# STUDY ON ACCURACY OF SELF-PERCEPTION ON CARDIOVASCULAR RISK AMONG PERI AND POST-MENOPAUSAL WOMEN ATTENDING KLINIK RAWATAN KELUARGA HUSM

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### ABBREVIATION

BMI	Body Mass Index
CAD	Coronary artery disease
CI	Confidence interval
CHD	Coronary heart disease
CVD	cardiovascular disease
FRS	Framingham risk score
HDL	High density lipoprotein
HRT	Hormone replacement therapy
HUSM	Hospital Universiti Sains Malaysia
KRK	Klinik Rawatan Keluarga
LDL	Low density lipoprotein
NCD	Non-communicable disease
NHMS	National health and morbidity survey
COCP	Combine oral contraceptive pill
OR	Odd ratio

SBP	Systolic blood pressure
SPSS	Statistical Package for Social Sciences
SCORE	Systematic Coronary Risk Evaluation
PRHDS	Perception of Risk of Heart Disease Scale
ТС	Total cholesterol
TG	Triglyceride
WC	Waist circumference
WHO/ ISH	World Health Organization/ International Society of
	Hypertension

### ABSTRACT

# STUDY ON ACCURACY OF SELF PERCEPTION ON CARDIOVASCULAR RISK AMONG PERI AND POST MENOPAUSAL WOMEN ATTENDING KLINIK RAWATAN KELUARGA, HUSM

Introduction : Cardiovascular diseases are among the major cause of mortality and morbidity worldwide including Malaysia. WHO estimated that there would be a rapid increment in prevalence of cardiovascular related diseases in both sexes especially in South East Asia Pacific Region. Peri and post menopausal women are among the high risk group to develop cardiovascular diseases, yet most of this group of women have inaccurate perception regarding their risk of getting the cardiovascular diseases. The inaccurate perception of cardiovascular risk could be either underestimation or overestimation of the cardiovascular risk. The inaccurate perception of cardiovascular risk might lead to reduce health concern and non-optimize therapeutic lifestyle changes.

**Objective** : This study was conducted to determine accuracy of self-perception on cardiovascular risk in comparison with actual cardiovascular risk among perimenopausal and post-menopausal women attending primary care clinic of a university hospital as well as to identify the associated factors for underestimation and overestimation of cardiovascular risk.

**Methodology :** A cross sectional study was performed on 292 peri and postmenopausal women age 48 years and above who attend KRK, in between May till August 2015. Case report form used to assess socio-demographic data and translated (Malay) version of Perception of Risk of Heart Disease Scale (PRHDS) was used to assess participants' perception on cardiovascular risk. Anthropometry measurement including blood pressure, height, weight and waist circumference taken. Fasting lipid profile and fasting blood sugar were also taken. Actual cardiovascular risk was assessed using Framingham Risk Score (FRS) 2008. Data was analysed using SPSS version 22.0

**Results :** A total of 265 patients responded, giving a response rate of 90.8%. Mean age of the participants were  $57.4 \pm 7.2$  and majority (96.6%) are Malay. Most of the participants (87.5%) perceived themselves in moderate cardiovascular risk group, but the actual cardiovascular risk showed the predominant of high cardiovascular risk group (49.1%). More than three quarter of the participants (81.9%) inaccurately perceived their cardiovascular risk which can be further divide into those who underestimate (48.7%) and overestimate their cardiovascular risk (33.2%). Analysis showed that diabetes mellitus, increasing age and higher systolic blood pressure were associated with underestimation of cardiovascular risk. Meanwhile, overestimation of cardiovascular risk was associated with higher HDL level. Those hypertensive participants, elderly age group and higher systolic blood pressure were noted to be less likely to overestimate their cardiovascular risk.

**Conclusion :** With the significant proportion of participants who inaccurately perceived their cardiovascular risk and almost half of the total participants were underestimate their risk, it would be a pressing need for primary care practitioners to adequately address the cardiovascular risk issue during the community intervention as well as during consultation.

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### ABSTRAK

# KAJIAN KETEPATAN TANGGAPAN PERIBADI TERHADAP RISIKO PENYAKIT CARDIOVASCULAR DI KALANGAN WANITA HAMPIR AND TELAH MENOPAUS DI KLINIK RAWATAN KELUARGA, HUSM

**Pengenalan** : Penyakit kardiovaskular merupakan antara penyebab utama kematian dan morbiditi di dunia dan termasuk juga di Malaysia. WHO menganggarkan peningkatan yang ketara bagi penyakit berkaitan kardiovaskular melibatkan kedua-dua jantina terutamanya di kawasan tenggara Asia Pasifik. Wanita yang hampir dan telah menopaus adalah antara kumpulan berisiko tinggi untuk mengidap penyakit kardiovaskular, tetapi malangnya kebanyakan daripada wanita dalam kumpulan ini menunjukkan ketidak tepatan tanggapan peribadi berkenaan risiko mereka mengidap penyakit kardiovaskular. Ketidak tepatan tanggapan peribadi mengenai risiko penyakit kardiovascular ini boleh mengakibatkan kurangnya tahap kesedaran kesihatan dan membantutkan usaha kearah pelaksanaan carahidup sihat.

**Objektif** : Kajian ini dilaksanakan untuk mengenalpasti ketepatan tanggapan peribadi mengenai risiko penyakit kardiovaskular berbanding risiko sebenar di kalangan wanita hampir and telah menopaus yang mendapatkan rawatan di "primary care clinic" di sebuah hospital universiti serta mengenalpasti faktor yang mempengaruhi "kurang anggaran" dan "lebih anggaran" mengenai risiko peribadi untuk mengidap penyakit kardiovaskular

**Metodologi**: Satu kajian hirisan lintang telah dilaksanakan terhadap 292 wanita hampir and telah menopaus berumur 48 tahun ke atas yang mendapatkan

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rawatan di "primare care clinic" antara Mei hingga Ogos 2015. Borang kaji-selidik digunakan untuk mendapatkan data sosio-demografik manakala soalan kajiselidik "Perception of Risk of Heart Disease Scale (PRHDS)" versi terjemahan Bahasa Melayu telah digunakan untuk menilai tanggapan peribadi peserta terhadap risiko mengidap penyakit kardiovaskular. Pengukuran fizikal termasuk tekanan darah, tinggi, berat dan ukur lilit pinggang telah dilakukan. Pengambilan sampel darah juga dilaksanakan untuk profail lipid (puasa) dan paras gula darah(puasa). Pengiraan risiko penyakit kardiovaskular yang sebenar dinilai berdasarkan "Framingham Risk Score (FRS) 2008". Data di analisa menggunakan SPSS versi 22.0

**Keputusan** : Sejumlah 265 peserta telah memberi maklum balas lengkap menjadikan kadar maklum balas kebanyak 90.8%. Umur purata peserta kajian adalah 57.4 ± 7.2 and majority (96.6%) adalah berbangsa Melayu. Kebanyakan peserta (87.5%) bertanggapan bahawa mereka mempunyai risiko cardiovascular yang sederhana, tetapi keputusan risiko cardiovascular yang sebenar didominasikan oleh kumpulan yang berisiko tinggi (49.1%). Lebih daripada tiga perempat peserta (81.9%) menunjukan ketidak tepatan tanggapan peribadi mengenai risiko penyakit kardiovaskular. Ini terdiri daripada 48.7% peserta yang "terkurang anggar" dan 33.2% peserta yang "terlebih anggar" mengenai risikonya mengidap penyakit kardiovaskular. Analisa menunjukkan bahawas pengidap diabetes mellitus, peningkatan usia dan peningkatan tekanan darah sistolik mempunyai kaitan dengan "terkurang anggar" risiko penyakit kardiovasular berkadaran dengan peningkatan paras HDL. Pengidap penyakit tekanan darah tinggi, golongan berusia and mereka yang mempunyai tekanan darah sistolik

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yang lebih tinggi didapati kurang berkemungkinan untuk "terlebih anggar" risiko kardiovaskular mereka.

**Kesimpulan :** Dengan jumlah ketara peserta yang mempunyai salah tanggapan mengenai risiko penyakit kardiovaskular mereka di samping hampir separuh peserta yang "terkurang anggar" mengenai risiko kardiovaskular, pengkaji merasakan bahawa terdapat keperluan yang mendesak agar pengamal perubatan primer membincangkan isu risiko penyakit kardiovaskular semasa program di komuniti serta semasa konsultasi di klinik.

### **CHAPTER 1**

#### INTRODUCTION

Cardiovascular diseases (CVD) are still the major cause of morbidity and mortality worldwide as well as in Asia Pacific region.(1) Total of 57 million deaths occurred in the world during 2008; 36 million (63%) were due to non-communicable diseases (NCD)s, principally cardiovascular diseases which causes 17 million deaths, or 48% of NCD deaths)(2). WHO estimates that the NCD deaths are projected to increase by 15% globally between 2010 and 2020. The greatest increases will be in South-East Asia , Africa and the Eastern Mediterranean ,where they will increase by over 20% (3)

In Malaysia, survey showed that heart disease and disease of the pulmonary system were among the 10 most common causes of death in Ministry of Health hospitals in 2010 which were covering up to 16.05% of total hospital mortality cases. This result shows an increment in number and proportion compare to our cardiovascular mortality of 14.2% in 1980<sup>th</sup>. Although Malaysia was classified under the' intermediate mortality' country for cardiovascular problem but this upward trend, both amongst the man as well as the women need to be given serious attention. (4) Other than that, Data from National Health and Morbidity Survey, NHMS III had reported the increasing prevalence of cardiovascular related disease amongst adult population. This result including 32.7% of population with hypertension (5.8 milions), 15.2% have diabetes (2.6 millions), 35.1% have hyperlipidaemia (6.2 millions) and 25% are smoking (4.4 milions)(5)

Other than that, Data from National Health and Morbidity Survey, NHMS III had reported the increasing prevalence of cardiovascular related diseases amongst adult population. This result including 32.7% of population with hypertension (5.8 milions), 15.2% have diabetes (2.6 millions), 35.1% have hyperlipidaemia (6.2 milions) and 25% are smoking (4.4 milions)(5)

These cardiovascular problems should not only focused for the men, but also the women, particularly those who are in perimenopausal and post-menopausal age. Data from Framingham heart study showed that the lifetime risk for CVD was 2 in 3 for men and more than 50% for women approaching 40 years old. It was also noted that more than half of the cardiovascular events that occur in men and women under age 75 years old, were contributed by coronary heart disease (CHD). The lifetime risk of developing CHD after age 40 was 49% for men and 32% for women. It was also mentioned that 50% of men and 64% of women who presented with sudden coronary heart disease death had no previous symptoms of the disease with significantly increasing incident occur among advancing age female. (6) Beside, data from study by Khoo et al took placed at West Malaysia was noted that there were significant raised in cardiovascular mortality among women from 0.8% in 1960 to 29.8% in 1989. (4)

Post-menopausal had been identify by many studies as one of the risk factors for cardiovascular disease. It was noted that women with increasing age would had increase other cardiovascular risk factors. However, the steeply rise in the cardiovascular risk following menopause inadequately explained by the rising of the other cardiovascular risk alone. Studies by rossi, van der and kannel

suggested that the menopausal and its related hormonal changes itself were the main factors that influence this cardiovascular risk changes. (7-9)

Few studies had found that women who were in transitional period towards the menopause or in perimenopausal state were actually had started to show increase cardiovascular risk in almost similar trend seen in post-menopausal women. (10-12). Study by mattew et al in 2001 showed that the peri-menopausal women even had worse lipid profile changes compared to post-menopausal women; those in peri-menopausal state showing greater reduction in HDL cholesterol and more increase in LDL cholesterol and triglycerides. However, blood pressure and fasting glucose level were more significantly rise in post-menopausal state. (11) Besides, the European cardiologist and gynaecologist also had emphasized the important of early detection and the need for further intervention to reduce and manage related cardiovascular risk factors among peri-menopausal women. (12)

### **CHAPTER 2**

#### LITERATURE REVIEW

#### 2.1 CARDIOVASCULAR DISEASE AND WOMEN

Historically, women's health issues focused on menopause and breast cancer, leading women not to think about CVD as an important problem for them. In fact, menopause women itself are exposed to osteoporosis-related problem, cancer and cardiovascular disease; while the first two problems are well studied, the later seem to be neglected despite being the leading cause of death in women. As a result, women may be inadequately informed about the disease. Most women are far more afraid of breast cancer than of cardiovascular disease even though in Malaysia, cardiovascular related death was 2.5 times more common as a cause of death as all cancers combined. (13)

The major risk factors for cardiovascular diseases in women are similar to men except few additional risk which were unique to women; using combine oral contraceptive pill and premature menopause. Compared to men, the cardiovascular risks in women even multiply enormously when they approached post-menopausal age. In Malaysia, a study among rural Malaysian's women noted the prevalence of hypertension and obesity was 26.8% and 11.4% respectively. (14) National health and morbidity survey 2015 on non-communicable diseases, risk factors and other health problems have found quite significant proportion of cardiovascular risk factors among women (15). It was noted in this report that prevalence of hypertension among women was 29.7 %, diabetes was 18.5%, dyslipidaemia 52.2%. Other than that, the prevalence of

obesity was quite high among women with 30.9% were overweight, 33.6% were obese and 60.2% showed significant abdominal obesity. The prevalence of smoking was only 1.4% which was not high but there was significantly sedentary lifestyle noted with physical inactivity was 38.2 %.(15) In another study assessing the cardiovascular risks factor among Malay elderly adult found 31.6% of postmenopausal women had 5 risk factors for cardiovascular diseases and 12.5% belongs to very high risk group. (16)

Prevention of cardiovascular diseases would be much aided by the efforts on reducing the risk factors. Besides health promotion, early detection through screening is a central element of minimizing the effect of cardiovascular disease. The most effective means of decreasing the impacts of cardiovascular problems on women's health is by modifying the contribution of specific risk such as obesity, abnormal plasma lipid, hypertension, diabetes mellitus, cigarette smoking, sedentary life style, high blood viscosity, stress and autonomic imbalance. Perhaps one of the largest and most neglected groups that could be benefit from prevention is asymptomatic peri and post-menopausal women with multiple risks factor.

#### 2.2 PERCEPTION ON CARDIOVASCULAR DISEASE IN WOMEN

Initiation of behavioural changes for modification of cardiovascular risk factors would involves a complex and complicated personal belief and understanding. Although the psychological determinacies for personal behavioural changes to reduce the related risk was poorly understood, the personal self-perception were postulated to significantly give impact toward persons' behavioural changes. (17)

Understanding the nature of risk perception would be an important element to modify the subsequent behavioural changes.

The "perception" term had been defined by Schacter and Daniel as the organization, identification, and interpretation of sensory information in order to represent and understand the environment

The "risk" term had been defined in various ways in literature. Short Jr defined the risk term as the possibilities of an individual to encounter the effect of danger (18). Meanwhile, Sjoberg defined the "risk perception" as "the subjective assessment of the probability of a specified type of accident happening and how concerned we are with the consequences". (19). It was believed that the risk perceptions would be modify by the personal evaluation of the possibility and the outcome of the events. However, Weinstein postulated that the risk perception concepts were beyond the individual capacity, but it was involving the social, cultural values and ideology as well.(20)

Measuring a personal perception of risk would be a quite tough construct as it was very subjective and differ interpersonally. Kendra et al relate the perception of risk to probability of a person to experience and adverse event and the degree of the situation poses a threat to an individual along a continuum from no risk at all to high risk.(21) Besides, Fischhoff and Paul Slovic et al mentioned in articles regarding the domain used in risk perception; dread risk was explained at its high end as reflecting uncontrollable, catastrophic, dread, increasing and high future risk consequence whereas the unknown risk was defined at its lower end as unobservable, delayed, new and unknown in exhibition of harm. (22, 23)

Local qualitative study by Juwita S et al showed that all categories women (premenopause and post-menopause) perceived their risk to develop cardiovascular was low and assume that the cardiovascular disease is "man disease". (24)When comparing the self-perception to actual cardiovascular risk, the perception that women are "protected" against heart disease were frequently encounter which lead to the underestimation of the risk of heart disease among women. However, women might not aware that this cardiovascular protection effect were not long lasting and diminished once they approached their menopausal state. Hence, this finally would leave the women with untreated risk factors who highly susceptible for cardiovascular events.(25) Furthermore, clinical manifestation of ischaemic heart disease in women may be different from those commonly observed in men. This may account for under recognition of the disease. (25) As the Malaysian population is getting older, numbers of women living with cardiovascular diseases are expected to be increased.

Few studies had identified the association between the socio-demographic and medical background with accuracy of self-perception on cardiovascular risk. Study by Hussein et all 2008 showed that the accuracy was predicted by age younger than 45 years old (26). Meanwhile, other study finds poor agreement between self-perceived and actual cardiovascular risk, with a high prevalence of risk underestimation. As a consequent of that, the people at low CVD risk are the most likely to correctly estimate their cardiovascular risk. Furthermore, higher levels of agreement between perceived and objective risk are associated with being female, being younger, having more education, being a non-smoker or on hypertensive medication, or having a lower than average BMI. (27)

Various studies have reported regarding factors which were associated with inaccurate perception of self-cardiovascular risk. It is stated that women, African Americans, patients with fewer years of education and younger patients were all more likely to have optimistic biases (underestimation) for perceived heart attack risk, whereas men and older patients were more likely to have pessimistic biases (overestimation) for perceived heart attack. (28). However, other studies showed that older women and high risk women have inaccurate and unrealistic perceptions of personal cardiovascular risk and that they may benefit from tailored health promotion interventions that alter the risk (29)

Misconceptions seem to be common among primary care patients. Patients may adopt an active or passive role toward cardiovascular disease prevention, depending on their ideas, perceptions, fears, and expectations. Knowing patients' fears and risk perceptions and bringing them into line with the actual risk seems a prerequisite for effective management. Involving the patients in decision making on the management of high risk may improve patients' satisfaction, well-being, and even lifestyle and health outcomes. Thus, it is important for effective cardiovascular risk management that the primary care physician have a clear view of patients' actual cardiovascular risk, their risk perceptions, and their preferences and expectations regarding the risk management.

Various theories were developed to explain and predict the individual health behaviours in relation to risk perceptions. One of them was the Health Belief Model which were originally developed by Rosenstock. The main components identify in this model which would moulded the persons behaviour were the persons perceived susceptibility and severity of the disease, the perception of

barrier and the benefits of the risk reduction as well as the cues for action. (30, 31)

According to social cognitive theory, relationships between personal factors and behaviour were demonstrated by the way in which people behave.(32). Behaviour was said to be moulded by people's self-perceptions, beliefs, expectations, goals as well as intentions. Thus, what people think, believe, and feel impacts how they act. Patient's accurate perceptions of cardiovascular risk had been showed to be associated with demonstrable behaviours that were suggestive of risk reduction. Hence, accurate perceptions of cardiovascular risks were necessary for health behaviour to be aligned with measures to treat and prevent cardiovascular disease (33). Behaviour change had been described as difficult and multifaceted processes nonetheless accurate perceptions of cardiovascular risk were necessary for behaviour change to occur. (34)

#### 2.3 CARDIOVASCULAR RISK ASSESSMENT TOOLS

Cardiovascular risk scores are risk assessment tools that predict the risk of developing a cardiovascular event in a specified time period from risk factors determined by history, physical examination or investigations. These tools are developed from cohort studies where multiple potential risk factors are measured at baseline and the study population subsequently followed-up over time to identify those who develop the outcome of interest. Mathematical models are then used to determine which of the risk factors significantly and independently predict the risk of having a cardiovascular event and these are combined in multivariable formulations to determine an individual's global cardiovascular risk. (4)

Multiple studies to assess the usage of the cardiovascular risk score showed unfavourable results. Findings from quantitative studies indicate that the usage of the risk scores ranged from 48-68.5%.(16, 26) More than a third of doctors did not use the cardiovascular risk scores to assess risk in clinical practice. The studies were carried out in Europe with the exception of the survey by Sposito et al, which also included North, Central and South American countries. The usage of the risk scores in other regions is not known

There were numbers of cardiovascular risk assessment tools had been developed to estimate the initial risk of cardiovascular events in asymptomatic healthy adults. Studies showed that the different risk assessment tools might gave different value and had their own advantages and disadvantages over others. (35, 36)The selection of risk assessment tools to be used should be individualized with reference to patient's background characteristics like age, gender and races.

The various risk assessment tools are listed as below

**Framingham risk score** – This scoring tools were derived from a landmark study involving Caucasian population of European descent. This scoring would be discussed in next sections.

**ATP III hard CHD risk score (2002)** – This is the modified version of Framingham risk score base on the third Adult Treatment Panel (ATP III) which was mainly recommended to be used in screening and management of dyslipidaemia. The variables used include age, gender, total cholesterol, HDL,

systolic blood pressure, blood pressure treatment and current smoking. The endpoints assessed include CHD death and non-fatal myocardial infarction. (37)

SCORE CVD death risk score (2003) – This scoring tool was developed base on pooled 12 cohort studies from European. The studies mainly took place in community settings involving more than 200 thousands persons. The variables used include age, gender, total and HDL cholesterol, systolic blood pressure, smoking status and region of Europe. Cardiovascular endpoints assessed were composite of all cardiovascular disease death.(38)

WHO/ISH risk prediction chart (2007) – this predictive chart were produced by WHO to be used in 14 WHO epidemiological sub-regions base on specific chart for the region. There were 2 difference predictive chart can be used either in setting of blood cholesterol result available or not. The other variables used was age, sex, blood pressure, smoking status and diabetes mellitus status. The endpoints outcome measured were 10-year risk of a fatal or nonfatal major cardiovascular event. (39)

**Reynolds CVD risk score for women (2007) and for men (2008)** – These two scoring were derived from 2 different prospective cohort study involving American women and men without establish diabetes mellitus. The significant difference between this scoring with other cardiovascular risk predictive tools were the additional usage of high-sensitivity C-reative protein (hs-CRP) and family history of myocardial infarction. Other than that, the difference between scoring for women and men was the usage of diabetes mellitus status in women but not used for risk calculation in men. The endpoints outcome assessed by these scoring

was include cardiovascular death, non-fatal stroke, non-fatal myocardial infarction and coronary revascularization events. (40, 41)

**QRISK (2007) and QRISK2 (2008)** – This cardiovascular risk assessment tools were derived from a prospective open cohort study in United Kingdom. The variables used was similar with modified Framingham/ATP III model with added on few additional medical and social-economic background. The additional variables used including family history of CVD in first degree relative age lesser than 60 years old, BMI and region of residents in United Kingdom. This model were assessed the composite all fatal and non-fatal cardiovascular event. It was also found to be more accurate than Framingham/ ATP III model in identified those in the studied population. (42, 43)

**ACC/AHA pooled cohort hard CVD risk calculator (2013)** – this risk calculator were derived from several cohorts involving large population of Caucasian and African-American patients. The variables included in this model were similar with the FRS 2008, but the endpoints predicted only for cardiovascular death as well as non-fatal stroke and myocardial infarction.(44)

#### 2.3 FRAMINGHAM RISK SCORE (FRS)

The Framingham Risk Assessment tool have been used extensively for cardiovascular risk assessment in asymptomatic men and women. This assessment tool was derived from a well-known landmark study, Framingham Heart Study 1948. The earlier Framingham Risk Assessment tools; Framingham Risk Score (FRS) 1991 (45) and Framingham Risk Score (FRS) 1998 (46) were developed based on multiple categorical variable. These FRS predict multivariate

coronary heart disease risk in asymptomatic patients without establish coronary heart disease. This version of FRS had been undergone transformation, adaptation and being integrated into various guidelines for cardiovascular disease prevention including with the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in adults (NCEP/ATPIII).(37) It also had been used to guide for risk factors modification and management in USA.(37, 47). Risk factors used in FRS 1998 include age, total cholesterol, high density lipoprotein cholesterol, blood pressure, cigarette smoking which divides persons with multiple risk factors into percentage of 10-year risk for coronary heart disease.

The FRS 1998 had been tested and validated in various population worldwide including in European and population (48-50) as well as among Chinese population.(51) This FRS 1998 also had been used in Malaysia for cardiovascular risk assessment. There was also an epidemiological survey to assess the cardiovascular risk in community in Kuala Langat involving 1417 participants. The study which was accomplished by chin et al and published in 2009 was using the FRS 1998 as the screening tools.(52)

Unfortunately, this FRS 1998 was noted to have different accuracy in different populations, with tendency to under predict in high-risk population and vice versa. Its accuracy was also slight limited in Asian population. In Malaysia, there was a retrospective cohort carried out to find the accuracy and appropriateness of FRS in Malaysia which was published in 2008. The study was using 600 patients attending a primary care clinic from year 1997 and the subsequent coronary heart disease (CHD) event were identified up to 10 years from the baseline years. The

initial FRS was calculated and placed the patient into 3 CHD risk group which were either low risk (<10%), medium (10-20%) or high (>20%). Subsequent observed CHD events over a 10-year period for each of the group from low risk to high risk were 7%, 15% and 19 respectively. This showed that the FRS accurately stratified the possibilities of 10 years risk of CHD in low to moderate risk groups, but might be less accurate in predicted the coronary heart disease event in high risk group in this population. (53)

The Framingham risk assessment tools had been undergone continuous update and improvement. Later in 2008, D'Agostino et al had come out with improved version of Framingham general cardiovascular risk score which was more applicable to be used in primary care setting.(54) This new Framingham Risk Score (FRS 2008) was modified to add another variables for treated and untreated blood pressure level besides other previous variables. The FRS 2008 was mentioned in Malaysian Clinical Practice Guidelines (CPG) for prevention of cardiovascular disease in women 2008 and CPG Management of Dyslipidaemia 2011 for cardiovascular risk assessment in our population. (55, 56)

Initially, in year 2010, the data from an epidemiological survey was used to see and compared the accuracy between FRS 1998 and FRS 2008. In that study, the distribution of the different risk categories were changed from 14.9% to 11.8% in low risk group and 48.5% to 24.5% for medium risk group. For high risk group, the changes are from 36.6% to 63.7% based on the FRS 1998 and FRS 2008 respectively. The researcher in that study concluded that the FRS 2008 able to identify more population with higher cardiovascular risk and might be a better tool for cardiovascular risk assessment. (57)

Interestingly, this FRS 2008 had been recently validated to be used among Asian population. The validation of FRS 2008 to be use in multi-ethnic group in primary care setting in Asian population was carried out by Chia et al and was published in end of 2014.(58) The study was a 10-year retrospective cohort study done at one of the teaching hospital in Malaysia base on 967 patients' records from clinic. The study concluded that the Framingham general CVD risk prediction chart is applicable to be referred in primary care setting in our Malaysian population as well as Asian population in general.

Besides, there was another study by Selvarajah et al assessing four cardiovascular risk prediction models in Asian population. The models were The FRS 2008, Systematic Coronary Risk Evaluation (SCORE), high and low cardiovascular risk regions and the World Health Organization/ International Society of Hypertension (WHO/ ISH) models. This retrospective cohort study used data from a national population-based survey of 14,863 participants' age 40 to 65 years old. The findings of this study showed that the FRS 2008 and SCORE models could stratify risk in Asian men and women and most importantly the FRS model stratified risk better than the SCORE models in women. (59)

#### 2.4 JUSTIFICATION OF STUDY

Studies showed that there were increasing trend of cardiovascular mortality and morbidity worldwide as well as in Asia Pacific region which also include Malaysia.(1) It was known that the major cardiovascular risk factors for women were similar to men, but the risk was significantly increase even when the women approaching the peri-menopausal state. Studies from oversea showed that these high risk group of women still showing inaccurate perception regarding their

cardiovascular risk. Unfortunately, there were limited local data on the accuracy of self-perception on cardiovascular risk amongst peri and post-menopausal women in Malaysia as well as its associated factors. These data would be important to guide us in identifying those women who might require more attention in education on cardiovascular risk during clinic consultation or in community program. Besides, the misconception regarding the cardiovascular risk would give a negative impact towards the cardiovascular risk reduction behaviour. Thus, this study aims to determine the accuracy of cardiovascular risk perception in peri and post-menopausal women and the associated factors for their inaccurate perceptions; either underestimation or overestimation of the cardiovascular risk.

#### 2.5 CONCEPTUAL FRAMEWORK



Figure 1: Conceptual framework for the study

### **CHAPTER 3**

#### **OBJECTIVES**

#### 3.1 GENERAL OBJECTIVE:

To determine accuracy of self-perception on cardiovascular risk in comparison with actual cardiovascular risk among perimenopausal and post menopausal women attending Klinik Rawatan Keluarga, HUSM

#### 3.2 SPECIFIC OBJECTIVE:

- 1. To determine the proportion of participants who self-perceived low, moderate and high cardiovascular risk.
- 2. To determine the proportion of participants who were in low, moderate and high actual cardiovascular risk groups.
- 3. To determine the proportion of participants who accurately and inaccurately perceived their cardiovascular risk
- To identify the socio-demographic and related medical associated factors for underestimation of cardiovascular risk
- To identify the socio-demographic and related medical associated factors for overestimation of cardiovascular risk

#### **3.3. RESEARCH HYPOTHESIS**

There is an association between socio-demographic and medical risk factors with underestimation and overestimation of cardiovascular risk.

#### **3.4 OPERATIONAL DEFINITION**

**Cardiovascular risk**: The likelihood of a woman developing a cardiovascular event, fatal or non fatal, over a period of time (55)

**Perceived cardiovascular risk** : Individual's personal subjective risk for developing heart disease in the future including within a 10 year period of time which was assessed based on translated (Malay) version of Perception of Risk of Heart Disease Scale (PRHDS) developed by Ammouri et al.

**Perceived low cardiovascular risk**: Those with total PRHDS score between 16-31

**Perceived moderate cardiovascular risk**: Those with total PRHDS score between 32-47

**Perceived high cardiovascular risk** : Those with total PRHDS score between 48-64

Actual cardiovascular risk: Objective cardiovascular risk score to estimate the 10-year risk of developing coronary heart disease base on the Framingham Risk Score (FRS) 2008.

Low actual cardiovascular risk : Those with total FRS 2008 score less than 10%

**Moderate actual cardiovascular risk**: Those with total FRS 2008 score between 10-20%

**High actual cardiovascular risk**: Those with total FRS 2008 score more than 20% or have diabetes mellitus

Accuracy : the level of concordance/ agreement between perceived cardiovascular risk group with the actual cardiovascular risk group

Accurate cardiovascular risk perception - Self-perceived of cardiovascular risk group was concordance with the actual cardiovascular risk group

**Inaccurate cardiovascular risk perception** - Self perceived of cardiovascular risk group was discordance with the actual cardiovascular risk group.

**Underestimation of cardiovascular risk**: Self perceived of cardiovascular risk group was in lower group compare to the actual cardiovascular risk group

**Overestimation of cardiovascular risk**: Self perceived of cardiovascular risk group was in higher group compare to the actual cardiovascular risk group.

**Perimenopausal women** – Women age 48 years old and above who still have menses until 12 months after she has the last menstrual period. (60-63)

**Post-menopausal women** – Women age 48 years old and above who have no menstrual bleeding for the past 12 months (60-63)

**Framingham Risk Score (FRS) 1998** : Cardiovascular risk calculation using the equation base on study "Prediction of Coronary Heart Disease Using Risk Factor Categories" by Wilson et al which was published in 1998.
**Framingham Risk Score (FRS) 2008** : Cardiovascular risk calculation using the equation base on study "General Cardiovascular Risk Profile for Use in Primary Care" by D'Agostino et al which was published in 2008.

Using combined oral contraceptive pill (COCP): using oral combined contraceptive pill of at least 6 months. (64)

**Premature menopause:** Women at 40 years old or younger who have no menstrual bleeding for the past 12 months secondary to any reasons either have or did not have menopausal symptom

**Diabetes mellitus:** Ever been diagnosed by physician to have diabetes mellitus either on medication or not

**Hypertension:** Ever been diagnosed by physician to have hypertension either on medication or not

**Taking anti-hypertensive treatment:** Those who was prescribed antihypertensive medication by physician for treatment of hypertension.

**Dyslipidaemia:** Ever been diagnosed by physician to have dyslipidaemia either on medication or not

**Smoking:** Any cigarette, vape or shisha smoking within past 1 month.

**Sudden premature cardiovascular mortality:** Sudden death due to cardiovascular related causes for men younger than 55 or women younger than 65

### **CHAPTER 4**

#### METHODOLOGY

#### 4.1 STUDY DESIGN

This was a cross sectional study

#### 4.2 DURATION OF STUDY

This study was conducted in May 2015 till August 2015

#### 4.3 STUDY POPULATION

#### 4.3.1 References and source population

**References population**: Peri-menopausal and post-menopausal women attending primary care facilities in Kota Bharu district

**Source population:** Perimenopausal and post menopausal women attending Klinik Rawatan Keluarga (KRK), Hospital Universiti Sains Malaysia, Kubang Kerian

#### 4.3.2 Inclusion criteria

i. All women aged 48 years old and above who attend KRK, HUSM during the data collection day

#### 4.3.2 Exclusion criteria

- i. Underlying psychiatric illness
- ii. Physical handicap deaf, dumb and blind
- iii. Had establish cardiovascular diseases including stroke, transient ischemic attack or ischemic heart disease

iv. Unsure diabetes mellitus status or under investigation to diagnose diabetes mellitus

#### 4.4 SAMPLING METHODS

All the participants were selected by systematic random sampling in ratio of 1:3 base on the attendance list during data collection day.

#### 4.5 SAMPLE SIZE CALCULATION

The largest calculate sample size was from objective 1 which was 292 and was used for this study

4.5.1 Sample size calculation for objective 1

## To determine the proportion of participants who self-perceived low, moderate and high cardiovascular risk.

Based on estimated result from perception of risk of heart disease scale (PRHDS) score in each group; unknown risk, risk and dread risk base Hussein et al.(26)

The sample size is calculated by using single proportion formula

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

N = required sample size

z = 1.96

 $\Delta = \text{precision} (0.06)$ 

p = expected proportion of women who had self-perception of cardiovascular risk in each group (low, moderate and high)

Group	Р	Calculated	Calculate sample
		sample size	size after added
			20% (non
			response)
Unknown risk	0.65	243	292
Risk	0.30	224	269
Dread risk	0.05	51	62

Table 1: Sample size calculation for objective 1

4.5.2 Sample size calculation for objective 2

To determine the proportion of participants who were in low, moderate and high actual cardiovascular risk groups

The sample size is calculated by using single proportion formula for each category of score based on selvarajah et all (59)

P(risk)	Calculated sample size	Calculate sample size
		after added 20% (non
		response)
Low (0.67)	236	284
Moderate (0.21)	178	214
High (0.12)	113	136

 Table 2: Sample size calculation for objective 2

#### 4.5.3 Sample size calculation for objective 3

### To determine the proportion of accurately and inaccurately perceived cardiovascular risk

The sample size is calculated by using two proportion formula by Power and Sample size Calculation software version 3.0.10 based on Hussein HM et al. (26)

 $\alpha$ = level of significant = 0.05

Power of the study = 80%

Po= proportion of population who accurately perceived CVD risk in each group

P<sub>1</sub>= expected proportion of participant who inaccurately (wrongly) perceived CVD risk in each group

m= Ratio of accurately perceived CVD risk to wrongly perceived CVD risk was 1.

Table 3:	Po	Calculated sample	Calculate sample
	D4	size	size after added
	P1		20% (non
			response)
Low	Po = 0.81	21 x 2 = 42	51
	P1 = 0.40		
Moderate	Po = 0.28	25 X 2 = 50	60
	P1= 0.67		

Table 3 : Sample size calculation for objective 3

High

P1= 0.75

#### 4.5.4 Sample size calculation for objective 4

## To identify the socio-demographic and related medical associated factors for underestimation of cardiovascular risk

The sample size for the objective 4 was calculated using two proportions formula by Power and Sample size Calculation software version 3.0.10 based on Diaz et al.(26)

 $\alpha$ = level of significant = 0.05

Power of the study = 80%

P<sub>0</sub>= proportion of exposure amongst women who not underestimating CVD risk base on expert opinion

 $\Psi$  = relative risk of exposure amongst women who underestimate the CVD risk

m= Ratio of accurately perceived CVD risk to wrongly perceived CVD risk was 1.

Associated	Po	Colculated cample	Colculato complo
ASSOCIATED	FU	Calculated sample	Calculate sample
factors	Ψ	size	size after added
			20% (non
			response)

Table 4 : Sample size calculation for objective 4

Po = 0.20	30 x 2 = 60	72
Ψ = 4.74		
Po = 0.06	36 x 2 = 72	87
Ψ = 4.74		
Po = 0.02	33 x 2 = 66	80
Ψ = 4.74		
	Po = 0.20 $\Psi = 4.74$ Po = 0.06 $\Psi = 4.74$ Po = 0.02 $\Psi = 4.74$	Po = 0.20 $30 \times 2 = 60$ $\Psi = 4.74$ Po = 0.06 $36 \times 2 = 72$ $\Psi = 4.74$ Po = 0.02 $33 \times 2 = 66$ $\Psi = 4.74$

#### 4.5.5 Sample size calculation for objective 5

To identify the socio-demographic and related medical associated factors for overestimation of cardiovascular risk

The sample size for the objective 4 was calculated using two proportions formula by Power and Sample size Calculation software version 3.0.10 based on avis et al

 $\alpha$ = level of significant = 0.05

Power of the study = 80%

P<sub>0</sub>= proportion of exposure amongst women who not overestimate CVD risk base on expert opinion

 $\Psi$  = relative risk of exposure amongst women who overestimate the CVD risk

m= Ratio of accurately perceived CVD risk to wrongly perceived CVD risk was 1.

Associated	Ро	Calculated sample	Calculate sample
factors		size	size after added
	Ψ		20% (non
			response)
Death of parents	Po = 0.10	92 x 2 = 184	221
due to heart			
disease	$\Psi = 2.72$		

Table 5 : Sample size calculation for objective 5

#### 4.6 RESEARCH TOOLS

The tools used for this study were:

- i. Case Report Form (CRF)
- ii. Questionnaire on self-perception on cardiovascular risk
- iii. Framingham risk score form

#### 4.6.1 Case Report Form (CRF)

The Case Report Form was obtained responses on

- Socio-demographic data
- Clinical history
- Physical examination
- Laboratory result

#### 4.6.1.1 Socio-demographic data are include

- Age
- Race
- Marital status

- Educational level
- Occupational sector
- Household income

#### 4.6.1.2 Clinical history data are include

- Menopausal status
- History of using combined oral contraceptive pill
- Premature menopause
- Presence of diabetes mellitus
- Presence of hypertension
- Taking anti-hypertensive treatment
- Presence of dyslipidaemia
- Smoking

#### 4.6.1.2 Physical examination data are include

- Blood pressure
- Height (m) and weight (kg) and calculation of body mass index (BMI)
- Waist circumferences (cm)

The measurement of blood pressure were carried out as the participants were relaxed and seated with supported, outstretched arm using standard digital blood pressure machine Omron which was calibrated on schedule. Height and weight of the participants were measured by using calibrated "Seca" scale, with participants wearing clothing without shoes. (BMI was calculated as weight in kg divided by the square of height in meter (kg/m<sup>2</sup>), which was done later via SPSS version 22).

The waist circumference were measured using stretch resistant-measuring tape over bare stomach at the midpoint between the lower margin of last palpable rib and superior border of iliac crest. The measuring tape was make sure to be parallel to the floor and was snug to the body, but not so tight that it compresses the skin. Measurement were performed while the participants stand with feet together and arm at side and were done at end of normal expiration. The measurement was repeat twice and then recorded in the participants's CRF.

#### 4.6.1.3 Laboratory result

- Fasting blood sugar
- Fasting lipid profile
  - Total cholesterol (TC)
  - High density lipoprotein (HDL)
  - Low density lipoprotein (LDL)
  - Triglyceride (TG)

Researcher initially asked the participants regarding their last blood sugar and fasting lipid profile result. If they had taken the blood within past 6 months, the researcher would re-obtain verbal consent from the participants to review the record. If no recent blood investigation done, the participants were given a follow up at 2 weeks' time for fasting lipid profile and fasting blood sugar. 4 ml of blood would be drawn and put in different specimen bottles for fasting lipid profile and

fasting blood sugar. These blood sample would be then sent to laboratory for analysis.

## 4.6.2 Self Perception on cardiovascular risk questionnaire (Perception of risk of heart disease scale, PRHDS)

Self-perception on cardiovascular risk was assessed based on Perception of Risk of Heart Disease Scale (PRHDS). This was quite difference from other studies as in most of the published studies assessing the self-perception on cardiovascular risk, the researchers used the semi-qualitative or a direct single questionnaire to assess the personal or self-perception of cardiovascular risk. However, the reliability of assessment using the single item measure were questionable. Moreover, single item measures was not strong enough to defy the fact that the multi-item measures were needed to gauge the relatively complex construct (65-67) including in case of assessing the perception of cardiovascular risk.(68-70) Therefore, assessment for cardiovascular risk perceptions in this study was using a multi-item measured as advised based on study by Loo et al (65), Wanous et al (66) and Oshagbemi et al (67) to increase the accuracy of the construct measured.

PRHDS was a 20-item instrument which was developed to measure an individual's perception of the likelihood for he or she to develop heart disease. It is a self-report scale containing 20 questionnaires that takes approximately 10-15 minutes to complete. Initial testing was done by ammouri et al with a primary care sample of 295 person age more than 15 years old without heart disease. His validation study demonstrated internal consistency of 0.68 to 0.80. Total scale alpha was 0.80. Test-retest reliability was between 0.61 to 0.76. Construct validity

was demonstrated by achieving a significant correlation between the PRHDS and the Health Promotion Lifestyle Profile II (r = .20-.39, p < .01).(71)

Each item on the PRHDS has a 4-point Likert scale response option ranging from 1 (strongly agree) to 4 (strongly disagree). Item scores may be summed for subscales and a total scale score. Subscales include dread risk, risk, and unknown risk. For this study, only overall scale used to decide the group of the personal cardiovascular risk perception. The original author described that the total score of this questionnaire was proposed to categorize the person into a range from low to high perception of cardiovascular risk which was named as unknown risk, risk and dread risk. The "unknown risk" was further explained by Ammouri et al base on study by Slovic as reflecting hazards judged to be unobservable, unknown, new and delayed in their manifestation of harm whereas the "dread risk" is defined as reflecting perceived lack of control, dread, catastrophic potential and fatal consequences. For the "risk" term, it was defined as reflecting a hazard that has few, moderate, known outcomes and consequences. In overall, this questionnaire can be equally stratified the personal cardiovascular risk perception into low risk (unknown risk), moderate risk (risk) and high risk (dread risk) group.(71)

The Perception of Risk of Heart Disease Scale (PRHDS) questionnaire was originally in English version. This PRHDS questionnaire was translated and validated before used for this study. The translation, including forward and backward translations and the cross-cultural adaptation of this questionnaire was carried out according to international standards. The original English version of the PRHDS questionnaire was initially translated to Malay language by two Malay

translators who were fluent in English, one being a health professional (family physician) and the other was the English language tutor who has no technical or scientific knowledge of the topic under studied. The two translations were compared by the researcher in charge and the required adjustments were subsequently made with the consent of both translators. This resulting into a single version of the translation. This Malay version then was back translated into English by two bilingual translators, whose mother tongue is English, who had no access to the original English version of the questionnaire, thus preserving its ambiguity. The backward translation was compared and considered equivalent to the original version.

In the second phase of the study, the translated version of questionnaire of The Perception of Risk of Heart Disease Scale (PRHDS) was piloted at other out patient clinic of the university hospital involving 50 participants (women more than 48 years old) to see their understanding of the attitude of the questionnaires as well as to estimate length of time of data collection.

Data from the validation study were analysed using "Statistical Package for Social Sciences, SPSS" software version 22. Item analyses were done including internal consistency reliability by using Cronbach's alpha statistic and exploratory factor analysis which evaluate the construct validity of the items. The final questionnaires of PRHDS were consist of 16 out of 20 items of the original English version of PRHDS. The item analyses were satisfied for these 16-item as Cronbach's alpha was ranging from 0.714 to 0.720. The final total scoring for this study range between 16 - 64. The range score for each component of the perceived cardiovascular perception was than readjust base on the original

questionnaires. The range score for unknown risk (perceived low cardiovascular risk) group were between 16 - 31, whereas 32 - 47 for risk (perceived moderate cardiovascular risk) group and range more 48 to 64 for dread risk (perceived high cardiovascular risk) group.

On exploratory factor analysis (EFA) of the 20 items, principal axis factoring extraction with promax rotation was applied. Kaiser-Meyer-Olkin was 0.642, Bartlett's test of sphericity was significant (*P*-value<0.001). 4 items (Q3, Q6, Q19 and Q20) were removed due to low communalities and factor loading. Finally 16 items kept to used in this study.

Item	Factor loading	Communality	Cronbach's alpha
Question 1	0.670	0.680	0.714 – 0.720
Question 2	0.573	0.630	
Question 4	0.626	0.677	
Question 5	0.627	0.613	
Question 7	0.590	0.501	
Question 8	0.712	0.670	
Question 9	0.915	0.795	
Question 10	0.498	0.534	
Question 11	0.453	0.475	
Question 12	0.637	0.560	
Question 13	0.688	0.534	
Question 14	0.717	0.566	
Question 15	0.605	0.550	
Question 16	0.610	0.482	
Question 17	0.597	0.637	
Question 18	0.347	0.303	

Table 6 : Exploratory factors analysis for translated (Malay) version of PRHDS

#### 4.6.3 Framingham risk score form

The Framingham Risk Score used in this form is derived from Framingham Heart Study by D'Agostino et al which had been mentioned in Malaysian Clinical Practice Guidelines; Prevention of Cardiovascular Disease in Women 2008. The Framingham Risk Score is a gender-specific algorithm used to estimate the 10year cardiovascular risk of an individual. It was first developed based on data obtained from the Framingham Heart Study, to estimate the 10-year risk of developing coronary heart disease.

The variable used to calculate the cardiovascular risk by Framingham risk score include age, systolic blood pressure in treated or untreated individual, smoking, diabetes, total cholesterol and HDL-cholesterol. The point ranges given for each variable are ranges from -3 to 12. Using the given table, the total point obtained will give the percentage of 10 year cardiovascular risk. Then, this ten year risk were determined either low (<10% risk), moderate (10-20%) or high (>20%). This calculation are formulated and performed via "Statistical Package for Social Sciences, SPSS" software version 22.

#### 4.7 STUDY PROCEDURE

Questionnaires preparation and pilot study were done after getting permission from the original author of the PRHDS as well as approval from ethics committee of USM. The questionnaires was piloted on 8<sup>th</sup> March to 26<sup>th</sup> of March at other out patient clinic of HUSM involving 50 participants. Correction of the questionnaires was done base on the feedback from the pilot study.

#### 4.7.1 Data collection

#### 4.7.1.1 Questionnaires distribution

Data collection was started in May 2015 till August 2015. All eligible participants were identified during their visit to the primary care clinic for various medical reasons. The eligible women were explained regarding the study procedures and reassured about the confidentiality of all the information gathered. Those who agreed to participate were required to sign a consent form including the consent for blood taking and the laboratory record. Then, a set of self-administered questionnaire given. The participants answered the CRF in private room in the clinic. If the participants have difficulty to read the questionnaire or other problems, they would be assisted by the researcher. Each of the CRF were tagged with a code number which was only known to the researches as part of confidentiality measures and kept in an envelope. Physical examination would be carried out. Researcher then ask the participants regarding their last blood sugar and fasting lipid profile result, if not recent blood taking (less than 6 months), participants would be given subsequent follow up in 2 weeks' time for blood sampling.

#### 4.7.2 Data entry and analysis

Data entry and analysis were using "Statistical Package for Social Science" version 22. Data checking and cleaning were performed before analysis. Meaningful and appropriate data decoded and commuted were performed.

Descriptive analysis was used for demographic characteristics. Categorical variables were expressed using percentage and numerical variables were

expressed using mean (standard deviation). Descriptive analysis were used for the objective 1, 2, and 3. Simple and multiple logistic regression statistics were used for the objective 4. The dependant variable was inaccurately perceived cardiovascular risk, underestimation and overestimation of cardiovascular risk which was performed separately. The independent variables were

- socio-demographic age, race, marital status, educational level, working sector, household income
- medical factors menopausal status, taking OCP, premature menopause, diabetes mellitus, hypertension, on anti-hypertensive, dyslipidaemia, smoking, medical illness in first degree relative
- Biological factors BMI, WC, SBP, TC, HDL

#### 4.7.2.1 The procedure of simple and multiple logistic regression

The distribution and frequencies were examined. All continuous variables were expressed as mean and 95% confidence interval (CI). Categorical variables were calculated by frequency and percentage. Categories with small sample size and skewed distribution were noted. Meaningful combination of categories was done when indicated.

Simple logistic regression was done on all independent variables at uni-variable level. The analysis was continued was multiple logistic regression. Since this was a confirmatory analysis, all the potential variables were included in the model and "preliminary main effect" model was obtained. All the possible 2-way interactions were checked and variance inflation factors were obtained to check for multicollinearity. Then, preliminary final model were obtained. Fitness of the model was tested by Hosmer and Lemeshow goodness of fit test. The model was fit if the p value was more then 0.05 or perfectly fit if approached to one. The

classification table and receiver operating characteristic (ROC) curve were also used to determine the fitness of the model. The high overall percentage in the classification table and area under the curve towards one in the ROC curve showed that the model was fit. Finding were presented with crude and adjusted odds ratio (OR), 95% CI and *p*-value. Level of significance was set at 0.05 with two tailed fashion.

#### **4.8 ETHICAL APPROVAL**

The study proposal was presented to the academic lecturers in the Department of Family Medicine USM, with the presence of lecturers from Community Medicine Department USM. Later, it was reviewed and approved by Ethics Committee of USM on 17<sup>th</sup> September 2014.

#### 4.9 FLOW CHART OF THE STUDY



#### Figure 2 : Flow chart of study

### **CHAPTER 5**

#### RESULTS

A total of 292 women age 48 years old attending Primary Care Clinic of University Hospital were recruited. However only 265 fully responded and hence, the respond rate was 90.8%. Those 27 participants who had been dropped from the study were those who did not complete the questionnaires (8), did not complete minimal physical examination required for analysis (4) or not come for blood taking (11) and inconclusive for diabetic mellitus status base on FBS result in diabetic range (4)

#### 5.1 SOCIODEMOGRAPHIC AND MEDICAL CHARACTERISTICS

#### 5.1.1 Sociodemographic characteristics

The mean age for the participants involve in this study were  $57.4 \pm 7.20$ . Majority of the participants were Malay 96.6% with more than three quarter were married (79.6%). Near half of the participants (46.4%) have educational level up to secondary school whereas 3.8% of the participants never attending school at all. Working in the public sectors (45.3%) and housewife (43.8%) were the predominant occupation noted in this study. 59.2% of the participants were having household income of more than RM 5000 per month. Overall, 73.2% of the participants were already in post-menopausal state.

Characteristic	Mean (SD)	N (%)
Age (years)	57.4 (7.20)	
Race		
Malay		256 (96.6%)
Non Malay		9 (3.4%)
Marital status		
Single		4 (1.5%)
Married		211 (79.6%)
Widow/Divorce Educational level		50 (18.9%)
Not attending school		10 (3.8%)
Primary school		49 (18.5%)
Secondary school		123 (46.4%)
College and universities Occupation		83 (31.3%)
Public sector		120 (45.3%)
Private sector		14 (5.3%)
Self employed		15 (5.7%)
Housewife		116 (43.8%)
Monthly household income		

Table 7: The socio-demographic characteristics of 265 participants.

< RM 3000	66 (24.9%)
RM 3000- RM 5000	42 (15.9%)
> RM 5000 Menopausal status	157 (59.2%)
Yes	194 (73.2%)
No	71 (26.8%)

#### 5.1.2 Clinical characteristic

Only 24.5% of the participants ever took combine contraceptive pill for at least 6 months. There were 2 participants (0.8%) experience premature menopause. Overall, more than half of the participants were having cardiovascular related disease including 45.3% of the participants had diabetes mellitus, hypertension (69.4%), on anti-hypertensive treatment (68.7%) and dyslipidaemia (72.8%). Only 1 participant was a smoker.

Table 8: Clinical characteristic of the	participants (n=265).
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Characteristic	1	N (%)
	Yes	No
Taking COCP	65 (24.5)	200 (75.5)
Premature menopause	2 (0.8)	263 (99.2)
Diabetes mellitus	120 (45.3)	145 (54.7)
Hypertension	184 (69.4)	81 (30.6)
On anti-hypertensive	182 (68.7)	83 (31.3)
Dyslipidaemia	193 (72.8)	72 (27.2)
Smoking	1 (0.4)	264 (99.6)

#### 5.1.3 Medical illness in first degree relatives

There were quite significant percentage of the participants who had first degree relatives with cardiovascular related diseases. 66% of the participants had first degree relatives with hypertension, whereas 46.4 % and 46% have first degree relative with dyslipidaemia and diabetes mellitus respectively. Other medical illness present in first degree relatives of the participants were stroke (23.4%), heart disease (22.3%) and history of sudden premature cardiovascular mortality (11.3)

Characteristic	N (%)		
	Yes	No	
Diabetes mellitus	122 (46.0)	143 (54.0)	
Hypertension	175 (66.0)	90 (34.0)	
Heart disease	59 (22.3)	206 (77.7)	
Stroke	62 (23.4)	203 (76.6)	
Sudden premature cardiovascular mortality	30 (11.3)	235 (88.7)	
Dyslipidaemia	123 (46.4)	142 (53.6)	

Table 9 : Laboratory characteristics of participants (n=265).

#### 5.1.3 Laboratory characteristics of participants

Mean BMI for participants in this study was  $28.3 \pm 4.52 \text{ kg/m}^2$  whereas mean waist circumference was  $87.2 \pm 11.51 \text{ cm}$ . Mean for fasting lipid profile were  $3.5 \pm 1.15 \text{ mmol/L}$  for LDL,  $1.4 \pm 0.32 \text{ mmol/L}$  for HDL and  $1.5 \pm 1.10 \text{ mmol/L}$  for TG

Characteristic	Mean (SD)	
BMI (kg/m2)	28.3 (4.52)	
Waist circumference	87.2 (11.51)	
(cm)		
LDL (mmol/L)	3.5 (1.15)	
HDL (mmol/L)	1.4 (0.32)	
TG (mmol/L)	1.5 (1.10)	

Table 10 : Laboratory characteristics of participants (n=265).

#### **5.2 SELF PERCEPTION OF CARDIOVASCULAR RISK**

The participants' personal perception of their own cardiovascular risk were shown in Table 11. Majority of the participants perceived their cardiovascular risk in moderate cardiovascular risk group which are 88.7% amongst peri-menopausal group and 87.1% amongst post menopausal group of participants. The rest in perimenopausal group perceived themselves in low risk (8.5%) and high risk (2.8%) whereas in post-menopausal group of participants 8.2% perceived low cardiovascular risk and 4.6% perceived high cardiovascular risk. For total participants, 87.5% perceived themselves at moderate cardiovascular risk, followed by 8.3% in low risk and 4.2% in high risk. The mean score was 39.9 with standard deviation of 5.51.

Menopausal		N (%)				
status	Low risk	Moderate risk	High risk	Total		
Peri-menopausal	6 (8.5) <sup>a</sup>	63 (88.7) <sup>a</sup>	2 (2.8) <sup>a</sup>	71 (100) <sup>a</sup>		
Post menopausal	16 (8.3) <sup>b</sup>	169 (87.1) <sup>b</sup>	9 (4.6) <sup>b</sup>	194 (100) <sup>ь</sup>		
Total	22 (8.3) <sup>c</sup>	232 (87.5) <sup>c</sup>	11 (4.2) <sup>c</sup>	265 (100) <sup>c</sup>		

Table 11: Self perception of cardiovascular risk base on PRHDS

- ()<sup>a</sup> percentage within peri-menopausal group
- ()<sup>b</sup> percentage within post-menopausal group
- ()<sup>c</sup> percentage within total participants

#### **5.3 ACTUAL CARDIOVASCULAR RISK**

The participants' actual cardiovascular risk base on Framingham Risk Score (FRS) 2008 were shown in Table 11. Majority of the perimenopausal participants are in low cardiovascular risk group (53.5%), followed by high cardiovascular risk group (31%). Contradicted result found in post-menopausal participants which showed 55.7% of them were in high actual cardiovascular risk group followed by 27.3% in low actual cardiovascular risk group. Least of the participants were in moderate cardiovascular risk group which were 15.5% among peri-menopausal participants and 17% in post-menopausal participants. For the total participants near half of the participants 49.1% were in high actual cardiovascular risk group, followed by 34.3% in low risk and moderate actual cardiovascular risk group 16.6%

Menopausal	N (%)				
status	Low risk	Moderate risk	High risk	Total	
Peri-	38 (53.5) <sup>a</sup>	11 (15.5) <sup>a</sup>	22 (31.0) <sup>a</sup>	71 (100) <sup>a</sup>	
menopausal					
Post	53 (27.3) <sup>b</sup>	33 (17.0) <sup>b</sup>	108 (55.7) <sup>b</sup>	194 (100) <sup>b</sup>	
menopausal					
Total	91(34.3) <sup>c</sup>	44 (16.6%) <sup>c</sup>	130 (49.1) <sup>c</sup>	265 (100) <sup>c</sup>	

Table 12: Actual cardiovascular risk base on FRS

- ()<sup>a</sup> percentage within peri-menopausal group
- ()<sup>b</sup> percentage within post-menopausal group
- ()<sup>c</sup> percentage within total participants

# 5.4 THE PROPORTION OF PARTICIPANTS WHO ACCURATELY AND INACCURATELY PERCEIVED THEIR CARDIOVASCULAR RISK

The result were showed in table 12. Only 18.1% of the participants accurately perceived their cardiovascular risk and the rest 81.9% were inaccurately perceive their cardiovascular risk. The inaccurately perceived cardiovascular risk can be divided into two subgroups which were those who underestimate their risk which was 48.7% and those who overestimate their risk which consist of 33.2% of all participants.

Self		Actual cardiovascular risk N (%)			
perception					
	Low risk	Moderate risk	High risk	Total	
Low risk	5 (1.9)	4 (1.5)	13 (4.9)	22 (8.3)	
Moderate risk	82 (30.9)	38 (14.3)	112 (42.3)	232 (87.5)	
High risk	4 (1.5)	2 (0.8)	5 (1.9)	11 (4.2)	
Total	91 (34.3)	44 (16.6)	130 (49.1)	265 (100)	
Self perc	eption of cardio	ovascular risk		N (%)	
Accur	rate		48 (18.1)		
Inaccu	ırate		217 (81.9)		
Unde	erestimation		129 (48.7)		
Over	restimation		88 (33.2)		

Table 13: Comparison between self-perception and actual cardiovascular risk

### 5.5 ASSOCIATION BETWEEN UNDERESTIMATION OF CARDIOVACULAR RISK WITH SOCIO-DEMOGRAPHIC AND MEDICAL BACKGROUND

## 5.5.1 Associated factors for underestimation of cardiovascular risk by simple logistic regression

Variable	Regression	Crude Odds Ratio	Wald	<i>p</i> -value
	coefficient	<sup>a</sup> (95% CI)	statistic	
	(b)			
Marital status				
Married	0			
Single	-0.86	0.423 (0.04, 4.13)	0.55	0.459
Widowed	1.09	2.961 (1.53, 5.75)	10.29	0.001
Monthly household				
income				
>RM 5000				
	0	1		
RM 3000 – RM 5000	-1.67	0.188 (0.09, 0.41)	17.62	< 0.001
< RM 3000	-1.27	0.281 (0.15, 0.52)	16.62	< 0.001
Post-menopausal	1.01	2.739 (1.54, 4.88)	11.71	0.001
Diabetes mellitus	5.69	294.462	94.20	< 0.001
		(93.417, 928.179)		
Hypertension	1.23	3.427 (1.95, 6.03)	18.28	< 0.001

Table 14: Associated factors for underestimation of cardiovascular risk by simple logistic regression

Dyslipidaemia	2.04	7.697 (3.89,	34.22	< 0.001
		15.25)		
Family history of	- 0.42	0.658 (0.40, 1.20)	2.57	0.109
hypertension				
Age	0.101	1.106 (1.06, 1.15)	22.250	< 0.001
Systolic blood	0.027	1.027 (1.01, 1.05)	10.02	0.002
pressure				

## 5.5.2 Associated factors for underestimation of cardiovascular risk by multiple logistic regression

Simple and multiple logistic regression showed significant association between underestimation of cardiovascular risks with diabetes mellitus, elderly age and higher systolic blood pressure

Diabetic participants were found to have 447.53 times higher odds compared to non-diabetic to underestimate their cardiovascular risk after adjusted to age and systolic blood pressure.

Those with 1 year increased in age was found to have 88% higher odds to underestimate their cardiovascular risk after adjusted other factors.

Current study also found that a participants with 1 mmol increase in systolic blood pressure had 96% greater odds to underestimate their cardiovascular risk after adjusting other variable.

Variable	Regression	Adjusted Odds <sup>a</sup>	Wald	<i>p</i> -value
	coefficient	Ratio (95% CI)	statistic	
	(b)			
Diabetes mellitus	6.10	447.535	78.86	< 0.001
		(116.35, 1721.40)		
Age	0.115	1.122 (1.05, 1.20)	11.86	0.001
Systolic blood	0.043	1.043 (1.01, 1.07)	8.309	0.004
pressure				

Table 15 : Associated factors for underestimation of cardiovascular risk by multiple logistic regression

<sup>a</sup> Forward and backward LR Multiple Logistic Regression model was applied. Multicollinearity and interaction term were checked and not found. Hosmer-Lemeshow test, (p=0.035), classification table (overall correctly classified percentage = 93.6%) and area under the ROC curve (97.6%) were applied to check the model fitness

#### 5.6 ASSOCIATION BETWEEN OVERESTIMATION OF CARDIOVACULAR

#### RISK WITH SOCIO-DEMOGRAPHIC AND MEDICAL BACKGROUND

#### 5.6.1 Associated factors for overestimation of cardiovascular risk by simple

#### logistic regression

Table 16 : Associated factors for overestimation of cardiovascular risk by simple logistic regression

Variable	Regression	Crude Odds Ratio	Wald	<i>p</i> -value
	coefficient	<sup>a</sup> (95% CI)	statistic	
	(b)			

Marital status

Married	0	1		
Single	0.53	1.705 (0.24,	0.279	0.597
Widowed	-1.13	12.35)	7.48	0.006
		0.325 (0.15, 0.73)		
Post-menopausal	-0.95	0.387 (0.22, 0.68)	10.98	0.001
Hypertension	-1.91	0.148 (0.08, 0.26)	42.05	< 0.001
Dyslipidaemia	-1.16	0.313 (0.18, 0.56)	16.32	< 0.001
Family history of	-0.59	0.552 (0.33,0.93)	4.92	0.027
diabetes mellitus				
Age	-0.15	0.861 (0.81,0.91)	27.20	<0.001
Systolic blood	-0.07	0.933 (0.91, 0.96)	32.58	< 0.001
pressure				
Diastolic blood	-0.07	0.937 (0.91,0.97)	15.87	< 0.001
pressure				
Waist circumference	-0.04	0.959 (0.93, 0.98)	8.60	0.003
HDL	0.92	2.520 (1.13, 5.64)	5.05	0.025
TG	-0.46	0.633 (0.43, 0.93)	5.58	0.018

## 5.6.2 Associated factors for overestimation of cardiovascular risk by multiple logistic regression

Simple and multiple logistic regression showed presence of association between overestimation of cardiovascular risk with HDL level, age, hypertension and systolic blood pressure.

This study discovered that those with 1 mmol/L increase in HDL level had 4.35 higher odds to overestimate their cardiovascular risk after adjusted to age, hypertension and systolic blood pressure.

Other than that, those with 1 year increase in age were noted to had 14% lesser odds to overestimate their cardiovascular risk after adjusted to other variables.

Hypertensive participants were also found to 71% lesser odds to overestimate their cardiovascular risk compared to non-hypertensive participants after adjusted other factors.

Those participants with 1 mmol increase in systolic blood pressure were also identified to had 6% lesser odds to overestimate their cardiovascular risk after adjusting the other confounders.

Variable	Regression	Adjusted Odds <sup>a</sup>	Wald	<i>p</i> -value
	coefficient	Ratio (95% CI)	statistic	
	(b)			
HDL	1.47	4.350 (1.59,	8.185	0.004
		11.91)		
Age	-0.15	0.861 (0.81, 0.92)	19.72	< 0.001
Hypertension	-1.233	0.291 (0.15, 0.57)	12.82	< 0.001
Systolic blood	-0.067	0.936 (0.91, 0.96)	21.78	< 0.001
pressure				

Table 17 : Associated factors for overestimation of cardiovascular risk by multiple logistic regression

<sup>a</sup> Forward and backward LR Multiple Logistic Regression model was applied Multicollinearity and interaction term were checked and not found Hosmer-Lemeshow test, (p=0.091), classification table (overall correctly classified percentage = 80.4%) and area under the ROC curve (86.9%) were applied to check the model fitness

### **CHAPTER 6**

#### DISCUSSION

### 6.1 PROPORTION OF PARTICIPANTS WHO SELF-PERCEIVED LOW, MODERATE AND HIGH CARDIOVASCULAR RISK.

Present study found that 87.5% of participants perceived themselves at moderate risk for cardiovascular disease, followed by 8.3% perceived low risk and 4.2% perceived high cardiovascular risk.

In comparison for the perception of cardiovascular risk, there were 3 main studies assessing the women perceptions' on cardiovascular risk which were carried out by Mosca et al Mc Donnel et al, and Oerteld Prigione et al(72-74). Study by Mosca et al was took place in United States in 2006 involving 1485 women age 25 years old with 65% of the participants were age 45 years old and above. Cardiovascular perception was assessed using respondents self-rated of their risk for disease in either high, moderate or low. Result of Mosca's study showed that 41% of the participants perceived themselves in moderate cardiovascular risk and followed by 40% and 19% in low and high cardiovascular risk perception group respectively. (73)

Study by Mc Donnel et al was took place in Canada later in 2013 involving 1654 women participants with almost similar characteristic with Mc Donnel et al. The cardiovascular perception was assessed using similar method as Mc Donnel et al. The results shows that 52% of participants perceived themselves in moderate

cardiovascular risk group, followed by 32% perceived low risk and 12% high risk. The other 4% of the participant unable to decide their cardiovascular risk. (72)

The another latest, the BEFRI study by Oerteld prigione et al were carried out in Berlin German involving urban female age also 25 years old and above. Total participants involved were 1 062 persons with mean age of 50.3. A single direct question about subjective estimation of absolute cardiovascular risk in 10 year using 3 points likert scale were used; either low, medium or high. Findings showed that the highest proportion of the participants consider themselves in medium cardiovascular risk 47% and least in perceived high risk group, 9.7%.(74)

When comparing the result of current study with other 3 studies mention earlier (72-74), all these studies had showed a similar distribution trend for each group of personal perception on cardiovascular risk; most of the participants perceived themselves as in moderate cardiovascular risk, followed by low risk perception group and high cardiovascular risk perception.

However, in term of percentage, current study found slight different value compare to these 3 studies which had gained almost similar findings; 41% to 52% of the women perceived themselves in moderate cardiovascular risk group, followed by 32% to 43% in perception of low cardiovascular risk and the least 9.7% to 19% of the women thought themselves to be in high cardiovascular risk group. Meanwhile in this study, for the overall participants 87.5% perceived themselves as in moderate cardiovascular risk, followed by 8.3% and 4.2% for perceived low risk and high risk group.

The reason for the different in percentage for this group most likely can be explained by the difference in age of women who involve all these study. In current study, the participants involved were women age 48 years old and above whereas for the other 3 studies the participants were women age 25 years old and older with more than 60% of them age more than 45 years old (in Canadian and US study). The younger age group of women most likely perceived themselves in lower cardiovascular risk which increase the proportion of the low perception risk group in these 3 studies. This statement were supported by few others studies.

Few studies also had recognized that being female gender with younger age are among the factors contributes to perceptions of low cardiovascular risk. (28, 75) Other factors which was noted by other studies are those who exercise regularly (76), past good lifestyle habits or receiving regular health care for chronic condition(75) and lower educational level (28). On the other hand, perceive higher susceptibilities to get cardiovascular disease showed to be associated with male gender (28), having family history of heart disease and self-perceived as overweight(77). Those elderly age group, hypertensive, having family history of heart attack, (78) diabetes, current smoker and having previous heart attack (75) had also been noted associated with high perception of cardiovascular risk. Besides, Laurinavicius et all noted that high cardiovascular risk perception also associated with taking medication for treatment of diabetic, dylipidaemia and most significantly for patients on anti-hypertensive medications.(79)

In this study, most of the participants perceived themselves in moderate cardiovascular risk with least of them perceived higher cardiovascular risk. It can

be postulated that, as this study population mainly involved Malay race, the perception on CVD risk may be a challenging construct to assess because of the cultural taboo amongst Malays; they may be unwilling and hesitate to admit they are at risk of certain illness because of a cultural belief that this would bring the negative consequence. (80)

There were also other study assessing the cardiovascular risk perception done by Katz et al (81), Hussein at al (26) and Nancy Avis et al (82). However these studies involved both sexes. The result of this studies showed that most of the participants perceived themselves in low cardiovascular risk (57% to 65%), followed by perceived average or moderate cardiovascular risk (30-30.2) and perceived high cardiovascular risk 6% - 13%. This difference in trend and percentage of these three study compare to present study most likely due to additional male sex in the studies might affect the perception of cardiovascular risk.

For studies using the PRHDS questionnaires, most of the studies presented their result as mean total score. For this study, mean total score was  $39.9 \pm 5.51$  whereas other studies have mean total score between  $43 \pm 7.46$  to  $54.5 \pm 6.61$ . (83-86)This different in mean between this study compare to other studies could be due to reduce numbers of questionnaire used in this study. This study just using 16 questionnaire out of 20 which resulted in maximum score of 64 if compared to other studies which might get maximum score of 80 for 20 questionnaires. If this mean score is translated to percentage, the result would be similar with other studies as the percentage for mean total score for this study

would be 62.3% whereas percentage for mean score in other studies would range between 53.8% to 68.1%.

### 6.2 PROPORTION OF PARTICIPANTS WHO WERE IN LOW, MODERATE AND HIGH ACTUAL CARDIOVASCULAR RISK GROUPS.

This study found that near half of the participants, 49.1% were in high actual cardiovascular risk with the lowest proportion were in moderate actual cardiovascular risk which were 16.6% of total participants. The rest 34.3% were in low actual cardiovascular risk group.

There were multiple local and international studies which assessed the actual cardiovascular risk amongst women. There were variable result produced among these studies as well as when compared to current study. Trend of distribution of the group according to actual cardiovascular risk group in this study was found most similar with an Australian study by Fiona Turnbull et al which noted that the largest proportion of the women participants were in high actual cardiovascular risk group (54%), followed by low risk (36%) and moderate actual cardiovascular risk(10%).(87) Study by Fiona Turnbull et al was an Australia nationally represented survey involving 5000 participants with 2968 women participants. If compare to other local study, finding of present study was most similar to study by Chia et al in 2015 which had found that the largest proportion of the women participants with high cardiovascular risk which covering for 41.9%. (58)

Most proportion of participant in all these three studies (present study, Fiona Turnbull et al and Chia et al) were classified in high actual cardiovascular risk
group. The reason behind this similarity can be due to similar site of study which took place at primary care setting which took all the participants with medical illness without establish cardiovascular diseases. Other than that, the mean age of the participants involved in these 3 studies are in elderly range (56.5, 57.4 and 68 years old).(58, 87) So, higher proportion of the participants in high actual cardiovascular risk group in all these 3 studies can be due to above reasons; as it is well known that the associated medical illness and increasing age would increase the likelihood of the person to be categorize into a higher cardiovascular risk according to Framingham risk score. (54)

When comparing to other local or international study amongst women which used FRS 2008, other studies by selvarajah et al. (59) Su Tin Tin et al. (88) and Laura flink et al(89) had shown a totally different and reverse trend of distribution of women in each risk group. These 3 studies have found most of the participants were in low actual cardiovascular risk (53.7% - 67%), followed by moderate (21% - 36.9%) and high actual cardiovascular risk group of participants (11.2% -12%).(59, 88, 89) The reason behind these significant different might be due to younger age group of participants involve in study by selvarajah et al (mean age of women participant 50 years old) and Laura et al (mean age 45 years old). In study by Su Tin Tin et al, 22% of the participants were age less than 40 years old. Other than that, study by selvarajah et al and Su Tin Tin were took place at community level which using national community survey and community study respectively which may include healthy women with no underlying medical illness. This younger age criteria as well as lesser associated medical illness would contributed to larger proportion of women in lower actual cardiovascular risk group. (54)

Other local and international studies were found different trend; half of the women participant were in moderate cardiovascular risk. The epidemiology survey by chin et al in 1993 in Selangor state involving resident age 55 years old and older had found 51.4% of the women participants were in moderate cardiovascular risk. Meanwhile, BEFRI study in among Germany women also found about similar finding 55.1% in moderate risk of cardiovascular disease.

# 6.3 PROPORTION OF PARTICIPANTS WHO ACCURATELY AND INACCURATELY PERCEIVED THEIR CARDIOVASCULAR RISK

This study found that only 18.1% of the participants accurately perceived their cardiovascular risk and the rest 81.9% were inaccurately perceive their cardiovascular risk. Participants with incorrect perception on cardiovascular risk can be further classified into underestimation of risk which account near half of the study sample, 48.7% whereas the rest 33.2% overestimated their risk. If compare to other studies, the percentage of the participants who inaccurately perceived their cardiovascular risk was higher in this study. Most of the studies assessing the cardiovascular risk perception among women had found that the percentage of incorrect perception regarding cardiovascular risk was around 51-60%. (72-74, 76, 90)

The highest percentage of inaccurately perceived cardiovascular risk which was the closest findings to this study was 60% which was done by Karen DeSolva et al (90) took place at an urban clinic in New Orleans in 2005. The participants involve in DeSolva's study was 128 black women with mean age 56 years old. Single question used to ask the participants to decide their cardiovascular risk perception either low, moderate, high or very high which would then further collapse into categories of low or high perceived risk perception. Actual cardiovascular risk was using simple counting of the risk factors; participants with 3 or more risk factors were defined as high risk while the rest was considered low actual cardiovascular risk. De Solve found that, the inaccurately perceived cardiovascular risk group of participants were contributed 55% by those who underestimate their risk and the rest 5% overestimate their risk. (90)

However, if comparing this study with the BEFRI study (74) which used FRS 2008 to calculate the actual cardiovascular risk, the result for those who underestimate their cardiovascular risk was similar. The BEFRI study found that 48.6% of participants underestimate their cardiovascular risk whereas this study also showed almost similar finding of 48.7%. (74)

In term of similarities between this study with other studies on accuracy of cardiovascular perception among women, it was noted that the participants who underestimate their cardiovascular risk was predominant in inaccurately perceived cardiovascular risk group.(74, 76, 90) In this study, 48.7% of the participants were underestimate their cardiovascular risk if compare to 33.2% who overestimate their cardiovascular risk. Other studies found the proportion of participants who underestimate their risk range from 29% and up to 55% of the total women participants. Meanwhile, those who overestimated their cardiovascular risk apparently lower with range as low as 5% till 26% of the participants involve. (73, 76)

When looked at other studies which include both sexes with about similar age group, the result shown was mixed up. Study by Katz et al and Van der weijden showed that those who accurately perceived their cardiovascular risk were more

dominant with 57.6% and more than 70% respectively. However, study by Frijling et al and Hussein et al showed vice versa, those who inaccurately perceived their cardiovascular risk had the largest proportion of the participants with 98.5% in Frijling et al study and 66% in Hussein et al study.

The difference result between this study and other studies could be due to different method used to assess personal perception and actual cardiovascular risk. Besides, different socio-demographic, settings and medical risk factors might also contributed.

# 6.4 ASSOCIATED FACTORS FOR UNDERESTIMATION OF CARDIOVASCULAR RISK

Analysis for underestimation group of participants in this study found that underestimation of cardiovascular risk was significantly associated with being diabetic patients, being older and those who have higher systolic blood pressure.

### Diabetes mellitus

This study revealed that diabetic participants had 447.53 times higher odds compared to non-diabetic to underestimate their cardiovascular risk after adjusted to age and systolic blood pressure.

The association between underestimation of cardiovascular risk with diabetic which had been found in this study actually had been identified in few other earlier studies. Multiples cross sectional and qualitative studies amongst diabetic patients had shown that most of the diabetic patients were unaware and did not relate the diabetes that they had with increase cardiovascular risk.(76, 91-93).

These studies took place in United State of America, (91, 92) United Kingdom (76) and also in Asia (Iran)(93). Besides, a cross sectional study by Diaz et al in South Carolina amongst adult age more than 18 years old also had found that the underestimation of cardiovascular risk was associated with diabetes mellitus (OR 16.45). The other associated factors for underestimation of cardiovascular disease found in Diaz et al study were male sex, hypertensive patients, dylipidaemia patients, those with lesser years of education and those with family history of heart attack. (94)

## Elderly age

Those with 1 year increased in age was found to have 88% higher odds to underestimate their cardiovascular risk after adjusted other factors.

This finding was consistent with numbers of the studies including study by Oerteld Prigione et al(74) in Berlin, Germany, study by Hussein et al(26) in New Jersey and Kreuter et al (28) in North Carolina. Oerteld Prigione et al found that those age more than 50 years old were 3.5 times odds to underestimate their cardiovascular risk, wheares Hussein et all found age more than 45 years old associated with underestimation with od ratio 12.44. Meanwhile, study by Kreuter found association with older age group with OR of 1.06.

This findings could be explained by the reluctant of the women in this study to commit themselves to be in higher cardiovascular risk group due to cultural taboo as describes earlier. (80) Other that than, there would be also possibilities of the women to demonstrate the minimization effect as one of the denial or defence mechanism to comfort themselves like study done by Croyle et al. (95) Beside,

there was a study by Wilcox et al among 200 middle and elderly women in San Francisco to assess the knowledge and perception of the women regarding major diseases including heart disease. The study found that the older women had tendency to underestimated the fatal complication of heart disease as well as not perceived themselves to be in higher risk for heart disease.(96)

There were other associated factors which were not found significant in BEFRI, Hussein et al and Kreuter et al study. In BEFRI study by Oerteld Prigione et al, beside age > 50 years old factor, underestimation of cardiovascular risk was found related to, being jobless, those with 3 or more social risk factors and among those who give positive marking for personal subjective health rating.(74) For Hussein et al study, beside older age group, other associated factors for underestimation were those with higher serum cholesterol level, non-African American race and alcohol drinker.(26) Other than that, male sex and those with higher educational level were other associated factors found by Kreuter et al. (28) The different finding between this study and other 3 studies could be due to different socio-demographic of the participants involved.

## Higher systolic blood pressure

Another factor found to be associated with underestimation in this study was higher systolic blood pressure. Multiple logistic regression in this study found that the participants with 1 mmHg increment in systolic blood pressure had 96% higher odd to underestimated their cardiovascular risk. When comparing this finding with other studies, the results was quite controversial. Most of the study did not mentioned directly regarding the patients' perception in relation to systolic blood pressure, but more on the high blood pressure effect in general.

A series of focus group discussions amongst a low income community in South Africa had found that most of the participants did not perceive the high blood pressure as one of the cardiovascular risk.(70)The study, which was conducted by Surka et al postulated that the absence of external symptoms might be contribute to the underestimation in their judgement.

It was also found in another study that, even women with establish coronary heart disease failed to identify high blood pressure (hypertension) can lead to CHD. For example, there was a study by Murphy et all to assess perception on general and causative factors related to personal coronary heart disease among female cardiac patients who were admitted after an acute myocardial infarction or for coronary artery bypass grafting surgery (CABG). Murphy et al found that only 5% participants with hypertension thought of the that high blood pressure(hypertension) were the cause of their coronary heart disease (97). In this study, reason for underestimation among those with higher blood pressure could be due to similar reason given in other studies; participants had lack of knowledge regarding the disease. On the top of that, there might be unaware of the risk due to asymptomatic nature of high blood pressure.

However, contradict findings were showed by few other studies. Prendergast HM et al found in his study that more than half of the participants (56%) were identified hypertension as one of the cardiovascular risk factors. (98) Meanwhile, Surka et al also noted that participants with underlying cardiovascular risk illness including hypertension had 1.86 times odds to be able to recognize that hypertension was associated with increase cardiovascular risk. (99) Besides, qualitative study by Green et al in New England also showed that most of the participants thought

that high blood pressure are more serious problem compare to high cholesterol. They have been recognized the complication of high blood pressure for quite sometimes and viewed that the high blood pressure have direct effect to cardiac event. (100)

# 6.5 ASSOCIATED FACTORS FOR OVERESTIMATION OF CARDIOVASCULAR RISK

Overestimation of cardiovascular risk in this study was noted to be associated with those who have higher HDL level, whereas those with increasing age, hypertension and having higher systolic blood pressure were less likely to overestimate their cardiovascular risk.

## Higher HDL level

This study discovered that those with 1 mmol/L increase in HDL level had 4.35 higher odds to overestimate their cardiovascular risk after adjusted to age, hypertension and systolic blood pressure.

Overestimation of cardiovascular risk amongst those with higher HDL level in this study could be attributable by the mismatch between the participants' perception on the risk of high total cholesterol with the actual way Framingham risk score calculation being done. The participants might thought that the total cholesterol was important and had lack of understanding regarding the difference effect of each subgroup of cholesterol as well as misconception regarding HDL; Participants' thought that higher total cholesterol level (despite any level of HDL) would increase the cardiovascular risk, but in fact, Framingham risk calculation give lower score for higher HDL level. Even those with higher educational level

might had this misconception. This was supported by a study by Green et al which was done among college men and women in 2003. Green found that 22% of the participants did not understand that high level of HDL was good and give inverse impact toward heart disease risk. (101)

### Younger age

Other than that, this study also found that those with 1 year increasing in age would be 14% less probability to overestimate her cardiovascular risk. This finding most likely due to elderly women in this study have higher odds to underestimate their cardiovascular risk due to various reasons as explained earlier. Similar findings were seen in study by Oerteld et al and Kreuter et al. Besides the age factors, Oerteld also found that overestimation was associated with negative subjective personal health rating and depression and less probability among those with low income and working in simple/ middle level of job. Meanwhile, Kreuter et al also found that being male sex was another associated factor related to overestimation.

## Higher blood pressure and hypertension (reverse relation)

This study also found that those with higher blood pressure as well as hypertensive patients were less likely to overestimate their cardiovascular risk. The reason for this findings are because in this study, the participants with hypertension as well as higher blood pressure were more likely to underestimate their cardiovascular risk. The further explanation for this finding are as described earlier.

# **CHAPTER 7**

## CONCLUSION

More than 3 quarter or the participants (87.5%) perceived their cardiovascular risk in moderate cardiovascular risk group. In actual cardiovascular risk assessment, half of the participants were in high actual cardiovascular risk (49.1%) and least of participants were in moderate actual cardiovascular risk (16.6%). Very significant numbers of participants were inaccurately perceived their cardiovascular risk (81.9%), with approaching half of them were actually underestimate their risk(48.7%). It was found that underestimation of cardiovascular risk was associated with diabetic, hypertensive and those with higher systolic blood pressure. Overestimation noted to be associated with those with higher HDL level and elderly age whereas those with hypertension and higher systolic blood pressure were noted to be less likely to overestimate their cardiovascular risk.

# **CHAPTER 8**

## LIMITATIONS

- This study only involves peri and post-menopausal women who attended Primary care clinic of a university hospital. Hence, the results are probably not representing the whole characteristics of this group of women who attend primary care clinic in the state.
- 2. Assessment of perceived cardiovascular risk was relied on how the participants answer the PRHDS questionnaires. As the PRHDS was quite newly developed questionnaires, there were limited studies on perception of cardiovascular risk in women using PRHDS. Therefore, we are unable to have a better comparison for our findings.
- 3. It was noted during conducting this study that, assessing the personal perception of cardiovascular risk in this population were a quite difficult construct as many of the participants involved in this study appeared to be bounded by the cultural taboo about the "tempt fate" which avoid themselves to perceived self in higher cardiovascular risk group.
- 4. This study was only assessed the accuracy of participants perceptions on cardiovascular risk and its related associated factors, but did not studied the subsequent behavioural effect related to their perception.

# **CHAPTER 9**

# RECOMMENDATIONS

- More researches should be encouraged to find a better way in assessing personal perception of cardiovascular risk in this cultural bound population. More cultural friendly questionnaires should be developed to overcome this issue.
- 2. It is very important for the women to accurately perceive their cardiovascular risk. Accurately perceived cardiovascular risk may encourage them to practice healthy therapeutic lifestyle changes as well as improve their controlled of the underlying medical illness if present.
- Besides treating the underlying medical illness, practicing physicians should educate their patients regarding their cardiovascular risk during counselling to improve the patients' perception regarding their cardiovascular risk.
- 4. There is a pressing need to adequately address the issues surrounding cardiovascular risk, both during the community awareness programme and during personal consultation for medical follow up.

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# **APPENDIX**

## **APPENDIX A : CASE REPORT FORM**

SERIAL NUMBER

## KAJIAN KETEPATAN PERSEPSI PERIBADI TERHADAP RISIKO PENYAKIT KARDIOVASKULAR DI KALANGAN WANITA HAMPIR MENOPAUS DAN TELAH MENOPAUS DI KLINIK RAWATAN KELUARGA, HUSM

ARAHAN: SILA TANDAKAN ( $\sqrt{}$ ) PADA JAWAPAN YANG BERKENAAN. KERJASAMA ANDA AMATLAH DIHARGAI DAN DIDAHULUI DENGAN JUTAAN TERIMA KASIH.

### Bahagian 1: Latarbelakang

1.	Umur: tahun	
2.	Bangsa: 🗌 Melayu 🗌 Cina 🗌 India 🗌 Siam 🗌 Lain-lain,	Nyatakan
3.	Status perkahwinan: 🗌 Bujang 📄 Berkahwin 🗌 Janda	/Duda
4.	Tahap pendidikan: Sekolah rendah Sekolah Menengah	STPM
	Diploma Jjazah Sarjana	PhD
5.	Pekerjaan: Sektor kerajaan Sektor swasta Sendiri	Surirumah
6.	Pendapatan peribadi :RM sebulan	
7.	Pendapatan isirumah :RM sebulan	
8.	Sudahkah anda mengalami putus haid? 🗌 Ya 📄 Tidak	
9.	Bilakah tarikh haid terakhir anda?, nyatakan (bulan)/	(tahun)

### Bahagian 2: Soalselidik untuk mengesan risiko

1. Sila tandakan ( $\sqrt{}$ ) dalam kotak yang sesuai bagi setiap pernyataan.

	Penyataan	Ya	Tidak
a.	Saya mengambil pil perancang		
b.	Saya telah putus haid sebelum umur 40 tahun		
C.	Saya mengidap penyakit kencing manis (diabetes mellitus)		
d.	Saya mengidap penyakit darah tinggi		
e.	Saya sedang menerima rawatan untuk penyakit darah tinggi		
f.	Saya mengidap penyakit hyperlipidaemia (tahap kolesterol tinggi dalam		
	darah)		
g.	Saya merokok		

2. Sila tandakan ( $\sqrt{}$ ) pada penyakit yang terdapat dalam adik-beradik atau ibubapa anda

	Penyakit	Ada	Tiada
a.	Kencing manis		
b.	Tekanan darah tinggi (Hipertensi)		
С.	Sakit jantung koronari/saluran jantung tersumbat		
d.	Angin ahmar/strok		
e.	Kematian mengejut		

	(semasa umur kurang daripada 55 tahun untuk lelaki dan umur kurang daripada 65 tahun untuk perempuan)	
f.	Penyakit hyperlipidaemia (Tahap kolesterol yang tinggi dalam darah )	

# Bahagian 3 : Tanggapan untuk diri sendiri mendapat masalah kardiovaskular

# <u>Skala Persepsi Risiko Mendapat Penyakit Jantung</u> <u>(The Perception of Risk of Heart Disease Scale , PRHDS)</u>

	Sangat tidak setuju (1)	Tidak setuju (2)	Setuju (3)	Sangat setuju (4)
1. Ada kemungkinan yang saya mengidap penyakit jantung sekarang				
2. Saya berkemungkinan akan mengidap penyakit jantung dalam masa 10 tahun akan datang				
4. Saya berkemungkinan tinggi mendapat penyakit jantung disebabkan sikap saya yang lepas				
5. Saya pasti yang saya akan mendapat penyakit jantung kelak				
7. Besar kemungkinan yang saya akan mengidap penyakit jantung				
8. Saya berisiko untuk mendapat penyakit jantung				
9. Ada kemungkinan yang saya akan mengidap penyakit jantung				
10. Buat masa ini saya tidak membuat apa- apa perkara yang tidak sihat untuk jantung saya				
11. Saya masih muda untuk mendapat penyakit jantung				
12. Orang seperti saya tidak akan mendapat penyakit jantung				
13. Saya sangat sihat oleh itu badan saya dapat melawan penyakit jantung				
14. Saya tidak risau yang saya berkemungkinan mendapat penyakit jantung				

	Sangat tidak setuju (1)	Tidak setuju (2)	Setuju (3)	Sangat setuju (4)
15. Individu pada peringkat umur saya adalah terlalu muda untuk mendapat penyakit jantung				
16. Individu pada peringkat umur saya tidak mendapat penyakit jantung				
17. Tabiat gaya hidup saya tidak meletakkan saya pada keadaan berisiko mendapat penyakit jantung				
18. Sekiranya saya telah ditakdirkan mengidap penyakit jantung, saya akan tetap mendapat penyakit itu walau apa pun yang saya lakukan				

### TERIMA KASIH DI ATAS KERJASAMA ANDA

# APPENDIX B : CONSENT FROM ORIGINAL AUTHOR OF PRHDS QUESTIONNAIRES

Ali Ammouri

Mon 11/3/2014 1:44 PM

To:ireny zarina <inaireny@hotmail.com>;

1 attachment (30 KB)

Final Instrument.doc;

Dear Ireny,

Attached is the questionnaire with scoring. I give the permision to use and translate it. Regarding the cut point I leave it to you based on the population you assess. If it is a regular population you can join agree and strongly agree option togather (3 &4) and clculate the percentages. I suggest the 60% as the cut off point. Thank you Ali Ammouri

On Sun, Nov 2, 2014 at 12:19 PM, ireny zarina <<u>inaireny@hotmail.com</u>> wrote: hi...

i'm zarina from malaysia... i'm a third year master of medicine student (family medicine) in Malaysia Science University..

Actually, i planned to do reseach on " patient perception on cardiovascular risk and practice towards cardiovascular screening". The research is part of the requirement for my master degree.

I've came across the the perception of heart disease scale which you developed in 2008.. I'm really interested with this set of questionnaire, however there is limited information regarding this questionnaire on internet... Actually, i would like to request your permission to used your questionnaire in my study and i will mentioned you and your colleague name as the owner and developer for this questionnaire... i would like to translate your PRHDS questionnaire to Malay language for my study.

I'm also would like to ask regarding how we can actually calculate the risk base on the questionnaire, including the cut point for dread risk, risk and unknown risk.

I'm really looking forward to hear good news from you. Your cooperation and helps are very much appreciated.. thank you...

# **APPENDIX C : ORIGINAL QUESTIONNAIRES FROM AUTHOR**

# PERCEPTION OF RISK OF HEART DISEAS SCALE (PRHDS)

# Scoring Instruction

Item are scored as	Strongly disagree	=	1
	Disagree	=	2
	Agree	=	3
	Strongly agree	=	4

To score the instrument, item scores are summed for each subscale, as well across subscales for a total scale score. Higher scores on PRHDS subscales indicate a higher perception of risk of getting heart disease. The Items included on each scale are as follows:

Dread Risk	1, 2, 4, 5, 7, 8, 9
Risk	3, 11, 12, 14, 15, 16
Unknown Risk	6, 10, 13, 17, 18, 19, 20

Note: Reverse scoring of the following items is required (item 6, 10, 11, 12, 13, 14,

15, 16, 17, 18, 19, 20)

	Strongly			Strongly
	disagree	disagree	agree	agree
1. There is a possibility that I have heart disease	1	2	3	4
2. There is a good chance I will get heart disease during the next 10 years	1	2	3	4
3. A person who gets heart disease has no chance of being cured	1	2	3	4
4. I have a high chance of getting heart disease because of my past behaviors	1	2	3	4
5. I feel sure that I will get heart disease	1	2	3	4
6. Healthy lifestyle habits is something unattainable*	1	2	3	4
7. It is likely that I will get heart disease	1	2	3	4
8. I am at risk for getting heart disease	1	2	3	4
9. It is possible that I will get heart disease	1	2	3	4
10. I am not doing anything now that is unhealthy to my heart*	1	2	3	4
11. I am too young to have a heart disease*	1	2	3	4
12. People like me do not get heart disease*	1	2	3	4
13. I am very healthy so my body can fight off heart disease <sup>*</sup>	1	2	3	4
14. I am not worried that I might get heart disease*	1	2	3	4
15. People my age are too young to get heart disease*	1	2	3	4
16. People my age do not get heart disease*	1	2	3	4
17. My lifestyle habits do not put me at risk for heart disease*	1	2	3	4
18. No matter what I do, if I am going to get heart disease, I will get it*	1	2	3	4
19. People who don't get heart disease, are just plain lucky*	1	2	3	4
20. Heart disease has unknown cause"	1	2	3	4

Note: \*Reverse scoring of the item is required.

Total scoring :

- 20 39 = unknown risk
- 40 59 = risk
- 60 80 = dread risk

# APPENDIX D : ETHICAL APPROVAL LETTER



Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

17<sup>th</sup> September 2014

Assoc. Prof. Dr. Juwita Shaaban Department of Family Medicine School of Medical Sciences Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan. Universiti Sains Malaysia Kampus Kesihatan, 16150 Kubang Kerian, Kelantan. Malaysia. T: 609 - 767 3000 samb. 2354/2362 F: 609 - 767 2351 E: jepem@usm.my www.jepem.kk.usm.my

### JEPeM Code : USM/JEPeM/140392

Protocol Title : Study on Perception of Cardiovascular Risk and Behaviour toward Cardiovascular Screening among Perimenopausal Women in Kelantan.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/140392**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid until **August 2015**.

The following documents have been approved for use in the study.

1. Summary of Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

- 1. Participant Information Sheet and Consent Form (English version)
- 2. Participant Information Sheet and Consent Form (Malay version)
- 3. Questionnaires

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

- 1. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using JEPeM-USM FORM 3(A) 2014: Study Protocol Amendment Submission Form.
- 2. Reports of adverse events (if any) including from other study sites (national, international) using the JEPeM-USM FORM 3(G) 2014: Adverse Events Report.
- 3. Notice of early termination of the study and reasons for such using JEPeM-USM FORM 3(E) 2014.
- 4. Any event which may have ethical significance.
- 5. Any information which is needed by the JEPeM-USM to do ongoing review.
- 6. Notice of time of completion of the study using JEPeM-USM FORM 3(C) 2014: Final Report Form.
- 7. Application for renewal of ethical clearance 90 days before the expiration date of this approval through submission of JEPeM-USM FORM 3(B) 2014: Continuing Review Application Form.

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with International Conference on Harmonization–Guidelines for Good Clinical Practice (ICH-GCP) guidelines and Declaration of Helsinki.

Thank you.

### "ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

The

PROF. DR. HANS AMIN VAN ROSTENBERGHE Chairperson Jawatankuasa Etika Penyelidikan (Manusia) JEPeM Universiti Sains Malaysia

# APPENDIX E : APPROVAL OF PROPOSAL AMENDMENT



Jawatankuasa Etika Penyelidikan Manusia USM (JEP Human Research Ethics Committee USM (HREC)

12<sup>th</sup> February 2015

Assoc. Prof. Dr. Juwita Shaaban Department of Family Medicine School of Medical Sciences Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan Universiti Sains Mala Kampus Kesihatan, 16150 Kubang Kerian, Kelantan. Malaysia. T: 609 - 767 3000 samb. 25 F: 609 - 767 2351 E: jepem@usm.my www.jepem.kk.usm.my

#### JEPeM USM Code: USM/JEPeM/140392

Study Protocol Title: Study of Perception of Cardiovascular Risk and Cardiovascular Screenir among Women in Kelantan.

Dear Dr:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malays (JEPeM-USM) approved the proposed amendments in your study entitled, "Study of Perception (Cardiovascular Risk and Cardiovascular Screening among Women in Kelantar [USM/JEPeM/140392] during its meeting on 18<sup>th</sup> December 2014. Upon review, the followir amendments have been approved:

- 1. Change the study title to, "Study on Accuracy of Self Perception on Cardiovascular Ris among Women Attending Klinik Rawatan Keluarga, USM".
- 2. Change the site of the study the study would be carried out only in Hospital USM.
- 3. Changes of investigators The Principal Investigator (PI) will be Dr. Norzarina Ireny Moh Nazri and the rest would be the supervisors for the study.
- 4. Changes in questionnaire for self-perception on cardiovascular risk.

Thank you.

#### "ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

(PROF. DR. MOHD SHUKRFOTHMAN) Deputy Chairperson Jawatankuasa Etika Penyelidikan (Manusia), JEPeM

C.C Secretary

Jawatankuasa Etika Penyelidikan (Manusia) JEPe

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia

# **APPENDIX F : PATIENT INFORMATION SHEET AND INFORMED CONSENT**



JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA) - JEPeM HUMAN RESEARCH ETHICS COMMITTEE - HREC

### BORANG MAKLUMAT DAN KEIZINAN PESAKIT/ SUBJEK

#### (PROJEK PENYELIDIKAN)

Tajuk Penyelidikan : Kajian ketepatan persepsi peribadi terhadap risiko penyakit kardiovaskular dalam kalangan wanita di klinik rawatan keluarga, HUSM

#### 1. Nama penyelidik

Dr Norzarina Ireny Binti Mohd Nazri (No MMC : 47209)

### 2. Pengenalan

Anda telah dijemput untuk menyertai kajian ini kerana anda mendapat rawatan di klinik rawatan keluarga. Untuk menyertai kajian ini, anda perlu memberi maklumat sejarah kesihatan ataupun penyakit anda yang lalu. Penyertaan anda dalam kajian ini adalah secara sukarela. Jika anda tidak mahu menyertai kajian ini, tindakan anda tidak akan menjejaskan segala hak dan keistimewaan perkhidmatan perubatan dan kesihatan yang selayaknya anda terima.

Penyelidikan ini telah mendapat kelulusan Jawatankuasa Etika Penyelidikan Manusia, HUSM (JEPeM)

Penyakit kardiovaskular merupakan punca utama kematian di seluruh dunia. Walaupun tahap rawatan dan penjagaan kesihatan yang bertambah baik, risiko untuk mendapat penyakit kardiovaskular adalah tinggi untuk wanita yang berusia 50 tahun dan ke atas

Di Malaysia, kajian menunjukkan bahawa penyebab utama kematian di Hospital di bawah Kementerian Kesihatan Malaysia adalah disebabkan oleh penyakit jantung dan sistem pernafasan yang merangkumi sehingga 16.05% daripada keseluruhan kes. Ini menunjukkan peningkatan peratusan kes berbanding 14.2% pada sekitar tahun 1980-an. Selain daripada itu, didapati bahawa 1 daripada 4 kes kematian wanita malaysia adalah disebabkan oleh penyakit jantung coronari yang mana adalah 2.5 kali lebih tinggi berbanding kematian disebabkan oleh kanser.

Skor risiko kardiovaskular telah digunakan untuk mengira kemungkinan seseorang individu itu untuk mendapat penyakit kardiovaskular berdasarkan maklumat dari sejarah perubatan, pemeriksaan klinikal dan ujian makmal.

### 3. Tujuan penyelidikan

Tujuan kajian ini dilakukan adalah untuk mengetahui ketepatan persepsi(tanggapan) wanita yang hampir menopaus dan telah menopaus mengenai risikonya mengidap penyakit kardiovascular. Ianya di

jalankan di kalangan wanita yang hadir ke klinik rawatan keluarga HUSM.

Objektif kajian ini adalah:

- 1. Untuk mengetahui persepsi peribadi responden terhadap risikonya mendapat penyakit kardiovaskular.
- 2. Untuk mengukur risiko sebenar responden untuk mendapat penyakit kardiovaskular berdasarkan skor risiko kardiovascular Framingham
- Untuk membanding ketepatan penilaian risiko mendapat penyakit kardiovaskular yang dibuat oleh responden dengan skor risiko kardiovaskular Framingham.
- Untuk mengenalpasti faktor-faktor sosio-demografik dan taraf kesihatan yang mempengaruhi responden yang dapat menilai dengan tepat mengenai risikonya mendapat penyakit kardiovaskular.

### 4. Kelayakan penyertaan

Doktor yang bertanggungjawab dalam kajian ini telah membincangkan dengan anda mengenai kelayakan untuk menyertai kajian ini. Adalah penting anda berterus terang dengan doktor tersebut tentang pendapat diri anda. Anda tidak seharusnya menyertai kajian ini sekiranya anda tidak memenuhi semua syarat kelayakan. Beberapa keperluan untuk menyertai kajian ini adalah :

Kelayakan penyertaan

1. Wanita

2. Berumur 48 tahun dan ke atas

Anda tidak boleh menyertai kajian ini sekiranya

- 1. Mengidap penyakit psikiatrik / mental
- 2. Kurang upaya fizikal pekak, bisu atau buta
- 3. Telah disahkan mengidap penyakit jantung atau angin ahmar

4. Tidak pasti mengenai status penyakit kencing manis atau sedang dalam penyiasatan untuk di diagnos sebagai pesakit kencing manis

### 5. Prosedur-prosedur kajian

Selepas anda memberi persetujuan bertulis untuk menjalani kajian ini, anda akan diminta untuk mengisi borang soal-selidik mengenai data peribadi/ latar belakang kesihatan dan borang soal-selidik mengenai tanggapan risiko penyakit kardiovaskular dan saringan penyakit kardiovaskular. Jika anda mempunyai sebarang kemusykilan atau tidak memahami mana-mana bahagian di dalam soal selidik tersebut, anda boleh merujuk masalah tersebut kepada penyelidik yang akan sentiasa berada di situ bagi membantu anda. Kemudian, pemeriksaan fizikal akan dijalankan di mana berat badan, tinggi dan saiz ukur lilit pinggang anda akan diukur. Selepas itu, pengambilan dan pemeriksaan darah akan dilakukan bagi menentukan paras gula dan lemak di dalam badan anda. Prosedur pengambilan darah ini melibatkan cucukan pada bahagian sebelah dalam lipatan lengan anda (kawasan "antecubital fossa") samaada kanan atau kiri dan sebanyak 4 mililiter darah vena anda akan diambil untuk pemeriksaan. Ini adalah bagi

membolehkan risiko kardiovascular sebenar ditentukan berdasarkan skor kardiovaskular Framingham. Anda dikehendaki berpuasa sekurang-kurangnya 8 jam bagi tujuan pemeriksaan darah tersebut. Sekiranya anda tidak berpuasa pada hari tersebut, temujanji lain akan diberi untuk prosedur pengambilan darah.

### 6. Risiko

Kajian ini hanya melibatkan risiko yang minimal yang berkaitan dengan prosedur pengambilan darah. Anda mungkin merasa sakit sedikit ketika prosedur pengambilan darah di laksanakan. Tempat pengambilan darah tersebut mungkin akan lebam atau mengalami pendarahan selepas cucukan tersebut. Sepanjang kajian ini, jika anda didapati mempunyai faktor risiko kardiovaskular, nasihat dan rawatan yang berkaitan akan diuruskan. Sekiranya anda mempunyai sebarang kemuskilan disebabkan kajian ini, anda berhak menghubungi penyelidik untuk penjelasan

### 7. Faedah

Kajian ini mungkin akan mendatangkan manfaat ataupun langsung tiada memberi apa- apa manfaat kepada anda. Anda mungking dapat mengetahui mengenai tahap kesihatan anda berdasarkan pemeriksaan fizikal dan keputusan pemeriksaan makmal yang dijalankan semasa kajian ini. Segala maklumat yang diperolehi daripada penyelidikan ini akan dapat membantu dalam penambahbaikan kaedah pengurusan risiko kardiovaskular pesakit lain.

Sedikit saguhati akan diberikan sebagai tanda menghargai masa yang diluangkan dalam menjayakan kajian ini.

### 8. Penyertaan dalam kajian

Penyertaan anda dalam kajian ini adalah sukarela. Anda boleh menolak untuk menyertai kajian ini atau anda boleh menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang hukuman atau kehilangan manfaat yang sepatutnya anda perolehi.

Penyertaan anda juga mungkin boleh diberhentikan oleh doktor yang terlibat dalam kajian ini tanpa persetujuan anda. Sekiranya anda berhenti menyertai kajin ini, doktor yang terlibat di dalam kajian ini atau salah seorang kakitangan akan berbincang dengan anda mengenai apa-apa isu perubatan berkenaan dengan pemberhentian penyertaan anda.

### 9. Soalan

Sekiranya anda mempunyai sebarang soalan mengenai kajian ini atau hak-hak anda, sila hubungi

Dr Norzarina Ireny Binti Mohd Nazri, Jabatan Perubatan Keluarga, USM Kampus kesihatan, 16150 Kubang Kerian, Kelantan. Tel : 09-7676608/ 09-7673497 (KRK) Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan Etika atau sebarang pertanyaan dan masalah berkaitan kajian ini, sila hubungi;

En. Mohd Bazlan Hafidz Mukrim Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM Pusat Inisiatif Penyelidikan -Sains Klinikal & Kesihatan USM Kampus Kesihatan. No. Tel: 09-767 2354 / 09-767 2362 Email : bazlan@usm.my/Jepem@kk.usm.my

## 10. Kerahsiaan

Maklumat perubatan anda akan dirahsiakan oleh doktor dan kakitangan kajian. lanya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian yang tidak mengenalpasti anda secara perseorangan mungkin akan diterbitkan untuk tujuan memberi pengetahuan baru.

Rekod perubatan anda yang asal mungkin akan dilihat oleh pihak penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori untuk tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat perubatan anda mungkin akan disimpan dalam komputer dan diproses dengannya.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemindahan data seperti yang dihuraikan di atas.

### 11. Tandatangan

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan (Lihat contoh Borang Keizinan Pesakit di LAMPIRAN S <u>atau</u> LAMPIRAN G (untuk sampel genetik) <u>atau</u> LAMPIRAN P).

Tarikh (dd/MM/yy)

Borang Keizinan Pesakit/ Subjek (Halaman Tandatangan)

*Tajuk Kajian:* Kajian ketepatan persepsi peribadi terhadap risiko penyakit kardiovaskular dalam kalangan wanita di klinik rawatan keluarga, HUSM

Nama Penyelidik:

Dr Norzarina Ireny Binti Mohd Nazri (No MMC : 47209)

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Pesakit untuk simpanan peribadi saya.

 Nama Pesakit (Dicetak atau Ditaip)
 Nama Singkatan & No. Pesakit

 No. Kad Pengenalan Pesakit (Baru)
 No. K/P (Lama)

 Tandatangan Pesakit atau Wakil Sah
 Tarikh (dd/MM/yy) (Masa jika perlu)

 Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan (Dicetak atau Ditaip)
 Tarikh (dd/MM/yy)

Nama Saksi dan Tandatangan

Nota: i) Semua subjek/pesakit yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

# Borang Keizinan Pesakit/ Subjek untuk *Sampel darah* (Halaman Tandatangan)

*Tajuk Kajian:* Kajian ketepatan persepsi peribadi terhadap risiko penyakit kardiovaskula dalam kalangan wanita di klinik rawatan keluarga, HUSM

Nama Penyelidik:

Dr Norzarina Ireny Binti Mohd Nazri (No MMC : 47209)

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Pesakit untuk simpanan peribadi saya.

Nama Pesakit (Dicetak atau Ditaip)	Nama Singkatan & No. Pesakit
No. Kad Pengenalan Pesakit (Baru)	No. K/P (Lama)
 Tandatangan Pesakit atau Wakil Sah	Tarikh (dd/MM/yy) Masa (jika perlu)
	Tarikh (dd/MM/yy)

Nama Saksi dan Tandatangan

Tarikh (dd/MM/yy)

<u>Nota:</u> i) Lebihan sampel kajian ini akan dilupuskan dan tidak akan digunakan untuk tujuan lain kecuali setelah mendapat kebenaran daripada Jawatankuasa Etika Penyelidikan (Manusia), USM.

ii) Semua subjek/pesakit yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.
## Borang Keizinan bagi Penerbitan Bahan yang berkaitan dengan Pesakit/ Subjek (Halaman Tandatangan)

*Tajuk Kajian:* Kajian ketepatan persepsi peribadi terhadap risiko penyakit kardiovaskular dalam kalangan wanita di klinik rawatan keluarga, HUSM

Nama Penyelidik:

Dr Norzarina Ireny Binti Mohd Nazri (No MMC : 47209)

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini.

Dengan menandatangani mukasurat ini, saya memahami yang berikut:

- Bahan yang akan diterbitkan tanpa dilampirkan dengan nama saya dan setiap percubaan yang akan dibuat untuk memastikan ketanpanamaan saya. Saya memahami, walaubagaimanapun, ketanpanamaan yang sempurna tidak dapat dijamin. Kemungkinan sesiapa yang menjaga saya di hospital atau saudara dapat mengenali saya.
- Bahan yang akan diterbitkan dalam penerbitan mingguan/bulanan/dwibulanan/suku tahunan/dwi tahunan merupakan satu penyebaran yang luas dan tersebar ke seluruh dunia. Kebanyakan penerbitan ini akan tersebar kepada doktor-doktor dan juga bukan doktor termasuk ahli sains dan ahli jurnal.
- Bahan tersebut juga akan dilampirkan pada laman web jurnal di seluruh dunia. Sesetengah laman web ini bebas dikunjungi oleh semua orang.
- Bahan tersebut juga akan digunakan sebagai penerbitan tempatan dan disampaikan oleh ramai doktor dan ahli sains di seluruh dunia.
- Bahan tersebut juga akan digunakan sebagai penerbitan buku oleh penerbit jurnal.
- Bahan tersebut tidak akan digunakan untuk pengiklanan ataupun bahan untuk membungkus.

Saya juga memberi keizinan bahawa bahan tersebut boleh digunakan sebagai penerbitan lain yang diminta oleh penerbit dengan kriteria berikut:

- Bahan tersebut tidak akan digunakan untuk pengiklanan atau bahan untuk membungkus.
- Bahan tersebut tidak akan digunakan di luar konteks contohnya: Gambar tidak akan digunakan untuk menggambarkan sesuatu artikel yang tidak berkaitan dengan subjek dalam foto tersebut.

Nama Pesakit (Dicetak atau Ditaip)

No. Kad Pengenalan Pesakit

T/tangan Pesakit

Tarikh (dd/MM/yy)

Tarikh (dd/MM/yy)

Nama Singkatan atau No. Pesakit

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan (Dicetak atau Ditaip)

<u>Nota:</u> i) Semua subjek/pesakit yang mengambil bahagian dalam projek penyelidikan ini <u>tidak dilindungi insuran</u>.

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