



EFFECT OF NURSE-LED MOTIVATIONAL
CONSTRUCT INTERVENTION PROGRAMME ON
LIFESTYLE CHANGES AND CARDIOMETABOLIC
RISK AMONG OBESE ADULTS: A SINGLE-BLIND
RANDOMISED CONTROLLED TRIAL

BY

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A thesis submitted in fulfilment of the requirement for the
degree of Doctor of Philosophy in Biobehavioral Health
Sciences

Kulliyyah of Nursing
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OCTOBER 2018

ABSTRACT

This randomised controlled trial aimed to determine the effect of nurse-led motivational construct intervention programme, in comparison to the standard lifestyle modification intervention (LMI), on lifestyle changes and cardiometabolic risk (CMR) profiles among obese adults in Kuantan, Pahang. One hundred obese adults (50 participants in each group) were randomised into either an intervention or control group. Both groups received lifestyle advice on dietary modification, physical activity and behavioural modification skills at baseline. The intervention group also received monthly home visits follow-up for subsequent nurse-led, tailored lifestyle advice. Seventy-nine participants completed the study (39 participants in the control and 40 participants in the intervention group). The outcome measures for lifestyle changes include dietary intake and physical activity level and the CMR includes body mass index (BMI), waist circumference (WC), blood pressure (BP), fasting blood glucose (FBG), low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglyceride (TG) and high-sensitivity C-reactive protein (hs-CRP) levels, assessed at baseline and after six months. Data were analysed using SPSS Version 21. No significant difference in the lifestyle and CMR measures between groups found at baseline. The post-intervention assessments showed that there are no significant changes in the physical activity level and dietary intake except for a reduction in saturated fat intake among the obese adults in the control group after six months ($p < 0.05$). In addition, the post-intervention assessment reported that the intervention group resulted a significant reduction in BMI, WC, diastolic BP and a significant rise in HDL levels (all $p < 0.05$). Similarly, the control group exhibited a significant reduction of WC and TG levels after six months ($p < 0.05$). However, the control group showed a significant rise in the FBG level after six months ($p < 0.05$), while it stabilised in the intervention group. Additionally, the intervention group also achieved a reduction in the LDL and hs-CRP levels after six months. Nonetheless, there were no statistically significant differences in the lifestyle and CMR measures between the groups after six months ($p > 0.05$). This study demonstrates that the nurse-led motivational construct intervention programme may be beneficial to treat obesity as well as stabilising the diastolic BP, hs-CRP and the FBG level of adults with obesity. Hence, a larger trial with modifications, sensibly informed by this trial, can now build upon and confirm these results.

خلاصة البحث

هدفت التجربة العشوائية المنتظمة هذه إلى تحديد تأثير برنامج تدخلي ببنية تحفيزية بقيادة الممرضات بالمقارنة مع البرنامج التدخلي النموذجي لتعديل النمط الحياتي (LMI) على تغيير نمط الحياتي وتغيير بروفيلات المخاطر الأيضية القلبية بين البالغين الذين يعانون من السمنة المفرطة في كواتن بولاية باهانج. تم اختيار بصورة عشوائية 100 من البالغين الذين يعانون من السمنة المفرطة موزعين في مجموعة التدخل والمجموعة الضابطة (50 مشاركا في كل مجموعة). تلقى كلا المجموعتين نصائح حول النمط الحياتي في تعديل النظام الغذائي، والنشاط البدني، ومهارات تعديل السلوكيات على خط الأساس. تلقت مجموعة التدخل أيضا زيارات متابعة منزلية شهرية لإعطاء نصائح في النمط الحياتي مصممة خصيصا لكل منهم وتم إعطاؤها من قبل الممرضات. أكمل الدراسة تسعة وسبعون مشاركا (39 مشاركا في المجموعة الضابطة و 40 مشاركا في مجموعة التدخل). حسب النتائج تغيير النمط الحياتي وشملت الاستهلاك الغذائي، ومستوى النشاط البدني، والمخاطر الأيضية القلبية مثل مؤشر كتلة الجسم (BMI)، ومحيط الخصر (WC)، وضغط الدم (BP)، ومستوى السكر الصومي في الدم (FBG)، والبروتين الدهني منخفض الكثافة (LDL)، والبروتين الدهني عالي الكثافة (HDL)، والدهون الثلاثية (TG)، ومستويات بروتين سي التفاعلي عال الحساسية (hs-CRP)، والتي تم تقييمها على خط الأساس وأيضا بعد ستة أشهر. تم تحليل البيانات باستخدام برنامج SPSS الإصدار 21. لم يكن هنالك فرق كبير على خط الأساس في النمط الحياتي وتدابير المخاطر الأيضية القلبية بين المجموعات. أظهرت تقييمات ما بعد التدخل أنه لا توجد تغييرات كبيرة في مستوى النشاط البدني والاستهلاك الغذائي باستثناء انخفاض في كمية الدهون المشبعة بين البالغين الذين يعانون من السمنة المفرطة في المجموعة الضابطة بعد ستة أشهر ($p > 0.05$). أفاد تقييم ما بعد التدخل أيضا أن مجموعة التدخل أدت إلى انخفاض كبير في مؤشر كتلة الجسم، ومحيط الخصر، وضغط الدم الانبساطي، وارتفاع كبير في مستويات HDL ($p > 0.05$ جميعها). وبالمثل أظهرت المجموعة الضابطة انخفاضا كبيرا في مستويات محيط الخصر والدهون الثلاثية بعد ستة أشهر ($p > 0.05$) ومع ذلك أظهرت المجموعة الضابطة ارتفاعا ملحوظا في مستويات FBG بعد ستة أشهر ($p > 0.05$)، بينما استقرت في مجموعة التدخل. حققت مجموعة التدخل أيضا انخفاضا في مستويات LDL و hs-CRP بعد ستة أشهر. ومع ذلك لم تكن هناك فروق ذات دلالة إحصائية في النمط الحياتي وتدابير المخاطر الأيضية القلبية بين المجموعتين بعد ستة أشهر ($p > 0.05$)، وضحت هذه الدراسة أن البرنامج التدخلي بالبنية التحفيزية بقيادة الممرضات قد يكون مفيدا لعلاج السمنة، وكذلك لاستقرار ضغط الدم الانبساطي، ومستويات hs-CRP و FBG في البالغين الذين يعانون من السمنة. ومن ثم فإنه بالإمكان الآن إجراء تجربة أكبر مع بعض التعديلات، مبلغ عنها بشكل منطقي من خلال هذه التجربة، معتمدة على هذه النتائج وتؤكددها في نفس الوقت.

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DECLARATION

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ACKNOWLEDGEMENTS

First and foremost, all thanks to Allah the Almighty, for the strength given to me to complete this PhD project. I would like to express my deepest thanks and recognition to Kulliyah of Nursing, International Islamic University Malaysia, for giving me the precious opportunity to pursue my study in this excellent institution. Special thanks to my main supervisor, Assistant Professor Dr Azlina binti Daud, as well as my co-supervisors, Assistant Professor Dr Muhammad Lokman bin Md. Isa, Associate Professor Dr Samsul bin Deraman, and Associate Professor Dr Muhammad bin Ibrahim, for their continuous support, encouragement and leadership, for which I will be forever grateful.

I am grateful to my husband, Mohamad Firdaus bin Mohamad Ismail, for his patience and support throughout my PhD journey. My dear parents, Shahadan bin Abd. Manan and Yon Nazihah binti Abu, my siblings, my daughters: Balqis Miftahul Jannah and Ainul Mardhiah too deserve my sincere gratitude for their unwavering belief in my ability to accomplish this goal. Thank you for your support, love and patience. It is my utmost pleasure to dedicate this work to them.

Last but not least, I wish to express my highest appreciation and thanks to those who provided their time, effort and support for this project.

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LIST OF ABBREVIATIONS

AE	Adverse event
BMI	Body mass index
BP	Blood pressure
CDC	Centers for Disease Control and Prevention
CMR	Cardiometabolic risk
CPG	Clinical Practice Guidelines
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
e.g.	For example
etc	and the rest
FBG	Fasting blood glucose
g	Gram
HDL	High-density lipoprotein
hs-CRP	High-sensitivity C-reactive protein
IIUM	International Islamic University Malaysia
IMB	Information-Motivation-Behavioural skills model
IREC	IIUM Research Ethics Committee
Kcal	Kilocalorie
Kg/m ²	kilograms per square metre
LDL	Low-density lipoprotein
LMI	Lifestyle modification intervention
mg	Milligram
mg/dL	Milligram per decilitre
mmHg	Millimetre of mercury
mmol/L	Millimoles per litre
MOH	Ministry of Health of Malaysia
NHMS	National Health and Morbidity Survey
NIH	National Institutes of Health
RCT	Randomised controlled trial
SAE	Serious adverse event
SBP	Systolic blood pressure
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
TEI	Total daily energy intake
TG	Triglyceride
WC	Waist circumference
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 THE BACKGROUND OF THE STUDY

Poor lifestyle, including unhealthy dietary practices and physical inactivity, as a result of environmental and societal changes, is increasingly common in adults (World Health Organization [WHO], 2014). This poor lifestyle is a public health issue because it is the fundamental cause of non-communicable diseases (NCDs) including obesity and cardiometabolic diseases such as type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD) (Ministry of Health Malaysia [MOH], 2017b; WHO, 2014). In Asian countries, the prevalence of cardiometabolic diseases is at an alarming level and is the highest contributor to the region's disease burden (WHO, 2015a). In the countries of the South-East Asia Region including Bangladesh, India, Indonesia and Myanmar, CVDs cause an estimated 3.6 million deaths or a quarter of all deaths annually (WHO, 2011). Also, WHO (2012) pointed out that nearly 71 million of the population of countries in the South-East Asia Region in 2010 had diabetes. Similarly, in the countries of the Western Pacific Region including the Philippines, Australia and Malaysia, the epidemics of cardiometabolic diseases are roughly double the size of that in Europe (WHO, 2011b). Nonetheless, cardiometabolic diseases are highly modifiable through lifestyle modifications (Blüher et al., 2012; WHO, 2011).

In Malaysia, poor lifestyle, including unhealthy dietary practices and physical inactivity, has contributed to the obesity epidemics (Abdull Hakim, Muniandy, and Ajau Danish, 2012; Bachok, 2014; Cheng, 2013; Jamil, Singh, Ismail, and Omar, 2015; Mohamed et al., 2014). Obesity is defined as an abnormal or excessive fat accumulation that may impair health (WHO, 2014). There are several ways to

measure obesity, namely using the calculation of body mass index (BMI), waist circumference (WC) measurement, waist-to-hip ratio (WHR), skinfold thickness and high-tech imaging options, such as computed tomography (CT) and magnetic resonance imaging (MRI). Above all, BMI is the most inexpensive and accessible yet reliable method to measure obesity in adults (MOH, 2004; WHO, 2014). Globally, the United States of America (USA) Centers for Disease Control and Prevention (CDC), as well as the WHO, refer to adult obesity as an adult with a BMI of 30.0 kg/m² or higher (CDC, 2016; WHO expert consultation, 2004). Nonetheless, Asian populations found to have different associations between BMI, percentage of body fat, and health risks than do European populations and the WHO experts concluded that the proportion of Asian people with a high risk of T2DM and CVD is substantial at BMIs lower than the existing WHO cut-off point for overweight (≥ 25 kg/m²) (WHO Expert Consultation, 2004). Hence, the Malaysian Clinical Practice Guidelines (CPG) on obesity refer to adult obesity as an adult with a BMI of 27.5 kg/m² or higher (MOH, 2004). In other words, a lower cut-off point of BMI to define obesity in Malaysian adults might reflect that this population are at higher risk of developing obesity-related diseases such as T2DM and CVD, than the global population (Blackstone, 2016; MOH, 2004).

A cluster of risk factors that predispose to T2DM and CVD is referred to as cardiometabolic risk (CMR) (MOH, 2017b). CMR is a concern because it occurs in the “subclinical stage” in which it leads to the pathogenesis of T2DM and CVD, yet shows no recognisable signs and symptoms (Bhupathiraju and Hu, 2016; Chang et al., 2014). In general, there are fourteen CMR factors listed by Cefalu and Cannon (2007), namely, insulin resistance, hyperinsulinemia, elevated BMI or waist circumference (WC), high triglycerides (TG) level, low high-density lipoprotein (HDL) level, small

dense low-density lipoprotein (LDL) level, adipocyte dysfunction, elevated fasting blood glucose (FBG) level, fatty liver, increased blood pressure (BP) level, endothelial dysfunction, renal dysfunction, polycystic ovary syndrome, increased C-reactive protein (CRP) level or other inflammatory markers, hypercoagulability and atherosclerosis. However, the latest version of CPG of obesity (MOH, 2004), hypertension (MOH, 2013) and the Malaysian CPG of T2DM (MOH, 2015) highlighted five most significant CMR factors, which are being incorporated into the definition of metabolic syndrome. The five CMR factors are elevated WC measurement, elevated BP, FBG and TG levels and a reduced HDL level. Other than that, there is growing evidence stating that increased levels of high-sensitivity C-reactive protein (hs-CRP), indicating a subclinical inflammation state, also plays a significant role in the pathogenesis of CVD and T2DM in obese adults (Alissa, Al-Salmi, Alama, and Ferns, 2016; Misra and Khurana, 2011). The importance of assessing hs-CRP levels to provide incremental information to traditional risk factor assessment in certain asymptomatic individuals at intermediate CVD risk has been highlighted in the CPG for the prevention of CVD in women (MOH, 2008). Hence, this study chooses to measure the hs-CRP level together with five CMR factors of WC, BP, FBG, HDL, and TG level, thus these factors will be referred to as CMR profile (see Table 1.1).

Table 1.1 Cardiometabolic risk (CMR) profile

Risk factors	Cut-off points for CMR
Raised waist circumference (WC) ^a	≥ 80 cm for women ≥ 90 cm for men
Raised systolic blood pressure (SBP) ^b	120 to 139 mmHg
Raised diastolic blood pressure (DBP) ^b	80 to 89 mmHg
Elevated fasting blood glucose (FBG) ^c	≥ 6.1 to 6.9 mmol/L
Reduced high-density lipoprotein (HDL) ^d	≤ 1.0 mmol/L for men ≤ 1.3 mmol/L for women
Raised triglyceride (TG) ^d	> 1.7 mmol/L
Elevated high-sensitivity C-reactive protein (hs-CRP) ^d	> 2 mg/L

Note. Source: ^aCPG of Obesity (MOH, 2004); ^bCPG of Hypertension (MOH, 2013); ^cCPG of T2DM (MOH, 2015); ^dCPG of Dyslipidaemia (MOH, 2017a)

1.2 STATEMENT OF THE PROBLEM

The global prevalence of obesity in adults is alarmingly high (Blackstone, 2016). The data from the country profiles compiled by the WHO showed that the prevalence of obesity was highest among Americans (26%), followed by the adult population of the Eastern Mediterranean (24%) and Europeans (23%), and the prevalence of obesity was still less than 10% among adults in the Western-Pacific region (WHO, 2015). Even so, it is noticeable that the prevalence of obesity in countries of the Western-Pacific region is increasing. For instance, Huse et al. (2017) reported that the age-standardised prevalence of overweight and obesity combined among Australian adults has increased in recent decades, with a current prevalence of obesity of 27.9%. Other than that, a review paper on the epidemiology of strokes among Asian populations

reported a high prevalence of obesity, which resulted in a high mortality rate due to strokes in Asian countries (Venketasubramanian, Yoon, Pandian, and Navarro, 2017).

Similarly, looking at Malaysia as one country of the Western-Pacific region, the prevalence of obesity has been increasing over the years. The Malaysian National Health and Morbidity Survey (NHMS) reports showed that the prevalence of obesity (BMI ≥ 27.5 kg/m²) has increased from 27.2% in 2011 to 30.6% in 2015 (Institute for Public Health [IPH], 2015). Other than that, the NHMS 2015 also reported that the prevalence of obesity in Malaysian adults is higher than the global prevalence of obesity (IPH, 2015). These statistics revealed the importance of the issue of obesity in Malaysia. Particularly in Pahang, the NHMS report from the year 2008 to 2015 indicated that the prevalence of obesity is higher than in the general Malaysian adults' population and has been increasing along with the prevalence of obesity-related diseases such as undiagnosed hypertension and hypercholesterolemia (IPH, 2008; IPH, 2015). Pahang is the largest state in the east of Peninsular Malaysia, with a total population of 1.65 million (Department of Statistics Malaysia [DOSM], 2017). There are eleven districts in Pahang including Bera, Bentong, Cameron Highlands, Jerantut, Kuantan, Lipis, Maran, Pekan, Raub, Rompin and Temerloh, and Kuantan is its capital city, contributing the most extensive population concentration (Kuantan estimated population: 450,000) (DOSM, 2010). In Kuantan during the period in question, the majority of young adults practised unhealthy dietary intake with the majority eating snacks (95.5%), and fast food (97.8%) and having a sedentary lifestyle, with most of the leisure time spent on social media (72.1%), watching television (67.3%) and sitting passively (33.8%) (Institute for Youth Research Malaysia, 2016). Due to these unhealthy lifestyle behaviours, the risk of obesity increases (Chin, Kahathuduwa, and Binks, 2016). These findings point out the need to

modify the lifestyle behaviours of adults, or better yet, of obese adults in Kuantan, so that the behavioural changes can assist in overcoming obesity, thus avoiding the negative effects of obesity.

There are multiple negative effects of obesity, in terms of health outcomes, the quality of life and the financial status. Obesity affects health outcomes by causing insulin resistance (Karki, Ngo, Bigornia, Farb, and Gokce, 2014). Insulin resistance is a state in which a higher amount of insulin is required for its normal response, and the situation will disturb the regulation of blood glucose level (Iryani, Ismail, Samat, Zainol, and Eshak, 2014). In particular, the high concentration of adipose tissues in obese adults increases the delivery of free fatty acids from the systemic circulation to the peripheral tissue, which in turn reduces the glucose uptake to lead to an increase of systemic blood glucose level (hyperglycaemia) and hyperinsulinemia as in the hyperglycaemic state, more insulin is secreted to neutralise the blood glucose level (Cefalu, 2007c). After a while, the hyperglycaemic as well as the hyperinsulinemia states initiate insulin resistance and trigger various unfavourable pathways including the disturbance of glucose and uric acid metabolism, dyslipidemia (elevation of triglyceride and small dense low-density lipoprotein (LDL) molecules), hypertension, and elevation of CRP level, and subsequently leading to the development of T2DM and CVD (Aung, Lorenzo, Hinojosa, and Haffner, 2014).

Furthermore, obesity brings a significant negative impact on the quality of life of the individuals involved. Obesity causes limited mobility due to heaviness, reduced postural control, and stability (Forhan and Gill, 2013). Later, a condition called accelerating sarcopenia may develop, where the progressive loss of skeletal muscle mass and strength occurs and causes physical and functional disability (Anton, Karabetian, Naugle, and Buford, 2013). In the long term, the physical and functional

impairment can lead to unemployment (Kang, Lee, Lee, Linton, and Shim, 2013) and financial limitation (Cheah, 2014). Other than affecting the individual's physical state and mobility, obesity also causes negative body image, low self-esteem (MOH, 2004; Moy and Bulgiba, 2010), and depression (Lo Coco, Gullo, Salerno, and Iaconopelli, 2011). Eventually, these psychological disturbances may interfere with the personal, social, and occupational activities, which will result in a reduced quality of life.

In addition, obesity also affects the financial status from the perspective of the health care system and the employers (Zhang, Shrestha, and Li, 2014). According to Hammond and Levine (2010) and Mustapha (2014), the estimated direct and indirect cost of obesity is substantial. Specifically, Blackstone (2016) quantified that the global economic cost of obesity is about 2 trillion dollars annually. Also, Imes and Burke (2014) also stated that in the United States (US), obesity and obesity-related diseases contribute to significant economic implications for both the cost of treatment and the associated loss of productivity. As a result, allocation of funding to different healthcare sectors including the infrastructure and preventive medicine becomes insufficient. Besides that, obesity affects the financial status of the employers, as it may impose a financial situation on the employers due to loss of productivity (absenteeism on the ground of health reasons) of the obese employees (Zhang et al., 2014). According to Blackstone (2016), the absenteeism due to obesity also represents huge economic impacts on the employer (8.65 billion dollars per year expense). Therefore, treating obese adults by means of promoting weight loss and CMR reduction may result in improved productivity among obese adults and economic benefits to employers. Therefore, this study will provide an intervention targeted at obese adults to initially improve the health outcomes which subsequently will promote a better quality of life as well as financial security.

Across the world, there are three phases involved in the management of obesity, namely, lifestyle modification intervention (LMI), pharmacological intervention, and surgical intervention, and the pharmacological and surgical intervention is used as an adjunct to the LMI (MOH, 2004). LMI is the initial component of treatment for obese adults who are apparently healthy (with or without comorbidities), which includes dietary modification, exercise, and behavioural intervention (MOH, 2004; Zetaryalai and Abas, 2013). The objective of LMI is to achieve body weight loss by decreasing calorie consumption and increasing energy use. A periodic review of the progress of the weight loss, initially weekly to biweekly and subsequently monthly for at least one year are recommended (MOH, 2004).

Nevertheless, as the prevalence of obesity, as well as the T2DM and CVD among adults in Malaysia, is increasing by years, the effectiveness of the current standard practice of LMI is debatable. The main concern regarding the practical aspect of the standard LMI was the accessibility of the services, which refers to the screening activities and the treatment delivery was bound to the hospital and primary care clinic setting. It is undeniable that LMI services have helped, but the coverage of the services is limited. According to the report by the “Komuniti Sihat Perkasa Negara” (KOSPEN), a community health programme implemented by the MOH to promote healthy lifestyles, since the initiation of the KOSPEN programmes in 2013, still more than half of the Malaysian community is unaware of the KOSPEN programmes, and the report also revealed that the screening coverage was only 21% in 2016. This report suggests that the accessibility of the LMI services is limited (Institute for Public Health [IPH], 2016a). On top of that, the limitation in terms of low socioeconomic status, physical disturbance, and time limitation might also contribute to the reduced accessibility of the LMI services targeted at obese adults. Besides that, the issue of

accessibility to health care services has been highlighted as one of the challenges in implementing the Tenth Malaysian Plan (MOH, 2011c). Hence, this study believes that improving the accessibility of LMI for obese adults in a Malaysian healthcare setting might help increase the coverage of the LMI services thus making it possible to promote more body weight loss among obese adults and reduce the prevalence of obesity-related diseases in Malaysia.

In the previous Malaysian health plan (2011 to 2015), several strategies to increase the coverage of health care services included improving the existing facilities, such as those supporting information and communication systems (MOH, 2011c). Besides that, the current Malaysia Plan of Action for the Ministry of Health (2016–2020) stated that by increasing the number of new “1Malaysia Clinics” per year may improve the accessibility and coverage of health care services to the target populations (MOH, 2016). Nevertheless, the increased number of 1Malaysia clinics was not targeted to provide the focused care for the obese adults alone, rather it covers the general population for basic medical services for illnesses and injuries such as fever, cough, colds, wounds and cuts, diabetes, and hypertension (1Malaysia, 2018). Recent findings also indicate that the objective of the 1Malaysian clinic is not being met in terms of offering services that cater for the communities who have restricted access to health care services (Kenny, Omar, Kanavathi, and Madhavan, 2017).

In spite of previous strategies, the home visit approach has been shown to improve the accessibility and coverage of health care services in several specialties, including child health, pregnancy, postnatal care and elderly care (MOH, 2000; Stark et al., 2014; Tappenden, Campbell, Rawdin, Wong, and Kalita, 2012). Home visits can be defined as planned activities aimed at the promotion of health and prevention of disease (Health Technology Assessment Unit, 2017). A study by Wen et al. (2009)