CLINICAL, ECONOMIC AND HUMANISTIC EVALUATION OF A WORKSITE HEALTH PROMOTION PROGRAM CONDUCTED AMONG EMPLOYEES OF A PUBLIC UNIVERSITY IN MALAYSIA

by

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LIST OF ABBREVIATIONS

ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
BMI	Body mass index
BP	Blood pressure
BP*	Bodily pain
CEA	Cost-effectiveness analysis
CER	Cost-effectiveness ratio
CHD	Coronary heart disease
CPG	Clinical practice guideline
CUA	Cost-utility analysis
CV	Cardiovascular
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
EAC	Equivalent annual cost
FBS	Fasting blood glucose
FLP	Full lipid profile
FRS	Framingham risk score
FRS-CVD	10-year Framingham-cardiovascular disease risk
FRS-CHD-LDL	10-year Framingham coronary heart disease risk based on low-density lipoprotein cholesterol points
FRS-CHD-cholesterol	10-year Framingham coronary heart disease risk based on cholesterol points
GH	General health
HDL-C	High-density lipoprotein cholesterol

HRQoL	Health-related quality of life
ICER	Incremental cost effectiveness ratio
LDL-C	Low-density lipoprotein cholesterol
LYG	Life-years gained
MANOVA	Multivariate analysis of variance
MCS	Mental component score
MH	Mental health
MoH	Ministry of Health
NCEP-ATP III	National Cholesterol Education Program-Adult Treatment Panel III
OR	Odds ratio
PCS	Physical component score
PF	Physical-functioning
QALY	Quality-adjusted life years
QoL	Quality of life
RE	Role limitation due to emotion problem
RF	Risk factor
RP	Role limitation due to physical problem
SBP	Systolic blood pressure
SF	Social-functioning
SF-12	Short-Form 12-item Health Survey
SF-36	Short-Form 36-item Health Survey
SOC	Stages of change
TC	Total cholesterol
TG	Triglyceride
TTM	Transtheoretical Model

USM	Universiti Sains Malaysia
VT	Vitality
WC	Waist circumference
WHR	Waist-hip ratio

PENILAIAN KLINIKAL, EKONOMI DAN HUMANISTIK DARIPADA PROGRAM PROMOSI KESIHATAN DI TEMPAT KERJA YANG DIJALANKAN DALAM KALANGAN PEKERJA SEBUAH UNIVERSITI AWAM DI MALAYSIA.

ABSTRAK

Beban penyakit kardiovaskular (CV) semakin meningkat di Malaysia. Keadaan ini boleh menyebabkan wujudnya kesan yang berbahaya terhadap kesihatan, sosial dan ekonomi negara. Objektif am penyelidikan ini adalah untuk membangunkan suatu program promosi kesihatan di tempat kerja yang berkesan dan boleh mengurangkan faktor risiko (RF) penyakit CV dalam kalangan pekerja di Kampus Kejuruteraan, Universiti Sains Malaysia (USM). Penyelidikan ini merupakan suatu kajian kuasi–eksperimen yang dijalankan di antara 2009 dan 2010. Program enam bulan ini merangkumi kaunseling secara individu dan seminar yang mensasarkan pada lima RF tingkah laku, iaitu merokok, minum arak, pengambilan buah-buahan dan sayur-sayuran yang tidak mencukupi, ketidakatifan fizikal dan berat badan yang berlebihan/obesiti. Kaunseling secara individu dijalankan berdasarkan prinsip Model "Transtheoretical". Kedua-dua kumpulan intervensi dan kumpulan kawalan dinilai status RF semasa masing-masing, kesihatan berkaitan kualiti hidup dan pengetahuan tentang RF penyakit CV. Temu bual separa struktur dijalankan dengan para peserta program untuk mendalami persepsi mereka tentang kualiti dan keberkesanan program. Akhir sekali, analisis keberkesanan kos dilaksanakan daripada perspektif pembayar (universiti). Sejumlah 136 orang pekerja USM direkrut dalam kajian ini. Kesahihan ramalan, tumpuan dan keselarian daripada skor risiko global berdasarkan "WHO STEPS instrument for chronic disease risk factors surveillance" disokong

apabila ianya dibandingkan dengan skor risiko Framingham 10-tahun. Pengambilan buah-buahan dan sayur-sayuran, aktiviti fizikal dan glukosa darah selepas puasa adalah lebih baik dalam kumpulan intervensi jika dibandingkan dengan kumpulan kawalan dari segi min RF dan perkadaran peserta yang mencapai sasaran RF. Analisis daripada skor Tinjauan Kesihatan *Short-Form* 12-item mendapati skor komponen minda [intervensi (min 52.42 (SD = 5.99); kawalan (min 52.21 (SD 6.53), P = 0.001], fungsi fizikal [intervensi (min 55.04 (SD = 4.00); kawalan (min 51.68 (SD 7.61), P = 0.005], kesihatan secara am [intervensi (min 47.14 (SD = 6.44); kawalan (min 43.72 (SD 8.39), P = 0.049] dan semangat [intervensi (min 56.51 (SD = 5.19); kawalan (min 52.69 (SD 8.13), P = 0.008] secara signifikannya lebih tinggi dalam kumpulan intervensi selepas enam bulan. Hanya seorang peserta dalam kedua-dua kumpulan mampu menyebut sekurang-kurangnya satu RF sepanjang tiga titik penilaian. Kekerapan RF yang disebut adalah ketidakaktifan fizikal, diet-lemak dan pengambilan sayur-sayuran dan buah-buahan yang tidak mencukupi. Sejumlah 17 orang peserta daripada kumpulan intervensi ditemu bual untuk menilai kualiti program. Secara amnya, responden berpuas hati dengan aspek struktur dan proses program. Kesihatan dan gaya hidup mereka semakin bertambah baik dan mereka telah mula menitikberatkan kesihatan di samping perkara yang lain. Kos program intervensi dan kawalan dianggarkan sebanyak MYR304.52 dan MYR169.90 bagi setiap peserta masing-masing. Analisis keberkesanan kos mendapati bahawa program intervensi adalah berkesan-kos dalam meningkatkan pengambilan buah-buahan dan sayur-sayuran, aktiviti jasmani dan lilitan/ukuran pinggang. Program promosi kesihatan pengubahsuaian RF komprehensif didapati berkesan dan berkesan-kos dalam memperbaiki beberapa RF penyakit CV, terutamanya pengambilan buah-buahan dan sayur-sayuran yang tidak mencukupi, ketidakaktifan fizikal dan glukosa

darah–puasa dengan peningkatan yang signifikan dalam beberapa domain Tinjauan Kesihatan *Short-Form* 12-item.

CLINICAL, ECONOMIC AND HUMANISTIC EVALUATION OF A WORKSITE HEALTH PROMOTION PROGRAM CONDUCTED AMONG EMPLOYEES OF A PUBLIC UNIVERSITY IN MALAYSIA

ABSTRACT

The burden of cardiovascular (CV) diseases is increasing in Malaysia. This has an adverse effect on the country's health, society and economy. The general objective of this research was to develop an effective and efficient worksite health promotion program that could reduce the cardiovascular risk factors among employees at the Universiti Sains Malaysia (USM) Engineering campus. This was a quasi-experimental study conducted between 2009 and 2010. The six-month program consisted of individualized counseling and seminars targeted at five behavioral risk factors (RFs) i.e. smoking, alcohol consumption, inadequate fruit and vegetable intake, physical inactivity and overweight/obesity. Individualized counseling was conducted based on Transtheoretical Model principles. Both intervention and control groups were assessed for their current RF status, health-related quality of life and knowledge of cardiovascular risk factors. Validity of the arbitrary global risk score developed from the WHO STEPS instrument for chronic disease risk factors surveillance was assessed against Framingham risk score. Semi-structured interviews were conducted with participants of the program to explore their perception of the quality and effectiveness of the program. Finally, cost-effectiveness analysis was performed from the payer's (university) perspective. A total of 136 USM employees were recruited into the study. The predictive, convergent and concurrent validity of the global risk score based on the WHO STEPS instruments for chronic disease risk factors surveillance were confirmed and supported when compared with the 10-year

Framingham risk scores. Fruit and vegetable intake, physical activity and fasting blood glucose were consistently significantly better in the intervention group as compared to the control group in terms of the mean RF and proportion of participants reaching RF targets. Analysis of the Short-Form 12-item Health Survey scores found that mental component scores [intervention (mean 52.42 (SD = 5.99); control (mean 52.21 (SD = 6.53), P = 0.001], physical functioning [intervention (mean 55.04 (SD = 4.00); control (mean 51.68 (SD = 7.61), P = 0.005], general health [intervention (mean 47.14 (SD = 6.44); control (mean 43.72 (SD = 8.39), P = 0.049] and vitality [intervention (mean 56.51 (SD = 5.19); control (mean 52.69 (SD = 8.13), P = 0.008] scores were significantly higher in the intervention group at the six-month follow-up. All but one of the participants in both groups was able to mention at least one RF during the three evaluation points. The RF frequently mentioned were physical inactivity, dietary fat and inadequate fruit and vegetable intake. A total of 17 participants from the intervention group were interviewed to assess the quality of the intervention program. The respondents were generally satisfied with the structural and process aspects of the program. Their health and lifestyle had improved and they felt more responsible for the health of others as well. The costs of the intervention and control program were estimated to be MYR304.52 and MYR169.90 per participant, respectively. Cost-effectiveness analysis found that the intervention was cost-effective in improving fruit and vegetable intake, physical activity and waist circumference. An individualized, comprehensive RF modification health promotion program was found to be effective and cost-effective in improving several cardiovascular risk factors, most notably inadequate fruit and vegetable intake, physical inactivity and fasting blood glucose with significant improvements in several SF-12 domains.

CHAPTER ONE

GENERAL INTRODUCTION

1.1 BACKGROUND

Malaysia, as a developing country has entered into the stage three of the Demographic Transition Model (Omran, 1971). The Demographic Transition Model describes a shift in mortality and disease patterns from pandemics of infections to degenerative and man-made diseases as the primary cause of morbidity and mortality. At stage three, the main public concern is the high prevalence of chronic disease and its associated lifestyle and behavioral risk factors (RFs) (Feinleib, 2008).

Similarly, the prevalence of chronic diseases worldwide is increasing. As a result, health organizations have placed a great deal of emphasis on health promotion and disease prevention. The World Health Organization recognizes the importance of primary prevention and has launched several campaigns to tackle this problem. "Health for All" was launched at the Alma Ata Primary Healthcare Conference in 1978. One of the six principles advocated in this program is "emphasis on health promotion and prevention of diseases" (World Health Organization, 2006). Following this, the "stop the global epidemic of chronic diseases" campaign was launched on October 5, 2005 by the World Health Organization, with a goal of reducing the death rates from chronic diseases by two percent each year till 2015 (Abegunde et al., 2007, World Health Organization, 2008c). More recently, the World Health Report (2008) put greater emphasis on primary healthcare (World Health Organization, 2008d).

The Malaysian Government, serving a population of 28.4 million, is committed to improving and sustaining the health of the nation (Department of Statistics Malaysia, 2010). Healthcare in this country is heavily subsidized by the government. In 2008, over MYR12.9 billion (approximately 7.29% of the national budget) was allocated to the Ministry of Health (MoH). Furthermore, thrust four of the Ninth Malaysia Plan

outlined the need for improving the standard and sustainability of the quality of life (QoL) of the Malaysian population. It emphasized efforts to promote lifelong wellness and a proactive approach to maintaining health. It is hoped that this in return will decrease the burden on the scarce health resources available for the optimum benefit of the population (Ministry of Health, 2010).

Similarly, the MoH of Malaysia has been actively involved in health promotion activities, especially regarding lifestyle-related disease, through community-wide strategies such as providing health education material (in both printed and electronic versions), radio and television talk shows and health camps (Ministry of Health, 2008). In August 2002, the Malaysian Government set up the Malaysian Health Promotion Foundation with the following objectives: tobacco control, promoting healthy lifestyles, creating and sustaining healthy environments and promoting health through sports and culture (Ministry of Health, 2007a).

1.2 PROBLEM STATEMENT

In Malaysia, circulatory system diseases (as described by ICD-10: 100–199) accounted for a total of 144,198 admissions (6.99% of all admissions) to hospitals for the year 2008. They were the fifth cause of hospitalizations in MoH hospitals for that year. Moreover, heart disease and disease of the pulmonary circulation (as described by ICD-10: 100–152) together with cerebrovascular disease (as described by ICD-10: 160–169) were the leading causes of deaths in MoH hospitals for the same year, accounting for 25.19 percent of all deaths (Ministry of Health, 2010). Figure 1.1 summarizes the incidence of hospitalizations and deaths due to cardiovascular disease (CVD) from 2000 to 2008. It can be concluded that there was an increasing trend of hospitalizations and deaths at MoH hospitals.

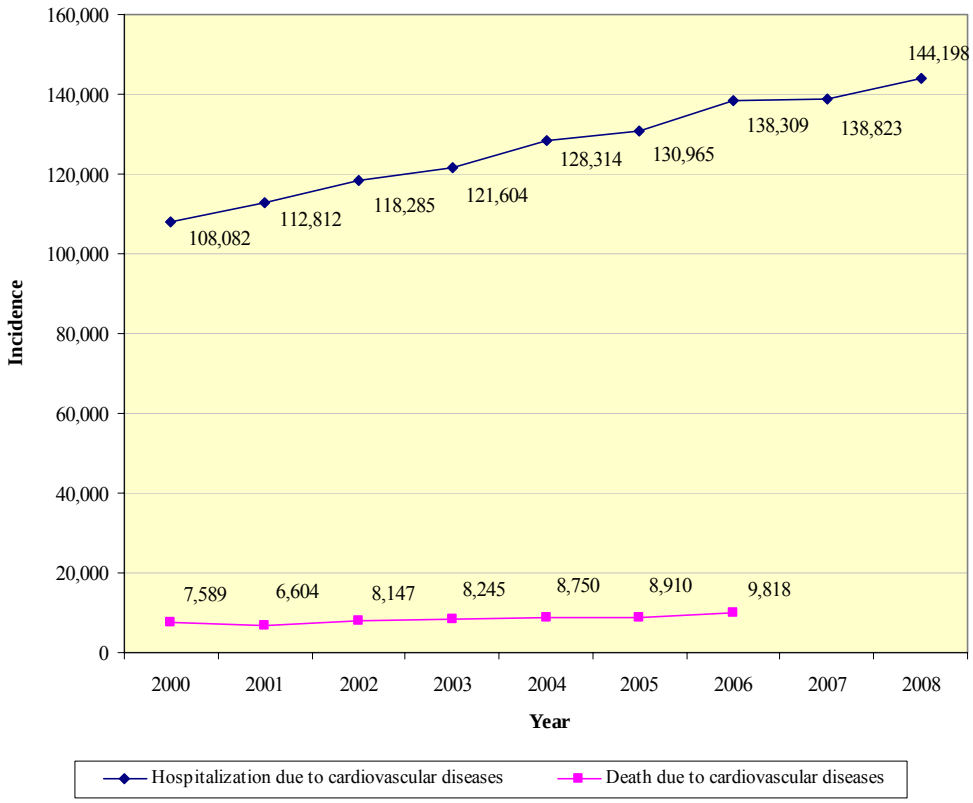

Figure 1.1. Incidence of hospitalizations and deaths due to cardiovascular disease from 2000 to 2008 at Ministry of Health Hospitals (Ministry of Health, 2010)

However, the true incidences of cardiovascular (CV) events and deaths are unknown. The incidences presented were reported by the 128 hospitals under the MoH. However, the incidences at the six non-MoH hospitals and 233 private hospitals were not included in this report. Nevertheless, it can be concluded that the incidences can only be higher than reported. Moreover, one can expect a further increase in health expenditure due to the continued rise in the incidence and prevalence of CV events if nothing is done to halt this epidemic. Surviving a CV event will also have a negative impact on the patients' QoL and productivity (Erhardt, 2007).

Despite the greater emphasis on the prevention of CVD, the burden of CVD is growing. This is having a negative impact on the health, social and economic situation of Malaysia.

Globally, CVD is the number one cause of death, with an estimated 17.5 million people dying from it in the year 2005, accounting for 30 percent of all deaths worldwide (World Health Organization, 2007). What is more worrying is that more than 80 percent of these deaths occurred in low- and middle-income countries that have limited resources and capability to counter this problem in terms of the prevention and treatment of diseases (Abegunde et al., 2007).

A review of the expenditure on drugs in Malaysia (both private and public sector) in 2006 found that eight out of the top 10 prescribed drugs were for the management of CVD, lipid lowering and diabetes (Lim et al., 2009). The 10 most prescribed drugs in Malaysia for the year 2006 are listed in Table 1.1.

Table 1.1. Top ten prescribed drugs in Malaysia for the year 2006

Drugs	Therapeutic category	Amount prescribed (MYR)
Amlodipine	Cardiovascular	30.78 million
Atorvastatin	Lipid lowering	26.57 million
Metoprolol	Cardiovascular	25.08 million
Simvastatin	Lipid lowering	21.79 million
Cefuroxime	Anti-infective	21.56 million
Metformin	Diabetes	20.65 million
Gliclazide	Diabetes	19.43 million
Risperidone	Psychiatric	18.81 million
Atenolol	Cardiovascular	18.47 million
Captopril	Cardiovascular	Not available

[Adapted from Malaysian Statistics on Medicines, 2006 (Lim et al., 2009)]

1.3 RATIONALE OF THE STUDY

A wealth of epidemiological research has demonstrated that a number of RFs are associated with a significant increase in the risk of developing CV events. INTERHEART, a worldwide case-control study on patients with myocardial

infarction, has estimated nine RFs that can be attributable to 70 to 90 percent of the risk of myocardial infarction in men and 94 percent in women. These are inadequate fruit and vegetable consumption, alcohol consumption, physical inactivity, abdominal obesity, psychosocial stress, smoking, raised blood pressure (BP), raised blood glucose and elevated apoB-A-I ratio (Yusuf et al., 2004, Smith, 2006, Abegunde et al., 2007).

There is overwhelming evidence of the role of these RFs in the development and progression of chronic diseases.

i) Tobacco use: Smokers and passive smokers have an increased risk of cancers, CVD, stroke and pulmonary disease (World Health Organization and World Heart Federation, 2005, World Health Organization, 2008b).

ii) Inadequate fruit and vegetable intake: It was estimated that a low fruit and vegetable intake causes 26.7 million (1.8%) disability-adjusted life years worldwide, mostly in the form of CVD, stroke and cancer (World Health Organization, 2008a).

iii) Physical inactivity: Physical inactivity causes about 1.9 million deaths worldwide each year. It can lead to ischemic heart disease, stroke, diabetes and cancer as well as being a major RF for becoming overweight or obese (World Health Organization, 2002, Breckenkamp et al., 2004).

iv) Alcohol consumption: Excessive alcohol use causes cancer, liver disease and seizures, and increases the risk of CVD and stroke (O'Keefe et al., 2007).

v) Overweight/obesity: There is a significant association between body mass index and most of the physiological RFs (BP, cholesterol and blood glucose) and this subsequently leads to an increased risks of CVD and diabetes mellitus (Baranowski et al., 2003, Panico et al., 2008).

vi) Raised BP: Raised BP is a major RF for CVD. For every 20 mmHg increment in systolic BP and 10 mmHg increase in diastolic BP, the risk of CVD doubles (World Health Organization, 2002).

vii) Raised blood glucose: Diabetes is a very powerful RF for CVD. There is a seven- to eight-fold increase in CVD risk in diabetics compared with non-diabetics (World Health Organization, 2002).

viii) Abnormal blood lipids: Raised cholesterol is estimated to cause 18 percent of global cerebrovascular disease and 56 percent of global ischemic heart disease, a total of 4.4 million deaths (7.9% of the total). A 10 percent increase in total cholesterol is associated with a 20 to 30 percent increase in CVD (World Health Organization, 2002).

The prevalence of these RFs among the Malaysian population was assessed in a number of large population surveys, i.e. the National Health and Morbidity Survey and Malaysia Non-Communicable Disease. It can be summarized that the prevalence of most of the RFs has increased tremendously since 1996, especially that of physiological RFs (Institute for Public Health, 2008, Ministry of Health, 2007b). The results of these surveys are summarized in Table 1.2.

Table 1.2. Prevalence of cardiovascular risk factors

Risk factors	NHMS II 1996 (n = 17,390) (%)	NHMS III 2006 (n = 34,539) (%)	MyNCDs 2006 (n = 2572) (%)
Tobacco use	24.8	21.5	25.5
Excessive alcohol consumption	Not available	16.2	12.2
Unhealthy diet	Not available	Not available	72.8
Physical inactivity	Not available	43.7	60.1
Overweight/obesity	21.0	43.1	47.9
Raised blood pressure	33.0	43.0	25.7
Raised blood glucose	8.3	14.9	11.0
Abnormal blood lipids	20.1	20.7	53.5

MyNCDs = Malaysia Non-Communicable Disease survey; NHMS = National Health and Morbidity Survey

Therefore, it can be concluded that the primary RF that causes premature CV events is an unhealthy lifestyle. Hence, lifestyle interventions are recognized as the main basis to reduce the need for drug therapy.

These RFs almost always occur in clusters, which means that the presence of a single RF will increase the likelihood of the other RFs being present (Schuit et al., 2002, Gu et al., 2005, Poortinga, 2007). Moreover, the risk of a CV event is greater than the summation of the effect of an individual RF (Erhardt, 2007). Therefore, there is a need for a comprehensive and integrated program that targets these RFs simultaneously (Bakx et al., 2002).

In Malaysia, both community-wide and individualized health promotion activities are often conducted. Community-wide strategies can reach a large number of individuals but their effectiveness and efficiency are neither consistent nor superior to the individualized strategy (Department of Human Services, 2008). On the other hand, individualized counseling on healthy lifestyles is conducted routinely in hospitals and clinics. However, the strategies used are not standardized and most of these activities target one RF at a time. As a result, numerous health-promotive clinics are created, thus increasing the workload of the healthcare providers in maintaining the services of these clinics. Moreover, employees with multiple RFs might need to attend several health-promotive clinics at a time. Therefore, there is a need for a comprehensive individualized health promotion program.

Finally, the lack of previous research relating to the individualized strategy in primary prevention of CVD in Malaysia has prompted this study. Most of the published CV primary prevention studies were carried out in developed countries and predominantly among Caucasians. Hence, there is a need to develop preventive strategies that cater for the Malaysian population based on our local settings: the

societal, environmental and biological causes of development of these RFs. Thus, this study is regarded as timely in the development of a comprehensive and individualized health promotion program.

1.4 STUDY OBJECTIVES

The general objective of this research was to develop an effective and efficient worksite health promotion program that can reduce the cardiovascular risk factors among the employees of the engineering campus of the Universiti Sains Malaysia.

The specific objectives were as follows:

i) To assess the validity of the global risk score derived from the WHO STEPS instrument for chronic disease risk factors surveillance.

ii) To evaluate the effectiveness of the six-month comprehensive health promotion program on the modifiable RFs related to CVD.

iii) To assess the effect of the health promotion program on the health-related quality of life of the participants.

iv) To explore the knowledge of the participants regarding cardiovascular risk factors and their health risks.

v) To evaluate participants' perception of the quality and effectiveness of the standardized health promotion intervention.

vi) To assess the cost-effectiveness of the proposed worksite health promotion program.

1.5 SIGNIFICANCE OF THE STUDY

The positive findings from this study are beneficial to various stakeholders. These include the employees themselves, the employer as the payer for healthcare for its employees and the country as a whole.

For the employees, an improved lifestyle with modification of cardiovascular risk factors will result in improved health and probably a better QoL. Apart from an improvement in physical health, mental health will be improved by a healthy lifestyle. Those who are mentally healthy can handle stress better and are more self-disciplined in their daily lives.

Cardiovascular diseases are chronic diseases that almost always require lifelong treatment and these are expected to cause a grave economic burden for both the employers and the country. The prevention of such diseases would decrease the healthcare financing burden for the employers and increase productivity.

Health policy makers need concrete data on the efficiency and economic impact of a prevention program before it can be implemented. Therefore, analyses of the clinical effectiveness, cost-effectiveness and effect on health-related QoL will give an insight into the effectiveness, relevance and cost-effectiveness of its implementation in other institutions.

It is hoped that the proposed comprehensive and integrated health promotion program will contribute to the improvement of the lifestyle of the members of the population and especially their cardiovascular risk factors. The positive results from this study can be used as a stepping stone for implementing an individualized health-promoting program in other institutions in the country by adopting and adapting the practice model used in this study.

CHAPTER TWO

LITERATURE REVIEW,

CONCEPTUAL FRAMEWORK AND THEORETICAL FRAMEWORK

2.1 LITERATURE REVIEW

2.1.1 Background

Lifestyle modification to reduce the prevalence of cardiovascular disease (CVD) and its risk factors (RFs) has been extensively studied. A review of the available literature will give an overview of the topics and become a stepping stone in planning further research, so that the gaps in the current literature can be filled. Secondly, there was significant heterogeneity of the various components of these studies. Ideally, only results from studies with good methodological quality should be adopted. Hence, a critical review of the literature can aid in separating out the poor-quality papers. Studies with established internal and external validity will produce valid and reliable results. Internal validity is associated with the quality of the research itself and thus the relationship between the treatment and the observed outcome. The internal validity of a study is determined by evaluating the design components of a study. Among the criteria of concern are the study design, high retention rates, valid and reliable measures used, clearly defined interventions, the inclusion of all the important outcome measures, sufficient outcome measures and the use of intention to treat analyses. External validity refers to the extent to which the results can be generalized to a wider population. Generalizability of a study is assumed if the study participants are representative of the targeted population (Slack and Draugalis J R, 2001). Moreover, a limited number of studies have been reported from Malaysia. A brief summary of the studies that involved interventions in various RFs, the economic evaluation of these programs, their effect on health-related quality of life (HRQoL) and knowledge of cardiovascular risk factors was presented. Finally, existing studies on the quality assessment of health promotion programs as well as risk assessment tools for estimating the risk of CVD were presented.

2.1.2 Search Strategy

The published literature was identified by a systematic search strategy. Computerized English-language searches were performed of the databases available at the university library, which include Medline, Pubmed, Scopus, Ebsco Host, Ovid, Blackwell Synergy, Wiley Interscience, Sage, Springerlink and Science Direct. The strategy used a series of keywords to identify the topic of interest using the text word search. Primary Medical Subject Headings terms were used to combine keywords for the search. Some of the keywords used included "primary prevention," "cardiovascular disease," "stages of change," "Transtheoretical Model," "economic evaluation," "quality of life," "knowledge" and "risk assessment tools." These were supplemented by examining the reference list of each of the studies identified. The corresponding author of each study was contacted to request any relevant data not included in the published report and also to obtain the full clinical paper. The eligibility criteria for the studies for this review included published, peer-reviewed and English language studies. Thereafter, a database of references was compiled.

2.1.3 Applicability of Cardiovascular Risk Assessment Tools Among Asians

Risk assessment has often been used in guiding the intensity of RF management in primary prevention programs. The findings from a study published in 2006 supported the concept of estimating global risk to make treatment decisions because of the better discrimination of lifetime risk with the aggregate RF burden (Lloyd-Jones et al., 2006).

Risk assessment tools have been used in the quantification of total cardiovascular (CV) risk in the near future. Many risk assessment tools have been developed over the years. There is no consensus yet regarding a standard universal and

comprehensive risk-assessment tool. The prevailing consensus is that in order for any risk assessment tool to be used with confidence in a population, several elements need to be considered. The nature and strength of association between each RF, the risk of CV events, the prevalence of RF and lastly the incidence of CV events have to be comparable among the population concerned (Giampaoli et al., 2005, Barzi F et al., 2007).

These principles were applied in a review of 25 risk assessment tools (Liau et al., 2010). A summary of their characteristics is presented in Appendix A.

Most of the tools were derived from American or European populations. Only two of these tools (the USA-PRC Collaborative Study of Cardiovascular and Cardiopulmonary Epidemiology cohort and the Japanese Nippon Data 80 cohort) recruited Asian members of the population as part of their cohort (Ueshima et al., 2006, Wu et al., 2006).

The cohort of the Framingham Heart Study was recruited from residents of Framingham in Massachusetts, USA. It was commonly used in the derivation of risk assessment tools (Dawber et al., 1963). Due to the unique genetic characteristics and numerous ethnic groups among Asians, the nature and strength of the association between each RF and risk of the CV events might not be generalizable to Asians (Giampaoli et al., 2005). Furthermore, this cohort started enrollment in 1948 and follow-up is still ongoing (Dawber et al., 1963). Most of the tools used were based on analyses of this data from this cohort in the 1960s–1980s, during which time the incidence of CVD and diabetes was at its peak (Kubo et al., 2003). This might result in an over-estimation of the CV risk.

There is a wide range of RFs that contribute to the incidence of CV events. These RFs are commonly classified as modifiable and non-modifiable RFs (Zambahari et

al., 2008). Three common non-modifiable RFs (age, sex and family history) were regularly included in the risk assessment tools.

However, there were some concerns regarding the modifiable RFs. The physiological RFs which included blood pressure (BP), cholesterol level and diabetes status were regularly included in the available risk assessment tool. Behavioral RFs such as dietary habits, physical activity and adiposity were often overlooked even though these RFs have a strong influence on the physiological RFs (Mozaffarian et al., 2008). The exclusion of the behavioral RFs resulted in the incomplete management of increased CV risk. The exclusion of behavioral RFs could be due to the reliability of the assessment of these RFs because it almost always involved the self-report method. Increasing age is known to be a strong non-modifiable RF for CV events. Generally, the risk of CV events increases steeply with advancing age, particularly for those older than 50 years (Lloyd-Jones et al., 2006). In the case of the Framingham risk score, it classified younger men and women as low risk despite having multiple cardiovascular risk factors. At times, clinicians failed to see the seriousness of these RFs in view of the low CV risk (Jackson, 2000).

Secondly, the quantification and level of measurement of these RFs by the developer of these tools differed in many ways. The dichotomous scoring system was used in some of the risk assessment tools. This system ignored the gradient effect of the severity and seriousness of the RF status. For example, a certain score was given to someone with high BP. In this case, no consideration was given to the level of severity of some of these RFs, such as BP, cholesterol level and glucose level (Kannel et al., 2004). Research has shown that there is a graded relationship between an increased risk level (especially raised BP, raised blood glucose and raised

cholesterol, being overweight and smoking) and CV events and mortality (Yusuf et al., 1998).

2.1.4 Lifestyle Modification Studies

A search of the existing literature on the topics of lifestyle intervention yielded 60 studies. Each study was systematically summarized and compared (Appendix B). Table 2.1 summarizes the methodological aspects of these studies.

Table 2.1. Summary of methodological aspects of lifestyle modification studies (n = 60)

Bibliographical/Methodological findings		Number of studies
Settings	United States/Canada	22
	European countries	25
	Australia/New Zealand	5
	Asia countries	8
Study design	Randomized controlled trial	34
	Cluster randomized trial	5
	Quasi-experimental	14
	Prospective cohort	1
	Not stated	6
Sample size estimation	Yes	20
	No	40
	Range	11 – 6339 per group
	All groups meet sample size estimation	9
	At least one group did not meet sample size estimation	11
Sample characteristics	Men and women	55
	Men only	4
	Women only	1
Age	Described	53
	Not described	7
	Range	17 – 85 years
Disease state	General population/primary care patients	32
	Diseased/high risk for cardiovascular disease	28
Retention rate	Yes	46
	No	14
	Range	44% - 100%
Risk factors targeted	Single	24
	Multiple	36
	Range	1 - 8
Training for providers	Described	19
	Not described	41
Control group treatment	Described	41
	Not described	10
	No control group	9

Table 2.1. Continued

Bibliographical/Methodological findings		Number of studies
Intervention strategy	Individualized counseling	35
	Group counseling	3
	Mixed methodology (individualized + group)	4
	Other methods (for example: web-based, mail feedback, booster phone call)	22
Use of health behavior theory	Transtheoretical Model	25
	Other health behavior model	6
	Not used	29
Duration of follow-up	Less than six months	8
	Six months to one year	24
	More than one year	26
	Not mentioned	2
	Range	4 weeks – 10 years
Intention to treat analyses	Done	11
Quantification outcome	Analyze change individually	53
	Index of overall status	8
	Index reflecting number of risk factors reaching criterion	2
	Overaching measures of change (health-related quality of life)	3
Findings	Intervention improve outcomes	60

The setting in which a study is conducted has an effect on the generalizability of the study. Due to the differences in terms of society and environment between Asia and the European countries, care should be taken when interpreting the results of these studies. Out of the 60 studies reviewed, only eight studies originated from Asian countries.

The study design of a study plays a major role in the validity of the results reported. A randomized controlled trial is placed in the highest level among the study designs and is considered the most robust (Evans, 2003). A randomized controlled trial, if conducted correctly, will provide sound and valid evidence (Thorogood and Coombes, 2000). However, there are some arguments that by conducting a study in a controlled environment and among participants with strict inclusion and exclusion criteria, its external validity will be compromised (Thorogood and Coombes, 2000, Smith, 2002). Moreover, it is difficult to prevent the spillover effect from the

intervention providers to the control-group participants because of the close proximity of both the intervention group and the control group. This might result in an underestimation of the true effects of the intervention. One of the ways to overcome this is to use a cluster randomized design whereby the providers are randomized rather than the participants. The disadvantage of a cluster randomized design is its lower statistical power and therefore a much larger sample size is normally needed (Grimshaw et al., 2000).

Secondly, some researchers have argued that it is not practical to use a randomized design in behavioral studies because it is essential that the participants should have the intention to change in order for change to occur. Therefore, a quasi-experimental study design is recommended. Even if studies are conducted following the existing practice with no randomization of participants, they can still produce sound evidence if they are well planned and conducted (Thorogood and Coombes, 2000). Three of the most common quasi-experimental designs are uncontrolled before and after studies, time series designs and controlled before and after studies (Grimshaw et al., 2000).

A sufficient sample size is required to ensure that the difference between/among the groups can be seen if there is indeed a difference. The sample size should not be so large that it is either difficult to handle or too costly to follow up. The sample size estimation is based on the effect size, which is empirically determined from existing studies, dropouts, the level of significance and the power of the study (Hulley et al., 2001). In the studies reviewed, the recruited sample size ranged from 11 to 6339 per group. Out of the 20 studies that explained their sample size estimation, 11 had at least one group with a smaller than estimated sample size (Cupples and McKnight, 1994, Oldroyd et al., 2001, Tsuyuki et al., 2002, Cornuz et al., 2002, Karlehagen and

Ohlson, 2003, Nakamura et al., 2004, Chan et al., 2007, Racette et al., 2009, Ma et al., 2009, Jafar et al., 2010, Bredie et al., 2010).

The characteristics of the sample will determine the generalizability of the results of the study. Among others, the gender, age and disease state of the sample should be representative of the target population. Gender has a role to play in the outcome of an RF modification study. The distribution of RFs as well as the responses and acceptability of certain advice may differ between men and women. Therefore, it is crucial that both men and women are included in a study (Melloni et al., 2010).

Secondly, the age group of a study should be comparable with the targeted population in order to be able to translate the results confidently to the population. Most of the studies reviewed recruited participants aged between 20 and 60 years.

Another important feature to consider during the process of generalization of the results of a study is the disease state of the study subjects. The outcome of the study, especially the biochemical tests and BP, will be influenced by the disease state of the study subjects.

Prospective studies with active intervention tend to experience participant dropouts. Any degree of dropout or non-responder can potentially affect the validity of the results. Hence, there is a need to minimize the non-responders by following up and good planning of the study (Smith, 2002). Generally, an 80 percent retention rate is considered acceptable for most studies and 70 percent for longer-term studies (van Sluijs et al., 2004). The retention rate in the studies reviewed ranged from 44 to 100 percent.

Most of the studies on multiple RFs' intervention targeted five or fewer RFs with a maximum of eight RFs. There was heterogeneity in the targeted RF in single RF studies and multiple RF studies. Among the studies that targeted one RF, the most

commonly targeted RFs were being overweight (n = 7) and physical inactivity (n = 6). Multiple RF intervention studies commonly targeted smoking (n = 26) and physical inactivity (n = 26).

A large variation in the profession of providers was observed and this included research staff, nurses, doctors, physiotherapists and dietary counselors. Training for providers is especially applicable to studies that are based on health behavior theories and concepts to ensure sufficient skills and knowledge to conduct the intervention program (Salmela et al., 2008). Most of the studies reviewed (n = 41, 68.3%) did not describe the training undertaken by these providers.

In general the intervention group was compared with a control group based on usual care or nothing at all. Substantial variability was evident in the intensity of the control group. It ranged from no intervention to usual treatment and also to minimal education via electronic mail and group counseling. The intensity of the control group will have an impact on the effect size of the intervention by creating awareness among the control group.

There are several methods of delivering the message of health behavior change. Individualized intervention whereby participants are provided with information tailored to them, mostly through face-to-face counseling was frequently used. This allows for greater possibilities of personal influence and thus increases the likelihood of behavior change. However, individualized intervention is not appropriate for primary prevention involving a large sample size because it is labor and time intensive. In this case, group counseling whereby a small group of participants meet and discuss their problem is more appropriate. If possible, a combination of individualized and group counseling is preferred. Other methods reported were web-based individualized feedback, mail feedback and self-monitoring (Kypri and

McAnally, 2005, Hennessy et al., 2006, Chan et al., 2007, Sternfeld et al., 2009). Additional materials were often used to facilitate the intervention sessions. These included videos, self-instruction manuals or pamphlets, booster phone calls and social and environmental support.

A search of the literature uncovered numerous behavioral intervention programs that were based on the Transtheoretical Model (TTM) and/or other health behavior modification theories. The TTM is considered to be one of the six commonly cited behavioral change models (Salmela et al., 2008). The main construct in the TTM is the stages of change (SOC). However, several systematic reviews conducted failed to support conclusively the effectiveness of RF modification based on SOC principles (Riemsma et al., 2002, Grol and Wensing, 2004). Other theories used were social cognitive theory, theory of planned behavior and motivational interviewing.

Various ways were reportedly used to obtain information on the behavioral RFs, such as physical activity, diet and smoking. So far, there is no ideal data collection method or tool. The methods used included self-reported physical activity/dietary questionnaires, food and physical activity diaries and point prevalence smoking cessation. Most of these instruments use subjective measures and thus are subject to recall bias.

A review of the 60 studies found tremendous variability in the duration of the follow-up, which ranged from four weeks to 10 years. Ideally, the duration of the study should reflect the balance between the sustainability of the changed behavior, its feasibility and the cost of the study. Secondly, certain changes may take some time to develop, such as blood lipid profiles. A follow-up duration of at least six months is considered acceptable (van Sluijs et al., 2004).

Intention-to-treat analyses compare the outcomes of all the participants assigned initially to the intervention group and the control group, irrespective of whether they completed follow-up or not. Studies that use intention-to-treat analyses are reported to have higher internal validity and are thus encouraged. Among the studies reviewed, only 11 studies reported intention-to-treat analyses (Tsuyuki et al., 2002, Engberg et al., 2002, Hennessy et al., 2006, Harting et al., 2006a, Hardcastle et al., 2008, Wood et al., 2008, Nolan and Thomas, 2008, Bosworth et al., 2009, Ma et al., 2009, Sternfeld et al., 2009, Jafar et al., 2010).

With the increasing interest in multifactorial behavioral change and the increasing number of studies being carried out to evaluate the effect of interventions, the quantification of behavior change is crucial. A standard method of quantification will enable a comparison to be made between studies and their results. There are five different methods to quantify and report change in behavioral interventions (Prochaska et al., 2008b). The traditional and easiest way of reporting change is to analyze change individually. This method of reporting can be seen in almost all the studies reviewed. However, even for the same RF, the quantification method differs. This method overlooks the overall effect of an intervention as these RFs tend to occur at the same time and have an effect on each other (Prochaska et al., 2008b). Alternatively, all the RFs can be combined to create an index of overall status. This is often seen with the use of risk scores to quantify the overall risk. Many risk scores have been developed and each has its advantages and disadvantages. The Framingham risk score was one of the earliest risk scores and is very popular among researchers. Some researchers have developed their own risk functions based on the RF being studied (Gomel et al., 1997). These calculated risk scores might have greater statistical power due to the continuous data but they may lack meaning in

terms of health benefits and whether the risk assessment tools are generalizable to different populations (Prochaska et al., 2008b). The third approach is to create an index reflecting the number of RFs reaching the criterion. This method dichotomizes the outcome and this in itself downgrades the scale of continuous measurement, which has greater sensitivity in statistical analysis (Prochaska et al., 2008b). Among the 60 studies reviewed, only two reported their results using this approach (Sargent et al., 2000, Bosworth et al., 2009). The fourth approach is to create an expanded impact formula for multiple behavior change. This formula takes into consideration the number of behaviors, their efficacy and the recruitment rate. By incorporating efficacy and recruitment rate data into the calculation, the overall impact of an intervention can be obtained, but there has not yet been any consensus on the interpretation of the impact figure (Prochaska et al., 2008b). This approach was only reported in the study by Johnson et al. (2008). It was reported that the population impact was 68.8 percent which equates to 0.7 behaviors changed per person (Johnson et al., 2008). Lastly, other measures of the effect of the intervention can be a measure of the extended effectiveness of the intervention, such as HRQoL. Overarching measures of change enable researchers to gather information on other important outcomes of an intervention apart from improvements in behavior: measures such as HRQoL, cost savings, length of hospital stay or even SOC movement (based on the construct of TTM of change). One of the disadvantages of these measures is that the study might not be powered to obtain statistically significant results for these powers or that the preset duration of the study might not be sufficient to observe positive change (Prochaska et al., 2008b).

Finally, all of the studies reported improved outcomes in improving behavior and other measures of change among intervention groups. Thus, behavioral change is possible, feasible and should be encouraged.

2.1.5 Sequential or Simultaneous Risk Factors Intervention

There is limited and inconsistent evidence on the best method to undertake multiple behavior change, in relation to whether to intervene in the RFs simultaneously or sequentially. Simultaneous intervention is of benefit in the case of limited contact opportunities and time and is thought to produce a synergistic effect on the outcome due to the clustering of RFs (Prochaska, 2008, Prochaska et al., 2008a). However, the other argument is that simultaneous interventions in several behavioral changes may be too overwhelming and fail to address any single RF in sufficient depth in order to maintain the change. Furthermore, the SOC of each behavior may differ and this will complicate the intervention program (Vandelanotte et al., 2008).

Hyman et al. (2007) conducted a randomized trial to compare the effectiveness of sequential or simultaneous intervention to stop smoking, reduce dietary sodium intake and increase physical activity. Three experimental conditions were conducted: comparing simultaneous intervention versus usual care (n = 92), comparing sequential intervention versus usual care (n = 96) and lastly comparing simultaneous intervention versus sequential intervention (n = 93). The required sample size was 97 per group to have at least 70% power. They concluded that the simultaneous approach may be more superior but this did not reach statistical significance (Hyman et al., 2007).

Spring et al. (2004) compared these two approaches to multiple behavior change in diet, exercise and cigarette smoking. It was reported that weight gain was slower in the group that was randomized to receive sequential treatment (Spring et al., 2004). Vandelanotte et al. (2007) studied the multiple behavior changes in physical activity and fat intake. It was found that both the sequential and the simultaneous mode produce similar behavior change outcomes after a six-month follow-up (Vandelanotte et al., 2005, Vandelanotte et al., 2008). These patients were followed up for another two years and it was found that the sequential intervention mode was slightly more effective in maintaining long-term health behavior change (Vandelanotte et al., 2007).

2.1.6 Effect of the Health Promotion Program on Health-Related Quality of Life

Health-related quality of life measures the physical, psychological, social and role functioning of an individual from the perspective of the individual (Hennessy et al., 1994, Emery et al., 2005). It has been recognized as a valid indicator and determinant of behavior change. In preventive medicine, mortality and morbidity do not give a full picture of the effectiveness of an intervention, because improvement in functional capacity is also part of the expected outcome in preventive medicine. Moreover, the participants' response to health and quality of life might differ and this might influence their acceptability of an intervention. In this case, HRQoL data can be used to measure these changes from the perspective of the participants themselves (Guyatt et al., 1993, Hennessy et al., 1994).

A review of 23 published reports on the effect of lifestyle modification studies on HRQoL was performed. A summary of the studies that reported the effect of lifestyle