ***one day represents weekday*** *and* ***one day represents weekend.***
2. *Respondents will be asked to list all foods usually consumed in each meal in a day.*
3. *The respondents need to describe the serving size of each food consumed.*

Hari / *Day*:

Waktu makan / *Mealtime*	**Saiz hidangan / *Serving size***
Sarapan pagi / *Breakfast*	
Makan tengah hari / *Lunch*	
Snek petang / *Evening snack*	
Makan malam / *Dinner*	

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Hari / *Day*:

Waktu makan / *Mealtime*	**Saiz hidangan / *Serving size***
Sarapan pagi / *Breakfast*	
Makan tengah hari / *Lunch*	
Snek petang / *Evening snack*	
Makan malam / *Dinner*	

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BAHAGIAN F / *SECTION F:* PEMATUHAN PEMAKANAN/ *DIETARY ADHERENCE*

Bahagian ini akan **DIISI OLEH PENYELIDIK** dengan merujuk kepada sesi temu bual.

*This section is **TO BE FILLED BY RESEARCHER** by referring to the interview sessions.*

Arahan: Soalan-soalan dalam bahagian ini adalah berkaitan aktiviti pengawalan penyakit kencing manis sepanjang 7 hari yang lalu. Jika anda sakit sepanjang 7 hari yang lalu, fikirkan 7 hari sebelum anda sakit.

Instructions: The questions below ask about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please recall the last 7 days that you were not sick.

No.	Soalan/Questions	Hari/Days
1.	Sepanjang 7 hari yang lalu, berapa harikah anda mengamalkan kaedah kawalan pemakanan yang sihat? *How many of the last 7 days have you followed a healthful eating plan?*	
2.	Secara purata dalam sebulan, berapa harikah dalam seminggu anda mengamalkan kaedah kawalan pemakanan yang sihat? *On average, over the past month, how many days per week have you followed your eating plan?*	
3.	Sepanjang 7 hari yang lalu, berapa harikah anda makan 5 atau lebih hidangan buah-buahan dan sayur-sayuran? *On how many days of the last 7 days did you eat 5 or more servings of fruits and vegetables?*	
4.	Sepanjang 7 hari yang lalu, berapa harikah anda makan	

	makanan yang mengandungi kandungan lemak yang tinggi, contohnya makanan bergoreng atau makanan yang mengandungi susu berlemak penuh? *On how many of the last 7 days did you eat high fat foods such as red meat or full-fat dairy products?*	
5.	Sepanjang 7 hari yang lalu, berapa hari anda makan makanan yang kurang manis? (Contohnya, dessert (pencuci mulut), gula-gula, coklat, kek) *On how many of the last 7 days did you eat very few sweets? (For example, desserts, candy, chocolate, cakes)*	
6.	Sepanjang 7 hari yang lalu, berapa hari anda makan makanan yang tinggi serat seperti sayur-sayuran atau oat? *On how many of the last 7 days did you eat lots of food high in dietary fiber such as vegetables or oats?*	
7.	Sepanjang 7 hari yang lalu, berapa hari anda mengurangkan kalori dalam makanan untuk menurunkan berat badan anda? *On how many of the last 7 days did you reduce the number of calories you eat to lose weight?*	

APPENDICES 2

PATIENT CONSENT AND INFORMATION SHEET (ENGLISH VERSION)

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1. **Title of study:** Factors Associated with Glycemic Control Among Patients with Diabetes Attending Ophthalmology Clinic, Hospital Serdang

2. **Name of investigator:** Muhammad Harith Bin Zakaria
   Name of co-investigator: Dr Barakatun Nisak Mohd Yusof
   Name of institution: Hospital Serdang

3. **Name of sponsor:** This study is self-sponsored

4. **Introduction:**

   You are invited to participate in this study. The details of the research are described in this document. Please take your time to read through this information sheet and informed consent form before making any decision. Please ask the researcher if anything is unclear or if you like more information. If you wish to participate, you need to sign this informed consent form.

   Your participation in this study is voluntary. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study.

   This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the study?**

   The purpose of this study to determine factors associated with glycemic control among diabetes patients attending ophthalmology clinic of Hospital Serdang. This research is necessary because it can help improve the management of diabetes patients attending ophthalmology clinic to achieve improved glycemic control by understanding the significant factors associated with glycemic control.

   A total of 80 diabetes patients from ophthalmology clinic of Hospital Serdang will be participating in this study. The whole study will last about 3 months and your participation will be about 30 minutes throughout the face to face interview session.

6. What kind of study procedures will I receive?

If you agree to participate in the study, you will be face to face interviewed to complete a set of questionnaires and will be measured on several anthropometric measurements. Anthropometric measurement requires us to measure your weight, height, and waist circumference. You will be asked to remove your shoes then stand up straight on the weighing scale to measure weight and again stand up straight to measure your height and waist circumference. Some data will be accessed and retrieved from your medical records including: HbA1c level, blood glucose level, etc.

7. What will happen if I decide to take part?

You will be face to face interviewed, the researcher will fill a set of questionnaires which includes information regarding to your sociodemographic characteristics, nutritional status, medical profile, and dietary adherence.

8. When will I be interviewed?

You will be interviewed as soon as possible after you give informed consent.

9. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly during the interview session.

10. What kind of treatment will I receive after my participation in the trial?

This study does not involve any treatment or further medical references after your participation in this study.

11. What are the potential risks and side effects of being in this study?

There are minimal risks, but the chances and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests.

12. What are the benefits of being in this study?

You will be informed on your current nutritional status, but the study data and results will not be returned to you.

13. What if I am injured during this study?

There is no risk to be injured in this study. This is an interview and questionnaire-based study. You are only required to answer the questionnaire and be taken measurements of weight, height and waist circumference which pose a very minimal risk.

14. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your disease or condition.

15. Who is funding the research?

There is no sponsor funding for the research, and you will not be paid to participate in this study. You will also not be charged to participate in this study.

16. Can the research or my participation be terminated early?

You may withdraw from the study at any time. You will be informed if new information relevant to consent becomes available and you will be asked to reconsent.

17. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary. Data from the study will be archived but your identity will not be revealed at any time.

18. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the principal investigator, Muhammad Harith Bin Zakaria at phone number 01127518790 or email at harithzakaria@yahoo.com. You may also contact the co-investigator, Barakatun Nisak Mohd Yusof, 0193365686 or email at bnisakmy@gmail.com. If you have any questions

about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, and Ministry of Health Malaysia, at telephone number 03-3362 8407/ 8205 / 8888.

INFORMED CONSENT FORM

Title of Study: Factors Associated with Glycemic Control Among Patients with Diabetes Attending Ophthalmology Clinic, Hospital Serdang

By signing below, I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary, and I can at any time free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly, and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study. *(*delete which is not applicable)*

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date:

APPENDICES 3

PATIENT CONSENT AND INFORMATION SHEET (MALAY VERSION)

RISALAH MAKLUMAT PESERTA DAN BORANG PERSETUJUAN atau KEIZINAN PESERTA *(untuk subjek dewasa dan penyelidikan intervensi)*

1. **Tajuk penyelidikan**: Faktor-Faktor Berkaitan dengan Kawalan Glisemik Dalam Kalangan Pesakit Diabetes Menghadiri Klinik Oftalmologi, Hospital Serdang

2. **Nama Penyelidik:** Muhammad Harith Bin Zakaria
   Nama Penyelidik Bersama: Dr Barakatun Nisak Mohd Yusof
   Nama Institusi: Hospital Serdang

3. **Nama Penaja**: -

4. **Pengenalan:**

   Anda dijemput untuk mengambil bahagian dalam kajian ini. Butiran penyelidikan akan diterangkan dalam dokumen ini. Sila baca dan pertimbangkan maklumat ini dengan teliti sebelum anda membuat keputusan. Sila minta penyelidik jika ada sesuatu yang tidak jelas atau jika anda mahukan maklumat lanjut. Sekiranya anda ingin mengambil bahagian, anda perlu menandatangani borang persetujuan ini.

   Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak untuk tidak menjawab sebarang pertanyaan atau persoalan yang anda enggan jawab. Jika anda secara sukarela mengambil bahagian dalam kajian ini, anda boleh menarik diri pada bila-bila masa. Sekiranya anda melakukan sedemikian, sebarang data yang dikumpulkan daripada anda masih akan digunakan untuk kajian ini.

   Penyelidikan ini telah mendapat kelulusan Jawatankuasa Etika dan Penyelidikan Perubatan, Kementerian Kesihatan Malaysia.

5. **Apakah tujuan penyelidikan ini dilakukan?**

   Tujuan penyelidikan ini dilakukan adalah untuk menentukan hubungkait antara faktor sosiodemografi, latar belakang perubatan, status pemakanan, pematuhan pemakanan dengan kawalan glisemik dalam kalangan pesakit diabetes yang menghadiri klinik oftalmologi di Hospital Serdang, Selangor.

   Penyelidikan ini diperlukan kerana ia dapat membantu meningkatkan kecekapan pengurusan pesakit diabetes yang menghadiri klinik oftalmologi untuk mencapai kawalan glisemik yang lebih baik dengan memahami faktor-faktor penting yang berkaitan dengan kawalan glisemik.

   Sejumlah 80 pesakit diabetes yang menghadiri klinik oftalmologi Hospital Serdang, Selangor akan menyertai penyelidikan ini. Penyelidikan ini akan berlangsung selama 3 bulan dan tempoh pembabitan anda dianggarkan selama 30 minit.

6. Apakah prosedur penyelidikan yang akan saya terima?

Jika anda bersetuju untuk mengambil bahagian dalam kajian ini, anda akan ditemuduga untuk menyelesaikan satu set soal selidik dan beberapa ukuran antropometri akan diambil daripada anda. Ukuran antropometri memerlukan berat, tinggi, dan ukur lilit pinggang tubuh badan anda. Sebahagian maklumat akan diambil dari rekod perubatan anda termasuklah: tahap HbA1c, tahap gula dalam darah, dan lain-lain.

7. Apakah yang terjadi sekiranya saya bersetuju untuk menyertai penyelidikan ini?

Anda akan ditemubual untuk melengkapkan set soalan penyelidikan termasuk maklumat mengenai sosiodemografi, status pemakanan, maklumat perubatan, dan pematuhan pemakanan.

8. Bilakah saya akan ditemubual?

Anda akan ditemubual secepat mungkin selepas anda memberikan keputusan berkaitan persetujuan ini.

9. Apakah tanggungjawab saya sewaktu menyertai penyelidikan ini?

Adalah penting untuk menjawab semua soalan yang ditanya oleh penyelidik dengan jujur dan sepenuhnya.

10. Apakah jenis rawatan yang akan saya terima selepas menyertai penyelidikan ini?

Kajian ini tidak melibatkan apa-apa rawatan.

11. Apakah risiko dan kesan-kesan sampingan menyertai penyelidikan ini?

Risiko adalah pada tahap minima kerana aktiviti penyelidikan hanya melibatkan temuduga. ukuran berat, tinggi, dan ukur lilit pinggang tubuh badan anda.

12. Apakah manfaatnya saya menyertai kajian ini?

Anda akan dimaklumkan berkaitan status pemakanan semasa anda.

13. Apakah yang akan terjadi sekiranya saya tercedera semasa menyertai kajian ini?

Tidak ada risiko kecederaan dalam kajian ini. Ini adalah kajian berasaskan borang soal selidik. Anda hanya perlu menjawab boring soal selidik dalam kajian ini.

14. Apakah rawatan alternatif lain sekiranya saya tidak menyertai penyelidikan ini?

Anda tidak perlu menyertai kajian ini untuk mendapatkan rawatan bagi penyakit atau masalah kesihatan anda.

15. Siapakah yang membiayai penyelidikan ini?

Tiada pihak yang membiayai penyelidikan ini.

16. Bolehkah penyelidikan ataupun penyertaan saya ditamatkan lebih awal daripada yang dirancang?

Anda dibenarkan untuk menarik diri daripada penyelidikan ini pada bila-bila masa. Jika terdapat prosedur baharu dalam aktiviti penyelidikan ini, anda akan diberitahu dan diminta untuk memberi persetujuan sekali lagi.

17. Adakah maklumat perubatan saya akan dirahsiakan?

Segala maklumat anda yang diperolehi dalam penyelidikan ini akan disimpan dan dikendalikan secara sulit, bersesuaian dengan peraturan-peraturan dan/ atau undang-undang yang berkenaan. Sekiranya hasil penyelidikan ini diterbitkan atau dibentangkan kepada orang ramai, identiti anda tidak akan didedahkan tanpa kebenaran anda terlebih dahulu. Pihak- pihak tertentu seperti individu yang terlibat dalam penyelidikan dan rawatan perubatan anda, juruaudit dan jurupantau yang terlatih, pihak penaja atau pihak gabungannya, pihak berkuasa kerajaan atau undang-undang, boleh memeriksa dan membuat salinan laporan perubatan anda jika berkenaan dan diperlukan. Segala data yang berkaitan dengan penyelidikan ini akan diarkib, tetapi identiti anda tidak akan didedahkan sama sekali pada bila-bila masa.

18. Siapakah yang perlu saya hubungi sekiranya saya mempunyai sebarang pertanyaan?

Anda boleh menghubungi pegawai penyelidikan, Muhammad Harith Bin Zakaria pada sambungan telefon 011 27518790 ataupun emel kepada harithzakaria@yahoo.com sekiranya anda mempunyai sebarang pertanyaan mengenai penyelidikan ini atau jika anda mengesyaki anda mengalami kecederaan yang terhasil daripada penyelidikan ini. Anda boleh juga menghubungi pemantau penyelidikan ini iaitu Dr Barakatun Nisak Mohd Yusof, 03-9769 2606.

Jika anda mempunyai sebarang pertanyaan berkaitan dengan hak-hak anda sebagai peserta dalam penyelidikan ini, sila hubungi: Setiausaha, Jawatankuasa Etika & Penyelidikan Perubatan, Kementerian Kesihatan Malaysia, melalui talian telefon 03-3362 8407/ 8205 / 8888.

BORANG PERSETUJUAN/ KEIZINAN PESERTA

Tajuk Penyelidikan: Kecukupan tenaga dan faktor-faktor berkaitan di kalangan pesakit warga tua di Hospital Serdang, Selangor.

Dengan menandatangani di bawah, saya mengesahkan bahawa:

- Saya telah diberi maklumat tentang penyelidikan di atas secara lisan dan bertulis and saya telah membaca dan memahami segala maklumat yang diberikan dalam risalah ini.
- Saya telah diberikan masa yang secukupnya untuk mempertimbangkan penyertaan saya dalam penyelidikan ini dan telah diberi peluang untuk bertanyakan soalan dan semua persoalan saya telah dijawab dengan sempurna dan memuaskan.
- Saya juga faham bahawa penyertaan saya adalah secara sukarela dan pada bila-bila masa saya bebas menarik diri daripada penyelidikan ini tanpa harus memberi sebarang alasan dan ianya sama sekali tidak akan menjejaskan rawatan perubatan saya pada masa akan datang. Saya tidak mengambil bahagian dalam mana-mana penyelidikan lain pada masa ini. Saya juga memahami tentang risiko dan manfaat penyelidikan ini dan saya secara sukarela memberi persetujuan untuk menyertai penyelidikan ini di bawah syarat-syarat yang telah dinyatakan di atas. Saya faham saya harus mematuhi nasihat dan arahan yang berkaitan dengan penyertaan saya dalam penyelidikan ini daripada doktor penyelidikan (penyelidik).
- Saya faham bahawa kakitangan penyelidikan, pemantau dan juruaudit terlatih , pihak penaja atau gabungannya, dan pihak berkuasa kerajaan atau undang-undang, mempunyai akses langsung dan boleh menyemak laporan perubatan saya bagi memastikan penyelidikan ini dijalankan dengan betul dan data direkodkan dengan betul. Segala maklumat dan data peribadi akan dianggap sebagai SULIT.
- Saya akan menerima satu salinan 'Risalah Maklumat Peserta dan Borang Persetujuan atau Keizinan Peserta' yang telah lengkap dengan tarikh dan tandatangan untuk dibawa pulang ke rumah.
- Saya bersetuju/ tidak bersetuju* untuk doktor yang merawat keluarga saya diberitahu tentang penyertaan saya dalam penyelidikan ini. *(*Potong mana yang tidak berkenaan)*

Subjek:

Tandatangan: No. kad pengenalan:

Nama: Tarikh:

Penyelidik yang mengendalikan proses menandatangani borang keizinan:

Tandatangan: No. kad pengenalan:

Nama: Tarikh:

Saksi tidak-berpihak/adil: *(Diperlukan; jika subjek adalah buta huruf dan kandungan risalah maklumat peserta disampaikan secara lisan kepada subjek)*

Tandatangan: No. kad pengenalan:

Nama: Tarikh:

APPENDICES 4

MEDICAL RESEARCH & ETHICS COMMITTEE

APPROVAL LETTER

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Kompleks Institut Kesihatan Negara
Blok A, No 1, Jalan Setia Murni U13/52,
Seksyen U13, Bandar Setia Alam,
40170 Shah Alam, Selangor.
Tel: 03-3362 8888/8205

Ref : KKM/NIHSEC/ P19-2698 (6)
Date: 13-January-2020

MUHAMMAD HARITH BIN ZAKARIA
UNIVERSITY PUTRA MALAYSIA (UPM)

Dear Sir/ Mdm,

ETHICS INITIAL APPROVAL: NMRR-19-3364-51408 (IIR)
FACTORS ASSOCIATED WITH GLYCEMIC CONTROL AMONG DIABETES PATIENTS ATTENDING OPHTHALMOLOGY CLINIC, HOSPITAL SERDANG

This letter is made in reference to the above matter.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are to be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator / Hospital Director and all relevant heads of departments / units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations, including the Access to Biological and Benefit Sharing Act 2017.

3. The investigators and study sites involved in this study are:

HOSPITAL SERDANG
Dr Barakatun Nisak Mohd Yusof
Muhammad Harith Bin Zakaria (Principal Investigator)

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Study Protocol_Version 3, dated 30-December-2019
2. Participation Information Sheet & Informed Consent Form (English)_Version 3, dated 30-December-2019
3. Participation Information Sheet & Informed Consent Form (Malay)_Version 3, dated 30-December-2019
4. Questionnaire_Version 1, dated 07-November-2019
5. Other related research documents_Version 1, dated 30-December 2019
6. Investigator's documents : Declaration of Conflict of Interest (COI), IA-HOD-IA, and CV:
   a) Dr Barakatun Nisak Mohd Yusof
   b) Muhammad Harith Bin Zakaria (Principal Investigator)

5. Please note that ethical approval is valid until **12-January-2021**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the Medical Research Ethics Committee (MREC) website (http://www.nih.gov.my/mrec).
   i. **Continuing Review Form** has to be submitted to MREC within 2 month (60 days) prior to the expiry of ethical approval.
   ii. **Study Final Report** upon study completion to the MREC.