

**School of Public Health**

**A Community-based Physical Activity and Nutrition  
Intervention for Adults with Metabolic Syndrome in Vietnam**

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**This thesis is presented for the Degree of  
Doctor of Philosophy  
of  
Curtin University**

**August 2017**

## **Declaration**

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) – updated March 2014. The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee (EC00262), approval number: HR139/2014.

Signature

A handwritten signature in blue ink, appearing to be 'Tran Van Dinh', with a long diagonal stroke extending upwards and to the right.

Tran Van Dinh

Date: 31/8/2017

## **ABSTRACT**

### ***Introduction***

With rapid economic growth over the last few decades, many developing countries in the Asia-Pacific region have experienced a dramatic transition in disease patterns, with the burden of non-communicable diseases (NCDs) now overtaking traditional communicable diseases. Similar to other countries in the region, the burden of NCDs is increasing in Vietnam, accounting for 75% of the total disease burden in 2007. Modifiable behavioural risk factors, such as physical inactivity and unhealthy diets, are strongly associated with the NCDs burden in Vietnam.

Metabolic Syndrome (MetS) is a clinical entity characterised by a constellation of metabolically related abnormalities, cardiovascular diseases, and type 2 diabetes risk factors including central obesity, impaired glucose metabolism, dyslipidaemia, and hypertension. MetS is prevalent among Vietnamese adults, especially those aged 50-65 years. The aim of this study is to develop, implement, and evaluate a community-based physical activity and nutrition intervention for adults aged 50-65 years with MetS in Vietnam.

### ***Methods***

A 6-month community based cluster-randomised controlled trial was conducted, targeting adults aged 50-65 years with MetS from 10 communes in Hanam province, northern Vietnam. Outcomes were collected from intervention and control groups at baseline and post-test.

The ten selected communes were randomly allocated to either the intervention group (five communes, n=214) or the control group (five communes, n=203). The

intervention group participants received a health promotion package, consisting of an information booklet, education sessions, walking group, and a resistance band. The control group participants received one session of standard advice during the six month period.

### ***Results***

At the end of the 6 months period, 175 intervention participants (response rate 81.8%), and 162 control participants (response rate 79.8%) completed the post-test assessment. After controlling for demographic and other confounding factors, the intervention participants showed significant increases in moderate intensity activity ( $p=0.018$ ), walking ( $p<0.001$ ), total physical activity ( $p=0.001$ ), as well as a decrease in mean sitting time ( $p<0.001$ ), relative to their control counterparts. Significant improvements in dietary behaviours were also observed, particularly reductions in animal internal organs intake ( $p=0.001$ ) and using cooking oil for daily meal preparation ( $p=0.001$ ).

Moreover, after controlling for the effects of clustering and confounding factors, the intervention group showed significant mean improvements in high-density lipoprotein cholesterol (+0.42 mM,  $p<0.001$ ), waist circumference (-1.63 cm,  $p<0.001$ ), waist-to-hip ratio (-0.024,  $p<0.001$ ), weight (-1.44 kg,  $p<0.001$ ), and body mass index (-0.59 kg/m<sup>2</sup>,  $p<0.001$ ) when compared to the control group. A reduction in the MetS proportion was found in both intervention and control groups ( $p<0.001$ ), decreasing to 56.0% and 75.9%, respectively, but the post-program proportion was significantly lower among the intervention participants ( $p<0.001$ ). Furthermore, the mean number of MetS components exhibited by individuals decreased significantly in the intervention group ( $p<0.001$ ), but not the control group ( $p=0.942$ ).

The process evaluation showed that most participants (87% to 96%) reported the program resources and strategies useful, assisting them to increase their physical activity level and improving their diet. The education sessions were the most preferred strategy (97%) with high attendance (>78% of participants).

### ***Conclusion***

The community-based physical activity and nutrition intervention program successfully improved physical activity and dietary behaviours and reduced MetS proportion with significant improvements in several metabolic and anthropometric parameters for adults with MetS in Vietnam. The program reached and engaged the majority of participants throughout the six-month intervention.

## **Acknowledgments**

I wish to extend my earnest appreciation and gratitude to the following people who have supported me with the development, implementation and evaluation of this research.

First of all, I would like to express my sincere thanks to my supervisor, Professor Andy Lee, for his guidance and support. He contributed greatly to making the process a valuable learning experience and was always available to discuss aspects of the research. Prof. Lee, thank you for your strongly and continuously support me since I was a Master student. Without your support, I cannot get the current achievements.

I would like to extend sincere thanks to my co-supervisors, Associate Professor Jonine Jancey, and Dr. Tony James, for their guidance and advice. Their encouragement and sharp eye for detail enhanced my learning experience. I have learn a lot knowledge and skills from you. Your help is very important to me in my academic life now and then.

I would like to offer my sincere gratitude to my Associate-supervisor, Professor Peter Howat who was available at all times, to discuss aspects of the research and I am grateful to him for enriching my learning experience. My sincere thanks are extended to Dr. Le Thi Phuong Mai, my Associate-supervisor, for her encouragement and support throughout the course of the research, especially data collection phase.

I am grateful to my chairperson, Associate Professor Sharyn Burns, for her sound advice and encouragement.

I acknowledge the Curtin University for its financial support for me to complete this course and the research. The PhD student has been awarded the International

Postgraduate Research Scholarship (IPRS) 2014 to pursue PhD degree at Curtin University. In addition, I acknowledge Curtin Postgraduate Student Association (CUPSA) for their added funding for data collection (CUPSA data collection grant). Thanks also to Professor Andy, Professor Peter, and A/Professor Jonine for your research funding. Without these funds, the project could not completed.

I would like to thank all of my colleagues in the National Institute of Hygiene and Epidemiology, Department of Community Health and Network Coordination, Hanam Provincial Preventive Medicine Centre, the ten study Commune Health Centre for their strongly supports to complete the study. Special thanks to Dr. Nguyen Tu Quyet, Dr. Nguyen Van Trong, Dr. Nguyen Thanh Duong for their willing helps for the study completion.

Finally, I would like to thank all of my family for their understanding, encouragement, patience and support, which has enabled me to complete this research program. Special thanks to my beloved wife, Nguyen Thi Thu Ha, and my little son, Tran Anh Duy, who always with me during the journey. I would like to say sorry to my little son for shouting you when I was stress due to study. It is time to spend more time to take care of you.

## **Statement of Contribution of Others**

The School of Public Health at Curtin University provided the research environment that supported the PhD candidate to undertake this research. The PhD candidate was the co-investigator of the project and active in designing the methodology and intervention, undertaking recruitment, implementing the intervention program, and data collection and analysis. The PhD candidate was responsible for writing all publications presented as part of the thesis, with input from co-authors. Details are provided below.

- **Professor Andy Lee** contributed as PhD supervisor and provided close and ongoing support and involvement with the study. He participated in the study and intervention design, read drafts and suggested improvements for all four publications.
- **Associate Professor Jonine Jancey** contributed as co-PhD supervisor and provided advice on different steps of the research project. She also participated in the study design, read drafts and suggested improvements for all four publications
- **Dr. Anthony James** contributed as PhD co-supervisor and provided advice on collection and analysis of blood samples. He also participated in the study design, read drafts and suggested improvements for all four publications.
- **Professor Peter Howat** contributed as PhD associate-supervisor and provided ongoing support and involvement with the study. He participated in the study and intervention design, read drafts and suggested improvements for all four publications.
- **Dr. Le Thi Phuong Mai** contributed as PhD associate-supervisor and provided assistance with recruitment and data collection. She read and approved drafts for publications 1-4.

Appendix A provides signed statements of the contribution of each co-author listed above.

## List of Publications

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532> [*Impact factor: 2.56*]
2. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9> [*Impact factor: 1.86*]
3. **Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113> [*Impact factor: 2.12*]
4. **Van Dinh Tran**, Jonine Jancey, Andy Lee, Anthony James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation. *Evaluation and Program Planning*. 61. 128-133. <https://doi.org/10.1016/j.evalprogplan.2016.12.012> [*Impact factor: 1.0*]

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## List of Abbreviations

ATP III	Adult Treatment Panel III
BMI	Body Mass Index
CVD	Cardiovascular diseases
FFQ	Food Frequency Questionnaire
HDL-C	High-density lipoprotein cholesterol
IPAQ-SF	International Physical Activity Questionnaire – Short Form
IDF	International Diabetes Federation
LDL-C	Low-density lipoprotein cholesterol
NCD	Non-communicable diseases
MetS	Metabolic syndrome
MET	Metabolic Equivalent Task
RCT	Randomised controlled trial
STEPS	STEPwise approach to Surveillance
T2D	Type 2 diabetes
TG	Triglycerides
VPAN	Vietnam Physical Activity and Nutrition
WC	Waist circumference
WHO	World Health Organisation

## **1. INTRODUCTION**

### **1.1 Background**

Vietnam is a developing country with a population of almost 90 million in the Asia-Pacific region (United Nations 2011). With rapid economic growth over the last few decades, many developing countries in the Asia-Pacific region have experienced a dramatic transition in disease patterns, with the burden of non-communicable diseases (NCDs) now outweighs that of infectious diseases (Binns and Boldy 2003). Similar to other countries in the region (Binns and Low 2016), the burden of NCDs is increasing in Vietnam (Nguyen et al. 2015), accounting for 75% of the total disease burden (Harper 2011). It is known that cardiovascular events alone are responsible for about 110,000 deaths each year or 20% of the total mortality. The prevalence of type II diabetes (T2D) has tripled in the last two decades and continues to rise (Harper 2011). Modifiable behavioural risk factors, such as physical inactivity and unhealthy diets, are strongly associated with the NCDs burden in Vietnam. It is estimated that 28.7% of Vietnamese adults are insufficiently active (<600 Metabolic Equivalent Task (MET)-min per week) (Harper 2011). In addition, household food consumption patterns have rapidly changed (National Institute of Nutrition of Vietnam 2010), with the energy intake from fat rising from 8.4% to 17.6% within the last two decades (National Institute of Nutrition of Vietnam 2010).

#### ***Metabolic Syndrome***

Metabolic Syndrome (MetS) is a cluster of risk factors for cardiovascular diseases (CVD) and T2D, including central obesity, impaired glucose metabolism, dyslipidaemia and hypertension (Alberti et al. 2009). People with MetS have three

times the risk of suffering a heart attack or stroke, two times the risk of dying from such an event (Zimmet, KG, and Serrano Rios 2005), and a five-fold increased risk of incurring T2D (International Diabetes Federation 2006). MetS has become a major public health concern globally with an estimated 25% of the world's adult population have MetS (Eckel, Grundy, and Zimmet 2005) and it is often undiagnosed (Blaha et al. 2008, Grundy et al. 2005).

### ***Metabolic syndrome in Vietnam***

In Vietnam, few studies have investigated the extent of MetS in detail. A study conducted in Ho Chi Minh City reported that 17.3% of adults aged 25-64 years have two or more risk factors of MetS (Trinh et al. 2010). Another study found that 18.5% of people aged >20 years in Ho Chi Minh City have MetS (Son le et al. 2005). Similarly, 15.7% of the population aged >15 years were identified with MetS in south central Vietnam (Tran, Truong, and Nguyen 2004). A recent study estimated that 16.3% of Vietnamese adults exhibit the syndrome, with Vietnamese aged 55-64 having the highest prevalence ( $\approx 27\%$ ) (Binh et al. 2014). Although limited data are available in the country, MetS is considered a major public health issue in Vietnam as its burden of disease is similar to that in developed countries (Tran, Truong, and Nguyen 2004).

### ***Risk factors of MetS***

Risk factors of MetS consist of unmodifiable factors (e.g. genes, aging), and modifiable factors (e.g. physical inactivity, overweight and obesity) (International Diabetes Federation 2006). Positive associations between sedentary and poor dietary behaviours and MetS have been found in previous studies (Kim et al. 2011, Nguyen et al. 2010, Trinh et al. 2010). Studies in Vietnam also demonstrated the links between

overweight and obesity, sedentary behaviours, and MetS (Son le et al. 2005, Trinh et al. 2010).

### ***Lifestyle interventions***

Lifestyle intervention refers to any intervention including exercise, diet, and at least one other component such as smoking cessation, counselling, and stress management (Sumamo et al. 2011), while physical activity and dietary intervention has only physical activity and dietary components. Lifestyle interventions to reduce energy intake and increase physical activity levels thereby enhancing energy expenditure are the first priorities of MetS management (National Heart Lung and Blood Institute 1998, Grundy et al. 2005). Several recent systematic reviews and meta-analysis have shown strong evidence of the effectiveness of physical activity and nutrition intervention on MetS prevention and management (Bassi et al. 2014, Yamaoka and Tango 2012). Despite such significant evidence emerging from developed countries, there is still a lack of intervention research in Southeast Asian countries. It is important to develop, implement and evaluate a pertinent lifestyle intervention program for Vietnamese adults with MetS where the context and setting are substantially different from developed countries.

### **1.2 Scope of the thesis**

This Vietnam Physical Activity and Nutrition (VPAN) program aims to develop, implement, and evaluate a community-based physical activity and nutrition intervention for Vietnamese adults aged 50 to 65 years identified as having MetS. It is hypothesised that after the six-month intervention, levels of physical activity, dietary behaviours, lipid profile and fasting glucose, as well as anthropometric measures

among the intervention group will demonstrate statistically significant improvements when compared to the control group.

This six-month community-based cluster-randomised controlled trial was conducted in ten communes in Hanam province, northern Vietnam. Outcomes were collected from intervention and control groups at baseline and post-test. The trial was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12614000811606). The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014) (Appendix G). Written informed consent was sought from each participant prior to entry into the trial.

### **1.2.1 Aim**

This project aims to develop, implement, and evaluate a community-based physical activity and dietary behavioural cluster-randomised controlled trial intervention for adults aged 50-65 years with MetS in Vietnam.

### **1.2.2 Objectives**

1. Design and implement a cluster-randomised controlled trial of a community-based intervention to improve the physical activity and dietary behaviours of adults aged 50-65 years with MetS in Vietnam;
2. Assess at post-test the change in physical activity level and dietary behaviours of the intervention group relative to the control group;
3. Assess at post-test the change in features of MetS, MetS status, and other risk factors of the intervention group relative to the control group;

4. Assess the satisfaction of the intervention strategies and resources by the intervention group; and
5. Assess the fidelity, the participation, reasons for completing, and not-completing the intervention program.

### **1.3 Significance**

Levels of physical activity and nutritional intake are significantly associated with MetS and related NCDs. By improving the physical activity levels of adults and their dietary behaviours through a community-based lifestyle intervention program, this research contributed to the knowledge base of the risk factors associated with MetS and related chronic diseases. This is the first randomised controlled trial ever undertaken on Vietnamese adults with MetS according to our extensive literature search. Findings are potentially applicable for NCDs prevention in Vietnam.

### **1.4 Outline of the thesis**

This thesis contains 6 chapters, including (1) Introduction; (2) Literature review; (3) Methodology: Includes 1 publication; (4) Results: Includes 3 publications; (5) Discussion, and (6) Conclusions and Recommendations.

## **2. LITERATURE REVIEW**

### **2.1. Introduction**

MetS is a cluster for risk factors of CVD and T2D (Alberti et al. 2009). It has been demonstrated that the syndrome is common and that it has a rising prevalence worldwide (25%) (Grundy 2016), which relates largely to increasing obesity and sedentary lifestyles. As a result, MetS is now both a public health and a clinical problem (Alberti et al. 2009). There is evidence that lifestyle interventions are an effective way to prevent and manage MetS (Bassi et al. 2014). Given the increasing burden of NCDs as well as increasing prevalence of their risk factors, such as unhealthy diet, overweight/obesity, and insufficient physical activity, in Vietnam, it is important to develop and test the potential intervention strategies for people with MetS. This chapter provides an overview of definitions, epidemiology, and the control and prevention of MetS.

### **2.2. Metabolic syndrome review**

#### **2.2.1 Definitions**

Several definitions of MetS have been proposed by different organisations over the past decades. The first formalised definition was proposed in 1998 by a consultation group on the definition of diabetes for the World Health Organization (WHO) (WHO 1999). This group emphasized insulin resistance as the major underlying risk factor for T2D and required evidence of insulin resistance for diagnosis. A diagnosis of the syndrome by WHO criteria could thus be made on the basis of several markers of insulin resistance plus two additional risk factors, including obesity, hypertension, high triglyceride (TG) concentration, reduced high-density lipoprotein cholesterol (HDL-C) level, or microalbuminuria. In response, the European Group for the study

of insulin resistance countered with a modification of the WHO definition in 1999 (Balkau and Charles 1999). In 2001, the National Cholesterol Education Programme (NCEP) Adult Treatment Panel III (ATP III) proposed a new definition of MetS (ATP III 2002). The ATP III definition did not mention about insulin, but defined the MetS definition with at least three out of five components, including abdominal obesity, elevated blood pressure, reduced HDL-C, elevated TG level, and raised fasting plasma glucose (ATP III 2002). The American Association of Clinical Endocrinologists in 2003 supported the views regarding the definition of the syndrome (Einhorn et al. 2003).

The International Diabetes Federation (IDF) reported another definition of MetS in 2005 (International Diabetes Federation 2006). The definition has similar components to the ATP III (ATP III 2002), however, increased waist circumference (WC) was defined as a compulsory component of the syndrome. In 2005, the original ATP III criteria were revised to require a lower fasting glucose level [ $\geq 100$  mg/dl (5.6 mmol/l)] in accordance with the revised definition of impaired fasting glucose of the American Diabetes Association (Grundy et al. 2005). These definitions exhibit common features, but their differences in several parameters have led to challenges in terms of applicability and establishing positive predictive values (Kaur 2014) (Table 2.1). Among them, the level of WC that defines abdominal obesity varies between different populations and ethnicities and hence there is a need for different cut-off values for this parameter. Consequently, the IDF has proposed a new set of WC criteria with ethnic/racial specific cut-offs that are applicable across populations (Alberti, Zimmet, and Shaw 2006) (see Table 2.2). The proposed cut-points for WC based on previous recommendations from different organisations, and vary for different ethnic

populations (Alberti, Zimmet, and Shaw 2006). For example, European males, and females are  $\geq 94$  cm, and  $\geq 80$  cm, respectively,  $\geq 102$  cm for American males, and  $\geq 88$  cm for American females,  $\geq 90$  cm, and  $\geq 80$  cm for South Asians and Chinese males, and females, respectively (Alberti, Zimmet, and Shaw 2006).

A joint interim statement of harmonising the MetS has been made between the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity in 2009 (Alberti et al. 2009). The expert groups agreed that there should not be an obligatory component, but that waist measurement would continue to be a useful preliminary screening tool. Three abnormal results out of five would qualify a person for MetS. A single set of cut points should be used for all components except WC, for which further work is required. In the interim, national or regional cut points for WC can be used (Table 2.3).

**Table 2.1. Criteria for different Metabolic Syndrome definitions**

<b>Criteria</b>	<b>WHO (1998) (WHO 1999)</b>	<b>European Group for the study of Insulin Resistance (1999) (Balkau and Charles 1999)</b>	<b>ATP III 2001 (ATP III 2002)</b>	<b>American Association of Clinical Endocrinologists (2003) (Einhorn et al. 2003)</b>	<b>IDF (2005) (International Diabetes Federation 2006)</b>
Insulin resistance	Impaired glucose tolerance, Impaired fasting glucose, T2D, or lowered insulin sensitivity <i>plus any 2 of the following</i>	Plasma insulin >75th Percentile <i>plus any 2 of the following</i>	None, <i>but any 3 of the following 5 features</i>	Impaired glucose tolerance or Impaired fasting glucose <i>plus any of the following based on the clinical judgment</i>	None
Body weight/WC	Men: waist-to-hip ratio >0.90;  Women: waist-to-hip ratio >0.85 and/or BMI > 30 kg/m <sup>2</sup>	WC ≥94 cm in men or ≥80 cm in women	WC ≥102 cm in men or ≥88 cm in women	Body Mass Index (BMI) ≥ 25 kg/m <sup>2</sup>	Increased WC (population specific) <i>plus any 2 of the following</i>
Lipids	TG ≥150 mg/dL and/or HDL-C <35	TG ≥150 mg/dL and/or HDL-C <39	TG ≥150 mg/dL and/or HDL-C <40 mg/dL	TG ≥150 mg/dL and HDL-C <40 mg/dL in	TG ≥150 mg/dL or HDL-C <40 mg/dL in men or <50

	mg/dL in men or <39 mg/dL in women	mg/dL in men or women	in men or <50 mg/dL in women	men or <50 mg/dL in women	mg/dL in women or on HDL-C
Blood pressure	≥140/90 mmHg	≥140/90 mmHg or on hypertension	≥130/85 mmHg	≥130/85 mmHg	≥130/85 mmHg or on hypertension
Glucose	Impaired glucose tolerance, Impaired fasting glucose, or T2D	Impaired glucose tolerance or Impaired fasting glucose (but not diabetes)	>110 mg/dL (includes diabetes)	Impaired glucose tolerance or Impaired fasting glucose (but not diabetes)	≥110 mg/dL (includes diabetes)
Other	Microalbuminuria: Urinary excretion rate of >20 mg/min or albumin: creatinine ratio of >30 mg/g.			Other features of insulin resistance <sup>b</sup>	

<sup>a</sup>Insulin sensitivity measured under hyperinsulinemic euglycemic conditions, glucose uptake below lowest quartile for background population under investigation. <sup>b</sup>Includes family history of T2D, polycystic ovary syndrome, sedentary lifestyle, advancing age, and ethnic groups susceptible to T2D.

**Table 2.2. Criteria for clinical diagnosis of harmonising the Metabolic Syndrome**

Measure	Categorical cut points
Elevated WC	Population- and country-specific definitions
Elevated TG concentration (drug treatment for elevated TG concentration is an alternate indicator)	TG $\geq$ 150 mg/dL (1.7 mmol/L)
Reduced HDL-C concentration (drug treatment for reduced HDL-C concentration is an alternate indicator)	<40 mg/dL (1.0 mmol/L) in males; <50 mg/dL (1.3 mmol/L) in females
Elevated blood pressure (antihypertensive drug treatment with a history of hypertension is an alternate indicator)	Systolic $\geq$ 130 and/or diastolic $\geq$ 85 mmHg
Elevated fasting glucose concentration (drug treatment of elevated glucose concentration is an alternate indicator)	$\geq$ 100 mg/dL

**Table 2.3. Current recommended country-/ethnicity-specific values for waist circumference**

Country/ethnic group	Waist circumference (cm)	
	Male	Female
Europeans	≥ 94	≥ 80
South Asians	≥ 90	≥ 80
Chinese	≥ 90	≥ 80
Japanese	≥ 85	≥ 90
South and Central Americans	Use South Asian recommendations until more specific data are available	
Sub-Saharan African origin Eastern Mediterranean and Arab populations	Use European data until more specific data are available.	

### 2.2.2 Pathogenesis

It is still unclear the pathogenesis of the MetS and its components. It was hypothesized that insulin resistance, and abnormal fat distribution appear to be as potential causative factors of MetS (Alberti, Zimmet, and Shaw 2006). Recently, O'Neill & O'Driscoll (2015) has provided a closer associated pathologies of MetS, including dyslipidaemia, insulin resistance, and abdominal obesity.

### ***Dyslipidaemia***

Dyslipidaemia is a term used to describe abnormalities in lipid metabolism such as elevated fasting TG, low-density lipoprotein cholesterol (LDL-C), and low HDL-C concentrations (Kaur 2014). Excess free fatty acids, due to excess abdominal fat and its associated insulin resistance, increase the production of very LDC-C in the liver and decrease the clearance of LDL-C in the liver (Prasad et al. 2012). Additionally, HDL-C is correlated inversely with insulin resistance (Blaha et al. 2008) and elevated fasting TG is associated with a low concentration of HDL-C and high concentrations of LDL-C (Ebbert and Jensen 2013). There is sufficient evidence to suggest that higher HDL-C concentration is associated with reduced CVD risk (Ebbert and Jensen 2013).

### ***Insulin resistance***

An early hypothesis was that insulin resistance is the cause of MetS (Reaven 1988). Insulin resistance is a “*pathophysiological condition in which a normal insulin concentration does not adequately produce a normal insulin response in the peripheral target tissues*” (Kaur 2014, p.6). It is widely believed to be a main feature of MetS, although the mechanistic link between insulin resistance and other MetS parameters is not fully discovered (Alberti, Zimmet, and Shaw 2006).

Resistance to the actions of insulin necessitate higher plasma insulin concentration in an attempt to maintain normoglycaemia (Han and Lean 2011). However continued insulin resistance can lead to hyperglycaemia (Zimmet, KG, and Serrano Rios 2005), and increased LDL-C concentration, TG concentration, and blood pressure (Grundy et al. 2004). Insulin resistance and hyperglycaemia are therefore strongly associated with other MetS parameters, particularly excess central adiposity (Grundy et al. 2004).

### ***Abdominal obesity***

Another view sees abdominal obesity as the main cause of MetS (Alberti, Zimmet, and Shaw 2006). Abdominal obesity is defined as an excess accumulation of visceral fat, which tends to be found in the abdominal cavity around major organs (ectopic fat), possibly resulting from excess energy storage in the liver, skeletal muscles, and the heart (Despres and Lemieux 2006). Abdominal obesity therefore increases the risk of T2D and CVD developments (Grundy 2012).

It is thought that increased concentration of circulating non-esterified fatty acids and adipokines resulting from excess abdominal fat which can lead to a proinflammatory and prothrombotic state and is thought to contribute to the development of insulin resistance and hyperglycaemia (Prasad et al. 2012, Grundy 2012). Increase circulating concentrations of free fatty acids can also lead to increased concentration of TG, and a subsequent lowering of HDL-C (Grundy 2012). In summary, excess abdominal fat leads to overall systemic inflammation (Kaur 2014), which increases the presence of the other MetS parameters (hypertension, insulin resistance, and dyslipidaemia) (Despres and Lemieux 2006).

### **2.2.3 Prevalence of Metabolic Syndrome**

Many studies have reported the prevalence of MetS among different populations in recent years worldwide. However in these studies different definitions of MetS have been used to determine the MetS prevalence.

#### ***Worldwide***

The high prevalence of MetS is now a global concern (Alberti et al. 2009), with an increasing trend worldwide, yet it is often undiagnosed (Blaha et al. 2008). It is

estimated that almost one-quarter of the global adult population have MetS (Grundy 2008). However, the prevalence of MetS varies, ranging from <10% to 84%, depending on the definition used, the region, sex, age and ethnicity of the population being studied (Kolovou et al. 2007).

High prevalence of MetS was reported among adult populations in the America region. Results from the National Health and Nutrition Examination Survey 1999-2002 in the United State of America showed high unadjusted prevalence of MetS, 34.5% (ATP III), and 39.0% (IDF) among the adult population (Ford 2005). Similarly, a study conducted in five major Central American populations aged  $\geq 20$  years from 2003 to 2006 showed that the overall standardized prevalence of MetS in the region was 30.3% (95% CI: 27.1, 33.4) using the ATP III definition (Wong-McClure et al. 2015). Lower prevalence of MetS was reported among Latin-American countries. A recent systematic review found that the general prevalence of MetS in this region was 24.9% (95% CI: 18.8, 43.3) (ATP III) (Marquez-Sandoval et al. 2011), lower than that the United States of America and Central American countries.

In Europe, a combined 11 European prospective cohort studies comprising 6156 men and 5356 women without diabetes aged from 30 to 89 years found that the overall prevalence of MetS was 15% (according to WHO) (Hu et al. 2004). A high prevalence of MetS according to different definitions was found from a nationally representative study in Australia. The prevalence of MetS using the ATP III, WHO, IDF, and European Group for the study of Insulin Resistance definitions was 22.1% (95% CI: 18.8, 25.4), 21.7% (19.0, 24.3), 30.7% (27.1, 34.3), and 13.4% (11.8, 14.9), respectively in this study (Cameron et al. 2007). High prevalence of MetS was also reported in Asian countries. A recent systematic review in South Asia found that the

weighted mean prevalence of MetS was 26.1% (ATP III), 29.8% (IDF), 32.5% (modified ATP III) and 14.0% (WHO) (Aryal and Wasti 2016). Results from the China Health and Nutrition Survey in 2009 among 7488 Chinese adults reported that the overall age-standardized prevalence estimates of MetS were 21.3% (95%CI: 20.4, 22.2), and 18.2% (95% CI: 17.3, 19.1) based on definitions of revised ATP III, and IDF, respectively (Xi et al. 2013).

A systematic review of the Gulf countries reported that the prevalence of MetS in this region was 10% to 15% higher than in most developed countries (Mabry et al. 2010). Generally higher prevalence rates for women were reported in these countries. For women, the prevalence of MetS ranged from 32.1% to 42.7% (ATP III) and from 36.1% to 45.9% (IDF), while ranging from 20.7% to 37.2% (ATP III) and from 29.6% to 36.2% (IDF) in men (Mabry et al. 2010). African countries could be regions that have the lowest prevalence of MetS, ranging from 0 to 7.9% by any criteria among males and females (Fezeu et al. 2007).

### ***Vietnam***

Relatively little is known about the prevalence of MetS in Vietnam. A study conducted in Ho Chi Minh City, a big city in Southern of Vietnam, in 2001 showed that the prevalence of MetS among adults  $\geq 20$  years was 18.5% (ATP III with WC for Asian population) (Son le et al. 2005). Another study conducted in Khanh Hoa province among healthy people aged  $>20$  years found a lower prevalence of MetS of 10% (Son le et al. 2005), using the same definition (Tran, Truong, and Nguyen 2004). A recent study conducted in northern Vietnam indicated that the prevalence of MetS among adults aged 35-65 years was 18% (ATP III with WC  $\geq 80$  cm for females, and  $\geq 90$  cm for males) (Duc Son et al. 2004). The study also suggested that 40% of Vietnamese

aged 40-64 years possess at least two of the five components of MetS, the so called “pre-MetS” (Binh et al. 2014).

Similar with previous worldwide reports, Vietnamese women have higher prevalence of MetS than men. Tran et al (2004) showed that the prevalence of MetS among females in a southern central province in Vietnam aged 35-54 years was almost three times higher than their male counterparts, 21.7%, versus 9.7%. A similar result was found in the North of Vietnam, females (18.5%), versus males (13.9%) (Binh et al. 2014). Prevalence of MetS increased with age was observed in all studies in Vietnam (Binh et al. 2014, Son le et al. 2005, Tran, Truong, and Nguyen 2004). For example, the lowest prevalence was indicated among the 40-44 age group, and reached a peak at the 60–64 age group (Binh et al. 2014).

Beside studies conducted among Vietnamese healthy adults, several studies targeted the prevalence of MetS among specific populations in Vietnam with small and purposive sample sizes, such as women with early rheumatoid arthritis, and healthy women (Dao, Do, and Sakamoto 2010), males with primary gout (Dao, Harun-Or-Rashid, and Sakamoto 2010), or diabetic patients (Yokokawa et al. 2010). In addition, one study conducted in Ho Chi Minh City in 2007 found 3.9% of high-school students aged 13-16 years had MetS (Hong, Trang, and Dibley 2012).

## **2.2.4 Metabolic syndrome risk factors**

### ***2.2.4.1 Physical activity***

It is defined physical activity as “*Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure*” (Caspersen, Powell, and Christenson 1985, p.126). Physical activity includes activities performed during daily life such as working, playing, housework, and travelling. However, physical

activity should be distinguished from exercise. Exercise is one type of activity that is planned, structured, and aims to improve or maintain physical fitness. It is considered as a subcategory of physical activity (WHO 2017).

Epidemiological studies reported significant negative associations between physical activity levels and the incidence of MetS. A recent meta-analysis of prospective cohort studies (n=64354) found that a high level of leisure time physical activity was associated with a decreased risk of MetS, relative risk = 0.80, 95%CI: 0.75, 0.85 (He et al. 2014). A recent study conducted in rural China also showed that the highest tertile of vigorous physical activity was associated with 15–40% decreased odds of MetS and all of its components, except for LDL-C in men (Xiao et al. 2016).

### ***Physical activity measurement in daily life***

Several methods are available to measure levels of physical activity (Sylvia et al. 2014). These include objective measures such as determining energy expenditure using doubly labelled water, and calorimetry, heart rate monitoring, motion sensors (e.g. accelerometer, pedometer), log books (Ainsworth, Bassett, et al. 2000, Schmidt, Freedson, and Chasan-Taber 2003, Tudor-Locke et al. 2002), and questionnaires (Craig et al. 2003, WHO 2006). The limitations of these methods are well-documented (Welk 2002). There is currently no gold-standard method for physical activity measurement (Terwee et al. 2010).

### ***Objective measures***

Accelerators and pedometers are popular and accurate instruments to measure physical activity (Sylvia et al. 2014). They have been used for decades in many studies. Accelerometers have grown in popularity and are considered as the criterion validity for physical activity measurement. However, they cannot record the movements of

upper body or non-ambulatory physical activity (Schmidt, Freedson, and Chasan-Taber 2003), and may be inaccurate in counting steps (McMurray et al. 2004). Moreover, due to their high cost, accelerators are not usually used in large-scale studies (Hallal et al. 2003, Jiang et al. 2006).

Pedometers are popular to measure physical activity in population-based studies (Schmidt et al. 2007). Being an inexpensive form of body motion sensor, the pedometer has the ability to capture lower intensity activities such as walking. It can be attached to a belt, beltless slacks, skirt or training suit buttons by a clip (Tudor-Locke and Lutes 2009). Pedometers offer a simple estimate of physical activity volume in terms of steps taken. A step is recorded after a vertical acceleration above the manufacturer-designed force sensitivity threshold of the pedometer. In the meantime, the electronic circuitry within a pedometer is designed to accumulate steps and display updated steps on a digital screen continuously (Tudor-Locke and Lutes 2009). While pedometers are designed to detect vertical accelerations at the hip, they cannot measure slow walking speeds, upper body movement, and activities such as swimming, cycling and weight training. They are also unable to record the intensity of different activities (Tudor-Locke et al. 2004, Tudor-Locke and Lutes 2009).

It is evident that moderate-intensity walking (3.0 METs) appears approximately equal to at least 100 steps per min (Marshall et al. 2009). At a rate of 100 steps per minute, current recommendations for moderate-intensity physical activity (WHO 2010) would equate to walking at least 3000 steps in 30 minutes on five days each week, or three daily bouts of 1000 steps in ten minutes on five days each week (Marshall et al. 2009).

### ***Physical activity log***

A physical activity log is a simple method for assessing physical activity because of its ease in application. This method can provide information about the type and duration of activities based on 24h-recall. Either a semi-structured or open-structured logbook can be developed and distributed to participants, who report their own daily activities and the duration of each activity in the logbook at the end of morning, afternoon, or before going to sleep. However, there are several limitations of this method. Firstly, it does not differentiate between performance of activity continuously say in a ten minute period or accumulation of bouts of activity (Ainsworth, Bassett, et al. 2000). Secondly, it may be difficult for some participants to recall the time or intensity of different activities. Thirdly, the analysis of data from this method is time consuming (Welk 2002). Nevertheless, it is still an acceptable method of physical activity assessment in conjunction with other objective measures (Welk 2002).

### ***Physical activity questionnaires***

Many physical activity questionnaires have been developed in the literature. According to recent reviews, a wide range of physical activity questionnaires are available for different age groups; 85 for adults (Chinapaw et al. 2010), 61 for youths (Forsen et al. 2010), and 13 for elderly people (Forsen et al. 2010). They typically focus on a specific age group and have limitations across settings and cultures (Lee, Macfarlane, et al. 2011). Therefore, international comparisons are difficult (Craig et al. 2003).

Two widely used physical activity questionnaires are the International Physical Activity Questionnaire (IPAQ) and the Global Physical Activity Questionnaire (Craig et al. 2003, WHO 2006). The IPAQ was developed as an instrument for physical

activity monitoring. It has been tested for reliability and validity in various cultures and settings (Craig et al. 2003). The IPAQ has four versions, long and short versions for use by either telephone or self-administered. The IPAQ long form consists of 31 items, whereas the IPAQ short form (IPAQ-SF) has 9 items (IPAQ 2005b, Craig et al. 2003). The short form collects physical activity information during the last seven days among people aged 15-65 years at three intensity levels: 1) vigorous; 2) moderate; 3) walking, as well as sedentary behaviours (Craig et al. 2003). The IPAQ long form and IPAQ-SF are recommended for research requiring detailed assessment, and for physical activity surveillance, respectively (Craig et al. 2003). To improve IPAQ, WHO developed the Global Physical Activity Questionnaire. The Global Physical Activity Questionnaire comprises 15 core questions, plus one expanded question recording physical activity in a typical week in certain extents, such as work, travel to and from places, recreational activities, and sedentary behaviour (WHO 2006). It is a major component of the WHO STEPS Instrument in its STEPwise approach to surveillance (WHO 2008).

Five validation studies on physical activity instruments have been conducted in the Vietnamese context for different target groups, such as adolescents, pregnant women, and adults (Lachat et al. 2008, Ota et al. 2008, Trinh et al. 2009, Au et al. 2010, Hong et al. 2012). The Global Physical Activity Questionnaire was tested for validity and reliability two times on adults aged 25-64 years in two provinces in Southern Vietnam (Trinh et al. 2009, Au et al. 2010). In addition, Au et al (2010) compared the reliability and validity of the IPAQ long form and the Global Physical Activity Questionnaire among Vietnamese adults aged 25-64 years. They concluded that the Global Physical Activity Questionnaire does not outperform the IPAQ and may be less reliable for persons with more variable physical activity. Recently, the IPAQ-SF was validated for

adults 50-65 years and shown that it is a reliable and reasonably valid instrument to assess and monitor habitual physical activity for older adults in Vietnam (Tran, Lee, et al. 2013).

### **Physical activity intensity**

Three levels of physical activity have been suggested to classify population activity levels. These are low, moderate, and high. The criteria for these levels are shown below (IPAQ 2005a).

#### ***Category 1 Low***

This is the lowest level of physical activity. Those individuals who do not meet criteria for Categories 2 or 3 are considered to have a 'low' physical activity level.

#### ***Category 2 Moderate***

The pattern of activity to be classified as 'moderate' is either of the following: a) 3 or more days of vigorous-intensity activity of at least 20 minutes per day; OR b) 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day; OR c) 5 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum total physical activity of at least 600 Metabolic Equivalent Task (MET) -minutes/week. Individuals meeting at least one of the above criteria can be defined as accumulating a minimum level of activity and therefore be classified as 'moderate'.

#### ***Category 3 High***

A separate category labelled 'high' is used to describe higher levels of physical activity. The two criteria for classification as 'high' are: a) vigorous-intensity activity

on at least 3 days achieving total physical activity of at least 1500 MET-minutes/week;  
OR b) 7 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving total physical activity of at least 3000 MET-minutes/week.

### **Metabolic Equivalent Task**

One MET is defined as the energy cost of sitting quietly, and is equivalent to a caloric consumption of 1 kcal/kg/hour (Ainsworth, Haskell, et al. 2000). Taking the different intensities of the activity components into account, reported weekly minutes spent are multiplied by 8 METs for vigorous activities, by 4 METs for moderate activities, and by 3.3 METs for walking. Energy expenditure per individual can be obtained by adding the MET-minutes of the three activity components.

### ***Recommendations for physical activity***

WHO has recommended physical activity levels for specific age groups (WHO 2010). In general, adults should do at least 150 minutes of moderate-intensity aerobic physical activity per week, or at least 75 minutes of vigorous-intensity aerobic physical activity per week. A combination of moderate- and vigorous-physical activity equivalent to the recommended is acceptable. However, the aerobic activity should be performed in bouts of at least ten minutes duration.

Additional health benefits will be gained if 300 minutes of moderate physical activity or 150 minutes of vigorous-intensity aerobic physical activity are performed per week, or an equivalent combination of moderate- and vigorous-intensity activity (WHO 2010).

A variety of types of physical activities are recommended. These include leisure time physical activity, transportation (walking or cycling), occupational (work), household chores, playing games, sports or planned exercise, in the context of daily, family, and community activities. Warming up and cooling down are recommended to avoid injury during exercise.

### ***Physical inactivity***

It is defined “*physical inactivity to be an activity level insufficient to meet present recommendations*” (Lee et al. 2012, p.5). The high prevalence of physical inactivity can be observed in both developed and developing countries, in particular with women (WHO 2011). A recent report summarised data from 105 countries worldwide showed that 31% of people aged 15 years and over are physically inactive (Hallal et al. 2012). However, the prevalence varied substantially across regions, countries and settings (Dumith et al. 2011, Nawi et al. 2009, Guthold et al. 2008). Hallal et al. (2012) reported the lowest prevalence of physical inactive in Southeast Asia (17.0%) whereas the highest prevalence of physical inactivity was found in American and eastern Mediterranean countries (43.0%). A study conducted in nine rural health and demographic surveillance system sites in five Asian countries using the Global Physical Activity Questionnaire showed variability of the physical inactivity prevalence (Nawi et al. 2009). For men, the prevalence ranged from 12% in Indonesia to 63% in Vietnam. Similar variability was reported for women, ranging from 11% in Vietnam to 65% in Bangladesh (Nawi et al. 2009). The study also showed that the two age groups 25-34 and 55-64 years were more prevalent (Nawi et al. 2009). According to a pooled analysis of three studies conducted between 2000 and 2004, which used the validated IPAQ-SF in 76 countries, the global physical inactivity prevalence was

21.4%, ranging from 2.6% in Comoros to 62.3% in Mauritania. A higher prevalence of physical inactivity was found among women, elderly people and those living in wealthier and urban countries (Dumith et al. 2011). Physical inactivity is now increasing in many nations with major implications for health in general and for NCDs in particular (WHO 2009).

### ***Physical inactivity in Vietnam***

Several studies applying the general principles of the WHO STEPwise approach to assess the risk factors of NCDs, including physical activity level, have been implemented in Vietnam (Harper 2011). However, without a consistent and reliable surveillance system for NCDs and risk factors (Harper 2011), the reported results have been inconsistent.

A high prevalence of physical inactivity had been reported in Ho Chi Minh City, 43.8% (Oanh et al. 2008), and in Can Tho, 32.7% (Pham et al. 2009). Similarly, a high but varied prevalence of physical inactivity was reported in Northern Vietnam using the STEPwise approach with the Global Physical Activity Questionnaire, ranging from 13% in Chilalab, Hai Duong to 58% in Ba Vi, Hanoi (Nawi et al. 2009). Recently, results from a nation-wide survey showed that 29% of the adult population (25-64 years old) were insufficiently active, especially for about one-third of younger females aged 25-34 years (Harper 2011). Because the Global Physical Activity Questionnaire is recommended for people less than 65 years old (WHO 2006), data on physical activity for elderly over 65 years were not collected.

### ***Physical inactivity and health***

Physical inactivity has been considered as the biggest public health problem of the 21<sup>st</sup> century (Blair 2009). It is the fourth leading risk factor for mortality and contributes

to 3.2 million deaths annually (WHO 2009). Lee and colleagues (2012) estimated that 6–10% of all deaths from NCD globally can be attributed to physical inactivity. It is considered to be the principal cause for almost 21-25% of breast and colon cancer, 27% of the diabetes and approximately 30% of ischaemic heart diseases (WHO 2009).

Positive association between physical inactivity and MetS has been suggested in recent studies. A study of adults aged over 50 years conducted in Brazil showed that the occurrence of MetS was higher among those with the lowest percentile of leisure-time activity (Odds ratio = 1.48 (95% CI:1.08 – 2.05) (Turi et al. 2016). Similarly, another cross-sectional study also reported that lower physical activity level was associated with a higher prevalence of MetS ( $p < 0.001$ ) (Najafian et al. 2014).

#### ***2.2.4.2 Sedentary behaviour***

Pate, et al. (2008, p.174) defined that sedentary behaviour refers to “*activities that do not increase energy expenditure substantially above the resting level and includes activities such as sleeping, sitting, lying down, and watching television, and other forms of screen-based entertainment*” with energy expenditure at the level of 1.0-1.5 MET (Pate, O'Neill, and Lobelo 2008). Sedentary is not the same definition as physical inactivity or light physical activity since different MET activities are defined for these intensities (Pate, O'Neill, and Lobelo 2008). The association between sedentary behaviours and overweight/obesity among children (Troost et al. 2001), risk of obesity and T2D (Healy et al. 2007), and all-cause mortality (Crespo et al. 2002) have been well documented. A meta-analysis was conducted to assess the association between sedentary behaviour and MetS. The results showed that greater sedentary time increased the odds of MetS by 73% (OR=1.73, 95%CI: 1.55-1.94). The association was not affected by MetS definition, measurement of sedentary behaviour or sex

(Edwardson et al. 2012). Increase in the duration and percentage of sedentary time was associated with an increased metabolic risk in adults, whereas an increase in breaks from sedentary behaviour was associated with a decrease metabolic risk (Healy et al. 2008).

### ***Sedentary behaviour measurements***

Sedentary behaviour can be measured by methods similar to those for physical activity measurements, including subjective and objective measures (Reilly et al. 2008). For subjective measures, questionnaires have been developed and widely used to measure the sedentary behaviours. It captures daily television viewing time as a proxy marker of overall sedentary behaviours (Clark et al. 2009). However, poor validity has been consistently reported due to the lack of a gold standard reference measure of the behaviour (Dusenbury et al. 2003).

To improve the quality of sedentary behaviour measures, objective methods have been developed. The use of accelerometers and posture monitors can provide accurate measurement of physical activity and sedentary behaviour (Reilly et al. 2008). Accelerometers, in particular, allow researchers to measure physical activity, over the range from sedentary to vigorous intensity, in free-living subjects over a number of days (Reilly et al. 2008).

### ***2.2.4.3 Diet***

#### ***Diet measures***

Several methods are available for nutritional assessment, including 24 hour recall, food record, dietary history (Cantwell et al. 2005), biochemical markers (Arab 2003, Actis et al. 2005), and food frequency questionnaires. Each of these methods has benefits

and weaknesses accommodating different needs and target groups (Magkos and Yannakoulia 2003). The instruments that are capable of collecting detailed intake data are resource-intensive, expensive, and time-consuming, because they require a trained interviewer to administer (24-hour recall and dietary history) and are therefore not suitable for large studies (Kirkpatrick et al. 2014). Self-administered surveys such as dietary records and food frequency questionnaires are more suitable for large epidemiological studies, yet impose a relatively large respondent burden. They also assess usual intake rather than actual intake, and are subject to recall bias (Shim, Oh, and Kim 2014). Screeners, or food behaviour questionnaires, are useful in situations where rigorous assessment of dietary intake is impractical (Shim, Oh, and Kim 2014).

The WHO STEPwise approach to Surveillance (STEPS) is a simple, standardized method for collecting, analysing and disseminating data for NCD risk factors (WHO 2008). Diet behaviours measure is a component of this instrument (WHO 2008). The core questions of this questionnaire include fruit and vegetables intakes. Expanded questions such as oil or fat for meal preparation at home, and the frequency of dining-out meals per week are also added (WHO 2008).

In Vietnam, four validation studies of FFQ had been undertaken (Hong, Dibley, and Sibbritt 2010, Khan et al. 2008, Kusama et al. 2005, Ngoan le et al. 2008). However, two of them focused on assessing vitamin C (Ngoan le et al. 2008) and calcium intake (Khan et al. 2008), while another targeted adolescents (Hong, Dibley, and Sibbritt 2010). Only one study considered the validity and reproducibility of a FFQ for adults residing in Ho Chi Minh City, South Vietnam (Kusama et al. 2005). Because eating habits and the availability of food items vary greatly depending on cultural, ethnic and geographical areas, every FFQ should be tested with respect to the target group of

interest (Wakai 2009). Tran et al. (2013) confirmed the validity and reliability of a semi-structured FFQ to assess the habitual dietary intake in the North of Vietnam (Tran, Hoang, et al. 2013). Recently, the WHO STEPwise methodology has been adopted to assess the risk factors for NCDs in Vietnam (Bui et al. 2016).

### ***Food Based Dietary Guidelines in Vietnam***

From 1995 to the present, several versions of food based dietary guidelines have been developed and revised every 5 years by the Ministry of Health of Vietnam (Hop le, Van, and Thanh 2011). The guidelines for the period 2015-2020 has been released to give advice for the general Vietnamese population (National Institute of Nutrition of Vietnam 2013).

The Vietnam Food Based Dietary Guidelines is a three-dimensional food pyramid to represent the guideline messages (see Fig. 2.1). The pyramid is divided into seven layers according to the recommended levels of consumption. The guidelines are summaries in ten messages which make the guidelines easy to remember (National Institute of Nutrition of Vietnam 2013).

# THÁP DINH DƯỠNG CÂN ĐỐI

(Tháp Dinh dưỡng cân đối dành cho người trưởng thành. Giai đoạn 2010-2020)



Mức tiêu thụ Lương thực-Thực phẩm trung bình của một người trưởng thành trong 1 tháng

*Dinh dưỡng hợp lý là nền tảng của Sức khỏe, Tâm vóc và Trí tuệ*

Thiết kế và in: Trung tâm Truyền thông giáo dục dinh dưỡng VIÊN DINH DƯỠNG - BỘ Y TẾ



**Figure 2.1. Vietnam Food Based Dietary Guidelines 2015-2020.**

Source: <http://www.fao.org/3/a-as981o.pdf>

#### ***2.2.4.4 Overweight/obesity***

Overweight and obesity have been well-documented as the risk factors of many NCDs such as T2D and CVD (WHO Expert Consultation 2004), and MetS (Grundy 2016). Overweight and obesity are classified by BMI, calculating by weight in kilograms divided by height in metres squared ( $\text{kg}/\text{m}^2$ ). In 1993, WHO proposed BMI cut-off values of  $\geq 25$  as overweight or obese. Based on scientific evidence in the later years, WHO experts proposed new BMI cut off points for different populations (WHO Expert Consultation 2004), of which focusing on Asian populations. WHO has developed a new BMI classification for Asian countries, for the following reasons (WHO Expert Consultation 2004). Firstly, a high prevalence of T2D and increased cardiovascular risk factors were found in parts of Asia where the average BMI is below the cut-off point of  $25 \text{ kg}/\text{m}^2$ . Secondly, there was increasing evidence that the associations between BMI, percentage of body fat, and body fat distribution differ between populations. In particular, some Asian adults have a higher percentage of body fat than white or European adults for the same BMI. Thirdly, there had been two previous attempts to interpret the BMI cut-offs in Asian and Pacific populations (James, Chunming, and Inoue 2002). Therefore, a new set of BMI cut off values has been suggested for Asian adults, namely, BMI  $< 18.5$  as underweight;  $18.5\text{--}23$  as normal;  $23\text{--}27.5$  as overweight; and  $> 27.5$  as obese (WHO Expert Consultation 2004).

In addition to the BMI, WC is another measure of overweight, and obesity. The abdominal obesity is one component of MetS regardless of its definition versions (Kaur 2014). However, the cut-off values remain a controversial issue since different cut-off points were proposed by different organisations (Alberti et al. 2009). A set of recommended WC thresholds for abdominal obesity for different populations was launched in 2009 (Alberti et al. 2009). These thresholds included recommendations

from different organisations such as WHO, IDF, Health Canada, and cover all of the regions globally.

The waist/height ratio (waist circumference divided by height, both measured in centimetres) has been advocated as an effective and convenient measure of central adiposity that could potentially be superior to BMI alone in determining cardiometabolic risk (Lee et al. 2008). A waist/height ratio cut off of 0.5 is generally accepted as a universal cut off for central obesity in children (aged  $\geq 6$  years) and adults in both different sex and ethnic groups (Schneider et al. 2011).

Vietnam is a country in the Southeast Asian region. It, therefore, adopted the cut off points for overweight and obesity classification for Asian population with BMI  $\geq 23$  (WHO Expert Consultation 2004). This criteria of BMI has been used national wide (National Institute of Nutrition of Vietnam 2010). Similar to the BMI, Vietnam adopts the WC criteria of central obesity for Asian population,  $\geq 90$  cm for men, and  $\geq 80$  cm for women (Binh et al. 2014).

### **2.2.5 Populations with increased prevalence of metabolic syndrome**

A higher prevalence of MetS among women than men has been found in the majority of studies (Ford 2005). For example, among the Central American populations, 39.4% (95% CI: 36.6, 42.1) females and 21.3% (95% CI: 17.4, 25.4) males have MetS (Wong-McClure et al. 2015). A systematic review also reported a higher prevalence in women (25.3%) than men (23.2%) among Latin-American populations (Marquez-Sandoval et al. 2011). Similarly in American countries, higher prevalence in females than males was reported in South Asia region (ATP III: 29.5% vs 22.1%; IDF: 34.3% vs 18.8 %; modified ATP III: 35.8% vs 28.8%) (Aryal and Wasti 2016), China (women: 20.0% (95%CI: 18.8, 21.2; men: 16.2% (95%CI: 15.0%, 17.4%) (Xi et al. 2013).

The prevalence of MetS was observed to increase with age in the vast majority of studies. A study in China showed the crude prevalence of MetS among the age groups 18-39, 40-59, and  $\geq 60$  were 12.4%, 29.9%, and 27.6%, respectively based on the revised ATP III (Xi et al. 2013). Another study with a nationally representative sample of 15,540 Chinese adults aged 35-74 years in 2000-2001 reported that the age-standardised prevalence of MetS in women was almost double that of men, 17.8% versus 9.8% (Gu et al. 2005). Similarly, the results from the Korea National Health and Nutrition Examination Survey, 2007-2008 showed MetS prevalence increased with age, from 4.6% at age 19-29 years to 25.0% at age 50-65 years (Lim et al. 2012).

Similar to studies worldwide, Vietnamese women have a higher prevalence of MetS than Vietnamese men. The prevalence of MetS among females in a Southern central province in Vietnam aged 35-54 years was almost three times higher than their male counterparts, 21.7%, versus 9.7% (Tran, Truong, and Nguyen 2004). In addition, prevalence of MetS increased with age in Vietnam (Binh et al. 2014, Son le et al. 2005, Tran, Truong, and Nguyen 2004). The lowest prevalence was indicated in the 40-44 age group, and reached a peak at the 60-64 age group (Binh et al. 2014). The study also suggested that 40% of Vietnamese aged 40-64 years possess at least two of the five components of MetS (Binh et al. 2014).

### **2.2.6 Metabolic syndrome control and prevention**

Disease prevention is a range of strategies to reduce the risk factors or increase protective factors for health issues. Therefore, it can modulate the prevalence and severity of diseases (Hermosilla et al. 2017). Although, prevention has its limitations, it has potentially profound benefits (Hermosilla et al. 2017).

While primary prevention is defined as the prevention of initial occurrence of a disorder, secondary prevention refers to arrest the disease, and its subsequent effects by early diagnosis; or reduce the development of chronic conditions (Nutbeam 1986). Due to the links between MetS and NCD such as T2D and CVD, both primary and secondary prevention of the components of MetS or the cluster of MetS can delay or revert the progression of these diseases. The sections below present the primary and secondary prevention of MetS, mainly focusing on the components of MetS. In addition, effectiveness of lifestyle modification interventions targeting adults with MetS will also be discussed.

#### ***2.2.6.1 Primary prevention***

In the context of MetS, primary prevention includes interventions to address the major risk factors such as poor diet, physical inactivity, sedentary behaviour, and overweight/obesity. These interventions target individuals who may be at risk but not yet diagnosed with MetS.

A meta-analysis of nine studies found that the physical activity, dietary and/or combined interventions of at least 12 months are associated with declines in the fasting glucose tolerance compared to the control group (standardised mean difference -0.56, 95% CI: -1.01 to -0.10) (Gong et al. 2015). The study also found that either dietary or physical activity intervention only reduced fasting plasma glucose in the intervention group (Gong et al. 2015). Another systematic review confirmed the efficacy of lifestyle interventions in reducing the development of diabetes in populations with elevated glucose tolerance and other risk factors of MetS (Yoon, Kwok, and Magkidis 2013). For example, the American Diabetes Prevention Program confirmed the effectiveness of lifestyle interventions on reduction of diabetes incidence and other risk factors

(Diabetes Prevention Program Research Group 2002). The program consisted of 3,234 participants, of whom 1,079 belonged to the intervention group. The intervention included training sessions with booklet, self-monitoring weight, dietary modification, and physical activity improvement (The Diabetes Prevention Program Research 2002).

In a recent systematic review and meta-analysis of 56 studies of lifestyle interventions for overweight and obese populations significant improvements in risk factors for T2D and CVD risk factors were found (Baillot et al. 2015). Results from this review showed a mean reduction of WC (-4.7; 95% CI: -8.01, -1.555), diastolic blood pressure (-4.64; 95% CI: -6.71, -2.57), and fasting glucose (-0.53; 95% CI: -9.14, -2.44) (Baillot et al. 2015). In addition, results from the meta-analysis found a significant global effect of those lifestyle modification intervention on various clinical outcomes such as WC, blood pressure, total cholesterol, and fasting insulin ( $p \leq 0.001$ ) (Baillot et al. 2015).

#### ***2.2.6.2 Secondary prevention***

In the context of MetS, secondary prevention involves early detection/diagnosis of the syndrome, followed by implementation of interventions to address the syndrome as one entity (Grundy 2016).

#### ***Early diagnosis of MetS***

Diagnosis of MetS plays an important role to identify the risk of T2D, CVD and other chronic conditions. It is recommended that high risk people such as overweight or obese individuals should have blood test for MetS diagnosis (Alberti et al. 2009). Different criteria for MetS diagnosis has been developed by different organisations. However, the ATP III definition (Adult Treatment Panel III 2002) is the most widely adopted criteria (Kassi et al. 2011).

Besides invasive method, non-invasive method for early detection of MetS has been proposed based on anthropometric indicators such as waist-height ratio and blood pressure (Romero-Saldana et al. 2016). This method has a high degree of predictive validity and its use can be recommended in any healthcare context.

### ***Metabolic Syndrome interventions***

It is recommended that secondary prevention interventions should be implemented soon after the MetS has been diagnosed. A recent systematic review indicated that both lifestyle modification and pharmacological interventions are effective therapies in terms of resolving the MetS status. However, it was found that lifestyle interventions were more effective than the drug treatment interventions (Dunkley et al. 2012). The combination of physical activity training and dietary modifications have been recommended as a prioritised intervention for MetS (Blaha et al. 2008, Grundy et al. 2005). In other words, interventions that reduce weight through behavioural changes, such as reducing energy intake and enhancing energy expenditure, are the first priorities of MetS management (National Heart Lung and Blood Institute 1998, Grundy et al. 2005). A number of different lifestyle and behaviour intervention strategies have been developed and applied in health promotion programs designed for MetS control and prevention (Bassi et al. 2014). A review of 28 randomised controlled trials involving 6,372 patients found that motivation is a key factor in reversing MetS in lifestyle intervention programs. In addition, creating a supportive environment via team-based approach with monitoring and regular feedback is an effective way for behavioural change (Bassi et al. 2014).

A recent meta-analysis including 3,907 participants with MetS showed that lifestyle interventions were more likely to reverse MetS status 3.81 times (95% CI: 2.47, 5.88)

in intervention group in comparison to control group (Dunkley et al. 2012). Another meta-analysis also found that interventions comprising lifestyle modifications improved values of the MetS components (Yamaoka and Tango 2012). For example, a mean reduction of TG by 12.0 mg/dl (95% CI:-22.2, -1.7), WC by 2.7 cm (95% CI:-4.6, -0.9), fasting blood glucose by 11.5 mg/dl (95%CI: -22.4, -0.6) after intervention (Yamaoka and Tango 2012).

### ***2.2.6.3 Behavioural change interventions***

It is well documented that modifications of diet and physical activity behaviours are essential to address MetS and its subsequent health disorders. However, it is important to understand the effective intervention components and strategies for physical activity and dietary behaviour change. This section provides different strategies and their effectiveness in terms of improving physical activity and nutrition behaviour change.

#### ***2.2.6.3.1 Physical activity intervention***

The health benefits of physical activity are well documented. WHO suggests that adults should do at least 150 minutes of moderate or vigorous activity per week in order to promote and maintain health (WHO 2010). Therefore, promoting a physically active lifestyle is a priority for public health policy to improve community health and prevent many diseases and health disorders. Several strategies and methods have been developed to enhance physical activity in health promotion programs.

#### ***Walking group***

Walking groups have been widely used in lifestyle intervention programs (Kassavou, Turner, and French 2013). Walking in group has become a popular form of physical activity globally (Kassavou, Turner, and French 2013). It is suitable for different age

groups, including middle and older adults (Jancey et al. 2008). A systematic review of 48 studies to assess the effects of walking in individuals and populations (schools, workplaces) reported that such interventions could contribute substantially towards increasing the activity levels of the most sedentary individuals, although sustainability and generalisability remained uncertain. The results suggest that interventions tailored to people's needs, targeted to the most sedentary, at individual, household or at group levels, can encourage people to walk more (Ogilvie et al. 2007). A systematic review and meta-analysis of 19 studies with 4,572 participants found that interventions to promote group walking are effective at enhancing physical activity (Kassavou, Turner, and French 2013). Studies targeting older adults were more efficacious than those with younger participants (Kassavou, Turner, and French 2013). The review also found no significant difference in the effectiveness of the interventions delivered by professionals and the lay people. Training of lay people how to manage and deliver the interventions should be a worthwhile approach for these programs (Kassavou, Turner, and French 2013).

A RCT conducted in Australia also encouraged walking. It was designed to motivate older adults to improve their levels of physical activity over a six-month period (Jancey et al. 2008). The study demonstrated the appropriateness of small groups for social support and demonstration of new skills, the use of tertiary students in a supportive role for intervention programs, and walking as an appropriate method for older adults to improve their physical activity (Jancey et al. 2008).

### *Pedometers*

Pedometers have been used in a number of interventions aimed at increasing physical activity for different populations (Burke et al. 2013, Bravata et al. 2007). A systematic

review of 26 studies (8 RCTs, and 18 observational studies) with a total of 2,767 participants reported significant physical activity improvements of about 2,000 steps or 1 mile per day (Bravata et al. 2007). In particular, in the RCTs, the intervention group with pedometer increased their physical activity by 2,491 steps per day on average (95% CI: 1098, 3885). For observational studies, compared to baseline, the participants with pedometers increased their mean steps of 2,183 per day (95%CI: 1,571, 2,796) (Bravata et al. 2007). Setting a step goal as well as using a diary should be a key motivation to enhance walking among participants (Bravata et al. 2007). Another review also found the effectiveness of interventions using pedometers in enhancing physical activity among employees in workplace (Freak-Poli et al. 2013). In addition, Mansi et al. (2014) reviewed the effectiveness of studies using a pedometer to promote walking among patients with musculoskeletal diseases (Mansi et al. 2014). The authors found similar results with the previous systematic review for healthy people, with a mean increase of 1,950 steps per day compared to the baseline (Mansi et al. 2014). A physical activity and nutrition RCT was conducted targeting seniors aged 50-65 years in Australia (Burke et al. 2010). The provision of a pedometer for each intervention participant was an effective intervention component to improve physical activity for the seniors (Burke et al. 2010). After a six month intervention, a higher prevalence of participation in walking in the intervention group compared to the control group was reported (Burke et al. 2013).

### ***Flexibility, strength, and resistance training***

An increasing number of health promotion programs incorporate flexibility and strength as a component (Blackford et al. 2015, Burke et al. 2010). These flexibility and strength intervention programs have been demonstrated to improve balance,

strength, and endurance among the participants (Ferreira et al. 2012). In addition improvements in mobility have been reported among the older adults (Yeom, Keller, and Fleury 2009).

The Physical Activity and Nutrition for Seniors program aimed to improve physical activity and nutrition behaviours for older Australians (Burke et al. 2010). Each participant in the intervention group was provided with one resistance band, and charts detailing exercise routines. After 6 months of intervention, a significant increase in strength exercise was found among the intervention group when compared to the control group ( $p < 0.001$ ) (Burke et al. 2013). Another home-based physical activity and nutrition program targeting people with MetS, and at risk of MetS, was conducted recently in rural Western Australia (Blackford, Jancey, et al. 2016). This intervention also included a resistance band, booklet, and exercise chart for the intervention group. After a 6 month intervention, a significant increase in moderate physical activity, walking, and strength exercise among the intervention participants were evident (Blackford, Jancey, et al. 2016).

#### ***2.2.6.3.2 Nutrition intervention***

The aim of nutrition interventions is to improve healthy dietary behaviours. The intervention can be conducted in different settings such as community-based, home-based, or school-based (Dobbins et al. 2013). Different approaches have been adopted for the nutrition intervention, such as providing information (education, training, consultation, computer-tailored), providing healthy foods, or providing meals (Broekhuizen et al. 2012). These approaches showed to promote healthy eating habits (Alexander et al. 2010, Griffiths et al. 2006).

Three experimental conditions were tested to improve dietary behaviours (Wright et al. 2011). The study showed that the group with tailored, iterative, printed dietary feedback, reinforcing the message by emails, had the greatest increase in fruit intake relative to the groups with only a small education session and the control group. After three months of intervention that group increased 0.3 serves of fruit per day ( $p=0.031$ ) (Wright et al. 2011). In addition, a systematic review found that giving clear messages together with different strategies to reinforce the messages was the most effective intervention to increase fruit and vegetable consumption (Ciliska et al. 2000).

A community-based dietary and exercise intervention study was conducted among adults with T2D in rural Costa Rica. The intervention participants participated eleven weekly nutrition classes and also join walking groups three times per week while control participants received basic diabetes education. After 12-week intervention, significant improvements were observed in weight, fasting plasma glucose among intervention group relative to the control group (Goldhaber-Fiebert et al. 2003).

Another 6 month nutrition intervention program targeting older adults in United States of America was conducted (Bernstein et al. 2002). The program aimed to increase fruit and vegetable consumption as well as increase calcium-rich food intake. Different methods were incorporated in the intervention, including education (booklet, newsletters), face-to-face contact or via telephone to provide information. The control group received a package detailing exercise training at home. At the end of 6 month intervention, the nutritional intervention participants self-reported increases in the intake of fruit and vegetables by more than one serve per day, and milk by approximately one serving per day ( $p=0.001$ ) (Bernstein et al. 2002). However, the small sample size of this program makes it difficult to generalise the results of the study.

### ***2.2.6.3.2 Combination of physical activity and nutrition interventions***

Interventions that use a combination of physical activity and nutrition in order to improve physical activity and dietary behaviours have been widely conducted worldwide. Different settings have been considered for these interventions, including home-based, distance, and community. The following section provides an overview of selected physical activity and nutrition intervention programs and their effectiveness at improving physical activity and nutrition behaviour outcomes.

The Albany Physical Activity and Nutrition program targeted adults 50-69 years with or at risk of MetS at a regional area in Western Australia. It aimed to increase the lifestyle behaviours of this group (Blackford, Jancey, et al. 2016). The program randomly allocated 200 participants to the intervention group and 201 participants to the control group. This home-based intervention included a booklet, exercise charts, resistance band, and a website incorporating a progress tracker. In addition, motivational interviews were conducted by telephone. The results demonstrated a significant improvement in moderate intensity physical activity, a reduction in fat intake, an increased consumption of fibre and vegetable among the intervention group participants compared to the control group. The study demonstrated the effectiveness of a low-cost intervention to improve risk factors of T2D and CVD among at risk people in rural and remote area of Western Australia (Blackford, Jancey, et al. 2016).

Besides home-based, and community-based interventions, distance interventions has recently been used to change the lifestyle behaviours. Lee et al. (2011) evaluated the effectiveness of a postal and telephone intervention program for seniors in Australia. The 12 week home-based lifestyle program recruited 114 intervention participants, and 134 control participants. Interventions included an interactive booklet sent by email

and motivational interviewing via telephone, and included the use of a pedometer (Lee, Jancey, et al. 2011). After 12 weeks of intervention, the participants showed a significant increase in mean walking time by 27 minutes per week, and an improvement in fibre intake (Lee, Jancey, et al. 2011). Additionally, a systematic review of telephone-based intervention programs assessed the effectiveness of physical activity and dietary behaviour (Goode, Reeves, and Eakin 2012). The review provided strong evidence that telephone-delivered interventions could enhance lifestyle behaviours in the majority of the studies (20/25 RCTs) (Goode, Reeves, and Eakin 2012). The authors suggested that a longer duration of intervention might induce more effective physical activity and dietary behaviour changes.

The Sumida TAKE10! was a cluster RCT with three intervention community centres and 3 control community centres, targeting older adults >65 years in Japan to promote physical activity and maintain good dietary habits (Kimura et al. 2013). The intervention included lectures, five educational sessions, including 30 minutes for practicing healthy diet followed by one hour of exercise every fortnight. The results from this study showed that post-intervention, despite no walking and exercise improvement, significant increases in food intake frequency for six of the ten food groups, including meat, fish, eggs, potatoes, fruits, and seaweed were observed (Kimura et al. 2013).

Another review of 18 systematic reviews assessed the effectiveness of community-based interventions to promote physical activity and healthy eating habits among children and adolescents, a general adults group, and at risk groups (Brand et al. 2014). The review showed that community-based intervention was an important method for health promotion and prevention. Interventions using combined components and

delivered by organisations in the community were more effective. However, the mechanism of the combined approach must be assessed in future community-based programs (Brand et al. 2014). The authors recommended that effects of changing environment should be considered in health behaviour studies.

Several physical activity and dietary interventions have been conducted in low-middle income Asian countries. A brief structured education program conducted in three months addressed the self-care practices of diet, physical activity, self-monitoring of blood glucose among diabetes patients in Malaysia showed improvements in physical activity, and diabetes knowledge in intervention compared to the control group (Tan et al. 2011). Another three month dietary intervention program was conducted among adults with diabetes and obesity in Thailand (Wattanakorn et al. 2013). In this study, intervention participants received four education sessions on healthy eating and were provided a behavioural modification handbook, daily food record while control participants only received those materials and three 15 minute meetings. Significantly higher scores on eating behaviours, and improvements in BMI, body fat percentage, WC, and fasting glucose levels were found in the intervention group compared to the control group at post-evaluation of the program (Wattanakorn et al. 2013). A recent systematic review confirmed that lifestyle modification interventions are effective for glycemic control among adults with T2D in the Southeast Asian context (Htoo, Hsu, and Rosenkranz 2016). Improvement in glucose level was found in short-term intervention (3 months) but not in long-term intervention program (6 months). Exercise intervention was found to have the most significant effect on glycemic control in this region (Htoo, Hsu, and Rosenkranz 2016).

#### *2.2.6.4 Effectiveness of lifestyle interventions on features of MetS*

It has been suggested in the literature that lifestyle modification is the cornerstone therapy for the prevention and management of MetS (Alberti, Zimmet, and Shaw 2006, Alberti and Zimmet 1998). Effectiveness of lifestyle interventions on risk factors of MetS reduction and MetS reversion have been well documented in recent systematic reviews and meta-analyses (Bassi et al. 2014, Dunkley et al. 2012, Yamaoka and Tango 2012).

Data from a systematic review and meta-analysis involving in 13 studies with 3907 participants reported that although both lifestyle and pharmacological interventions can reduce MetS, lifestyle interventions are more effective at reversing the incidence. Lifestyle interventions alone or in combination with diet and/or physical activity were found to be effective in terms of resolving MetS, with the odds of MetS status reversal 3.81 times (95% CI: 2.47, 5.88) (Dunkley et al. 2012). Another systematic review and meta-analysis also confirmed the efficacy of lifestyle and medication interventions on MetS (Yamaoka and Tango 2012). The review showed improvements in MetS components among intervention groups in comparison to the control group, including significant mean reductions of WC by 2.7 cm, TG by 0.14 mM/L, fasting blood glucose by 0.64 mM/L, systolic blood pressure by 6.4 mmHg, and diastolic blood pressure by 3.3 mmHg. Mean HDL-C has found to be improved by 0.033 mM/L, however, this improvement was not statistically significant (Yamaoka and Tango 2012).

A recent systematic review of 69 studies also indicated the effectiveness of lifestyle interventions in reducing body weight and glucose-related outcomes (Sun et al. 2017). The use of a nutrition education session was an important component of a lifestyle

intervention program in terms of diabetes risk reduction. Programs with nutrition education showed a reduction of 2.07 kg ( $p < 0.001$ ) of mean weight after 12 months of intervention. In addition, greater weight loss was found for interventions delivered by nutrition experts/dietitians in comparison to programs delivered by other personnel (Sun et al. 2017).

Although the efficacy of lifestyle interventions for adults with MetS has been well documented, the magnitude of changes varied between studies. The Finnish Diabetes Prevention Study randomly allocated 522 middle-aged men and women, at risk of having T2D, into lifestyle intervention group ( $n=265$ ), and usual care control group ( $n=257$ ) (Ilanne-Parikka et al. 2008). After 3.9 years follow up, MetS prevalence decreased by 16% and 6.3% in the intervention group, and control group, respectively in the first year. At the end of the follow up, a significant difference for MetS prevalence was found between the two groups, a reduction of 11.4% in the intervention group, compared with 2.8% reduction in the control group (Ilanne-Parikka et al. 2008). Significant improvements in almost all MetS components except for TG were found in the intervention group after 1 year follow up. However, in comparison with the control group, statistically significant improvements were observed in mean WC and fasting glucose ( $p < 0.05$ ) (Ilanne-Parikka et al. 2008).

The importance of combined diet and exercise interventions in resolving MetS was further confirmed in the Oslo Diet and Exercise Study. In total, 137 people aged 40-49 years with MetS, using the IDF definition, were allocated into one of four groups, namely diet alone, exercise alone, a combination of diet and exercise, and control group. After a one year intervention, both dietary and physical activity interventions had reduced MetS prevalence ( $p < 0.005$ ) (Anderssen et al. 2007). However, the combination of physical activity and nutrition interventions were more effective than

interventions having only a diet or physical activity component in resolving MetS. Future studies should be conducted for different age groups, such as middle-aged and older adults. Physical activity and nutrition intervention testing must be done for MetS people with different definitions such as ATP III, WHO due to the different thresholds of these definitions (Anderssen et al. 2007).

Another two-arm RCT assessed the effect of a lifestyle intervention program on the changes in MetS components among 383 middle-aged adults 45-64 years with MetS (Bo et al. 2007). Both intervention and control groups received general information about the importance of a healthy lifestyle from trained physicians. For the intervention group, each participant further received detailed recommendations verbally, and in writing based on their clinical information. They also attended five education sessions to promote healthy diet behaviours and physical activity. After the one year intervention, significant improvements were observed in diastolic blood pressure, fasting glucose, HDL-C, and WC among the intervention participants. The study also demonstrated a statistically significant reduction in the proportion of subjects with MetS in the intervention group (-35.5%) when compared to the control group (-6.6%) ( $p=0.001$ ) (Bo et al. 2007).

Another review included 28 RCTs with 6372 patients to find the optimal approach for behavioural lifestyle intervention for MetS people (Bassi et al. 2014). The authors found that participants' motivation and adherence to the intervention's activities were the most important elements for the success of lifestyle intervention program targeting MetS people. In addition, interventions with interactive approaches, having monitoring and having regular feedback could enhance adherence and lead, more effectively to behavioural changes. The review also indicated that although technology

was a useful method, the role of personal contact was still the most important to achieve successful outcomes. Consideration of individual participant characteristics and preferences in intervention strategy would be an optimal approach of lifestyle behavioural change for adults with MetS (Bassi et al. 2014).

### **2.3 Process evaluation**

Process evaluation is used to monitor and document program implementation. It can aid in understanding the relationship between specific program elements and program outcomes (Durlak and DuPre 2008). It can be used to explain why certain interventions succeed or fail, and offers an opportunity to determine how the program was conducted and the characteristics, or mechanisms, associated with its implementation, which potentially affect the outcomes (Wilson et al. 2009, Burke, Jancey, et al. 2012, Blackford, Lee, et al. 2016, Aarestrup et al. 2014). Although evaluations of implementation are especially important, most outcome analyses are conducted without any assessment of program implementation (Saunders et al. 2006). Evidence from the literature has suggested that a great variability in program implementation and policy adoption in community and school settings (Durlak and DuPre 2008, Dusenbury et al. 2003). Therefore, another purpose of process evaluation is to ensure that the originally designed intervention is being implemented in the real-world, and being implemented as planned (Wilson et al. 2009).

### **2.4 Summary**

MetS and its clinical subsequent disorders are now a major public health problem worldwide. The syndrome increased the risk of T2D and CVD, major NCD burden globally in recent decades. Middle-age and older adults is the group with the highest prevalence of MetS. A combination of physical activity and nutrition intervention has

showed to be effective approaches for primary and secondary prevention of MetS as well as reducing the risk factors of T2D and CVD.

Process evaluation should be conducted during the implementation of a health promotion program. This type of evaluation will explain which intervention component is effective as well as being able to explain why a health promotion program succeeds or fails. The combination of targeted outcomes and results obtained from process evaluation will aid to identify the most effective mechanism for intervention activities, and behaviour change and health outcomes.

In Vietnam, MetS is now prevalent, with middle-aged and older adults having the highest prevalence. Although the effectiveness of lifestyle interventions on MetS prevention has been well documented, the majority of these interventions were conducted in developed countries where social and environments are different from Vietnam. In addition, the efficacy of these interventions on physical activity, nutrition outcomes, and components of MetS varies depending on what methods and strategies have been applied. It is important, therefore, to determine which lifestyle intervention strategies are appropriate for the Vietnamese context, considering the socio and cultural situations in Vietnamese settings. Based on our intensive literature search, no behavioural modification intervention program has been conducted for people with MetS in Vietnam. The development, implementation, and assessment of such intervention Vietnam is important in terms of NCD control and prevention in the country.

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### 3. METHODOLOGY

This chapter expands the published protocol paper provided at the end of this chapter which describes the study design, ethics, study location, participant selection and recruitment, interventions, measurements, and data analysis of the research.

#### 3.1 Study design

A 6-month community based cluster-RCT was conducted, targeting adults aged 50-65 years with MetS from ten communes in Hanam province, northern Vietnam. Outcomes were collected from intervention and control groups at baseline and post-test.

**Table 3.1. Study design**

<b>Study group</b>	<b>0 month (Baseline)</b>	<b>Intervention</b>	<b>6 month (Post-test)</b>
Intervention (5 communes)	O1	X	O2
Control (5 communes)	O1		O2

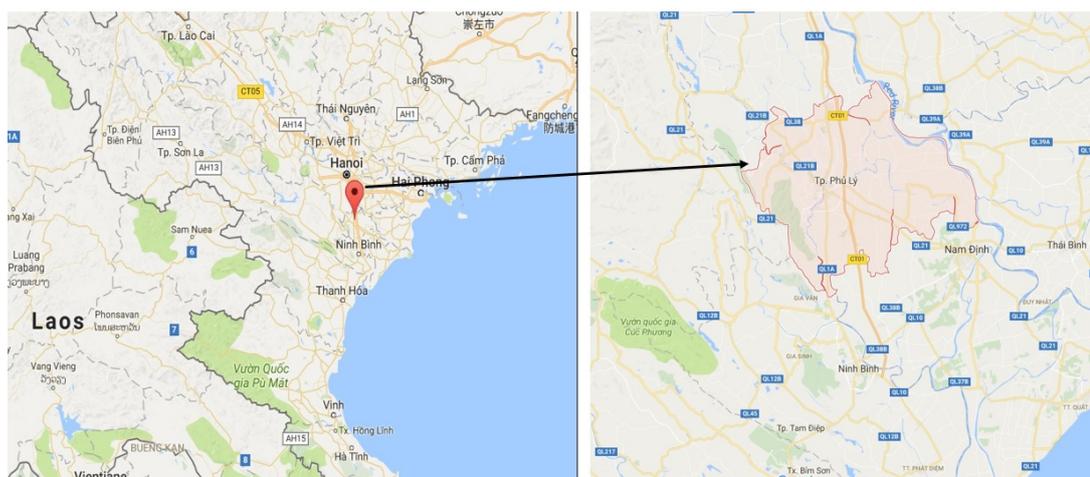
O: Observation; X: Intervention

#### 3.2 Ethics

All participants were (1) briefed about the study; (2) provided with an information sheet; (3) asked by the trained program staff to sign a consent form prior to entry into the program; and (4) be made aware that they are free to withdraw at any time. Only aggregated data were reported in publications. The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014) (Appendix G).

### 3.3 Study location

Hanam province was selected to represent the Red River Delta in northern Vietnam. The cluster-RCT was conducted in Hanam, a province located at about 60 km from Hanoi. Hanam province is a typical rural province in the Red River Delta region. In recent years, Hanam has gradually transited from agriculture to service industries. Hanam province has six districts with a population of 802,700 people in 2015 (General Statistics Office of Vietnam 2015). Phu Ly city was randomly selected to conduct this study. Phu Ly city has 21 communes of 136,654 residents. The ten selected communes were chosen randomly using a sequence of random numbers assigned to all communes within Phu Ly city, Hanam province.



**Study location** (Retrieved from [www.google.com.au/maps/place/Tp.+Phủ+Lý,+Hà+Nam,+Viet+Nam](http://www.google.com.au/maps/place/Tp.+Phủ+Lý,+Hà+Nam,+Viet+Nam))

### 3.4 Recruitment of participants

#### 3.4.1 Participants

Middle-aged adults 50-65 years in Vietnam are at risk of NCD development with the highest prevalence of MetS (Binh et al. 2014). Middle-aged adults aged 50-65 years with MetS were recruited from and invited to participate in the study. MetS status was

determined based on the modified National Cholesterol Education Programme Adult Treatment Panel III criteria of having three of the five risk factors (The Diabetes Prevention Program Research 2002): 1) large WC (male  $\geq 90$  cm, female  $\geq 80$  cm for Asian Population (Alberti et al. 2009); 2) raised TG ( $\geq 1.7$  mmol/L or 150 mg/dL); 3) reduced HDL-C (male  $< 1.03$  mmol/L or 40 mg/dL, female  $< 1.29$  mmol/L or 50 mg/dL); 4) raised blood pressure (systolic  $\geq 130$  mmHg or diastolic  $\geq 85$  mmHg); and 5) raised fasting plasma glucose ( $\geq 6.1$  mmol/L or  $\geq 110$  mg/dL).

Exclusion criteria were suspected T2D (fasting plasma glucose  $\geq 7.1$  mmol/L); taking or underwent treatment for T2D, CVD, dyslipidaemia, hyperglycaemia, and hypertension; or involvement in a physical activity and/or dietary program within the past year.

### **3.4.2 Procedure**

The participant selection phase, including initial screening and determination of MetS status, occurred between October 2014 and January 2015, and the post-test evaluation completed in November 2015.

#### ***3.4.2.1 Screening***

A total of 8,560 adults aged 50-65 years residing in ten randomly selected communes within Hanam province were contacted, and invited to attend their local commune health centre for screening. Small incentives (reimbursement for transport expense) were provided to encourage attendance. At these screening sessions, a short interview was conducted to obtain information about each participant's age, gender, physical activity levels, and medication history (Appendix C). Their height and weight were also measured. BMI was calculated as weight over height squared, and classified according to the WHO criteria for Asian populations, with BMI  $\geq 23$  being

'overweight' (WHO Expert Consultation 2004). Eligible people with BMI  $\geq 23$  were invited to participate in the next stage of screening.

#### ***3.4.2.2 Determining MetS status***

As shown in Figure 3.1, 1,515 eligible subjects were invited for blood test and measurement of WC and blood pressure to confirm their MetS status. A formal letter of invitation was delivered to eligible participants. The letter provided detailed information about the time, location, and guidelines for fasting overnight (except for water after 9 pm and in the morning before blood sample collection). However, only 1,244 people attended the clinic for blood sample collection and anthropometric measurements. Among them, 422 met the MetS criteria and were invited for baseline evaluation. Five individuals changed their mind and subsequently withdrew, leaving a total of 417 participants who completed the baseline assessment.

#### ***3.4.2.3 Allocation to control and intervention groups***

The ten selected communes were randomly allocated to either the intervention group (five communes, n=214) or the control group (five communes, n=203) by a staff at Hanam Provincial Preventive Medicine Centre using a table of random numbers. Due to the nature of the intervention strategy and the adopted process of cluster-randomisation, contamination between intervention and control communes was unlikely. Furthermore, the control participants were aware that they had been wait-listed to receive the VPAN program at a later stage. The intervention group received the VPAN program, whereas the control group participants were fully aware of their status, who received one session of standard advice and were wait-listed to receive the intervention package following completion of the post-test. At the end of the six months period, 175 intervention (response rate 81.8%), and 162 control participants

(response rate 79.8%) completed the post-test assessment; see Figure 3.1. CONSORT flowchart.

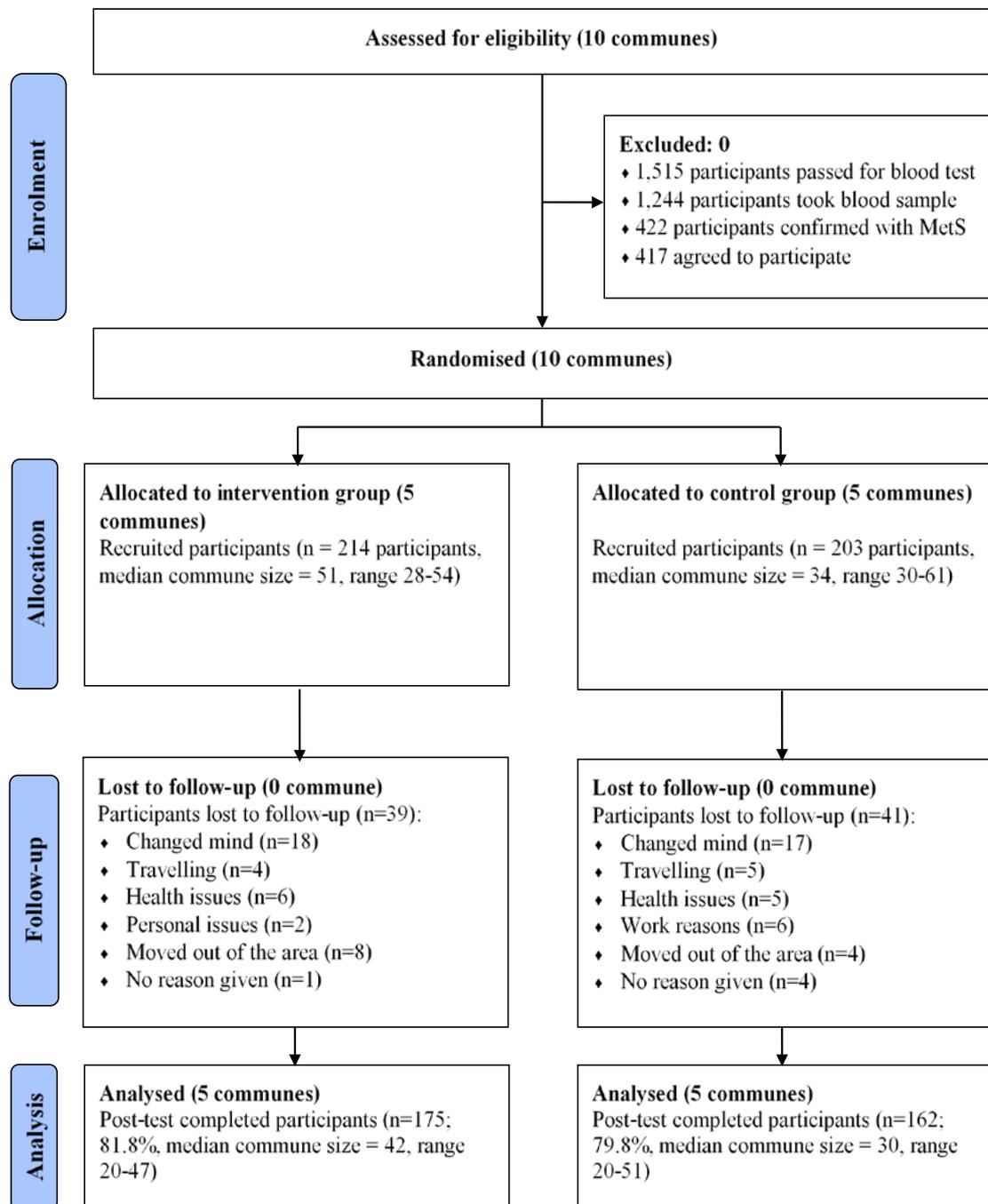


Figure 3.1. CONSORT flow chart

### **3.5 Theoretical basis**

Social Cognitive Theory, which underpins this research, is built on an understanding that the interactions between individual characteristics and environmental events shape how a person behaves (Bandura 1997, Glanz, Rimer, and Viswanath 2008). The Social Cognitive Theory perspective is that people are not driven solely by inner forces and not automatically shaped by external influences. Rather, human behaviour can be explained through its interaction with environmental events. These complex yet subtle interactions should be considered and well understood as they are essential to informing behavioural change interventions (Artinian et al. 2010). A key construct of Social Cognitive Theory is self-efficacy, which concerns with individuals' belief in their ability to perform a specific task. Self-efficacy is behaviour specific and invaluable in achieving successful behaviour change, such as increasing levels of physical activity or improving dietary intake (Artinian et al. 2010). Other major constructs of Social Cognitive Theory are outcome expectations, reinforcement (motivation/incentives), observational learning, goal setting and the environment (Glanz, Rimer, and Viswanath 2008). All these constructs help to inform the intervention strategies.

### **3.6 Intervention program**

#### **3.6.1 Description**

The adopted intervention strategies were based on previous successful interventions conducted by Curtin researchers (Burke et al. 2010, Burke, Lee, et al. 2012), as research has indicated that a combination of health education and walking programs can lead to improved lifestyle management and reduced risk of MetS (Lee et al. 2014). This community-based intervention included a range of strategies and resources to encourage participation and to improve retention, such as education sessions,

information booklet, resistance band and walking groups led by local walk leaders. They were designed to inform participants of the benefits of being physically active and maintaining a healthy diet as a means of preventing chronic diseases. Positive reinforcement, by way of encouragement and feedback, was facilitated through the trained walking group leaders.

#### ***3.6.1.1 Walk leaders***

A walk leader in each walking group was either a local middle-aged volunteer or the village health worker within the commune. The walk leaders were required to be enthusiastic, demonstrate leadership qualities, and respected by the commune residents. The research team maintained regular contact and monitored progress with them via telephone and a monthly face-to-face meeting. They were required to attend three two-hour training sessions and provided with a package containing the education materials, as well as a manual for managing the group walks. The manual was a comprehensive guide to mobilise walking groups, containing examples on walking activities and stretching and resistance exercises, benefits of being physically active and maintaining a healthy diet, supplemented by effective communication strategies. Beside mobilising and encouraging the participants for group walking, the group leaders also guided the participants but had the flexibility to tailor the prescribed program to suit individual needs, such as walking less or more, within their group. They were responsible for administrative work such as recording participant contact details.

#### ***3.6.1.2 Program delivery***

Program staff were selected from medical doctors and nurses employed by the Hanam Provincial Preventive Medicine Centre. These staff members were responsible for

conducting interviews, taking anthropometric measurements and blood samples collection, after receiving intensive training from the PhD candidate, who oversee all aspects of the program delivery including the development of resources, setting up walking groups and process evaluation.

### **3.6.2 Program resources**

#### **3.6.2.1 Education sessions**

The participants in each intervention commune were divided into small groups, ranging from 20 to 26 participants per group. Each group attended four two-hour education sessions on healthy diet and physical activity in months one, two, three, four of the program held at the local commune health centres. The duration and size of these education sessions were determined based on a previous study (Hollis et al. 2008). Sessions were participatory and interactive, rather than didactic. Small group activities would foster problem solving, social support, and program ownership. Table 3.2 describes the contents of the four education sessions and their linkages with behaviour change underpinned by the Social Cognitive Theory.

**Table 3.2. Education sessions linked to the theoretical basis of the study**

<b>Themes</b>	<b>Contents</b>	<b>Link with behaviour change techniques</b>
Session one (month one): Introduction to the project	<ol style="list-style-type: none"> <li>1. Getting to know each other</li> <li>2. Introduce the program</li> <li>3. Benefits of physical activity and nutrition on health, especially people with MetS, CVD, T2D</li> <li>4. Introduce and distribute the booklet</li> </ol>	<p>Interaction with other participants;</p> <p>Outcome expectation</p>

	5. Establishment of goal setting	
Session two (month two): Physical activity	<ol style="list-style-type: none"> <li>1. Demonstration and practice of exercises and walking, program such as warm up, cool down</li> <li>2. Barriers and enablers of being physically active</li> <li>3. How to identify and overcome barriers</li> </ol>	<p>Observational learning;</p> <p>Self-efficacy;</p> <p>Outcome expectation</p>
Session three (month three): Healthy diet	<ol style="list-style-type: none"> <li>1. Demonstration and discussion of healthy foods and healthy eating habits</li> <li>2. Barriers and enablers of maintaining a healthy diet</li> <li>3. How to identify and overcome barriers</li> </ol>	<p>Observational learning;</p> <p>Self-efficacy;</p> <p>Outcome expectation</p>
Session four (month four): Experience and lessons learnt	<ol style="list-style-type: none"> <li>1. Interactive session on overcoming barriers to being physically active and maintaining a healthy diet</li> <li>2. Discussion of food types</li> <li>3. Feedback from participants</li> <li>4. Encourage participants to read the relevant sections of the booklet to reinforce what they learnt in the sessions</li> <li>5. Review physical activity and nutrition goals</li> </ol>	<p>Observational learning;</p> <p>Reinforcement</p>

### **3.6.2.2 Information booklet**

At the first education session, each participant was given a booklet (in Vietnamese) designed to inform and support improvements in nutritional intake and physical

activity behaviours. This booklet was adapted from previously developed materials used in the Physical Activity and Nutrition for Seniors project (Burke et al. 2008) and modified to ensure suitability for the Vietnamese cultural context. The educational materials are simple, short, and easy to understand and comprise four sections. The first section introduces the program as well as the benefits of physical activity and a healthy diet. The second section focuses on various modes of physical activity, and contains illustrations and tips on how to perform physical activity (e.g. brisk walking) correctly and resistance, weight training and stretching exercises safely. The third section contains suggested meal plans, recipes, and tips for healthy eating, encouraging a higher consumption of fruits, vegetables and fibre while reducing intake of saturated fat, salt, and sugar. The last section provides information on the barriers to physical activity and healthy eating and how to overcome them, together with practical examples. Participants were also asked to set their own physical activity and nutrition goals and to enter their progress and achievements towards these goals in the booklet.

#### ***3.6.2.3 Resistance exercises***

Each participant was provided with a resistance band. Detailed instructions on usage, warming up and exercise techniques, as well as how to develop their own personal physical activity goals and plan were disseminated during the education sessions. Written information and pictorial illustrations are presented in the booklet.

#### ***3.6.2.4 Walking groups***

Walking groups in each commune were established immediately after the first education session. These walking groups served to mobilise the participants, supporting them to meet and walk together in order to achieve the physical activity guidelines for health benefits. All participants were encouraged to join a walking group

based on their geographic location within the commune and guided by their local walk leaders.

### 3.7 Outcome measures

Table 3.3 summarises the outcome variables and their corresponding measuring instruments.

**Table 3.3. Summary of outcome measures**

<b>Outcome variables</b>	<b>Measuring instrument</b>
Physical activity: walking, intensity, duration, and frequency	IPAQ-SF, Pedometer
Diet: fat, oil, salt, sugar intake, fruit and vegetable consumption	Modified dietary behaviour questionnaire from WHO STEPs
Plasma glucose, TG, total cholesterol, and HDL-C	Fasting blood sample
Anthropometric measurements: height, weight, WC, hip circumference	Portable stadiometer, tape measure, calibrated electronic scales
Blood pressure	Omron HEM-8712 automatic blood pressure monitor

#### 3.7.1 Demographics

The structured questionnaire was administered face-to-face to collect information about demographics of the participant, including gender, age, education level, marital status and occupation. Information on cigarette smoking and alcohol drinking was also solicited (Appendix D).

### **3.7.2 Physical activity**

The validated IPAQ-SF (Tran, Lee, et al. 2013) was administered to measure self-reported physical activity (Appendix D). The Yamax SW-200 (Yamax, Tokyo, Japan) pedometer was used to count the daily steps of each participant. This objective measure of physical activity has been reported to be accurate and reliable (Tudor-Locke and Lutes 2009). Pedometers offer a simple estimate of physical activity volume in terms of steps taken. A step will be recorded after a vertical acceleration above the manufacturer-designed force sensitivity threshold of the pedometer. In the meantime, the electronic circuitry within a pedometer is designed to accumulate steps and display updated steps on a digital screen continuously (Tudor-Locke and Lutes 2009). The participant was requested to wear the pedometer to the hip and worn for seven consecutive days except during sleep and water-based activities at baseline and post-test for the intervention group participants only. Post intervention data was collected after the final session of the walking group.

### **3.7.3 Diet**

The brief dietary habit questionnaire was adapted from the STEPS developed by the WHO (WHO 2008) (Appendix D). The STEPwise dietary questions were translated into Vietnamese and back-translated by independent translators. The original meaning of the words in the questionnaire were kept and adapted culturally. It underwent pilot testing with further modifications before actual application to suit the local context.

### **3.7.4 Blood samples**

Blood samples were collected by a phlebotomist in the morning after fasting for at least 8 hours during the community clinic visit at baseline and at six-month post-test. The collected blood samples were stored at 2–8°C in iceboxes and then transported to

the Hanam provincial biochemistry laboratory for analysis within six hours. Plasma glucose was measured by the glucose oxidase method. Lipid profile including total cholesterol, TG and HDL-C were measured by enzymatic methods. LDL-C and non-HDL-C levels were subsequently calculated (Nordestgaard and Varbo 2014).

### **3.7.5 Anthropometric measurements**

These were taken by program staff at baseline and at six-month post-test following the WHO's guidelines.(WHO 2008) Waist and hip circumferences were recorded to the nearest 0.5 cm using a plastic measuring tape, and waist-to-hip ratio was subsequently determined. Weight was recorded to the nearest 0.01 kg using a calibrated electronic scale, and height was recorded to the nearest 0.1 cm using a portable stadiometer while the participant was barefoot. BMI was then calculated.

### **3.7.6 Blood pressure**

Blood pressure was taken by trained program staff following the standard guideline (WHO 2008). Systolic and diastolic blood pressures were measured using an Omron HEM-8712 automatic blood pressure monitor, with participants sitting and their arm supported at heart level. A mean value was obtained after taking three consecutive measurements.

### **3.8 Statistical analysis**

Descriptive statistics were first applied to summarise the baseline demographic and lifestyle characteristics of the participants by group status of the program completers. Comparisons between and within intervention and control participants were undertaken across the two time points using independent samples and paired *t*-tests for continuous outcome variables, and Chi-square test for dichotomous outcomes. For variables with skewed distributions, Mann-Whitney U test and Wilcoxon signed rank

test were applied instead. To accommodate the correlation of observations due to the repeated measures (pre- and post-test) and the clustering of individuals within the ten randomly selected communes, multilevel generalized linear mixed models with random effects (participants and communes) were fitted to determine the impacts of intervention on changes in outcome variables over time and between groups, while accounting for the effects of potential confounding factors (age, gender, education level, relationship status, occupation, smoking status, and alcohol drinking).

These binary outcomes were modelled using logistic mixed regressions. Generalized linear mixed regression analysis was applied to continuous outcomes, which were logarithmic transformed for those with positively skewed distributions. A gamma mixed regression model was adopted for analysing the highly skewed outcome variables. All statistical analyses were performed in the SPSS package version 21. The statistically significance level was set at  $p < 0.05$ .

### **3.9 Process evaluation**

The scope of process evaluation has grown in complexity as its importance and utility have become more widely recognised. Different frameworks and models have been developed to guide a comprehensive evaluation plan for assessing implementation (Dane and Schneider 1998, Saunders, Evans, and Joshi 2005, Hogue et al. 2005). However, they share the common components for the evaluation. Saunders et al. (2006) developed a process evaluation plan for health promotion program implementation (Saunders, Evans, and Joshi 2005). According to the plan, the following components should be assessed: a) the extent to which implementation of the intervention occurred as planned (fidelity – quality); b) the number of intended intervention components delivered (dose delivered – completeness); c) the extent to

which participants used the resources as intended or recommended (dose received – exposure); d) participants’ satisfaction with the program and staff (dose received – satisfaction); e) the number of participants actively participating in the intervention (reach – participation rate); f) procedures used to attract participants and maintain involvement in the intervention (recruitment); and g) factors that influenced the implementation or study outcomes (context). Hogue et al (2005) added more worthy aspects of implementation which refer to changes made in the original program during implementation (program modification, reinvention). The purpose of the process evaluation was to assess the participation, fidelity and participant satisfaction, and reasons for completing and not completing the VPAN program. It was conducted in the midway of the intervention program for the intervention group only.

### 3.9.1 Process evaluation methods

Quantitative data were collected via self-administered questionnaires, and qualitative data gathered through brief post education session discussions and structured interviews. The participants were informed of the purpose of the survey/interview prior to commencing, and written informed consent was obtained. Table 3.4 shows the process evaluation components and measurements.

**Table 3.4.** Process evaluation components and measurements

<b>Variables and definition</b>	<b>Measurement approaches</b>		
	Self-reported questionnaire	Brief post education session discussions	Exit interviews
<b>Participation:</b> <i>The number of participants</i>		x	

<i>actively participating in the education sessions</i>			
<b>Fidelity:</b> <i>The extent to which implementation of the intervention occurred as planned</i>	X	X	
<b>Satisfaction:</b> <i>The satisfaction of participants with the intervention program</i>	X	X	X
<b>Reasons for completing the program:</b> <i>To what extent encouraged participants completed the program</i>			X
<b>Reasons for not-completing the program:</b> <i>To what extent stopped participants completed the program</i>			X

### 3.9.1.1 Self-administered questionnaire

At the end of the fourth education session (month four), the participants were asked to complete a brief self-administered questionnaire. This questionnaire assessed the usefulness, relevance and suitability of the intervention resources and strategies for supporting management and changes to physical activity and nutrition behaviours; and overall perception of the program (Appendix E). The questionnaire was adapted from previous studies, translated, and tested (Burke, Jancey, et al. 2012). A five-point Likert-scale was used for specific feedback on the resources. The participants were

required to select the closest statement they agreed with (e.g., *useful to not useful, relevant to not relevant, suitable to not suitable, strongly agree to strongly disagree*). The completed questionnaires were non-identifiable to encourage honest responses.

### ***3.9.1.2 Brief post education session discussions***

At the end of each education session, a ten-minute discussion was held between the PhD candidate and participants. The purpose was to identify the participation, fidelity, and suggest changes to improve the program.

### ***3.9.1.3 Exit interviews***

Twenty semi-structured exit interviews, involving ten completers and ten non-completers, all from the intervention group, were conducted by a trained native speaking researcher. The number of interviews undertaken was based on a similar community based study (Blackford, Lee, et al. 2016), along with evidence from the literature that suggests saturation occurs within the first twelve interviews (Guest, Bunce, and Johnson 2006). They were randomly selected from the list of participants who agreed to be interviewed. Completers were defined as those participants who attended at least three education sessions and undertook the post-evaluation. Questions included what participants thought about the intervention components, such as the booklet, resistance band, education sessions, walking group and walk leaders; their overall perceptions of the program; whether the program encouraged them to increase their level of physical activity; and any changes to their diet (Appendix F). The exit interviews also solicited recommendations for future programs. The interview was up to 40 minutes in duration. Permissions were sought for recording the interviews.

### **3.9.2 Process evaluation data analysis**

The Likert responses from the questionnaires were summed and percentages were calculated (e.g. strongly agree to strongly disagree) before collapsing into dichotomous variables (e.g. agree and disagree). Qualitative data from the exit interviews were documented and collated; and common key words and phrases were extracted from the participant responses.

**Related publication:**

*Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial.*

This publication addresses objective 1:

1. Design and implement a cluster-randomised controlled trial of a community-based intervention to improve the physical activity and dietary behaviours of adults aged 50-65 years with MetS in Vietnam.

**Citation:**

**Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>

# BMJ Open Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial

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**To cite:** Tran VD, Lee AH, Jancey J, *et al*. Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open* 2016;6:e011532. doi:10.1136/bmjopen-2016-011532

► Prepublication history and additional material is available. To view please visit the journal (<http://dx.doi.org/10.1136/bmjopen-2016-011532>).

Received 16 February 2016  
Revised 14 May 2016  
Accepted 17 May 2016



CrossMark

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## ABSTRACT

**Introduction:** Metabolic syndrome (MetS) is a cluster of risk factors for cardiovascular diseases and type II diabetes. In Vietnam, more than one-quarter of its population aged 50–65 have MetS. This cluster-randomised controlled trial aims to evaluate the effectiveness of interventions to increase levels of physical activity and improve dietary behaviours among Vietnamese adults aged 50–65 years with MetS.

**Method and analysis:** This 6-month community-based intervention includes a range of strategies to improve physical activity and nutrition for adults with MetS in Hanam, a province located in northern Vietnam. 600 participants will be recruited from 6 communes with 100 participants per commune. The 6 selected communes will be randomly allocated to either an intervention group (m=3; n=300) or a control group (m=3; n=300). The intervention comprises booklets, education sessions, resistance bands and attending local walking groups that provide information and encourage participants to improve their physical activity and healthy eating behaviours during the 6-month period. The control group participants will receive standard and 1-time advice. Social cognitive theory is the theoretical concept underpinning this study. Measurements will be taken at baseline and postintervention to evaluate programme effectiveness.

**Ethics and dissemination:** The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014). The results of the study will be disseminated through publications, reports and conference presentations.

**Trial registration number:** ACTRN12614000811606.

## INTRODUCTION

Vietnam is a developing country with a population of more than 90 million.<sup>1</sup> With socio-economic development occurring rapidly

## Strengths and limitations of this study

- This is the first community-based randomised controlled trial undertaken on Vietnamese adults with MetS. Finding will be potentially applicable for non-communicable disease prevention in Vietnam.
- Intervention strategies are developed taking into account the cultural context and underpinned by theory.
- Challenges in participant recruitment and minimising attrition during the follow-up of the intervention.
- Long-term follow-up to assess sustainability of the programme is not feasible due to budget constraints.

during the past two decades, risk factors for non-communicable diseases (NCDs) such as hypertension, overweight/obesity and physical inactivity are becoming increasingly prevalent.<sup>2</sup> NCDs are rising rapidly, accounting for 71% of the total disease burden in Vietnam. Cardiovascular events alone are responsible for about 110 000 deaths each year or 20% of the total mortality, while the prevalence of type II diabetes (T2D) has tripled in the past two decades and continues to rise.<sup>3</sup>

Metabolic syndrome (MetS) is a cluster of risk factors for cardiovascular diseases (CVDs) and T2D, including abdominal obesity, elevated blood pressure, reduced high-density lipoprotein cholesterol (HDL-C), elevated triglyceride levels and raised fasting plasma glucose.<sup>4</sup> People with MetS have twice the risk of suffering CVD over the next 5–10 years compared with those without the condition, together with another fivefold increase in risk of incurring T2D.<sup>4,5</sup>



Several definitions of MetS have been proposed by different organisations over the past decade, but the most common criteria<sup>6</sup> came from the WHO,<sup>7</sup> the National Cholesterol Education Programme Adult Treatment Panel III (ATP III)<sup>8</sup> and the International Diabetes Federation (IDF).<sup>5</sup> These definitions exhibit common features, but their differences in several parameters have led to challenges in terms of applicability and establishing positive predictive values.<sup>6</sup> Among them, waist circumference in defining abdominal obesity in different populations and ethnicities is the most controversial parameter. Consequently, the IDF has proposed a new set of waist circumference criteria with ethnic/racial specific cut-offs that are applicable across populations.<sup>4</sup>

MetS is now a global concern,<sup>4</sup> with an increasing trend worldwide, yet it is often undiagnosed.<sup>9–10</sup> The prevalence of MetS varies, ranging from <10% to 84%, depending on the region, sex, age and ethnicity of the population being studied.<sup>11</sup> Globally, almost one-quarter of the adult population have MetS.<sup>5</sup> In Vietnam, MetS is a major public health problem, with a high prevalence particularly in urban areas.<sup>12–14</sup> It is estimated that 18% of Vietnamese adults aged 35–65 years have MetS whose rate increases with age.<sup>15</sup> A recent study conducted in northern Vietnam indicated that the prevalence of MetS among those in the age group 55–64 years is ~27%.<sup>16</sup> The study also suggested that 40% of Vietnamese aged 40–64 years possess at least two of the five components of MetS, the so-called 'pre-MetS'.<sup>16</sup> Modifiable lifestyle factors, such as inadequate levels of physical activity and poor dietary habits, are known to be associated with the development of MetS.<sup>13–15</sup>

Weight reduction through behavioural changes, such as reducing energy intake and increasing physical activity levels, thereby enhancing energy expenditure, are the first priorities of MetS management.<sup>17–18</sup> Previous studies have demonstrated the effectiveness of lifestyle interventions aimed at increasing physical activity and achieving weight reduction, while reducing the prevalence of MetS and its components.<sup>19–22</sup> For example, the Dietary Approaches to Stop Hypertension diet could reduce blood pressure<sup>23</sup> and the risk of CVD,<sup>24</sup> while the Diabetes Prevention Program, a lifestyle intervention to control weight and increase activity levels, was successful in delaying the development of T2D.<sup>25</sup> Similarly, the Strong Women-Healthy Hearts Program was a community-based intervention to reduce the risk of CVD in sedentary midlife women through fitness and nutrition.<sup>26</sup> Despite such significant evidence emerging, and other studies from developed countries,<sup>27–28</sup> there is still a lack of intervention research in developing countries with emerging economies.<sup>16</sup>

In view of the high prevalence of MetS and pre-MetS in Vietnam, appropriate interventions and healthy lifestyle programmes must be developed and implemented in a timely manner.<sup>12–16</sup> This paper describes the protocol of a cluster-randomised controlled trial (RCT) for community-dwelling adults aged 50–65 years with MetS

in Vietnam. It is hypothesised that after the 6-month intervention, levels of physical activity, dietary behaviours, lipid profile and fasting glucose, as well as anthropometric measures among the intervention group, will demonstrate statistically significant improvements when compared with the control group.

## METHODS AND ANALYSIS

### Study design

This 6-month community-based cluster RCT is designed to improve physical activity and dietary behaviours for adults aged 50–65 years with MetS in Hanam province located in northern Vietnam. Hanam province comprises five districts and one city, with a total population of 799 400 in 2014.<sup>1</sup> It is estimated that ~950 people aged 50–65 years reside within each of the 98 communes in the province. Given this number of target residents per commune, and a conservative estimate of MetS prevalence (11%), six communes (N=5700) will be selected using random numbers and then assigned randomly to either the intervention group (m=3) or the control group (m=3), with about 100 eligible participants with MetS recruited per commune (cluster). Data will be collected at baseline and postintervention (6 months later) to assess changes in outcome measures. Figure 1 shows the schematic diagram of the study timeline.

### Power calculation

The power calculations are based on a logistic mixed regression model of the binary outcome variable moderate activity participation (yes, no) for each participant. We hypothesise that after the 6-month intervention, the intervention group will demonstrate an increase of 10% in moderate activity prevalence when compared with the control group. A final sample size of n=480 will provide sufficient power (80%) to detect such a medium effect size at 5% significance level for the group by time interaction term in the logistic mixed regression model accounting for gender but without other covariate adjustment. To allow for 80% complete data across the two assessments due to attrition and withdrawals, a total of n=600 participants with MetS will be initially recruited from the six selected communes at baseline. The power calculations were performed using the STATA software Release V.13 (StataCorp. Stata: Release 13. Statistical Software. College Station, Texas: StataCorp LP. 2013).

### Recruitment of participants

#### Screening

The RCT targets adults aged 50–65 years with MetS residing in six communes in Hanam province. The selected communes should be similar in terms of socioeconomic

Study group	0 month (Baseline)	Intervention	6 month (Post-test)
Intervention (n=300)	O1	X	O2
Control (n=300)	O1		O2

O = Observation X = Intervention

Figure 1 Study design.



and geographic conditions. A list of adults aged 50–65 years currently living in these communes will be obtained from the Hanam Provincial Preventive Medicine Centre. Potential participants (N=5700) will be invited to attend their local commune health centre to have their height and weight measured. Small incentives will be provided to encourage attendance. A screening interview seeking basic information on age, gender and physical activity levels will be administered face to face using a brief questionnaire. Body mass index will be classified using the cut-off points for Asian populations recommended by the WHO: <18.5, underweight; 18.5 to <23, normal weight; 23–27.5, overweight; >27.5, obese.<sup>29</sup> In terms of exclusion criteria, individuals who have been receiving treatment for T2D, CVD, hypertension, raised lipid profile, raised glucose, or have taken part in any dietary and/or physical activity programme within the past year will be excluded ( $\approx$ 10% of the target group).

#### Determining MetS status

With almost 37% of Vietnamese adults aged 50–60 years being overweight<sup>30</sup> and 31.9% of them having MetS,<sup>16</sup> approximately N=1900 will be classified as overweight/obese and subsequently invited to undertake a blood test and have their waist circumference, hip circumference and blood pressure measured to confirm MetS status (n=600).

A single overnight fasting blood sample will be collected and analysed to determine fasting plasma glucose, triglyceride, total cholesterol and HDL-C levels. On the basis of these results, people suspected to be diabetic (fasting plasma glucose  $\geq$ 7.0 mmol/L or >126 mg/dL) will be excluded from the study and recommended to attend a local hospital for confirmation of T2D instead. MetS status will be determined using the modified ATP III criteria with the waist circumference for Asia population being adopted,<sup>4</sup> which includes any three of the following five risk factors (inclusion criteria):<sup>8</sup>

- ▶ Waist circumference (male  $\geq$ 90 cm, female  $\geq$ 80 cm for Asia population;<sup>4</sup>)
- ▶ Raised triglycerides ( $\geq$ 1.7 mmol/L or 150 mg/dL);
- ▶ Reduced HDL-C (<1.03 mmol/L or 40 mg/dL for males, <1.29 mmol/L or 50 mg/dL for females);
- ▶ Raised blood pressure (systolic  $\geq$ 130 mm Hg or diastolic  $\geq$ 85 mm Hg);
- ▶ Raised plasma glucose (fasting plasma glucose  $\geq$ 6.1 mmol/L).

#### Allocation to control and intervention groups

The six communes (intervention m=3, controls m=3) will be randomly allocated to either the intervention or the 'wait-listed' control group using a table of random numbers, which are geographically separated to avoid contamination and information exchange between groups, giving a total of 600 participants at baseline evaluation. A staff member from the Hanam Provincial

Preventive Medicine Centre will independently perform the cluster-randomisation process. Figure 2 summarises the CONSORT flow chart of the study procedure.

#### Theoretical basis

Social cognitive theory (SCT), which underpins this research, is built on an understanding that the interactions between individual characteristics and environmental events shape how a person behaves.<sup>31–32</sup> The SCT perspective is that people are not driven solely by inner forces and not automatically shaped by external influences. Rather, human behaviour can be explained through its interaction with environmental events. These complex yet subtle interactions should be considered and well understood as they are essential to informing behavioural change interventions.<sup>33</sup> A key construct of SCT is self-efficacy, which is concerned with an individual's belief in their ability to perform a specific task. Self-efficacy is behaviour specific and invaluable in achieving successful behaviour change, such as increasing levels of physical activity or improving dietary intake.<sup>33</sup> Other major constructs of SCT are outcome expectations, reinforcement (motivation/incentives), observational learning, goal setting and the environment. All these constructs will help to inform the intervention strategies.

#### Intervention

##### Description

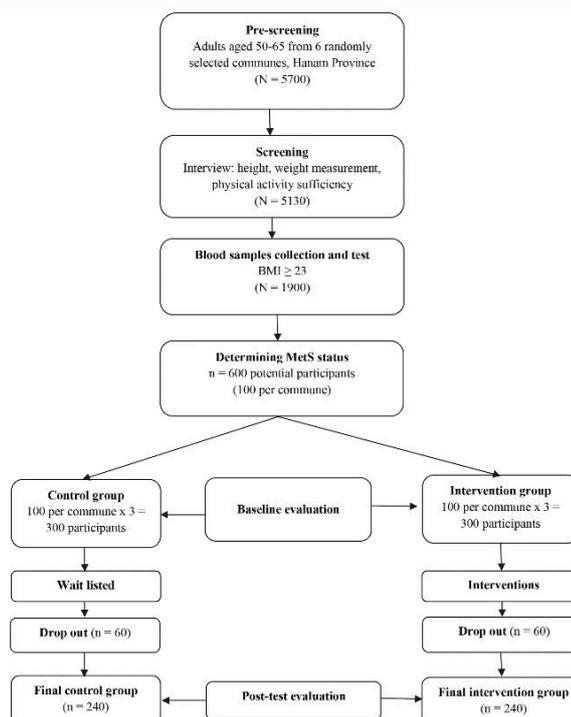
The adopted intervention strategies are based on our previous successful interventions,<sup>21–34</sup> as research has indicated that a combination of health education and walking programmes can lead to improved lifestyle management and reduced risk of MetS.<sup>35</sup> This community-based intervention will include a range of strategies and resources to encourage participation and to improve retention, such as education sessions, information booklet, resistance band and walking groups led by local walk leaders. All components of the programme will be conducted within the participant's commune to minimise participant burden. They are designed to inform participants of the benefits of being physically active and maintaining a healthy diet as a means of preventing chronic disease. Positive reinforcement, by way of encouragement and feedback, will be facilitated through the trained walking group leaders.

##### Walk leaders

A walk leader in each walking group will be either a local middle-aged volunteer or the village health worker within the commune. The walk leaders are required to be enthusiastic, demonstrate leadership qualities and be respected by the commune residents. The research team will maintain regular contact and monitor progress with them via telephone and a monthly face-to-face meeting. They are required to attend three 2-hour training sessions and will be provided with a package containing the



**Figure 2** The flow diagram of the research procedure. BMI, body mass index; MetS, metabolic syndrome.



education materials, as well as a manual for managing the group walks. The manual is a comprehensive guide to mobilise walking groups, containing examples on walking activities and stretching and resistance exercises, benefits of being physically active and maintaining a healthy diet, supplemented by effective communication strategies. Besides mobilising and encouraging the participants for group walking, the group leaders also guide the participants but have the flexibility to tailor the prescribed programme to suit individual needs, such as walking less or more, within their group. They will also be responsible for administrative work such as recording participant contact details.

#### Programme delivery

Programme staff will be selected from medical doctors and nurses who are employed by the Hanam Provincial Preventive Medicine Centre. These staff members will be responsible for conducting interviews and taking anthropometric measurements and blood sample collections, after receiving intensive training from the chief investigators, who oversee all aspects of the programme delivery including the development of resources, setting up of walking groups and process evaluation.

#### Programme resources

##### Education sessions

The participants (n=100) in each intervention commune will be divided into four groups, that is, 25 participants per group. Each group will attend four 2-hour education sessions on healthy diet and physical activity in months 1, 2, 3 and 4 of the programme held at the local commune health centres. The duration and size of these education sessions are determined on the basis of a previous study.<sup>36</sup> Sessions will be participatory and interactive, rather than didactic. Small group activities will foster problem-solving, social support and programme ownership. Table 1 describes the contents of the four education sessions and their linkages with behaviour change underpinned by the SCT.

##### Information booklet

At the first education session, each participant will be given a booklet (in Vietnamese) designed to inform and support improvements in nutritional intake and physical activity behaviours. This booklet is adapted from previously developed materials used in the Physical Activity and Nutrition for Seniors project<sup>37</sup> and modified to ensure suitability for the Vietnamese cultural context.



Table 1 Education sessions linked to the theoretical basis of the study

Themes	Contents	Link with behaviour change techniques
Session 1 (month 1): introduction to the project	<ol style="list-style-type: none"> <li>1. Getting to know each other</li> <li>2. Introduce the programme</li> <li>3. Benefits of physical activity and nutrition on health, especially people with MetS, CVD, T2D</li> <li>4. Introduce and distribute the booklet</li> <li>5. Establishment of goal setting</li> </ol>	Interaction with other participants; Outcome expectation
Session 2 (month 2): physical activity	<ol style="list-style-type: none"> <li>1. Demonstrate and practice of exercises and walking, programme such as warm up, cool down</li> <li>2. Barriers and enablers of being physically active</li> <li>3. How to identify and overcome these barriers</li> </ol>	Observational learning; Self-efficacy; Outcome expectation
Session 3 (month 3): healthy diet	<ol style="list-style-type: none"> <li>1. Demonstration and discussion of healthy foods and healthy eating habits</li> <li>2. Barriers and enablers of maintaining a healthy diet</li> <li>3. How to identify and overcome barriers</li> </ol>	Observational learning; Self-efficacy; Outcome expectation
Session 4 (month 4): experience and lessons learnt	<ol style="list-style-type: none"> <li>1. Interactive session on overcoming barriers to being physically active and maintaining a healthy diet</li> <li>2. Discussion of food types</li> <li>3. Feedback from participants</li> <li>4. Encourage participants to read the relevant sections in the booklet to reinforce what they learnt in the sessions</li> <li>5. Review physical activity and nutrition goals</li> </ol>	Observational learning; Reinforcement

CVD, cardiovascular disease; MetS, metabolic syndrome; T2D, type II diabetes.

The educational materials are simple, short and easy to understand and comprise four sections. The first section introduces the programme as well as the benefits of physical activity and a healthy diet. The second section focuses on various modes of physical activity, and contains illustrations and tips on how to perform physical activity (eg, brisk walking) correctly and resistance, weight training and stretching exercises safely. The third section contains suggested meal plans, recipes and tips for healthy eating, encouraging a higher consumption of fruits, vegetables and fibre while reducing intake of saturated fat, salt and sugar. The last section provides information on the barriers to physical activity and healthy eating and how to overcome them, together with practical examples. Participants will also be asked to set their own physical activity and nutrition goals and to enter their progress and achievements towards these goals in the booklet. Figure 3 shows the front page of the information booklet (available from the first author on request).

#### Resistance exercises

Each participant will be provided with a resistance band. Detailed instructions on usage, warming up and exercise techniques, as well as how to develop their own personal physical activity goals and plan, will be disseminated during the education sessions. Written information and pictorial illustrations are presented in the booklet.

#### Walking groups

Four walking groups per commune will be established immediately after the first education session. These

walking groups serve to mobilise the participants, supporting them to meet and walk together in order to achieve the physical activity guidelines for health benefits. All participants will be encouraged to join a walking group based on their geographic location within the commune and guided by their local walk leaders.

#### Outcome measures

Table 2 summarises the outcome variables and their corresponding measuring instruments.

#### Blood samples

Blood samples will be collected by a phlebotomist in the morning after fasting for at least 8 hours during the community clinic visit at baseline and at 6-month post-test. The collected blood samples will be stored at 2–8°C in iceboxes and then transported to the Hanam provincial biochemistry laboratory for analysis within 6 hours. Plasma glucose will be measured by the glucose oxidase method. Lipid profile including total cholesterol, triglycerides and HDL-C will be measured by enzymatic methods. Glucose and lipids will be analysed using a semiautoanalyser (Screen Master Laboratory; Hospitex Diagnostics LIHD112, Italy) with a commercial kit (Chema Diagnostica, Italy).

#### Anthropometric measurements

These will be taken by the programme staff at baseline and at 6-month post-test following the WHO's guidelines.<sup>38</sup> Such measurements include height, weight, waist and hip circumferences using a portable stadiometer, tape measures, and calibrated electronic scales.



**Figure 3** Front page of the information booklet.

#### Blood pressure

A physician or trained nurse will measure blood pressure using an Omron HEM-8712 automatic blood pressure monitor, with participants sitting and their arm supported at heart level. A mean value will be obtained after taking three consecutive measurements at baseline and post-test.

#### Physical activity

The validated International Physical Activity Questionnaire-Short Form (IPAQ-SF; Vietnamese version)<sup>39</sup> will be administered to measure self-reported physical activity. Pedometers will also be used to objectively measure walking. The device will be fitted to the hip and worn for 7 consecutive days at baseline and post-test for the intervention group participants only.

#### Diet

The brief dietary habit questionnaire is adapted from the STEPS developed by the WHO.<sup>38</sup> It will undergo pilot testing with further modifications before actual application to suit the local context. Information on cigarette smoking and alcohol drinking will also be solicited.

#### Demographics

Participant demographics include gender, age, education level, marital status and occupation. The structured questionnaire will be administered face to face.

#### Process evaluation

This type of evaluation assesses the following components of an intervention: fidelity (quality); dose delivered (completeness); dose received (exposure and satisfaction); reach (participation rate); recruitment and context (aspects of the environment influencing implementation or outcomes).<sup>40</sup> It will be conducted midway through the intervention using a brief questionnaire, asking participants to evaluate the resources (ie, readability, how easy to understand, usefulness of advice, suitability and relevance to their age group). An open-ended section will enable participants to comment specifically on features they like/dislike.<sup>41</sup> Process evaluation is important to identify the suitability of the intervention to the target group, and assesses the appropriateness of all aspects of the research procedure encompassing recruitment, data collection, evaluation, intervention implementation and dissemination.<sup>40</sup>

#### Exit interview

A total of 24 intervention participants will be randomly selected to participate in these interviews. The sample size is similar to that of a previous study.<sup>34</sup> While the literature has identified that sample size recommendations for non-probabilistic, purposive qualitative studies can range from 5 to 25 participants, saturation occurs within the first 12 interviews.<sup>42</sup> Therefore, 12 programme



Table 2 Summary of outcome measures

Outcome variables	Measuring instrument
Primary outcomes	
Physical activity: walking, intensity, duration and frequency	IPAQ-SF, pedometer
Diet: fat, oil, salt, sugar intake, fruit and vegetable consumption	Modified dietary behaviour questionnaire from the WHO STEPs survey
Secondary outcomes	
Plasma glucose, triglyceride, total cholesterol and HDL-C	Fasting blood sample
Anthropometric measurements: height, weight, waist circumference, hip circumference, blood pressure	Portable stadiometer, tape measure, calibrated electronic scales, Omron HEM-8712 automatic blood pressure monitor

HDL-C, high-density lipoprotein cholesterol; IPAQ-SF, International Physical Activity Questionnaire-Short Form.

completers and 12 non-completers will be asked if they are willing to participate in a face-to-face interview to gain information regarding their perceptions of the intervention programme and resources. The non-completers will be asked reasons for their withdrawal. It is estimated that each interview will take <20 min. Permission will be sought for recording the interviews.

#### Statistical analysis

In addition to descriptive statistics, generalised mixed regression models will be fitted to the repeated pre-post measures to evaluate the magnitude of the changes and associated effect sizes. Effectiveness of the proposed intervention, and comparisons between the intervention group and the control group over time, will be ascertained via the group by time interaction term in the multivariate regression models, taking into account the repeated measures, correlated data structure and the presence of missing observations, whereas intention-to-treat analysis will be undertaken to assess sensitivity of the inferences. All data entry and statistical analyses will be performed in the STATA package Release V.13.

#### Ethics and dissemination

All participants will be provided with an information sheet (see online supplementary file 1) and asked by the trained programme staff to sign a consent form (see online supplementary file 2) prior to entry into the programme and be made aware that they are free to withdraw at any time. Only aggregated data will be reported in publications. The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014). The results of the study will be disseminated through publications, reports and conference presentations.

#### DISCUSSION

Vietnamese adults aged 50–65 years account for 13.8% (equivalent to 12.4 million people) of the total population,<sup>43</sup> while 40% of the middle-aged population have pre-MetS.<sup>16</sup> Therefore, this study will contribute to the knowledge base of the risk factors associated with MetS and related chronic diseases in Vietnam. It is the first

community-based RCT ever undertaken on Vietnamese adults with MetS according to our extensive literature search. Findings from the study will be potentially applicable for NCD prevention in Vietnam.

**Contributors** VDT coordinated the programme and drafted the manuscript. VDT, AHL, JJ, APJ, PH and LTPM designed the study and revised the manuscript. All authors have read and approved the final version for publication.

**Funding** This study is financially supported by the School of Public Health, Curtin University, Perth, Western Australia, Australia.

**Competing interests** None declared.

**Patient consent** Obtained.

**Ethics approval** Curtin University Human Research Ethics Committee (approval number: HR139/2014).

**Provenance and peer review** Not commissioned; externally peer reviewed.

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#### 4. RESULTS

This chapter presents results of the research, including process evaluation, physical activity and nutrition behaviour outcomes, features of MetS, MetS status, and other risk factors after intervention. The results addressed the remaining objectives of the research and were published in three papers as follows:

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>

This publication addresses objective 2. Assess at post-test the change in physical activity levels and dietary behaviours of the intervention group relative to the control group.

2. **Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>

This publication addresses the objective 3. Assess at post-test the change in features of MetS, MetS status, and other risk factors of the intervention group relative to the control group.

3. **Van Dinh Tran**, Jonine Jancey, Andy Lee, Anthony James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation. *Evaluation and Program Planning*. 61. 128-133. <https://doi.org/10.1016/j.evalprogplan.2016.12.012>

This publication addresses the objectives 4. Assess the satisfaction of the intervention strategies and resources by the intervention group, and 5. Assess the fidelity from the participants' perspective, the participation, reasons for completing, and not-completing the intervention program.

It should be remarked that a total of  $n=417$  participants were recruited at baseline and  $n=337$  of them completed the post-test assessment, which fell short of the sample sizes required for attaining 80% power in the study.

#### **4.1 Process evaluation**

Related publication:

***Physical Activity and Nutrition Program for Adults with Metabolic Syndrome:  
Process Evaluation***

This publication addresses the objectives 4, and 5:

4. Assess the satisfaction of the intervention strategies and resources by the intervention group.
5. Assess the fidelity, the participation, reasons for completing, and not-completing the intervention program.

#### **Citation:**

**Van Dinh Tran**, Jonine Jancey, Andy Lee, Anthony James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation. *Evaluation and Program Planning*. 61. 128-133. <https://doi.org/10.1016/j.evalprogplan.2016.12.012>



## Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation



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### ARTICLE INFO

#### Article history:

Received 3 November 2016  
Received in revised form 23 December 2016  
Accepted 27 December 2016  
Available online 29 December 2016

#### Keywords:

Health promotion  
Process evaluation  
Physical activity  
Dietary behaviours  
Lifestyle  
Metabolic syndrome

### ABSTRACT

**Introduction:** The Vietnam Physical Activity and Nutrition (VPAN) program aimed to improve physical activity and nutrition for adults aged 50–65 years with Metabolic Syndrome in Vietnam. The VPAN program consisted of a range of resources and strategies, including an information booklet, resistance band, face-to-face education sessions, and walking groups. This process evaluation assessed the participation, fidelity, satisfaction, and reasons for completing and not-completing the VPAN.

**Methods:** Data were collected by mixed-methods from a sample of 214 intervention participants. Quantitative data were collected via surveys (n = 163); qualitative data via face-to-face exit interviews with intervention program completers (n = 10) and non-completers (n = 10), and brief post education session discussions.

**Results:** Most participants (87%–96%) reported the program resources and strategies useful, assisting them to increase their physical activity level and improving their diet. The education sessions were the most preferred strategy (97%) with high attendance (>78% of participants). The main reasons for withdrawal were work commitments and being too busy.

**Conclusion:** The evaluation indicated that the program reached and engaged the majority of participants throughout the six-month intervention. The combination of printed resources and face-to-face intervention components was a suitable approach to support lifestyle behavioural change in the Vietnamese population.

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### 1. Introduction

The World Health Organization estimated that almost three-quarters of deaths from non-communicable diseases (NCD) occur in low and middle income countries (World Health Organization, 2014). Unhealthy diets and physical inactivity are among the leading causes of NCDs (World Health Organization, 2014). About 3.2 million deaths annually can be attributed to insufficient physical activity (Lim et al., 2012), while diets with excess salt/sodium account for 1.7 million deaths from cardiovascular diseases

(Mozaffarian et al., 2014). Together with smoking and alcohol consumption, these behaviours support the development of key metabolic changes that increase the risk of NCD, namely, raised blood pressure, hyperglycemia, hyperlipidemia and overweight/obesity (World Health Organization, 2014).

With rapid economic growth over the last few decades, many developing countries in the Asia-Pacific region have experienced a dramatic transition in disease patterns, with the burden of NCD now overtaking traditional communicable diseases (Binns and Boldy, 2003). Similar to other countries in the region, the burden of NCDs is increasing in Vietnam (Nguyen, Pham, Lee, & Binns, 2015), accounting for 75% of the total disease burden in 2007 (Harper, 2011). Modifiable behavioural risk factors, such as physical inactivity and unhealthy diets, are strongly associated with the disease burden in Vietnam. It is estimated that 28.7% of Vietnamese adults are insufficiently active (<600 MET-min per week) (Harper, 2011). In addition, household food consumption patterns have rapidly changed (National Institute of Nutrition of

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<http://dx.doi.org/10.1016/j.evalprogplan.2016.12.012>  
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Vietnam, 2010), with the energy intake from fat rising from 8.4% to 17.6% within the last two decades (National Institute of Nutrition of Vietnam, 2010).

Metabolic Syndrome (MetS) is a cluster of risk factors for cardiovascular disease and type 2 diabetes, including central obesity, impaired glucose metabolism, dyslipidaemia and hypertension (Alberti et al., 2009). Similar to other Asian-Pacific countries, MetS is considered a major public health issue in Vietnam, with an estimated 16.3% of Vietnamese adults exhibiting the syndrome, and Vietnamese aged 55–64 having the highest prevalence (≈27%) (Binh, Phuong, Nhung, & Tung do, 2014).

The Vietnam Physical Activity and Nutrition (VPAN) program is a cluster-randomised controlled trial intended to enhance physical activity and dietary behaviours of adults aged 50–65 years with MetS in Hanam province, Vietnam. At the end of the six month intervention program, participants showed significant improvements in moderate intensity activity and walking, as well as reductions in the consumption of animal internal organs and cooking oil for daily meal preparation (Tran et al., 2016a).

It is important to monitor the implementation of community-based trials, so as to gain insights into why a program may succeed or fail (Blackford et al., 2016; Burke et al., 2012; Kennedy, Schenkelberg, Moyer, Pate, & Saunders, 2017; Wilson et al., 2009). Process evaluation offers an opportunity to determine how the program was conducted and the characteristics or mechanisms associated with its implementation, which potentially affected the outcomes (Aarestrup, Jørgensen, Due, & Krølner, 2014; Blackford et al., 2016; Burke et al., 2012; Wilson et al., 2009). Nevertheless, most outcome analyses are conducted without any assessment of program implementation (Saunders, Ward, Felton, Dowda, & Pate, 2006). The purpose of this article is to report the process evaluation of the participation, fidelity and participant satisfaction, and reasons for completing and not completing the VPAN program.

## 2. Methods

### 2.1. Setting and participants

The VPAN program was a 6-month community based cluster-randomised controlled trial targeting adults with MetS from 10 communes in Hanam province, northern Vietnam. The trial was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12614000811606). The research protocol (Tran et al., 2016b) was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014).

Overweight adults aged 50–65 years with MetS living in the 10 communes were invited to participate in the study. Details of the recruitment and participant selection have been published previously (Tran et al., 2016b). MetS status was determined according to the National Cholesterol Education Programme Adult Treatment Panel III criteria of having three of the five risk factors

(Adult Treatment Panel III, 2002) and a large waist circumference (male  $\geq 90$  cm, female  $\geq 80$  cm) for Asian Populations (Alberti et al., 2009). A total of 417 participants were recruited into the program (intervention n=214; controls n=203). The intervention participants made up the sample for the process evaluation.

### 2.2. Intervention components

The intervention was underpinned by Social Cognitive Theory taking into consideration the individuals and their interaction with the environment (Bandura, 1997; Glanz et al., 2008). The VPAN program included a range of resources and strategies designed to promote participants to be physically active and to maintain a healthy diet. All healthy lifestyle information was taken from the WHO's Recommendations for Physical Activity (WHO, 2010), and the Food Based Dietary Guidelines in Vietnam (National Institute of Nutrition of Vietnam, 2013).

The VPAN intervention participants were provided with a resistance band and an information booklet containing advice and suggested activities on how to enhance physical activity and dietary behaviours. They were required to attend four 2-h education sessions at months 1, 2, 3 and 4, and participated in walking groups established at each commune for 6 months. The walking groups met twice a week for 6 months. The participants nominated a walk leader in each walking group. The walk leaders were trained at three 2-h training sessions and provided with a package containing the education materials, and a manual detailing how to manage the group walks. For example, walk leaders were provided with a prescriptive progressive weekly walking program but were able to modify the program to suit the needs of the group members. The walking group leaders attended all of the walking group meetings. They mobilised participants for walking and supported them in achieving their physical activity and diet goals. Trained program staff from the Hanam Provincial Preventive Medicine Centre, conducted the education sessions, and collected data from participants at baseline and post-test the program staff. Community health workers assisted in mobilising participants and organising education sessions. A detailed overview of the resources and intervention strategies has been described elsewhere (Tran et al., 2016b).

### 2.3. Data collection

Quantitative data were collected via self-administered questionnaires, and qualitative data gathered through brief post education session discussions and structured interviews. The participants were informed of the purpose of the survey/interview prior to commencing, and written informed consent was obtained. Table 1 shows the process evaluation components and their corresponding measurement approaches.

**Table 1**  
Process evaluation components and measurements.

Variables and definition	Measurement approaches		
	Self-reported questionnaire	Brief post education session discussions	Exit interviews
Participation: The number of participants actively participating in the education sessions		x	
Fidelity: The extent to which implementation of the intervention occurred as planned	x	x	
Satisfaction: The satisfaction of participants with the intervention program	x	x	x
Reasons for completing the program: To what extent encouraged participants completed the program			x
Reasons for not-completing the program: To what extent stopped participants completed the program			x

#### 2.4. Self-administered questionnaire

At the end of the fourth education session (month 4), the participants were asked to complete a brief self-administered questionnaire. This questionnaire assessed the usefulness, relevance and suitability of the intervention resources and strategies for supporting management and changes to physical activity and nutrition behaviours; and overall perception of the program. The questionnaire was adapted, translated, and tested from previous studies. (Burke et al., 2012) A 5-point Likert-scale was used for specific feedback on the resources. The participants were required to select the closest statement they agreed with (e.g., *useful to not useful, relevant to not relevant, suitable to not suitable, strongly agree to strongly disagree*). The completed questionnaires were non-identifiable to encourage honest responses.

#### 2.5. Brief post education session discussions

At the end of each education session, a 10 min discussion was held between the research team and participants. The purpose was to identify the participation, fidelity, and suggest changes to improve the program.

#### 2.6. Exit interviews

Twenty semi-structured exit interviews, involving 10 completers and 10 non-completers, all from the intervention group, were conducted by a trained native speaking researcher. The number of interviews undertaken was based on a similar community based study, (Blackford et al., 2016) along with evidence from the literature that suggests saturation occurs within the first 12 interviews (Guest, Bunce, & Johnson, 2006). They were randomly selected from the list of participants who agreed to be interviewed for approximately 15 min. Completers were defined as those participants who attended at least three education sessions and undertook the post-evaluation. Questions included what participants thought about the intervention components, such as the booklet, resistance band, education sessions, walking group and walk leaders; their overall perceptions of the program; whether the program encouraged them to increase their level of physical activity; and any changes to their diet. The exit interviews also solicited recommendations for future programs. The interview was up to 40 min in duration. Permissions were sought for recording of all interviews.

#### 2.7. Data analysis

Descriptive univariate analysis was undertaken on participant characteristics. The Likert responses from the questionnaires were summed and percentages were calculated (e.g. strongly agree to strongly disagree) before collapsing into dichotomous variables (e.g. agree and disagree). The quantitative data were analysed using the SPSS package version 21.0. Qualitative data from the exit interviews were documented and collated; and common key words and phrases were extracted from the participant responses.

### 3. Results

#### 3.1. Demographic characteristics

Table 2 summarises the sample demographic characteristics. The majority of participants were female (81.3%), with an average age of 57 years. Over half had completed secondary school (52.0%) and retired (58.0%). The participants predominantly lived with their partner (91.6%).

**Table 2**  
Demographic characteristics of the participants (n=214).

Variable	n	%
Age: mean (SD) years	57.61 (4.92)	
Gender		
Female	174	81.3
Male	40	18.7
Relationship status		
No partner	18	8.4
With partner	196	91.6
Education level		
Primary school or below (Less than grade 5)	19	8.9
Secondary school (Grade 6 to 9)	111	51.9
High school (Grade 10 to 12)	55	25.7
College/University	29	13.6
Employment status		
Employed	90	42.0
Retired	124	58.0
Smoking status		
Never	186	86.9
Former	13	6.1
Current smoker	15	7.0
Alcohol drinking		
Yes	41	19.2
No	173	80.8

SD: Standard deviation.

#### 3.2. Self-administered questionnaire

Table 3 outlines the responses to the resources and strategies. In total, 163 intervention participants (response rate 76.1%) completed the self-administered questionnaire. The vast majority reported that the booklet provided “*useful advice*” (96.3%); was “*easy to read*” (95.7%) and “*easy to understand*” (96.9%); *encouraged them to think about physical activity*” (95.97%), and “*encouraged them to think about a healthy diet*” (96.9%). They also “*liked the resistance band*”

**Table 3**  
Participant responses in relation to program resources and strategies (n=163).

Agree with statement	n	%
Booklet		
Useful advice	157	96.3
Easy to read	156	95.7
Easy to understand	158	96.9
Encouraged me to think about physical activity	156	95.7
Encouraged me to think about a healthy diet	158	96.9
Resistance band		
I like the resistance band	155	95.1
Exercises with resistance band are simple and easy to follow	156	95.7
Encouraged me to do more exercises	154	94.5
Walking Group		
Satisfied with group walking	147	87.1
Encouraged me to walk more	146	89.6
Suitable for my age group	150	92.0
Walk leader mobilised people for walking	149	91.4
Walk leader encouraged me to walk more	145	88.9
Education sessions		
Provided useful information on health	158	96.9
Satisfied with the contents	158	96.9
Duration for each session was enough	154	94.5
The sessions were well organised	157	96.3
Happy with the facilitators	158	96.9
Facilitators motivated me to attend the sessions	157	96.3
Program overall		
Happy with the program materials and activities	158	96.9
Encouraged me to think about physical activity	155	95.1
Encouraged me to think about dietary changes	153	93.8
Helped me change my physical activity behaviours	150	92.0
Helped me change my dietary behaviours	149	91.4

(95.1%), and claimed that it “encouraged them to do more exercises” (94.5%). Eighty seven percent of the participants were “satisfied with the walking group”; since the walking group “encouraged them walking more” (89.6%); and was “suitable for their age” (92.0%). Most of the participants found the walk leader “helpful in mobilising them walking” (91.4%) and “encouraged them to walk more” (88.9%).

Almost all the participants (97%) reported that the education sessions provided “useful information for health”, “duration for each session was enough” (94.5%), and “well organised” (96.3%). They were “satisfied with the contents”, and “happy with the facilitators”, and “the facilitators motivated them to attend the sessions” (96.3%).

With respect to the program, the majority agreed that “they are happy with the materials and activities of the program” (96.9%); it “encouraged them to think about physical activity” (95.1%), “think about dietary changes” (93.8%), “changed their physical activity” (92.0%), and “changed their dietary behaviours” (91.4%).

### 3.3. Brief post education session discussions

Attendance record of the education sessions showed that 42 participants did not attend the first session. This acted as a catalyst for program staff to liaise with local commune health centres to follow-up these participants, providing them with the booklet and a brief summary of the intervention program and content of the first education session.

Reasons for non-attendance at the first session included: moved out of the area (n=5), caring for grandchildren (n=18), forgot to attend (n=7), unwell (n=6) and away on the day (n=6). Due to the reported challenges associated with attending the first education session, childcare was provided for the subsequent education sessions supervised by volunteer staff. Suitable times and dates for the next education sessions were identified to facilitate participation. In addition, there were a range of abilities in each walking group in regard to the distance and speed that participants could walk. This led to some walking groups being reorganised based on participant abilities.

Participants were only phoned after the first session as attendance remained stable after this point in time. Table 4 indicates that the education sessions were well attended. The main reasons for not attending sessions included they changed their mind (n=18); moved away from area (n=8), experienced health issues (n=6) and were travelling (n=5).

Participants reported that they all received the information booklet and resistance band and found them to be interesting and useful in supporting improvements in physical activity and diet behaviours. The walking groups were established in all communes and implemented as intended, meeting at regular times.

### 3.4. Exit interviews

Ten interviews were conducted with completers aged 52–65 years (eight females, two males) and 10 non-completers (nine females, one male) aged 53–64 years.

**Table 4**  
Number of participants attending education sessions (n=214).

Education sessions	n	%
Session 1	172	80.4
Session 2	185	86.4
Session 3	182	85.0
Session 4	168	78.5

### Program resources: information booklet and resistance band

All participants agreed that the booklet was good and easy to read: “it is coloured printed and eye-catching”. They found the booklet helpful and relevant: “it provides useful information about healthy diets, which food should be eaten, and which should not”; “it encouraged me to think about physical activity and healthy diets”. The completers also reported that the booklet reminded them to undertake physical activity and consume a healthy diet: “I read the booklet when I have free time and follow the instructions”; “I perform the stretch exercises and exercises with the resistance band following guidance from the booklet”.

The program completers indicated that the resistance band enhanced their exercise regime, “this is the first time I used the band for doing exercise”; “it looks simple but effective”; “I do exercises with the resistance band everyday”. They reported that the resistance band was suitable and helpful: “it encourages me to do more exercises, especially those using my hands”; “on raining days, I could not walk, so I did exercises with the band instead”.

### Program activities: education sessions and walking group

The majority of the completers found the education sessions useful: “Whenever I was invited for the sessions, I came”; “I learnt a lot of things in the education sessions to prevent myself from diabetes and heart disease”; “the sessions provided useful information to improve our health”. The education sessions were a good environment: “attending the sessions, we shared experiences to improve our health”; “we discussed how to improve physical activity and eat healthy”. The completers found that walking in groups encouraged them to walk more and regularly: “walking with other members does not let me to be lazy”; “I want to walk with the group every morning”. However, walking in groups posted some issues, such as: “sometimes I wanted to walk more but others did not”; “I can walk faster than other members”. Some participants did not join the group after a few days: “I walked with my husband, it is more convenient for me”.

### Program overall

Participants reported that the VPAN program encouraged them to be more physically active: “I woke up early and joined in walking with the walking group”; “I had commenced regular walking together”; “after walking I did another 30 min of exercises with the resistance band”; “I feel comfortable and strong after doing these exercises”.

Moreover, participants indicated that the program reminded them about good eating habits and to improve their diet: “I am trying to eat more fruit, vegetables and boiled foods, and less steamed rice, less fried foods”. Some participants managed to change their eating habits: “at meals, I eat one bowl of vegetables first, so I can eat more vegetables at every meal”; “before I just ate what foods I wanted, but now I am thinking more about eating healthy foods”.

### Reasons for completing the program

There were a range of reasons nominated by participants for completing the program with the majority stating that it “improved their health” (n=10), “prevents diabetes and heart disease” (n=8), “makes them more active” (n=8) and “enabled them to network with other participants” (n=7)."

### Reasons for not completing the program

According to non-completers (n=10), the main reasons for not completing the program were “too busy”, “time constraints due to

work”, “went to other provinces to take care of my grandchildren” and “know the information provided by the program already”.

#### Recommendations

Most participants reported that the VPAN program “should be continued” and held “at least one education session per three months”. The reasons for continuation of the education sessions were “the doctors [facilitators] of the education sessions provided useful information” and “the sessions will remind us to improve our health”. In addition, some modifications to the walking group were suggested: “walking as couples [husband and wife] is a good way”.

#### 4. Discussion

The process evaluation of the VPAN program was conducted to assess the participation, fidelity, satisfaction, and reasons for completing or not completing the program. The outcomes showed good program participation and acceptability with positive responses by the participants to program resources and strategies. The results increase our understanding of the program components that were embraced by participants and assisted in supporting behavioural changes (Tran et al., 2016a).

The Social Cognitive Theory which underpins this intervention program (Glanz et al., 2008) helps us to better understand the complex nature of health behaviour and how interactions between the individual and environmental influence these behaviours (Bandura, 1997; Glanz et al., 2008). The use of this theory in this community based intervention was invaluable in developing relevant program strategies to support behaviour change and increase the likelihood of the desired health outcomes (Morgan, Young, Smith, & Lubans, 2016). By incorporating information sharing, opportunities to practice new skills, goal setting, modelling and social support, self-efficacy increased and behaviour change was facilitated and hopefully will be sustainable. This community based intervention was informed by theory, resulting in significant improvements in moderate intensity activities and walking, as well as reductions in the intake of animal internal organs and the use of cooking oil for daily meal preparation (Tran et al., 2016a).

The study participants reported positive evaluations of the intervention resources (booklet and resistance band) and strategies (education sessions and walking group). The information booklet and resistance band were tools that supported the apparent increases in physical activity levels and healthy dietary behaviours. These strategies were found to be successful in previous studies (Blackford et al., 2015; Burke et al., 2013) and with our specific Vietnamese population group.

Establishing walking groups provided an environment that connected individuals with new social networks, enhancing positive behaviour change (Stahl et al., 2001). Moreover, the trained walk leaders played a key role in mobilising and motivating members to become and remain physically active (Jancey et al., 2008a; Jancey et al., 2008b). These program components, and in particular the social support, helped participants to improve their physical activity and nutrition behaviours (Tran et al., 2016a).

The provision of education sessions, the monitoring of attendance, and the adaption of program to meet the group needs were valuable, as observed through the positive feedback from the participants. Face-to-face education sessions are desirable for health promotion programs as they can be more effective than other communication means, which provide an opportunity for personal feedback and group support (Kristen, Ivarsson, Parker, & Ziegert, 2015). It is important to note that the majority of participants reported highly positive evaluations of the education sessions and the facilitators. These positive responses indicated

that this face to face approach with its interactive environment was very appropriate for this target group, achieving favourable results. Additionally, providing follow-up education sessions after the six-month intervention was suggested by the participants.

The brief discussion after each education session offered opportunities to review the program and attendance, as a type of continuous feedback. Changes implemented after the first session with the provision of childcare and composition of walking groups supported the involvement of participants, emphasising the importance of process evaluation to inform and enhance program implementation in on-going trials (Wilson et al., 2009). Such discussion contributes to determining the optimal action for health promotion programs to be relevant and acceptable to the target group (Brauer et al., 2015). Ongoing monitoring of program implementation followed by appropriate modifications is required to improve the fidelity of health promotion programs (Durlak and DuPre, 2008). This approach was a key factor in the success of the intervention.

Seventy percent of participants responded to the process evaluation, a response rate that is comparable to similar process evaluations (Blackford et al., 2016; Monteiro et al., 2014). Due to the close relationship between the program staff and the participants, there may have been a degree of social desirability associated with participant responses. However, all reported data were anonymous and non-identifiable which was likely to minimise potential biases.

#### 5. Conclusion

Our process evaluation demonstrated that the VPAN program reached and engaged the majority of participants throughout the six-month intervention. The target group gave positive responses to the various intervention components. A combination of printed resources, walking groups, and interactive face-to-face education sessions appeared to be a suitable approach in terms of improving physical activity and eating behaviours.

#### 6. Lessons learned

Undertaking this evaluation led to a refining of the program activities that included the provision of childcare during education sessions and re-configuration of walking groups, which supported on-going participation in the program. In addition, it led to an understanding of the acceptability of the program components, such as participants’ preference for the face-to-face education sessions and the value of the social support provided by the walking groups. In summary, the results of this process evaluation showed that the program was predominantly implemented as intended; it was of an expected quality, with program design changes to support participant retention. Process evaluation is an iterative process that is an essential component of health promotion programs and should be a regular inclusion in any community based intervention.

#### Conflict of interest

None of the authors have financial or non-financial competing interests.

#### Funding

This study was supported by the School of Public Health, Curtin University, Western Australia.

## Acknowledgements

We are grateful to the residents of Hanam province who participated in the study. Thanks are also due to the Hanam Provincial Preventive Medicine Centre for support during the study.

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## 4.2 Physical activity and nutrition behaviour outcomes

### **Related publication:**

*Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam*

This publication addresses objective 2:

2. Assess at post-test the change in physical activity levels and dietary behaviours of the intervention group relative to the control group.

### **Citation:**

**Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>

RESEARCH

Open Access



# Physical activity and nutrition behaviour outcomes of a cluster-randomized controlled trial for adults with metabolic syndrome in Vietnam

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## Abstract

**Background:** Metabolic syndrome is prevalent among Vietnamese adults, especially those aged 50–65 years. This study evaluated the effectiveness of a 6 month community-based lifestyle intervention to increase physical activity levels and improve dietary behaviours for adults with metabolic syndrome in Vietnam.

**Methods:** Ten communes, involving participants aged 50–65 years with metabolic syndrome, were recruited from Hanam province in northern Vietnam. The communes were randomly allocated to either the intervention (five communes,  $n = 214$ ) or the control group (five communes,  $n = 203$ ). Intervention group participants received a health promotion package, consisting of an information booklet, education sessions, a walking group, and a resistance band. Control group participants received one session of standard advice during the 6 month period. Data were collected at baseline and after the intervention to evaluate programme effectiveness. The International Physical Activity Questionnaire – Short Form and a modified STEPS questionnaire were used to assess physical activity and dietary behaviours, respectively, in both groups. Pedometers were worn by the intervention participants only for 7 consecutive days at baseline and post-intervention testing. To accommodate the repeated measures and the clustering of individuals within communes, multilevel mixed regression models with random effects were fitted to determine the impacts of intervention on changes in outcome variables over time and between groups.

**Results:** With a retention rate of 80.8%, the final sample comprised 175 intervention and 162 control participants. After controlling for demographic and other confounding factors, the intervention participants showed significant increases in moderate intensity activity ( $P = 0.018$ ), walking ( $P < 0.001$ ) and total physical activity ( $P = 0.001$ ), as well as a decrease in mean sitting time ( $P < 0.001$ ), relative to their control counterparts. Significant improvements in dietary behaviours were also observed, particularly reductions in intake of animal internal organs ( $P = 0.001$ ) and in using cooking oil for daily meal preparation ( $P = 0.001$ ).

**Conclusions:** The prescribed community-based physical activity and nutrition intervention programme successfully improved physical activity and dietary behaviours for adults with metabolic syndrome in Vietnam.

**Trial registration:** Australian New Zealand Clinical Trials Registry, ACTRN12614000811606. Registered on 31 July 2014

**Keywords:** dietary behaviours, health promotion, metabolic syndrome, physical activity, randomized controlled trial, Vietnam, walking

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## Background

Metabolic syndrome is a cluster of risk factors for cardiovascular disease and type 2 diabetes that includes abdominal obesity, elevated blood pressure, reduced high-density lipoprotein cholesterol levels, elevated fasting triglyceride and high glucose concentrations [1]. Metabolic syndrome is becoming a global epidemic [2] and is often undiagnosed [3, 4], with about one-quarter of the adult population worldwide affected by the condition [5]. In Vietnam, it has been reported that almost two-fifths of adults aged 35–65 years have metabolic syndrome [6]. A recent cross-sectional study found that 16.3% of the Vietnamese population aged 40–64 years have metabolic syndrome, while those aged 55–64 sustain the highest prevalence and account for 27% of the cases diagnosed [7].

Modifiable lifestyle factors, such as physical inactivity and unhealthy dietary habits, are associated with the development of metabolic syndrome [6–8]. It is estimated that 28.7% of Vietnamese adults are insufficiently active (<600 metabolic equivalent tasks (MET), min per week) [9]. Moreover, the household food consumption pattern has changed rapidly [10], with increases in intake of dietary sodium and saturated fat [10, 11]. The proportion of energy intake from fat has doubled from 8.4% to 17.6% in the last two decades [10]. It has been reported that physical inactivity and insufficient vegetable and fruit consumption are responsible for 0.7% and 3.07%, respectively, of the total burden of disease in Vietnam. These unhealthy lifestyle behaviours have also contributed to over 5% of deaths from non-communicable disease [9]. In recognition of the high mortality and morbidity associated with non-communicable disease in Vietnam, the National Strategy for Non-Communicable disease Control and Prevention 2015–2025 was established to reduce behavioural risk factors, such as smoking, alcohol consumption, physical inactivity and salt consumption [12].

Interventions that use a combination of physical activity training and dietary modification have been recommended for metabolic syndrome [3, 13]. A recent meta-analysis concluded that interventions that motivate participants to improve lifestyle behaviours and weight management are essential for controlling metabolic syndrome risk factors [14]. Reported outcomes of intervention strategies designed to improve physical activity and dietary behaviours vary in terms of effectiveness [14]. However, a systematic review found that participation in walking groups provides an effective way of increasing physical activity and is suitable for any age group, especially older adults [15]. Walking, as a moderate activity, is the most popular leisure activity across all socio-economic groups [16, 17]. Walk leaders, who are either volunteers or nominated by their group members, have been demonstrated to play a key role in motivating participants to become physically active [16, 18].

With regard to resources, interventions that incorporate an information booklet to improve knowledge are found to be effective [19–21]. For example, a recent study in rural Western Australia that made use of an information booklet achieved positive changes in physical activity and dietary behaviours for participants with or at risk of metabolic syndrome [22]. Furthermore, personal feedback and group support are important for lifestyle interventions to control metabolic syndrome and its risk factors [14].

In view of the high prevalence of metabolic syndrome among middle-aged people in Vietnam [7, 9, 23], the Vietnam Physical Activity and Nutrition programme was designed to target adults aged 50–65 years with metabolic syndrome. The aim of this study was to determine whether implementation of the Vietnam Physical Activity and Nutrition programme was effective in terms of improving physical activity levels and dietary behaviours of its participants after a 6 month intervention.

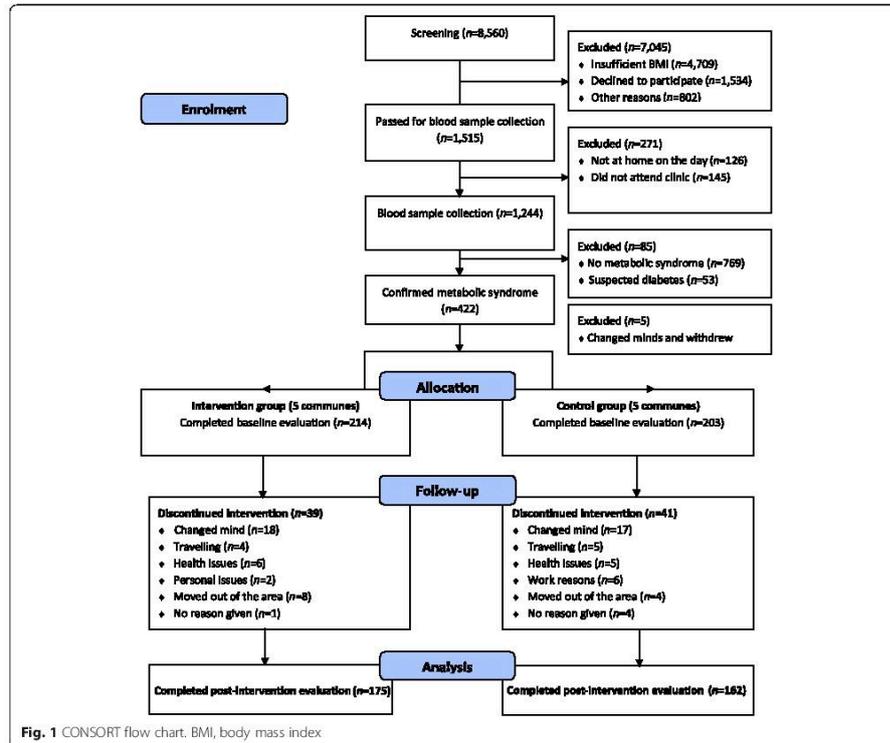
## Methods

### Study design

The protocol of the Vietnam Physical Activity and Nutrition programme has been described in detail previously [24], in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement (see Fig. 1 for the CONSORT flow chart and Additional file 1 for the CONSORT checklist of the trial). It was a 6 month community-based cluster-randomized controlled trial targeting adults aged 50–65 years with metabolic syndrome from 10 communes in Hanam province, northern Vietnam. Outcomes were collected from intervention and control groups at baseline and post-intervention testing. The trial was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12614000811606). The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014). Written informed consent was sought from each participant prior to entry in the trial.

### Participants

Adults aged 50–65 years with metabolic syndrome were recruited and invited to participate in the study. Metabolic syndrome status was determined based on the modified National Cholesterol Education Programme Adult Treatment Panel III criteria of having three of the five risk factors [25]: (1) large waist circumference (male  $\geq 90$  cm, female  $\geq 80$  cm, for Asian population [1]); (2) raised triglyceride levels ( $\geq 1.7$  mmol/l or 150 mg/dl); (3) reduced high-density lipoprotein cholesterol (male  $< 1.03$  mmol/l or 40 mg/dl, female  $< 1.29$  mmol/l or 50 mg/dl); (4) raised blood pressure (systolic  $\geq 130$  mmHg or diastolic  $\geq 85$  mmHg); and (5) raised fasting plasma glucose level ( $\geq 6.1$  mmol/l or  $\geq 110$  mg/dl).



Exclusion criteria were suspected type 2 diabetes (fasting plasma glucose level  $\geq 7.1$  mmol/l); treatment or a history of treatment for type 2 diabetes, cardiovascular disease, dyslipidaemia, hyperglycaemia, and hypertension; or involvement in a physical activity or dietary programme within the previous year.

**Procedure**

The participant selection phase, including initial screening and determination of metabolic syndrome status, occurred between October 2014 and January 2015, and the post-intervention evaluation was completed in November 2015.

**Screening**

A total of 8560 adults aged 50–65 years residing in 10 randomly selected communes within Hanam province were contacted, and invited to attend their local commune health centre for screening. Small incentives

(reimbursement of transport expenses) were provided to encourage attendance. At these sessions, a short interview was conducted to obtain information about each participant’s age, sex, physical activity levels, and medication history. The participant’s height and weight were also measured. Body mass index was calculated and classified according to the World Health Organization (WHO) criteria for Asian populations, with body mass index  $\geq 23$  being classed as ‘overweight’ [26]. Eligible people with body mass index  $\geq 23$  were invited to participate in the next stage of screening.

**Determining metabolic syndrome status**

As shown in Fig. 1, 1515 eligible subjects were invited for blood testing and measurement of waist circumference and blood pressure to confirm their metabolic syndrome status. A formal letter of invitation was delivered to eligible participants. The letter provided detailed information about the time, location, and

guidelines for fasting overnight (except for water after 9 p.m. and on the morning of blood sample collection). However, only 1244 people attended the clinic for blood sample collection and anthropometric measurements. Among them, 422 met the metabolic syndrome criteria and were invited for baseline evaluation. Five individuals changed their minds and subsequently withdrew, leaving a total of 417 participants who completed the baseline assessment.

#### **Allocation to control and intervention groups**

The 10 selected communes were randomly allocated to either the intervention group (five communes,  $n = 214$ ) or the control group (five communes,  $n = 203$ ) by a member of staff at Hanam Provincial Preventive Medicine Centre using a table of random numbers. The intervention group underwent the Vietnam Physical Activity and Nutrition programme, whereas the control group participants, who were fully aware of their status, received one session of standard advice and were wait-listed to receive the intervention package following completion of the post-intervention test. At the end of the 6 months period, 175 intervention (response rate 81.8%), and 162 control participants (response rate 79.8%) completed the post-intervention test assessment; see Fig. 1.

#### **Intervention**

The intervention was developed and underpinned by social cognitive theory [27, 28]. It was designed to promote physically activity and the maintenance of a healthy diet to participants. The Vietnam Physical Activity and Nutrition programme included four education sessions, a booklet, a resistance band and walking groups. All components of the Vietnam Physical Activity and Nutrition programme were conducted within the participants' communes to minimize subject burden. Participants attended four 2-hour education sessions at months 1, 2, 3 and 4 of the intervention, and participated in walking groups established at each commune for 6 months. During the first education session, each participant was provided with the health promotion booklet and a resistance band for strength exercises. Programme staff at the Hanam Provincial Preventive Medicine Centre, trained by the first author, conducted the education sessions, led the walking groups and collected data from participants at baseline and post-intervention testing. These trained walk leaders were provided with a package containing the education materials, as well as a manual for managing the group walks. The walk leaders mobilized participants for walking and encouraged them to achieve physical activity and diet goals. Details of the intervention materials are described elsewhere [24].

#### **Variables**

Demographic and personal information such as age, sex, occupation, marital status, smoking and alcohol consumption was obtained through a structured questionnaire administered to participants via face-to-face interview at baseline testing.

#### **Physical activity**

The International Physical Activity Questionnaire – Short Form, validated for Vietnamese adults [29], was used to measure physical activity levels, which included vigorous intensity activity, moderate intensity activity, walking and sitting time. In addition, a pedometer (Yamax SW-200, Japan) was given to each intervention participant to count daily steps taken. The device was fitted to the hip and worn for 7 consecutive days at both baseline and post-intervention testing. This objective measure of physical activity has been reported to be accurate and reliable [30].

#### **Diet**

The brief dietary habits questionnaire was modified from the STEPS questionnaire developed by the WHO [31] to gather information on the consumption of vegetables and fruits, and intake of animal internal organs, as well as the frequency of use of cooking oil and salt for preparing meals.

#### **Statistical analysis**

Descriptive statistics were first applied to summarize the baseline characteristics of the participants by group status. Comparisons between intervention and control participants were undertaken across the two time points using independent samples and paired  $t$  tests for continuous outcome variables, and the chi-squared test for dichotomous outcomes. For variables with skewed distributions, the Mann-Whitney  $U$  test and the Wilcoxon signed rank test were applied instead. To accommodate the correlation of observations due to the repeated measures (pre- and post-intervention testing) and the clustering of individuals within the 10 randomly selected communes, multilevel generalized linear mixed models with random effects (participants and communes) were fitted to determine the impacts of intervention on changes in outcome variables over time and between groups [32, 33], while accounting for the effects of potential confounding factors (age, sex, education level, relationship status, occupation, smoking status and alcohol consumption). All statistical analyses were performed in the SPSS package version 21.

#### **Binary outcomes**

In the presence of many zeros, vigorous activity and moderate activity were dichotomized by participation status (yes, no). For dietary behaviour outcomes,

consumption of fruit and vegetables, using cooking oil and salt to prepare meals at least once per day, as well as consumption of animal internal organs more than twice per month, were classified as frequent intake or usage (yes, no). These binary outcomes (vigorous activity, moderate activity, frequent fruit intake, frequent vegetable intake, frequent intake of animal internal organs, frequent use of cooking oil, frequent use of salt) were modelled using logistic mixed regressions.

#### Continuous outcomes

Walking time was considered a continuous variable in metabolic equivalent tasks (MET, min/week). Total physical activity for each individual was calculated by summing across the three activity domains, in which the reported time spent (min/week) was multiplied by

the corresponding MET score (8 for vigorous, 4 for moderate and 3.3 for walking) [34]. Sitting time was analyzed in terms of duration (min/week). Generalized linear mixed regression analysis was applied to walking time and total physical activity (MET, min/week), which were logarithmic transformed owing to their positively skewed distributions. A gamma mixed regression model was adopted to analyze the highly skewed sitting time.

#### Results

Table 1 presents the characteristics of participants at baseline, with no significant differences observed between the intervention and control groups ( $P > 0.05$ ). The mean age of the participants was 57 (standard deviation, 5) years, with the majority being women. More than 90% of the cohort completed secondary school or

**Table 1** Baseline characteristics of intervention and control participants ( $n = 337$ )

Variable	Intervention group ( $n = 175$ )	Control group ( $n = 162$ )	$P^a$
Age: mean (standard deviation), years	57.57 (4.93)	57.23 (4.87)	0.52
Weight: mean (standard deviation), kg	60.18 (7.70)	60.32 (7.82)	0.88
Body mass index: mean (standard deviation)	24.97 (1.92)	25.21 (2.29)	0.36
Waist circumference: mean (standard deviation), cm	87.12 (5.62)	87.59 (6.22)	0.47
Hip circumference: mean (standard deviation), cm	94.27 (4.77)	93.70 (6.04)	0.33
Sex			0.36
Female	144 (82.3%)	127 (78.4%)	
Male	31 (17.7%)	35 (21.6%)	
Education level			0.29
Primary school or below	14 (8.0%)	17 (10.5%)	
Secondary school	89 (50.9%)	94 (58.0%)	
High school	45 (25.7%)	34 (21.0%)	
College or university	27 (15.4%)	17 (10.5%)	
Relationship status			0.99
No partner	15 (8.6%)	15 (9.3%)	
With partner	160 (91.4%)	147 (90.7%)	
Occupation			0.55
Farmer or manual worker	41 (23.4%)	49 (30.2%)	
Office job	11 (6.3%)	8 (4.9%)	
Retired	55 (31.4%)	50 (30.9%)	
Business	18 (10.3%)	11 (6.8%)	
Home duties and others	50 (28.6%)	44 (27.2%)	
Smoking status			0.58
Never	154 (88.0%)	138 (85.2%)	
Former	10 (5.7%)	14 (8.6%)	
Current smoker	11 (6.3%)	10 (6.2%)	
Alcohol drinking			0.30
No	145 (82.9%)	127 (78.4%)	
Yes	30 (17.1%)	35 (21.6%)	

<sup>a</sup>Chi-square or *t* test between intervention and control groups

higher, and over 90% lived with a partner. Almost one-third of the sample were retired. On average, the participants were slightly overweight, with a mean body mass index of 25.1 (standard deviation, 2).

**Physical activity outcomes**

Table 2 compares the physical activity outcomes over time and between intervention and control groups. Both groups were similar in terms of physical activity levels at baseline. However, significant improvements ( $P < 0.001$ ) were observed in the intervention group from baseline to post-intervention testing for moderate activity participation, walking time and total physical activity, as well as a reduction in sitting time. There was also a significant increase ( $P = 0.011$ ) of over 5000 steps on average on 7 consecutive days between the two time points. For the control group, no significant change occurred from baseline to post-intervention testing, apart from an apparent decrease in mean sitting time.

Table 3 summarizes the results of mixed regression analyses of physical activity outcomes pre- and post-intervention. After controlling for commune clustering and the effects of confounding factors, significant improvements among the intervention participants relative to their control counterparts were evident in moderate activity participation ( $P = 0.018$ ), mean walking time ( $P < 0.001$ ), total physical activity ( $P = 0.001$ ) and mean sitting time ( $P < 0.001$ ), according to the group  $\times$  time interaction term of the mixed regression models. However, no significant change in prevalence of vigorous activity participation was found after the intervention ( $P = 0.643$ ).

**Dietary outcomes**

Table 4 shows that both groups were similar with respect to the reported dietary behaviour outcomes at baseline, but that the intervention participants appeared more likely to consume fruits than the controls. Significant improvements in some of these dietary outcomes from baseline to

post-intervention testing were observed for the intervention group, whereas no apparent changes were found in the control group, apart from a decrease in frequent use of salt for preparing meals. At 6 months, significant differences between groups were demonstrated for all dietary behaviours ( $P < 0.05$ ).

Table 5 summarizes the results of logistic mixed regression analyses of dietary behaviours before and after intervention. After controlling for commune clustering and the effects of confounding factors, the group  $\times$  time interaction term confirmed significant reductions in frequent intake of animal internal organs ( $P = 0.001$ ) as well as frequent use of cooking oil ( $P = 0.001$ ) by the intervention group relative to the control group over the 6 month period.

**Discussion**

In this study, Vietnamese adults with metabolic syndrome were identified from individuals initially screened and recruited from the community. The final sample of 337 participants at the post-intervention evaluation represented an overall retention rate of 80.8%, which was higher than in previous studies [22, 35]. The low attrition may reflect the acceptability of the Vietnam Physical Activity and Nutrition programme to the participants. Indeed, the group leaders were specifically trained to improve retention and engagement of participants in their walking groups, while the physical activity and healthy eating information provided in the booklet and education sessions was relevant and appropriate for the target group. Such strategies have been found to boost retention successfully in intervention studies [36, 37].

The results demonstrated changes in physical activity and dietary behaviours among the intervention participants when compared with the controls. Our findings were consistent with those from previous studies in terms of physical activity and nutrition outcomes [18, 22, 35, 38]. For example, a recent home-based intervention on Australian

**Table 2** Comparison of physical activity outcomes over time and between intervention and control groups ( $n = 337$ )

Outcome	Intervention group ( $n = 175$ )		$P^a$	Control group ( $n = 162$ )		$P^b$	$P^c$	$P^d$
	Baseline	Post		Baseline	Post			
Vigorous activity <sup>e</sup>	22 (12.6%)	12 (6.9%)	0.071	15 (9.3%)	6 (3.7%)	0.042	0.331	0.198
Moderate activity <sup>e</sup>	26 (14.9%)	61 (34.9%)	<0.001	24 (14.8%)	30 (18.5%)	0.371	0.991	0.001
Walking time: mean (standard deviation) <sup>f</sup>	366.3 (396.6)	588.3 (491.3)	<0.001	333.6 (394.3)	326.7 (355.0)	0.680	0.160	<0.001
Total physical activity: mean (standard deviation) <sup>f</sup>	478.5 (496.2)	862.7 (692.5)	<0.001	448.4 (447.9)	502.9 (496.6)	0.260	0.470	<0.001
Sitting time: mean (standard deviation) min/week	2,668.7 (764.0)	1,911.5 (769.8)	<0.001	2,733.5 (807.7)	2,371.2 (963.7)	<0.001	0.450	<0.001
Pedometer: mean (standard deviation), steps/week	48,722 (20,974)	53,882 (20,774)	0.011					

<sup>a</sup>Between baseline and post-intervention tests for intervention group

<sup>b</sup>Between baseline and post-intervention tests for control group

<sup>c</sup>Between intervention and control groups at baseline

<sup>d</sup>Between intervention and control groups at post-intervention testing

<sup>e</sup>Participation of at least 10 min

<sup>f</sup>Non-parametric test applied to MET, min/week

**Table 3** Mixed regression analyses of physical activity outcomes before and after intervention ( $n = 337$ )

Outcome	Group: intervention		Time: post		Group × Time		Random component	
	Coefficient (95% confidence interval)	$P^a$	Coefficient (95% confidence interval)	$P^a$	Coefficient (95% confidence interval)	$P^b$	$\sigma^2$	$\sigma^2$
Vigorous activity <sup>a</sup>	0.414 (-0.817, 1.645)	0.509	-1.023 (-0.020, -0.026)	0.044	0.297 (-0.962, 1.556)	0.643	0.751	0.714
Moderate activity <sup>a</sup>	-0.143 (-1.325, 1.040)	0.813	0.281 (-0.322, 0.883)	0.361	0.99 (0.169, 1.810)	0.018	0.782	0.501
Walking time <sup>bcd</sup>	-0.039 (-0.126, 0.048)	0.376	0.011 (-0.056, -0.078)	0.745	0.168 (0.080, 0.255)	<0.001	0.044	0.083
Total physical activity <sup>bcd</sup>	-0.032 (-0.129, 0.065)	0.518	0.059 (-0.009, 0.127)	0.091	0.154 (0.063, 0.244)	0.001	0.054	0.114
Sitting time <sup>c</sup>	-0.026 (-0.131, 0.079)	0.627	-0.146 (-0.218, -0.075)	<0.001	-0.191 (-0.291, -0.092)	<0.001	0.054	0.100

<sup>a</sup>Logistic mixed regression model<sup>b</sup>Linear mixed regression model<sup>c</sup>Gamma mixed regression model<sup>d</sup>Logarithmic transformed<sup>e</sup>Adjusted for age, sex, education level, relationship status, occupation, smoking status and alcohol drinking<sup>f</sup>Commune random effect<sup>g</sup>Participant random effect

adults with, or at risk of, metabolic syndrome reported a significant increase in moderate activity and a reduction in sitting time among intervention participants [22]. In particular, the Vietnam Physical Activity and Nutrition programme had led to significant improvements in moderate activity participation, walking time and total physical activity, as well as a reduction in sitting time for the intervention group. In addition, data recorded by pedometers confirmed a substantial increase of 5160 steps taken on average after the intervention, consistent with findings from a systematic review and meta-analysis [39]. Significant improvements in waist circumference (-1.63 cm,  $P < 0.001$ ) and weight (-1.44 kg,  $P < 0.001$ ) among the intervention group compared with the control group after controlling for the effects of clustering and confounding factors were also found [40].

The Vietnam Physical Activity and Nutrition programme followed the WHO's Recommendations for Physical Activity [41], encouraging participants to undertake at least 150 min of moderate intensity activity per week, or equivalent. This message was reinforced during the education sessions, while individuals were guided to tailor the programme to suit their own needs, such as walking

more or walking less. Advice and regular feedback were provided by the walk leaders and programme facilitators to monitor dietary and physical activity behaviours [14, 37]. The adopted approach not only supported participants but also enabled them to manage their own progress, thereby increasing their sense of ownership of the Vietnam Physical Activity and Nutrition programme. Walking in groups has been shown to increase moderate physical activity among adults. It is accessible for everyone and is suitable for all socio-economic groups [15] especially older adults [16, 17], even those with chronic diseases [15]. The dramatic increase in walking among the intervention participants suggested the suitability of the walking group for Vietnamese adults with metabolic syndrome.

The nutrition component of the Vietnam Physical Activity and Nutrition programme was developed based on the Food-Based Dietary Guidelines in Vietnam [42], which encouraged participants to eat more vegetables and fruits every day, reduce the amount of salt and cooking oil used when preparing meals, and reduce the consumption of animal internal organs. It also advised participants to eat boiled meals instead of stir-fried or

**Table 4** Comparison of dietary behaviour outcomes over time and between intervention and control groups ( $n = 337$ )

Outcome	Intervention group ( $n = 175$ )		$P^a$	Control group ( $n = 162$ )		$P^b$	$P^c$	$P^d$
	Baseline $n$ (%)	Post $n$ (%)		Baseline $n$ (%)	Post $n$ (%)			
Frequent vegetable intake <sup>e</sup>	164 (93.7)	168 (96.0)	0.333	152 (93.8)	143 (88.3)	0.080	0.966	0.008
Frequent fruit intake <sup>e</sup>	72 (41.1)	85 (48.6)	0.162	47 (29.0)	61 (37.7)	0.099	0.020	0.040
Frequent use of cooking oil <sup>e</sup>	64 (36.6)	36 (20.6)	0.001	41 (25.3)	50 (30.9)	0.266	0.026	0.030
Frequent use of salt <sup>e</sup>	171 (97.7)	90 (51.4)	<0.001	158 (97.5)	115 (71.0)	<0.001	0.910	<0.001
Frequent intake of animal internal organs <sup>f</sup>	49 (28.0)	19 (10.9)	<0.001	37 (22.8)	35 (21.6)	0.789	0.278	0.007

<sup>a</sup>Between baseline and post-intervention tests for intervention group<sup>b</sup>Between baseline and post-intervention tests for control group<sup>c</sup>Between intervention and control groups at baseline<sup>d</sup>Between intervention and control groups at post-intervention testing<sup>e</sup>At least once per day<sup>f</sup>More than twice per month

**Table 5** Logistic mixed regression analyses of dietary behaviour outcomes before and after intervention ( $n = 337$ )

Outcome	Group: intervention		Time: post		Group × Time		Random component	
	Coefficient (95% confidence interval)	$P^c$	Coefficient (95% confidence interval)	$P^c$	Coefficient (95% confidence interval)	$P^c$	$\sigma^d$	$\sigma^e$
Frequent vegetable intake <sup>a</sup>	-0.097 (-1.321, 1.127)	0.876	-0.738 (-1.558, 0.081)	0.077	1.229 (-0.055, 2.514)	0.061	0.603	0.333
Frequent fruit intake <sup>a</sup>	0.67 (-0.333, 1.672)	0.190	0.444 (-0.053, 0.942)	0.080	-0.081 (-0.762, 0.600)	0.816	0.678	0.761
Frequent use of cooking oil <sup>a</sup>	0.246 (-0.805, 1.298)	0.646	0.294 (-0.209, 0.797)	0.252	-1.216 (-1.939, -0.494)	0.001	0.736	0.001
Frequent use of salt <sup>a</sup>	0.109 (-1.444, 1.663)	0.890	-2.843 (-3.901, -1.784)	<0.001	-1.049 (-2.540, 0.442)	0.168	0.487	0.404
Frequent intake of animal internal organs <sup>b</sup>	0.047 (-1.240, 1.335)	0.942	-0.080 (-0.635, 0.475)	0.778	-1.469 (-2.351, -0.587)	0.001	0.904	0.768

<sup>a</sup>At least once per day<sup>b</sup>More than twice per month<sup>c</sup>Adjusted for age, sex, education level, relationship status, occupation, smoking status and alcohol consumption<sup>d</sup>Commune random effect<sup>e</sup>Participant random effect

deep-fried foods, together with tips on how to adhere to these guidelines, and goal setting. The intervention resulted in slight increases in the intake of daily fruit and vegetables, but since most participants already reported consumption at least once per day at baseline, further improvement was somewhat limited by the 'ceiling effect' [38]. However, significant reductions were achieved in the use of cooking oil ( $P = 0.001$ ) and the consumption of animal internal organs ( $P = 0.001$ ).

Understanding the barriers and enablers that influence physical activity and dietary behaviours can assist in the development of appropriate health promotion interventions [43]. The Vietnam Physical Activity and Nutrition programme undertook formative research to identify and address barriers that were subsequently incorporated into the programme. Experience, lessons and suggestions from other participants, as well as facilitators, on overcoming the barriers and on insights into enablers, were discussed throughout the education sessions and implemented in the programme.

Creating a supportive environment and establishing a network of new friends through the walking groups and education sessions also enhanced positive behaviour changes. These strategies have previously been documented to improve physical activity [44] and might contribute to the improved outcomes for this study. Although the Hawthorne effect might affect behavioural changes [45], such an impact was expected to be minor for randomized controlled trials [46, 47].

#### Limitations

There are several limitations in this study. The intervention programme was followed up for 6 months, in line with recommendation for metabolic syndrome control under supervision [48]. Assessment of sustainability of the programme and behavioural changes over a longer term is not feasible owing to budget constraint and resource limitations. Although demographic and other factors were controlled for in the mixed regression

analyses, residual confounding may still exist and potentially affect the results. Another shortcoming concerned the objective measurement of physical activity, whereby pedometers were provided to the intervention participants only to motivate walking. The use of objective physical activity measures, such as pedometers and accelerometers, in both intervention and control groups should be considered in future research.

#### Conclusions

The Vietnam Physical Activity and Nutrition programme was the first physical activity and nutrition intervention specifically targeting Vietnamese adults with metabolic syndrome. This cluster-randomized controlled trial demonstrated increases in moderate intensity activity, walking and total physical activity, as well as reductions in sitting time, intake of animal internal organs and using cooking oil for daily meal preparation among the intervention participants, when compared with the control group over a 6 month period. The findings confirmed that the prescribed community-based intervention with supportive environments can effectively improve physical activity and dietary behaviours for adults with metabolic syndrome in Vietnam.

#### Additional file

**Additional file 1:** CONSORT checklist of the trial. (PDF 138 kb)

#### Abbreviations

CONSORT: Consolidated Standards of Reporting Trials; MET: metabolic equivalent task; WHO: World Health Organization

#### Acknowledgements

We are grateful to the residents of Hanam province who participated in the study. Thanks are also due to the Hanam Provincial Preventive Medicine Centre for participant recruitment and support during the trial.

#### Funding

This study was financially supported by the researchers' institution only.

**Availability of data and materials**

The intervention materials are available from the first author upon request. Individual information will not be released owing to confidentiality agreements signed by the study participants.

**Authors' contributions**

VD coordinated the Vietnam Physical Activity and Nutrition programme and drafted the manuscript. AHL, JJ, APJ, PH, and LTPM designed the study, developed the research protocol and revised the manuscript. All authors have read and approved the final version for publication.

**Competing interests**

The authors declare that they have no competing interests.

**Consent for publication**

Not applicable.

**Ethics approval and consent to participate**

The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014). Written informed consent was sought from all participants prior to entry into the study.

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Received: 3 August 2016 Accepted: 21 December 2016

Published online: 13 January 2017

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### **4.3 Effects on features of MetS, prevalence of MetS, and other risk factors**

#### **Related publication:**

*Effectiveness of a Community-Based Physical Activity and Nutrition Behaviour Intervention on Features of the Metabolic Syndrome: A Cluster-Randomised Controlled Trial*

This publication addresses the objective 3:

3. Assess at post-test the change in features of MetS, MetS status, and other risk factors of the intervention group relative to the control group.

#### **Citation:**

**Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>

## Effectiveness of a Community-Based Physical Activity and Nutrition Behavior Intervention on Features of the Metabolic Syndrome: A Cluster-Randomized Controlled Trial

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### Abstract

**Background:** Metabolic syndrome (MetS) and its subclinical diseases are now public health problems in Vietnam. This study aimed at determining the effectiveness of a physical activity and nutrition program for reducing MetS proportion and its components among adults with MetS in Hanam province, Vietnam.

**Methods:** A total of 417 volunteers aged 50–65 years with MetS were recruited from 10 communes. The communes were randomly allocated to an intervention group (five communes,  $n = 214$ ) and a control group (five communes,  $n = 203$ ). The participants in the intervention group received a nutrition and physical activity program for 6 months, whereas participants in the control group received standard diet and physical activity advice on only one occasion. Anthropometry, lipid profiles, glycemic status, and blood pressure were measured at baseline and at 6 months to evaluate program effectiveness.

**Results:** In total, 175 intervention (81.8%) and 162 control (79.8%) participants completed the post-program evaluation. After controlling for the effects of clustering and confounding factors, the intervention group showed significant improvements in high-density lipoprotein cholesterol (+0.42 mM,  $P < 0.001$ ), waist circumference (−1.63 cm,  $P < 0.001$ ), waist-to-hip ratio (−0.024,  $P < 0.001$ ), weight (−1.44 kg,  $P < 0.001$ ), and body mass index (−0.59 kg/m<sup>2</sup>,  $P < 0.001$ ) when compared with the control group. A reduction in the MetS proportion was found in both intervention and control groups ( $P < 0.001$ ), decreasing to 56.0% and 75.9%, respectively, but the post-program proportion was significantly lower among the intervention participants ( $P < 0.001$ ). Furthermore, the mean number of MetS components exhibited by individuals decreased significantly in the intervention group ( $P < 0.001$ ).

**Conclusions:** The community-based physical activity and nutrition program reduced MetS proportion, with significant improvements in several metabolic and anthropometric parameters for Vietnamese adults with MetS.

**Keywords:** community-based intervention, health promotion, metabolic syndrome, non-communicable diseases, Vietnam

### Introduction

METABOLIC SYNDROME (METS) is a clinical entity that is characterized by a constellation of metabolically related abnormalities, cardiovascular diseases (CVD), and type 2 diabetes (T2D) risk factors, including central obesity, impaired glucose metabolism, dyslipidemia, and hypertension.<sup>1</sup> Consequently, individuals with MetS are at an increased risk of CVD and T2D.<sup>1,2</sup> MetS is considered a worldwide epi-

demic,<sup>3</sup> with an estimated one-quarter of adults worldwide exhibiting the syndrome.<sup>2</sup> Obesity resulting from poor diets and sedentary lifestyles are the likely culprit of the increased prevalence of MetS.<sup>4</sup>

Relatively little is known about the prevalence of MetS in Vietnam. The prevalence of MetS in Ho Chi Minh City was reported to be 12% among adults aged  $\geq 20$  years in 2001.<sup>5</sup> Using the US National Cholesterol Education Adult Treatment Panel III (ATPIII) criteria,<sup>6</sup> a recent cross-sectional

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study conducted in Hanam province found that 16.3% of the population aged 40–64 years have MetS.<sup>7</sup> The MetS prevalence in Vietnam was lower than that reported in Malaysia (33.3%),<sup>8</sup> and Indonesia (28.4%),<sup>9</sup> but higher than Taiwan (15.7%).<sup>10</sup> Similar to other studies globally,<sup>11,12</sup> the prevalence of MetS in Vietnam increases with age,<sup>5,7</sup> and in Vietnamese aged 55–64 having the highest prevalence of MetS ( $\approx 27\%$ ).

Modifiable lifestyle factors, such as physical inactivity and unhealthy dietary habits, are associated with the development of MetS.<sup>5,7,13</sup> These unhealthy lifestyle behaviors have also contributed to more than 5% of deaths from non-communicable disease (NCD) in Vietnam.<sup>14</sup> In recognition of the high mortality and morbidity associated with NCD, the National Strategy for NCD Control and Prevention 2015–2025 was established to reduce behavioral risk factors such as smoking, alcohol consumption, physical inactivity, and salt consumption.<sup>15</sup>

A combination of physical activity and dietary modification is recommended as a core intervention for managing people with MetS.<sup>16,17</sup> A recent meta-analysis of 13 studies, including 3907 participants with MetS, indicated that lifestyle interventions increased the odds of MetS status reversal 3.81 times (95% CI 2.47–5.88) in comparison to controls.<sup>4</sup> Furthermore, although both lifestyle interventions and pharmacological therapies were applicable, in terms of reversing MetS status, the former appeared to be more effective than the latter approach.<sup>4</sup>

A variety of lifestyle intervention strategies have been adopted in health promotion programs designed for MetS control and prevention.<sup>18</sup> A recent systematic review that included 28 randomized controlled trials (6372 patients) found that patient motivation, leading to improved lifestyle adherence, is a key factor in reversing MetS. In addition, a team-based interactive approach with the provision of regular feedback is an effective means for behavioral change.<sup>18</sup>

In view of the high burden of MetS, the Vietnam Physical Activity and Nutrition (VPAN) program was developed to target adults aged 50–65 years with MetS in Vietnam. The purpose of this study was to determine the effectiveness of the VPAN program for reducing the proportion and components of MetS in this population group.

## Methods

### Study design

The VPAN was a 6-month two-arm cluster-randomized controlled trial of a community-based physical activity and dietary behavior intervention targeting adults aged 50–65 years with MetS in Hanam province, Vietnam. Data were collected from intervention and control groups at baseline and post-test in 2014 and 2015. The trial was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12614000811606). The research protocol was approved by the Curtin University Human Research Ethics Committee (approval number: HR139/2014), and written consent was obtained from all participants. Details of the study design have been previously described.<sup>19</sup>

### Participants

The target population included sedentary and overweight adults between the ages of 50 and 65 years with MetS. The ATP III criteria were used to confirm MetS status.<sup>6</sup> Participants were classified as having MetS if they had any three

of the five risk factors: (1) large waist circumference (male  $\geq 90$  cm, female  $\geq 80$  cm for Asians<sup>1</sup>); (2) raised triglyceride ( $\geq 1.7$  mM or 150 mg/dL); (3) reduced high-density lipoprotein cholesterol (HDL-C) (male  $< 1.03$  mM or 40 mg/dL, female  $< 1.29$  mM or 50 mg/dL); (4) elevated blood pressure (systolic  $\geq 130$  mmHg or diastolic  $\geq 85$  mmHg); and (5) raised fasting plasma glucose ( $\geq 6.1$  mM or  $\geq 110$  mg/dL).

Adults aged 50–65 years living in 10 communes of Hanam province, Vietnam, were contacted and invited to undergo screening. Potential participants were screened for eligibility initially by being classified as overweight [body mass index (BMI)  $\geq 23$  according to the World Health Organisation (WHO) criteria for the Asian population<sup>20</sup>] and physically inactive ( $< 150$  min of moderate intensity activity per week). Eligible potential participants were then invited to undergo a fasting ( $\geq 10$  hr) blood sample, and measurement of their waist circumference, hip circumference, and blood pressure to confirm their MetS status. Eligible participants were then sent a formal letter of invitation. The letter provided detailed information about the time, location of the blood sampling collection, and guidelines for fasting overnight (except for water after 9 pm and in the morning of blood sample collection).

The 10 communes were randomly allocated to either an intervention group (5 communes) or a control group (5 communes) by using a random number table. The intervention group received the VPAN program for 6 months, whereas the control group was wait-listed to receive the intervention after completion of the post-test data collection. In this study, eligible adults were excluded if they were suspected of having T2D (fasting plasma glucose  $\geq 7.1$  mM); taking, or have taken, treatment for T2D, CVD, dyslipidemia, hyperglycemia, and hypertension; or involvement in a physical activity and/or dietary program within the past year.

### Outcome measures

The primary outcome was the proportion of participants with MetS. Secondary outcomes were blood parameters, blood pressure, and anthropometry, measured at baseline and post-test. Fasting blood samples were taken by a phlebotomist at commune health stations. Fasting plasma glucose, total cholesterol, HDL-C, and triglyceride concentrations were measured, and low-density lipoprotein cholesterol (LDL-C) and non-HDL-C levels were subsequently calculated.<sup>21</sup> Blood pressure and anthropometric measurements were taken by trained program staff by following the WHO's guidelines.<sup>22</sup> Systolic and diastolic blood pressures were measured by using an Omron HEM-8712 automatic blood pressure monitor, with participants sitting and their arm supported at heart level. A mean value was obtained after taking three consecutive measurements. Waist and hip circumferences were recorded to the nearest 0.5 cm by using a plastic measuring tape, and waist-to-hip ratio (WHR) was subsequently determined. Weight was recorded to the nearest 0.01 kg by using a calibrated electronic scale, and height was recorded to the nearest 0.1 cm by using a portable stadiometer while the participant was barefoot. BMI was then calculated.

### Intervention

The intervention was designed to promote being physically active and the consumption of a healthy diet based on

the WHO's Recommendations for Physical Activity<sup>23</sup> and the Food Based Dietary Guidelines in Vietnam.<sup>24</sup> Positive reinforcement, by way of encouragement and feedback, was facilitated through the use of trained walking group leaders. All components of the VPAN intervention were conducted within the participant's commune to minimize subject burden. The intervention consisted of comprehensive multi-component resources: (1) four education sessions, (2) an information booklet, (3) a resistance band, (4) and a walking group. Each participant was provided with a booklet (in Vietnamese) and a resistance band. The booklet contained educational materials, tips, and graphical illustrations on how to perform physical activity (e.g., brisk walking) correctly and resistance, weight training and stretching exer-

cises safely, as well as suggested meal plans, recipes, and tips for healthy eating. Walking groups were established in each commune to promote physical activity. A group leader for each commune was nominated by its group members. They attended three 2-hr training sessions on how to be an effective group leader and were provided with a package containing the education materials, together with a manual for managing the group walks. Further details of the intervention strategies are described elsewhere.<sup>19</sup>

#### Statistical analysis

Descriptive statistics summarized the baseline demographic and lifestyle characteristics, MetS parameters, and

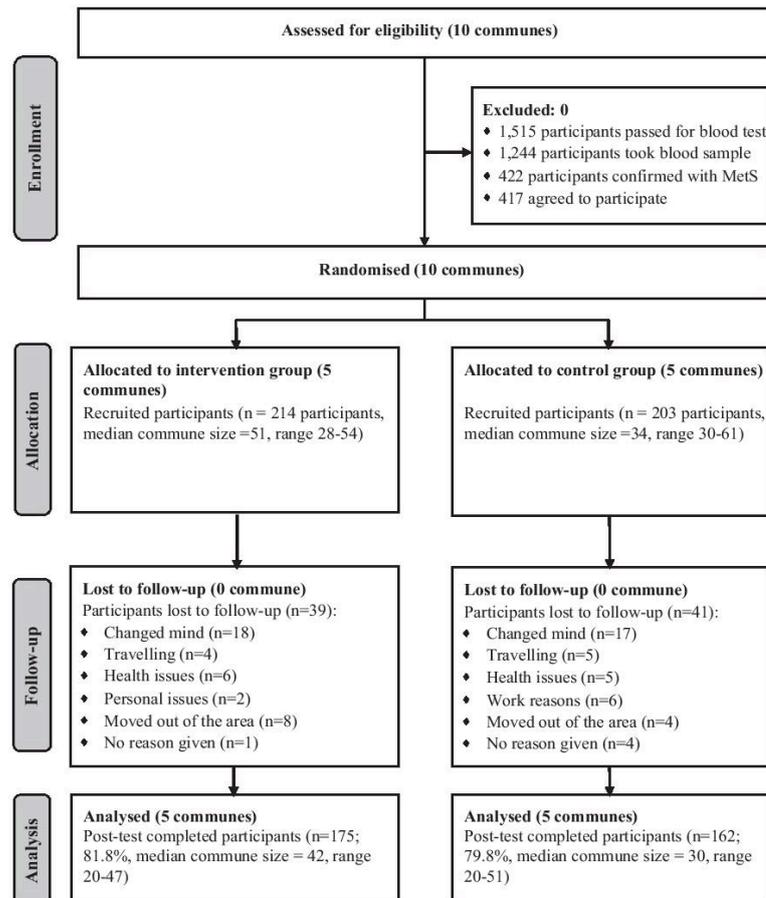


FIG. 1. CONSORT flow chart.

anthropometric measurements of the program completers. Continuous outcome variables were compared between and within groups by using independent and paired *t* tests, with non-parametric Mann–Whitney *U* tests and Wilcoxon Signed-Rank tests applied to variables with skewed distributions. To accommodate the correlation of observations due to the repeated measures (pre- and post-test) and the clustering of individuals within the 10 randomly selected communes, multilevel generalized linear mixed regression models with random effects (participants and communes) were fitted to determine the impacts of intervention on changes in the continuous outcome variables over time and between groups, while accounting for the fixed effects of potential confounding factors (age, gender, relationship status, education level, employment status, smoking status, and alcohol drinking). Usually, distributed continuous variables were assessed by using a linear mixed regression model, whereas skewed continuous variables with non-zero values were assessed by using a gamma mixed regression model. An intention-to-treat analysis was also conducted for all participants who had completed the baseline assessment to examine the sensitivity of the analysis. All data cleaning and statistical analyses were performed within the SPSS package version 21.

### Results

The participant recruitment and selection phase, including initial screening and determination of MetS status, occurred between October 2014 and January 2015, and the post-test was completed in November 2015. A total of 1515 eligible participants from 10 communes were invited to attend a screening visit for measurement of their waist circumference, blood pressure, and blood biochemistry to confirm their MetS status. However, only 1244 people attended. Of these, 422 met the MetS criteria and were invited for baseline data collection. Five individuals changed their mind and subsequently withdrew, leaving a total of 417 participants who completed the baseline assessment. The 10 selected communes were randomly allocated to either the intervention group (5 communes,  $n=214$ ) or the control group (5 communes,  $n=203$ ). At the end of the 6-month period, 175 (81.8%) intervention participants and 162 (79.8%) control subjects completed the post-test assessment. Figure 1 presents the consort flow chart of the study.

Table 1 shows no significant differences in the demographic profile between the two groups of completers ( $P>0.05$ ). The mean age of the participants was 57 [standard deviation (SD) 5] years, and the majority of them were women (80%). More than 90% of the cohort had completed secondary school or higher education, and more than 90% were living with their partner. Almost one-third of the sample had retired. On average, the participants were slightly overweight, with a mean BMI of 25.1 (SD 2). No differences in smoking and drinking habits were found between the two groups (Table 1).

As shown in Table 2, there were significant improvements in mean HDL-C (+0.42 mM,  $P<0.001$ ) and systolic blood pressure (−4.08 mmHg,  $P=0.002$ ) for the intervention group from baseline to post-intervention. The intervention group also exhibited reductions in waist circumference (−1.63 cm,  $P<0.001$ ), WHR (−0.024,  $P<0.001$ ), weight (−1.44 kg,

TABLE 1. DEMOGRAPHIC PROFILE OF INTERVENTION AND CONTROL PARTICIPANTS ( $N=337$ )

Variable	Intervention group ( $n=175$ )	Control group ( $n=162$ )	$P^a$
Age: mean (SD), years	57.57 (4.93)	57.23 (4.87)	0.52
Gender, $n$ (%)			0.36
Female	144 (82.3)	127 (78.4)	
Male	31 (17.7)	35 (21.6)	
Education level, $n$ (%)			0.29
Primary school or below	14 (8.0)	17 (10.5)	
Secondary school	89 (50.9)	94 (58.0)	
High school	45 (25.7)	34 (21.0)	
College/university	27 (15.4)	17 (10.5)	
Relationship status, $n$ (%)			0.99
No partner	15 (8.6)	15 (9.3)	
With partner	160 (91.4)	147 (90.7)	
Occupation, $n$ (%)			0.55
Farmer/worker	41 (23.4)	49 (30.2)	
Office job	11 (6.3)	8 (4.9)	
Retired	55 (31.4)	50 (30.9)	
Business	18 (10.3)	11 (6.8)	
Home duties and others	50 (28.6)	44 (27.2)	
Smoking status, $n$ (%)			0.58
Never	154 (88.0)	138 (85.2)	
Former	10 (5.7)	14 (8.6)	
Current smoker	11 (6.3)	10 (6.2)	
Alcohol drinking, $n$ (%)			0.30
No	145 (82.9)	127 (78.4)	
Yes	30 (17.1)	35 (21.6)	

<sup>a</sup>Chi-square or *t*-test between intervention and control groups. SD, standard deviation.

$P<0.001$ ), and BMI (−0.59 kg/m<sup>2</sup>,  $P<0.001$ ) over the 6-month period. However, glucose concentrations significantly increased in both intervention and control groups. No other within-group changes were observed for the control participants except for a decrease in mean weight (−0.39 kg,  $P=0.002$ ); however, this reduction from baseline to post-test was significantly less than that of the intervention participants ( $P<0.001$ ).

Table 3 demonstrates that after controlling for demographic and other potential confounders, significant improvements in the intervention group relative to the control group were observed for HDL-C ( $P<0.001$ ) and glucose ( $P=0.005$ ) concentrations through the group × time interaction term. For anthropometric outcome measures, relative to the control group, the multivariate analyses confirmed significant reductions in waist circumference ( $P=0.009$ ), WHR ( $P=0.013$ ), weight ( $P<0.001$ ), and BMI ( $P<0.001$ ) for the intervention group through the group × time interaction term in the mixed regression models (Table 3).

At 6 months, the proportion of MetS decreased to 56% ( $P<0.001$ ) in the intervention group, and to 76% ( $P<0.001$ ) in the control group (Table 4). This difference in MetS proportion between the two groups at post-test was statistically significant ( $P<0.001$ ). The mean number of MetS

TABLE 2. COMPARISON OF CHANGES IN METABOLIC SYNDROME PARAMETERS AND ANTHROPOMETRICS BETWEEN INTERVENTION AND CONTROL GROUPS (N=337)

Outcome	Intervention group (n = 175)			Control group (n = 162)							
	Baseline mean (SD)	Post-test mean (SD)	Difference mean (SD)	P <sup>a</sup>	Baseline mean (SD)	Post-test mean (SD)	Difference mean (SD)	P <sup>b</sup>	P <sup>c</sup>	P <sup>d</sup>	P <sup>e</sup>
Glucose (mM)	5.19 (0.91)	6.00 (1.23)	+0.81 (1.29)	<0.001	5.40 (0.83)	6.67 (1.75)	+1.27 (1.74)	<0.001	0.028	<0.001	0.005
HDL-C (mM)	1.36 (0.16)	1.78 (0.66)	+0.42 (0.66)	<0.001	1.35 (0.26)	1.48 (0.83)	+0.13 (0.87)	0.070	0.610	<0.001	0.001
Total cholesterol (mM)	5.23 (0.91)	5.62 (1.22)	+0.39 (1.40)	<0.001	5.12 (0.92)	5.20 (1.07)	+0.08 (1.23)	0.410	0.280	0.001	0.034
Triglycerides (mM) <sup>f</sup>	2.34 (1.20)	2.32 (1.09)	-0.02 (1.39)	0.950	2.46 (1.45)	2.52 (1.80)	+0.06 (1.94)	0.470	0.480	0.470	0.590
Non-HDL-C (mM)	3.86 (0.87)	3.83 (1.50)	-0.03 (1.66)	0.820	3.77 (0.88)	3.72 (1.65)	-0.05 (1.79)	0.761	0.321	0.522	0.937
LDL-C (mM)	2.78 (0.88)	2.76 (1.48)	-0.08 (1.69)	0.876	2.63 (1.10)	2.56 (1.79)	-0.07 (1.87)	0.639	0.164	0.260	0.800
Systolic blood pressure (mmHg)	137.37 (17.29)	133.29 (10.64)	-4.08 (16.85)	0.002	136.59 (17.25)	133.87 (21.67)	-2.72 (16.32)	0.030	0.680	0.780	0.452
Diastolic blood pressure (mmHg)	84.49 (10.64)	83.69 (10.73)	-0.80 (11.56)	0.360	86.48 (11.95)	86.04 (11.93)	-0.44 (11.19)	0.610	0.100	0.058	0.775
Waist circumference (cm)	87.12 (5.62)	85.49 (6.04)	-1.63 (3.76)	<0.001	87.59 (6.22)	87.05 (5.96)	-0.54 (3.90)	0.08	0.470	0.01	0.009
Hip (cm)	94.27 (4.77)	94.15 (4.90)	-0.12 (0.95)	0.09	93.70 (6.04)	93.61 (6.09)	-0.08 (0.62)	0.07	0.330	0.36	0.680
WHR	0.92 (0.05)	0.90 (0.04)	-0.02 (0.95)	<0.001	0.93 (0.06)	0.93 (0.06)	-0.001 (0.04)	0.100	0.060	<0.001	0.013
Weight (kg) <sup>f</sup>	60.18 (7.70)	58.74 (7.90)	-1.44 (2.73)	<0.001	60.32 (7.82)	59.93 (8.24)	-0.39 (1.55)	0.002	0.882	0.169	<0.001
BMI <sup>f</sup>	24.97 (1.92)	24.38 (2.14)	-0.59 (1.12)	<0.001	25.21 (2.29)	25.04 (2.50)	-0.17 (0.67)	0.003	0.360	0.018	<0.001

<sup>a</sup>Between baseline and post-test for intervention group.

<sup>b</sup>Between baseline and post-test for control group.

<sup>c</sup>Between intervention and control groups at baseline.

<sup>d</sup>Between intervention and control groups at post-test.

<sup>e</sup>Between intervention and control groups differences.

<sup>f</sup>Non-parametric tests applied due to skewed distributions.

BMI, body mass index; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; WHR, waist-to-hip ratio.

TABLE 3. MIXED REGRESSION ANALYSIS OF METABOLIC SYNDROME PARAMETERS AND ANTHROPOMETRICS BEFORE AND AFTER INTERVENTION (N=337)

	Group: intervention		Time: post-test		Group×time	
	Coefficient (SE) <sup>a</sup>	P	Coefficient (SE) <sup>a</sup>	P	Coefficient (SE) <sup>a</sup>	P
Glucose (mM) <sup>b</sup>	-0.184 (0.204)	0.366	1.277 (0.120)	<0.001	-0.465 (0.166)	0.005
HDL-C (mM) <sup>b</sup>	0.016 (0.113)	0.886	0.125 (0.058)	0.033	0.292 (0.081)	<0.001
Total cholesterol (mM) <sup>b</sup>	0.089 (0.19)	0.639	0.08 (0.104)	0.446	0.307 (0.145)	0.034
Triglycerides (mM) <sup>c</sup>	-0.042 (0.077)	0.587	-0.004 (0.046)	0.93	0.006 (0.064)	0.925
Non-HDL-C (mM) <sup>b</sup>	0.081 (0.138)	0.558	-0.045 (0.136)	0.741	0.015 (0.189)	0.937
LDL-C (mM) <sup>b</sup>	0.071 (0.143)	0.618	0.012 (0.141)	0.933	-0.065 (0.194)	0.737
Systolic BP (mmHg) <sup>b</sup>	0.842 (2.104)	0.689	-2.722 (1.304)	0.037	-1.363 (1.81)	0.452
Diastolic BP (mmHg) <sup>b</sup>	-1.864 (1.436)	0.195	-0.444 (0.895)	0.619	-0.356 (1.241)	0.775
Waist circumference (cm) <sup>b</sup>	-0.293 (0.697)	0.675	-0.541 (0.301)	0.073	-1.093 (0.418)	0.009
Hip (cm) <sup>b</sup>	0.757 (0.697)	0.278	-0.086 (0.064)	0.175	-0.036 (0.088)	0.680
WHR <sup>b</sup>	-0.012 (0.007)	0.096	-0.005 (0.003)	0.106	-0.011 (0.005)	0.013
Weight (kg) <sup>c</sup>	0.011 (0.019)	0.541	-0.008 (0.003)	0.014	-0.017 (0.004)	<0.001
BMI <sup>c</sup>	0.008 (0.009)	0.417	-0.008 (0.003)	0.014	-0.017 (0.004)	<0.001

<sup>a</sup>Adjusted for age, gender, relationship status, education level, employment status, smoking status, and alcohol drinking.

<sup>b</sup>Linear mixed regression model.

<sup>c</sup>Gamma mixed regression model.

SE, standard error.

components also decreased from baseline to post-test ( $P<0.001$ ) in the intervention group, but no change was evident in the control group ( $P=0.942$ ). Indeed, after the intervention, the mean number of MetS components was significantly less for intervention participants than control subjects ( $P<0.001$ ).

An intention-to-treat analysis was next performed. For both intervention and control groups, no significant differences in baseline variables were found between completers and non-completers, so that the post-program outcomes of the latter could be considered as missing at random (results omitted for brevity). With the inclusion of the non-completers' baseline data, the corresponding mixed regression fits are presented in the Appendix Table A1. The results were generally comparable with those in Table 3, with the exception of total cholesterol whose group×time interaction term became not significant ( $P=0.141$ ).

## Discussion

This study investigated the effectiveness of the VPAN program for adults with MetS in Vietnam.<sup>19</sup> The results confirmed that the 6-month community-based intervention reduced the MetS proportion, with significant improvements in several

metabolic and anthropometric parameters among intervention participants when compared with the control group. The final sample of 337 program completers represented an overall retention rate of 80.8%, which was comparable to previous studies.<sup>25-27</sup> The low attrition reflected the acceptability among participants of the intervention program. A number of strategies were adopted to create a supporting environment, such as the use of trained walk leaders and the provision of detailed information about healthy eating and physical activity in the booklet and education sessions. These strategies have been found to boost retention in intervention studies conducted in other countries.<sup>28,29</sup>

The implementation of this 6-month VPAN program achieved favorable outcomes for several clinical risk factors. The intervention group exhibited significant improvements in HDL-C, systolic blood pressure, weight, BMI, waist circumference, and WHR (Table 2). Furthermore, there were significant group×time interactions for these same parameters except for systolic blood pressure (Table 3). The observed improvements in anthropometric measures are consistent with those reported in previous studies and include a reduction in central adiposity as part of the weight reduction.<sup>30,31</sup> Although an increase in fasting glucose concentration was observed in both groups at

TABLE 4. CHANGES IN PROPORTION OF METABOLIC SYNDROME AND ITS COMPONENTS FOR INTERVENTION AND CONTROL GROUP (N=337)

	Intervention group (n=175)			Control group (n=162)			P <sup>c</sup>	P <sup>d</sup>
	Baseline	Post-test	P <sup>a</sup>	Baseline	Post-test	P <sup>b</sup>		
MetS status: n (%)	175 (100)	98 (56.0)	<0.001	162 (100)	123 (75.9)	<0.001	—	<0.001
MetS components: mean (SD)	3.11 (0.31)	2.65 (1.05)	<0.001	3.16 (0.36)	3.15 (1.03)	0.942	0.165	<0.001

<sup>a</sup>Between baseline and post-test for intervention group.

<sup>b</sup>Between baseline and post-test for control group.

<sup>c</sup>Between intervention and control groups at baseline.

<sup>d</sup>Between intervention and control groups at post-test.

MetS, metabolic syndrome.

post-test, the extent of such an increase was lessened among the intervention participants than the controls, as evident from the univariate changes (Table 2) and corresponding group  $\times$  time interaction term (Table 3). Increases in glucose levels in intervention and control groups after lifestyle intervention were also observed in previous studies.<sup>32,33</sup> A systematic review and meta-analysis reported that lifestyle interventions for those at high risk of diabetes showed a limited clinical benefit, as the adhered physical activity and exercise levels and duration by the participants might not be effective for them.<sup>33</sup> Also, since there was no change in LDL-C or non-HDL-C, it appears that the apparent rise in total cholesterol in the intervention group could be primarily due to the increase in the HDL-C post program.

The VPAN intervention comprised a range of resources and strategies to improve diet and physical activity. These included the establishment of a supportive environment through the walking groups, provision of their own resistance band, education sessions, and an information booklet.<sup>19</sup> The use of similar resources has been previously documented to enhance physical activity<sup>34</sup> and dietary behavior.<sup>25,26</sup> Improvements in weight and central adiposity via the adoption of a healthy diet and physical activity routine are important for individuals with MetS due to the association between weight loss and improvements in the clinical components of MetS.<sup>35,36</sup> Findings from the present study provide further support for the benefits of a physical activity program involving brisk walking for  $\geq 10$  min<sup>37,38</sup> to reduce risk factors of MetS such as waist circumference, HDL-C, and fasting glucose<sup>39</sup> as well as overweight and obesity.<sup>38</sup> In addition, exercises using the resistant band can build up muscle mass and improve body composition.<sup>37</sup>

Although decreases in body weight were observed in both groups, no significant changes in fasting triglyceride and LDL-C concentrations were found in the intervention group when compared with the control group post-intervention. The observation that LDL-C concentrations showed no significant changes over the 6-month period is consistent with previous studies.<sup>40</sup> A meta-analysis of 13 randomized controlled trials concluded that aerobic exercise was not associated with statistically significant changes in LDL-C.<sup>40</sup> The lack of significant improvements in triglyceride concentration in the intervention group was unexpected. Previous meta-analysis showed that aerobic exercise with dietary intervention could decrease triglyceride concentrations as well as body weight in overweight adults.<sup>40,41</sup> Our results regarding triglycerides could be attributed to insufficient intensity of the physical activities performed by the intervention participants. The lipid profile is likely to be dependent on the type of exercise undertaken, duration of each session, and its intensity and frequency.<sup>42</sup> In the VPAN program, improving diet and moderate intensity physical activity were the main strategies.<sup>19</sup> In support of our findings, a recent study reported that a moderate intensity physical activity intervention of 15 weeks duration did not affect fasting triglyceride concentrations in sedentary obese adults, despite significant improvements in weight.<sup>43</sup>

In this study, significant reductions in MetS proportion and number of MetS components were found at post-test among the intervention participants. The effectiveness of combining appropriate levels of physical activity with dietary interventions on the reduction of MetS has been well documented.<sup>44</sup> A recent systematic review and meta-

analysis of 16 studies reported MetS reversal in 14 of the studies.<sup>4</sup> It should be noted that the definition of MetS relates to components that may encompass borderline and not categorical risk factors; therefore, a small reduction in a borderline positive value is sufficient to return to normality. With the high reversal rate of MetS status in the intervention group, this community-based program appeared to be an effective means for MetS control and prevention for the Vietnamese adult population.

The present study has several limitations. First, although we observed the favorable effects of lifestyle modification on HDL-C, waist circumference, WHR, BMI, and weight, it is unclear which component(s) of the lifestyle changes were responsible and the most effective to improve these outcomes. Second, it is known that short-term weight loss programs are effective in the target group, but participants tend to regain weight once the intervention ends.<sup>18</sup> Longer-term studies beyond 6 months should be considered in the future to assess the sustainability of VPAN and similar lifestyle programs.<sup>45,46</sup>

In summary, this cluster-randomized controlled trial showed improvements in several metabolic and anthropometric parameters for Vietnamese adults with MetS, as well as reversal of their MetS status and reduction in the number of MetS components over a 6-month period. The findings confirmed that the VPAN program was effective for reversing MetS and its risk factors, and it supported the replication of this intervention in other parts of the country to prevent and control MetS.

#### Acknowledgments

This study was financially supported by the School of Public Health, Curtin University. The authors are grateful to the residents of Hanam province who participated in the study.

#### Author Disclosure Statement

The authors declare that they have no competing interests.

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## Appendix

APPENDIX TABLE A1. INTENTION-TO-TREAT MIXED REGRESSION ANALYSIS OF METABOLIC SYNDROME PARAMETERS AND ANTHROPOMETRICS BEFORE AND AFTER INTERVENTION (N=417)

	Group: intervention		Time: post-test		Group×time	
	Coefficient (SE) <sup>a</sup>	P	Coefficient (SE) <sup>a</sup>	P	Coefficient (SE) <sup>a</sup>	P
Glucose (mM) <sup>b</sup>	-0.165 (0.201)	0.412	1.274 (0.113)	<0.001	-0.477 (0.157)	0.002
HDL-C (mM) <sup>b</sup>	0.017 (0.097)	0.863	0.119 (0.053)	0.026	0.293 (0.074)	<0.001
Total cholesterol (mM) <sup>b</sup>	0.093 (0.209)	0.657	-0.990 (0.175)	<0.001	0.361 (0.245)	0.141
Triglycerides (mM) <sup>b</sup>	-0.044 (0.073)	0.549	0.009 (0.044)	0.834	0.001 (0.061)	0.981
Non-HDL-C (mM) <sup>b</sup>	0.037 (0.196)	0.849	-0.055 (0.127)	0.668	0.045 (0.177)	0.800
LDL-C (mM) <sup>b</sup>	0.090 (0.209)	0.667	-0.095 (0.131)	0.469	0.078 (0.183)	0.669
Systolic BP (mmHg) <sup>b</sup>	-0.227 (2.511)	0.928	-2.867 (1.266)	0.024	-0.953 (1.760)	0.588
Diastolic BP (mmHg) <sup>b</sup>	-1.944 (1.401)	0.166	-0.449 (0.862)	0.603	-0.274 (1.199)	0.819
Waist circumference (cm) <sup>b</sup>	0.083 (0.634)	0.896	-0.481 (0.296)	0.104	-1.189 (0.410)	0.004
Hip (cm) <sup>b</sup>	0.803 (0.665)	0.228	-0.086 (0.064)	0.177	-0.036 (0.088)	0.681
WHR <sup>b</sup>	-0.008 (0.007)	0.125	-0.005 (0.003)	0.150	-0.013 (0.004)	0.004
Weight (kg) <sup>c</sup>	0.015 (0.017)	0.402	-0.007 (0.003)	0.017	-0.018 (0.004)	<0.001
BMI <sup>c</sup>	0.004 (0.019)	0.847	-0.008 (0.003)	0.013	-0.018 (0.004)	<0.001

<sup>a</sup>Adjusted for age, gender, relationship status, education level, employment status, smoking status, and alcohol drinking.

<sup>b</sup>Linear mixed regression model.

<sup>c</sup>Gamma mixed regression model.

SE, standard error.

## **5 DISCUSSION**

This thesis described the development, implementation, and evaluation of a six-month cluster-RCT community-based intervention in northern Vietnam. The results demonstrated enhancements of dietary and physical activity behaviours, improvement of T2D and CVD risk factors, and reductions of MetS components and MetS proportion in the intervention group. This study also provided a comprehensive process evaluation of the intervention program which explained the links between intervention elements and outcomes, and indicated the most effective and preferred strategies for the intervention participants. The following paragraphs provide expanded discussions on physical activity, dietary outcomes, MetS outcomes, and process evaluation in addition to those already presented in the publications.

### **5.1 Physical activity**

This study showed significant improvement in walking and total physical activity, and decrease in mean sitting time in the intervention group. It has been reported by the intervention participants that they combined walking and resistance band during the program, however, resistance activities were not measure in the present study.

Pedometers were provided to the intervention participants at baseline and post-test. However, they cannot measure upper body movement, and activities such as swimming, cycling and weight training. They are unable to record the intensity of different activities (Tudor-Locke and Lutes 2009). Other objective measures, such as accelerometers can be difficult and are expensive to use in large population studies (Matthews et al. 2012). They are not ideal for the control group given the tendency to motivate behaviour change via direct feedback to the participant (Strath et al. 2013).

The intervention was conducted during summer and early autumn in Vietnam, which provided an ideal environment for walking groups (Chan and Ryan 2009). Future studies should consider seasonal factors since they can affect physical activity behaviours in various populations (Wagner et al. 2016).

## **5.2 Diet behaviours**

Although salt intake is a well-known risk factor for hypertension (Ha 2014), it is difficult to estimate the amount of salt added during cooking, salty seasonings and sauces used at the table. In this study, only one question was asked on using salt in preparing meals. This may partly explain the lack of difference in salt intake frequency between the intervention and control groups.

We have supplemented the STEPS questions on eating organ meats to reflect the Vietnamese culture, as evidence exists that organ meats are rich in cholesterol and increase the risk of MetS (Jesus 2015). An important educational message from the Vietnam government is to avoid eating internal animal organs, especially for people with high blood pressure, high cholesterol levels, and high risk of having CVD (National Institute of Nutrition of Vietnam 2015). It is noted that the focus of the VPAN intervention was on dietary behaviour change and not the actual quantity of fruit and vegetable intakes, therefore, the STEPS questions were appropriate and adopted for this study as well as to minimise subject burden.

## **5.3 Metabolic syndrome**

There was a decrease in MetS in the control group as well as the intervention group at post-evaluation. The Hawthorne effect (Parsons 1974) of making aware of MetS and one session of standard advice might lead to the apparent reduction in MetS prevalence

among the control participants, even though such an impact was expected to be minor for RCT (McCambridge, Witton, and Elbourne 2014).

#### **5.4 Process evaluation**

The process evaluation of the VPAN program was conducted to assess the participation, fidelity, satisfaction, and reasons for completing or not completing the program. The findings increase our understanding of the program components that were embraced by participants and assisted in supporting behavioural changes. The brief discussion after each education session offered opportunities to review the program and attendance, as a type of continuous feedback. Changes implemented after the first session with the provision of childcare, composition of walking groups, and suitable time and date for the following education sessions supported the involvement of participants, emphasising the importance of process evaluation to inform and enhance program implementation in on-going trials (Wilson et al. 2009). It is noted that many participants have to take care of their grandchildren during daytime, therefore, it is difficult for them to attend any meeting or training session. Therefore, suitable timing and provision of childcare service may encourage them to participate. It has been observed that the prevalence of MetS was higher among women than men (Binh et al. 2014). Participants of the present study were invited based on their MetS status, which explains why more women than men were recruited into the VPAN program.

#### **5.5 Strengths of the study**

First, this study employed a cluster RCT design which enabled the assessment of intervention effectiveness for the intervention group relative to the control group over time.

Second, this study investigated both primary and secondary outcome measures, so that changes in important health outcomes could be tracked and assessed as a result of the lifestyle behaviour change intervention.

Third, the study included a comprehensive process evaluation, which is typically underreported in RCTs. Process evaluation allows the assessment of intervention compliance and acceptability, which enhances internal validity. Results of the process evaluation may provide insights into the most effective intervention components and behaviour change techniques. These generalisability elements are necessary to guide dissemination of findings and enhance external validity (Laws et al. 2012).

## **5.6 Limitations of the study**

The present study has several limitations as follows.

First, due to limited resources, the VPAN was only followed up for six months. A longer term follow up should be considered to assess the sustainability of intervention program. The follow-up period of six months was adopted due to limited resources available for this study and to minimise loss-to-follow-up. Previous studies reported that intensive, short-term lifestyle behaviour intervention programs might be more effective than longer programs (Dunn et al. 1999).

Second, the results of the program can still be affected by residual confounding factors although various demographic and other lifestyle factors were controlled for in the mixed regression analyses.

Third, despite the results showed improvements in physical activity levels, nutrition behaviours, and health outcomes, it is unclear which intervention component (or combination of them) was responsible and most effective for these improvements.

Fourth, cost-effectiveness of the program was not performed in this study. Lifestyle interventions can affect many health issues and disorders such as T2D, CVD, cancers, and mental health (Saha et al. 2013), and cost-effectiveness analyses of these programs are very complicated. Thus, it is not included in this study design. However, the inclusion of economic evaluation in an intervention program is important due to scarce of resources in the health system of developing countries such as Vietnam (Wolfenstetter 2011).

Finally, although a pedometer was used to measure walking, it was provided to the intervention participants only. It has been shown that physical activity could be overestimated by using the IPAQ-SF (Lee, Macfarlane, et al. 2011) . Thus, the use of objective measures such as pedometers and accelerometers in both intervention and control groups can provide more accurate data on physical activity. They also serve as a tool to motivate participants to increase their physical activity levels.

## **6 CONCLUSIONS AND RECOMMENDATIONS**

### **6.1 Conclusions**

The VPAN program achieved all of the stated objectives in the section 1, sub-section 1.2.2. The program interventions was predominantly implemented as intended, reached and engaged the majority of the program participants. The VPAN program was effective in terms of improving physical activity and dietary behaviours, and other health outcomes, including MetS status, and MetS components among the intervention participants when compared to their control counterparts.

### **6.1.1 Process evaluation of the intervention program**

Findings from the process evaluation showed the intervention program reached and engaged the majority of participants throughout the intervention period. The process evaluation increased our understanding about the mechanism between the program components and behavioural changes.

Positive responses to the components of the program were reported by the intervention participants. Majority of the intervention participants agreed that program resources and strategies were useful. The intervention activities encouraged them to enhance their physical activity levels and healthy dietary behaviours. The integration of printed resources (booklet), face-to-face interaction (education sessions), with social support (walking group) appeared to be an effective strategy to improve physical activity and dietary behaviours.

### **6.2.2 Changes in physical activity and nutrition behaviours**

#### *Physical activity levels*

At baseline, physical activity levels were similar in both groups. However, after the six month intervention, significant differences ( $p < 0.001$ ) between groups were observed in various physical activity outcomes, including total physical activity, participation of moderate activity, walking time, and sitting time reduction when compared to the baseline. An increase of more than 5000 steps on average on seven consecutive days was found among the intervention group ( $p = 0.001$ ) between the two assessment time points.

According to the group  $\times$  time interaction term of the mixed regression models, significant improvements among the intervention group participants relative to their

control group counterparts were demonstrated in total physical activity ( $p=0.001$ ), moderate activity participation ( $p=0.018$ ), mean walking time ( $p<0.001$ ), and mean sitting time ( $p<0.001$ ), after controlling for commune clustering and the effects of covariates and confounding factors.

### ***Dietary behaviours***

The nutritional outcomes between the two groups were similar at baseline. However, at six months, significant differences between groups were demonstrated for two dietary behaviours ( $p<0.05$ ). After controlling for commune clustering and the effects of covariates and confounding factors, significant reductions in frequent intake of animal internal organs ( $p=0.001$ ), and frequent use of cooking oil ( $p=0.001$ ) in the intervention group relative to the control group over the six-month period were confirmed using the group  $\times$  time interaction term. No significant changes of frequent vegetable intake, fruit intake, and use of salt were observed according to the logistic mixed regressions.

### **6.2.3 Changes in features of MetS and other risk factors**

Improvements of several clinical risk factors were achieved after six month intervention of the VPAN program, including mean HDL-C (+0.42 mM,  $p<0.001$ ) systolic blood pressure ( $-4.08$  mm Hg,  $p=0.002$ ), WC ( $-1.63$  cm,  $p<0.001$ ), waist to hip ratio ( $-0.024$ ,  $p<0.001$ ), weight ( $-1.44$  kg,  $p<0.001$ ) and BMI ( $-0.59$  kg/m<sup>2</sup>,  $p<0.001$ ).

After controlling for demographic and other potential confounders, significant improvements in the intervention group relative to the control group were observed for HDL-C ( $p<0.001$ ) glucose ( $p=0.005$ ), WC ( $p=0.009$ ), WHR ( $p = 0.013$ ), weight

( $p < 0.001$ ) and BMI ( $p < 0.001$ ) through the group  $\times$  time interaction term in the mixed regression models.

After the six month intervention, the proportion of MetS decreased significantly by 44% ( $p < 0.001$ ), and 24% ( $p < 0.001$ ) in the intervention group and control group, respectively. A significant reduction of the mean number of MetS components was found in the intervention group, from 3.11 at baseline to 2.65 at post-test ( $p < 0.001$ ) whereas no change was reported in the control group, from 3.16, at pre-test, to 3.15 at post-test ( $p = 0.942$ ).

## **6.2 Recommendations**

The following recommendations are suggested for future studies based on the findings from the present study.

*First, long-term effectiveness of lifestyle intervention program should be evaluated.*

Maintenance of achieved intervention effects is a major goal of health promotion. Therefore, the long-term effect of health promotion program should be evaluated. It is evident that intervention program with a duration of more than 24 weeks achieved maintenance (Fjeldsoe et al. 2011). Although the short-term effectiveness of lifestyle intervention on MetS and other NCDs have been demonstrated, data on their long-term effectiveness and sustainability remain lacking (Dunkley et al. 2012, Bassi et al. 2014). Due to limited resources, the current study could not be follow-up after six months. Future studies should consider applying a booster intervention (Pasalich et al. 2013), and collect follow-up data to ascertain the longer-term effectiveness of lifestyle modification programs (Jancey et al. 2011). In addition, behavioural determinants on maintenance and initiation of lifestyle behaviours should also be analysed (Fjeldsoe et al. 2011).

***Second, physical activity and nutrition intervention program for MetS should be translational and evaluated in sustained settings.***

Since health promotion resources are limited and expectation of the health promotion program's success is high, the sustainability of a health promotion program is the most concerned (Swerissen and Crisp 2004). Primary healthcare workers are recommended to provide behaviour modification advice together with their standard clinical practice.

The VPAN program for MetS was successfully implemented with strong support from primary healthcare professionals, who mobilised the participants and organised education sessions. Primary healthcare is most accessible in developing countries because of attendance by majority of the population. Integration of lifestyle modifications into routine clinical care is an effective, low-cost intervention approach (Grandes et al. 2008). Potential translational health promotion programs targeting different community sub-groups should be developed, implemented, and up-scaled to reach to entire population.

***Third, effectiveness of different physical activity and nutrition intervention components should be examined.***

Personal behaviours are shaped by the interaction at individual, interpersonal, and community factors. In order to change individual behaviours, a range of strategies are normally combined. It is evident that the magnitudes of behaviour and health outcomes are different in lifestyle intervention programs when different strategies are applied, and interventions focusing solely on one lifestyle regimen might be insufficient.

Although significant improvements were observed in both lifestyle and clinical outcomes among the intervention participants in the present study, the most effective

and responsible intervention component for such improvement could not be identified. Future studies should examine which is the most effective component as well as the optimal intervention strategies to improve lifestyle and health outcomes for the Vietnamese adult population with MetS.

***Finally, mobile phone app-based intervention to improve physical activity and dietary behaviours for people with MetS.***

With the fast development of the internet, the internet-based interventions such as mobile phone apps, to promote weight loss and physical activity have been increasing in recent years (Middelweerd et al. 2014). Such smartphone apps have many advantages, including low cost, convenience for users, constantly accessible, timely feedback, and large reach (Middelweerd et al. 2014, Griffiths et al. 2006). The literature has shown that mobile phone apps-based interventions are effective for general population in weight loss (Flores Mateo et al. 2015), adults in physical activity improvement (Middelweerd et al. 2014), T2D self-management (Cui et al. 2016), and lifestyle change for people with MetS (Bassi et al. 2014). With the advent of smartphone technology and widespread use of mobile phone, and good coverage of mobile network in countries such as Vietnam, interventions via smartphone apps are now the trend with ever growing applications in different settings. Therefore, mobile phone apps-based intervention interact with or in conjunction with social media targeting people with MetS to improve lifestyle behaviours should be developed, implemented, and evaluated among Vietnamese adults, with the potential to reach the entire population. Caution should be taken when using mobile phone app-based interventions for this age group.

In summary, the present intervention program appeared to be suitable to improve physical activity and dietary behaviours, and other risk factors for adults with MetS in Vietnam. The intervention strategies and resources can be applied to improve physical activity levels and dietary behaviours in different locations in Vietnam.

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## APPENDIX A: STATEMENT OF CONTRIBUTION OF OTHERS

5 August 2017

To Whom It May Concern

I, Van Dinh Tran, contributed as the main person responsible for writing up all presented as part of the thesis. Details of those publications as below.

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>
2. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>
3. **Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>
4. **Van Dinh Tran**, Jonine Jancey, Andy Lee, Anthony James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation. *Evaluation and Program Planning*. 61. 128-133. <https://doi.org/10.1016/j.evalprogplan.2016.12.012>



I, as a Co-Author, endorse that this level of contribution by the candidate indicated above is appropriate.

Andy Lee



Jonine Jancey



Anthony James



Peter Howat



Le Thi Phuong Mai



10<sup>th</sup> July 2017

To Whom It May Concern

I, Prof. Andy Lee, contributed as a supervisor of the PhD. I had ongoing and close involvement with the research, including contributing to the study and intervention design, read draft manuscripts, and suggested improvements for the following publications:

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>
2. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>
3. **Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>
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Prof. Andy Lee (Supervisor)



Tran Van Dinh (Candidate)

6<sup>th</sup> July 2017

To Whom It May Concern

I, Associate Professor Jonine Jancey, contributed as a co-supervisor of the PhD. I had ongoing and close involvement with the research, including contributing to the study and intervention design, read draft manuscripts, and suggested improvements for the following publications:

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>
2. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>
3. **Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>
4. **Van Dinh Tran**, Jonine Jancey, Andy Lee, Anthony James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation. *Evaluation and Program Planning*. 61. 128-133. <https://doi.org/10.1016/j.evalprogplan.2016.12.012>



A/Professor Jonine Jancey (Co-supervisor)



Tran Van Dinh (Candidate)



4 August 2017

To Whom It May Concern

I, Doctor Anthony James, contributed as a co-supervisor of the PhD. I had ongoing and close involvement with the research, including contributing to the study and intervention design, read draft manuscripts, and suggested improvements for the following publications:

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>
2. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>
3. **Van Dinh Tran**, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a community-based physical activity and nutrition behaviour intervention on features of the metabolic syndrome: A cluster-randomised controlled trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>
4. **Van Dinh Tran**, Jonine Jancey, Andy Lee, Anthony James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition program for adults with metabolic syndrome: Process evaluation. *Evaluation and Program Planning*. 61. 128-133. <https://doi.org/10.1016/j.evalprogplan.2016.12.012>

Dr. Anthony James (Co-supervisor)

Tran Van Dinh (Candidate)

6<sup>th</sup> July 2017

To Whom It May Concern

I, Professor Peter Howat, contributed as an associate supervisor of the PhD. I had ongoing and close involvement with the research, including contributing to the study and intervention design, read draft manuscripts, and suggested improvements for the following publications:

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Emeritus Professor Peter Howat (Associate supervisor)



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6<sup>th</sup> July 2017

To Whom It May Concern

I, Doctor, Le Thi Phuong Mai, contributed as an associate supervisor of the PhD. I had ongoing and close involvement with the research, including contributing to the study and intervention design, read draft manuscripts, and suggested improvements for the following publications:

1. **Van Dinh Tran**, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>
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Dr. Le Thi Phuong Mai (Associate supervisor)



Tran Van Dinh (Candidate)

## APPENDIX B: COPYRIGHT PERMISSIONS

1. Van Dinh Tran, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2016). Community-based physical activity and nutrition programme for adults with metabolic syndrome in Vietnam: study protocol for a cluster-randomised controlled trial. *BMJ Open*. 6(6). <http://dx.doi.org/10.1136/bmjopen-2016-011532>

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2. Van Dinh Tran, Andy H Lee, Jonine Jancey, Anthony P James, Peter Howat, Le Thi Phuong Mai. (2017). Physical activity and nutrition behaviour outcomes of a cluster-randomised controlled trial for adults with metabolic syndrome in Vietnam. *Trials*. 18:18. <http://dx.doi.org/10.1186/s13063-016-1771-9>

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3. Van Dinh Tran, Anthony P James, Andy H Lee, Jonine Jancey, Peter Howat, Le Thi Phuong Mai. (2017). Effectiveness of a Community-Based Physical Activity and Nutrition Behaviour Intervention on Features of the Metabolic Syndrome: A Cluster-Randomised Controlled Trial. *Metabolic Syndrome and Related Disorders*. 15(2). 63-71. <http://dx.doi.org/10.1089/met.2016.0113>

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## APPENDIX C: SCREENING INSTRUMENTS

### Vietnam Physical Activity and Nutrition (VPAN) Program

#### Participant Information Sheet

You have been invited to participate in this study because you are a resident aged between 50 and 65 years living in Hanam province. Please read this document carefully and feel free to ask any questions. Do not sign the informed consent form unless you fully understand the nature of the study and the commitments you may need to make over the next 6 months.

#### *Background information*

As people age, the likelihood of suffering from chronic diseases such as type 2 diabetes and cardiovascular disease is increased. For many Vietnamese less than optimal dietary habits coupled with low levels of physical activity can exacerbate the risk. It is therefore important to support the adoption of a healthy lifestyle to help prevent such chronic diseases.

#### *What does the study involve?*

The purpose of this study is to assess the effects of a healthy lifestyle community-based program on physical activity and dietary behaviours over a period of 6 months. The initial screening interview will assess your suitability to participate in the study. If suitable, you will be taking part in a range of activities to enhance your physical activity level and healthy eating behaviours.

#### *Study plan*

Upon enrolment in VPAN, you will be requested to attend four education sessions at your local commune health centre. You will also be provided a booklet containing information on physical activity and dietary guidelines, in conjunction with the education sessions. In addition, you will be asked to join a walking group organised in the area where you live, as well as doing resistant exercises under the guidance of an experienced group leader.

You will first attend an information session about VPAN at the Hanam Provincial Preventive Medicine Centre and pay another visit again at the end of the program. This will include completion of a short interview about your physical activity levels and dietary behaviours, the taking of anthropometric measurements, and the collection of a blood sample to determine your suitability to join VPAN. Details and materials of the VPAN program will be provided and distributed to you via your assigned group leader shortly after.

#### *Screening and data collection*

A morning appointment will be set up for you to attend the Hanam Provincial Preventive Medicine Centre at Truong Chinh street, Phu Ly City, in a fasted state i.e. consume your last meal 12 hours before your appointment (e.g. 8pm the night before if you have an 8am appointment) and drink only water until after your appointment.

During this visit we will obtain 12ml of blood from a vein in your arm using a needle. Your blood sample will be sent to our laboratory and processed. The purpose is to measure triglyceride, cholesterol, glucose, insulin, and C-reactive protein in your blood. In addition to

the blood test, we will ask you a number of questions about you (demographic profile), smoking status, alcohol intake, dietary and physical activity behaviours. We will also measure your height, weight, waist and hip circumferences, and blood pressure at that time.

The data collected from you will be used to compile a combined health profile of all participants. These measurements will also be used to compare to those collected after completion of the program in 6 months' time, in order to assess the effectiveness of VPAN on the group as a whole. Only the research team members have access to your personal details and data records.

***Possible adverse effect***

There is the possibility of minor discomfort with venepuncture (blood collection). It is important that you inform us if you experience any discomfort. Your comfort during the procedure is of more concern than the collection of blood samples. In some people slight bruising and tenderness may appear afterwards at the site of blood collection. Bruising is usually minor and the arm will return to normal in one to two days.

***Benefits of the program***

As a result of taking part in this study, you will gain useful information about your current cholesterol levels, blood pressure and anthropometric measurements.

Your participation will provide us with important data, enabling us to investigate the role of healthy lifestyle programs in the prevention of chronic diseases. In Vietnam such diseases are the biggest cause of death and disability. We hope the knowledge gained from this study will further improve our understanding of ways to reduce the adverse health outcomes.

***Confidentiality and ability to withdraw***

All information provided by you will be treated strictly confidential and any publication arising from this work will not include your name or any identifying feature.

We will notify you within one week of your interview to determine whether you meet the selection criteria for participation in the VPAN program.

It must be stressed that your participation in this study is entirely voluntary; you are free to withdraw from the study at any stage, whether that is before, during or after any blood collection or recording of information. It is important that you do not feel any pressure to complete the study particularly if it is not what you had originally anticipated.

***Contact details***

If you have any queries or concerns please contact the following project staff:

- Mr Van Dinh Tran, Project Officer, on +84 439710791 or [tranvandinhi@gmail.com](mailto:tranvandinhi@gmail.com)
- Dr Le Thi Phuong Mai, Project Supervisor, on +84 439710791 or [lepmai@yahoo.com](mailto:lepmai@yahoo.com)
- Professor Andy Lee, Project Supervisor, on +61 8 92664180 or [andy.lee@curtin.edu.au](mailto:andy.lee@curtin.edu.au)

This project is conducted by Curtin University, Australia, in collaboration with the National Institute of Hygiene and Epidemiology, Hanoi. It has been approved by the Curtin University Human Research Ethics Committee (Approval Number: HR139/2014). The Committee is

comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning +61 8 92662784 or by emailing [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au)

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**QUESTIONNAIRE FOR SCREENING POTENTIAL PARTICIPANTS**  
**Vietnam Physical Activity and Nutrition (VPAN) Program**

1.	Name of interviewee:	ID:									
2.	Number: _____ ; Street: _____ commune/ward:										
3.	District:										
4.	Contact number (home phone/mobile)		.....	.....	.....						
5.	Sex	Female		0							
		Male		1							
6.	What is your date of birth?	<table border="0"> <tr> <td>□□□</td> <td>□□□</td> <td>□□□</td> </tr> <tr> <td>date</td> <td>month</td> <td>year</td> </tr> </table>	□□□	□□□	□□□	date	month	year		..... years	
□□□	□□□	□□□									
date	month	year									
7.	Are you currently taking treatment for raised blood sugar or diabetes?	Yes		1 → Stop							
		No		2							
8.	Are you currently taking treatment for hypertension?	Yes		1 → Stop							
		No		2							
9.	Are you currently taking treatment for high triglyceride/cholesterol?	Yes		1 → Stop							
		No		2							
10.	Have you been involved in a physical activity program in the last year?	Yes		1 → Stop							
		No		2							
11.	Have you been involved in a nutrition program in the last year?	Yes		1 → Stop							
		No		2							
12.	Are you working in a physically active occupation?	Yes		1							
		No		2 → Q14							
13.	If yes, in what way? What is your occupation?										
14.	Do you think you do more recreational exercise than the average person?	Yes		1							
		No		2							
15.	How long do you do physical activity each week - activity that makes you breath somewhat harder than normal?		..... hours	..... minutes							
16.	Height	□□□□ . □□□ cm									
17.	Weight	□□□□ . □□□ kg									

Interviewer: \_\_\_\_\_ Passed screening: NO  YES

## APPENDIX D: BASELINE AND POST-EVALUATION QUESTIONNAIRES

Date.....month.....year.....

### BASELINE AND POST INTERVENTION QUESTIONNAIRE Vietnam Physical Activity and Nutrition (VPAN) Program

DEMOGRAPHIC									
1.	Name of interviewee:	ID:							
2.	Number: ; Street: commune/ward: District:								
3.	Contact number (home phone/mobile)	.....	.....						
4.	Sex	Female	0						
		Male	1						
5.	What is your date of birth?	<table style="margin: auto; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">date</td> <td style="text-align: center; font-size: 8px;">month</td> <td style="text-align: center; font-size: 8px;">year</td> </tr> </table>				date	month	year	..... years
date	month	year							
6.	What is the highest level of education you have completed?	No formal schooling	1						
		Less than primary school	2						
		Primary school	3						
		Secondary school	4						
		High school	5						
		College/University	6						
7.	What is your marital status?	Never married	1						
		Currently married	2						
		Divorced	3						
		Widowed	4						
8.	Which of the following best describes your <b>main work</b> status over the past 12 months?	Farmer	1						
		Labour/Manual worker	2						
		Office clerk	3						
		Teacher	4						
		Home duties	5						
		Retired	6						
		Business job	7						
		Unemployment	8						
	Other:	9							
SMOKING									
9.	Are you a	Never smoker	1						
		Former smoker	2						
		Current smoker	3						
10.	On average, how many of the following tobacco products do you smoke per day?	Manufactured cigarettes	..... per day						
		Hand-rolled cigarettes	..... per day						
		Pipes full of tobacco	..... per day						
		Cigars, cheroots or cigarillos	..... per day						
		Number of water pipe sections	..... per day						
		Any others	..... per day						
		Specify: .....	..... per day						

Date.....month.....year.....

11.	How many years have (had) you been smoking?	..... years or since age .....	..... years
<b>ALCOHOL DRINKING</b>			
12.	Are you a	Non-drinker	1 → Q14
		Former drinker	2 → Q14
		Drinker	3
13.	In a typical week, how many <b>standard alcoholic drinks</b> do you consume? (USE SHOWCARD)	Number of standard drinks	..... per day or ..... per week
<b>DIET HABITS</b>			
14.	How often do you eat <b>fruit</b> ?	≥1 time per day	1
		2-6 times per week	2
		1 time per week	3
		2-3 times per month	4
		≤ 1 time per month	5
		None	6
15.	How often do you eat <b>vegetable</b> ?	≥1 time per day	1
		2-6 times per week	2
		1 time per week	3
		2-3 times per month	4
		≤ 1 time per month	5
		None	6
16.	How often do you eat <b>internal organs of animals</b> ?	≥1 time per day	1
		2-6 times per week	2
		1 time per week	3
		2-3 times per month	4
		≤ 1 time per month	5
		None	6
17.	How often do you use <b>cooking oil</b> to prepare daily meals?	≥1 time per day	1
		2-6 times per week	2
		1 time per week	3
		2-3 times per month	4
		≤ 1 time per month	5
		None	6
18.	How often do you use <b>salt in</b> preparing daily meals?	≥1 time per day	1
		2-6 times per week	2
		1 time per week	3
		2-3 times per month	4
		≤ 1 time per month	5
		None	6
<b>PHYSICAL ACTIVITY (IPAQ-SF)</b>			
<p>We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the <b>last 7 days</b>. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.</p> <p>Think about all the <b>vigorous</b> activities that you did in the <b>last 7 days</b>. <b>Vigorous</b> physical activities refer to activities that take hard physical effort and make you <b>breathe much harder than normal</b>. Think only about those physical activities that you did for at least 10 minutes at a time.</p>			

Date.....month.....year.....

19.	During the <b>last 7 days</b> , on how many days did you do <b>vigorous</b> physical activities like heavy lifting, digging, aerobics, or fast bicycling?	_____ <b>days per week</b> None → Q21	
20.	How much time did you usually spend doing <b>vigorous</b> physical activities on one of those days?	_____ <b>hours</b> _____ <b>minutes</b>	
Think about all the <b>moderate</b> activities that you did in the <b>last 7 days</b> . <b>Moderate</b> activities refer to activities that take moderate physical effort and make you breathe <b>somewhat harder</b> than normal. Think only about those physical activities that you did for at least 10 minutes at a time.			
21.	During the <b>last 7 days</b> , on how many days did you do <b>moderate</b> physical activities like carrying light loads, bicycling at a regular pace? <b>Do not</b> include walking.	_____ <b>days per week</b> None → Q23	
22.	How much time did you usually spend doing <b>moderate</b> physical activities on one of those days?	_____ <b>hours</b> _____ <b>minutes</b>	
Think about the time you spent <b>walking</b> in the <b>last 7 days</b> . This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.			
23.	During the <b>last 7 days</b> , on how many days did you <b>walk</b> for at least 10 minutes at a time?	_____ <b>days per week</b> No walking → Q25	
24.	How much time did you usually spend <b>walking</b> on one of those days?	_____ <b>hours</b> _____ <b>minutes</b>	
The last question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.			
25.	During the <b>last 7 days</b> , how much time did you spend <b>sitting</b> on a <b>weekday</b> ?	_____ <b>hours</b> _____ <b>minutes</b>	
26.	During the <b>last 7 days</b> , how much time did you spend <b>sitting</b> on a <b>weekend</b> ?	_____ <b>hours</b> _____ <b>minutes</b>	
<b>ANTHROPOMETRIC MEASUREMENT</b>			
27.	Waist circumference	_____ . _____ cm	
28.	Hip circumference	_____ . _____ cm	
29.	Height	_____ . _____ cm	



## APPENDIX E: PROCEES EVALUATION INSTRUMENTS

### PROCESS EVALUATION QUESTIONNAIRE Vietnam Physical Activity and Nutrition (VPAN) Program

- I. BOOKLET**
- 1. The booklet gives useful advice**  
Disagree 1 2 3 4 5 Agree
- 2. The booklet is easy to read.**  
Disagree 1 2 3 4 5 Agree
- 3. The booklet is easy to understand.**  
Disagree 1 2 3 4 5 Agree
- 4. The booklet encourages me to think about physical activity.**  
Disagree 1 2 3 4 5 Agree
- 5. The booklet encourages me to think about healthy diet.**  
Disagree 1 2 3 4 5 Agree
- II. RESISTANCE BAND**
- 6. I like the resistance band.**  
Disagree 1 2 3 4 5 Agree
- 7. Exercises with the resistance band are simple and easy to follow**  
Disagree 1 2 3 4 5 Agree
- 8. The resistance band encourage me to do more exercise**  
Disagree 1 2 3 4 5 Agree
- III. WALKING GROUP**
- 9. I am satisfied with the walking group.**  
Disagree 1 2 3 4 5 Agree
- 10. The walking group encourage me to walk more.**  
Disagree 1 2 3 4 5 Agree
- 11. The walking group is suitable for my age group**  
Disagree 1 2 3 4 5 Agree
- 12. The walk leader mobilised people for walking**  
Disagree 1 2 3 4 5 Agree
- 13. The walk leader encouraged me to walk more**  
Disagree 1 2 3 4 5 Agree
- IV. EDUCATION SESSIONS**
- 14. The education sessions provide useful information**  
Disagree 1 2 3 4 5 Agree
- 15. I am satisfied with the content of the education sessions.**  
Disagree 1 2 3 4 5 Agree
- 16. Duration (time) for each education session is enough**  
Disagree 1 2 3 4 5 Agree

**17. The education sessions were organized well (location, facilities...)**

Disagree 1 2 3 4 5 Agree

**18. I am happy with the facilitators of the education sessions**

Disagree 1 2 3 4 5 Agree

**19. The facilitators motivated me to attend the sessions**

Disagree 1 2 3 4 5 Agree

**V. OVERALL PROGRAM**

**20. I am happy with the program materials and activities**

Disagree 1 2 3 4 5 Agree

**21. The program encouraged me to think about physical activity**

Disagree 1 2 3 4 5 Agree

**22. The program encouraged me to think about dietary changes**

Disagree 1 2 3 4 5 Agree

**23. The program helped me change my physical activity behaviours**

Disagree 1 2 3 4 5 Agree

**24. The program helped me change my dietary behaviours**

Disagree 1 2 3 4 5 Agree

**Thank you very much for your time.**

## APPENDIX F: EXIT INTERVIEW INSTRUMENTS

### EXIT INTERVIEW SCHEDULE – PROGRAM COMPLETERS

#### Vietnam Physical Activity and Nutrition (VPAN) Program

**Target group:** Completers

#### **Objectives**

- 1. To identify the like or dislike in the intervention components of the VPAN program**
- 2. To establish changes in attitude to physical activity and eating habits since starting the VPAN program**
- 3. To identify reasons for being involved in the VPAN program**
- 4. To identify comments/suggestions for the VPAN program**

#### **Interviewer Introduction**

*Good morning/afternoon.*

My name is.....

I am going to ask you a series of questions about the VPAN program and its materials. We need to know what worked and what didn't work so that we can improve the program, so please try to be as honest as possible with your responses.

#### **Questions**

**(To identify the like or dislike in the intervention components of the VPAN program)**

*Firstly, I would like to ask you about the program and its materials*

- 1. What did you think of the VPAN program overall?*
- 2. What did you think of the VPAN program materials overall... (Booklet, etc.)*
- 3. Do you have any suggestions to improve the program materials?*
- 4. What did you think of the program in terms of:*

i

*Encouragement?*

*Motivation to improve your physical activity/diet?*

***Program resources***

*a. Booklet*

3. *What did you like about the booklet?*
4. *What did you dislike about the booklet?*
5. *What did you think about the content of the booklet?*
6. *Do you have any idea/suggestion to improve the booklet?*

*b. Resistance band*

7. *What did you like about the resistance band?*
8. *What did you dislike about the resistance exercises?*
9. *Did you do exercises with the band?*

*Yes/No*

*Why?*

***Program activities***

*a. Education sessions*

10. *What did you think about the education sessions?*

*Duration*

*Content*

*Facilitators*

11. *What did you like most in these sessions?*
  12. *What did you dislike in these sessions?*
  13. *Do you have any suggestion to improve the quality/effectiveness of these sections?*
    - b. *Walking group*
  14. *What did you like about the walking group? (e.g. time of walking, duration of walking, information provided)*
  15. *What did you dislike about the walking group? (e.g. time of walking, duration of walking, information provided)*
  16. *What did you think about the role of the walk leaders? (e.g. mobilising the group members for walking, encouraging the members walking more).*
- (To establish changes in attitude to eating habits since starting the VPAN program)  
I would now like to ask you about your attitude to eating habits since starting the VPAN program***
17. *Do you think the program encouraged you to increase your physical activity levels?  
Why/why not?*
  18. *Do you think the VPAN program motivated you to find out more information about physical activity? (suggestions from guides and information in the materials)  
How?*
  19. *Could you please tell me any changes in physical activity, doing exercises since taking part in the program?*
  20. *Do you think the program encouraged you to make any changes to your eating habits?  
Why/why not?*
  21. *Do you think the VPAN program motivated you to find out more information about healthy eating? (suggestions from guides and information in the materials)*

*How?*

22. *Could you please tell me any changes in eating habits since taking part in the program? E.g. tried any different foods or stopped eating some kind of foods since starting the VPAN program?*

**(To identify reasons for being involved in the VPAN program)**

***I would now like to ask about your reasons for being involved in the program***

*You completed the program*

23. *What motivated or enabled you to complete the program?*
24. *How do you think we could improve the program or make it more appealing to people in your age group?*
25. *Are there any other comments you would like to make about the VPAN program?*

**(To identify comments/suggestions for the VPAN program)**

26. *Do you have any comments/suggestion for the program?  
In terms of resources/activities*
27. *What would be your ideal physical activity program?*
28. *What would be your ideal nutrition program?*

**Thank you very much for your time!**

**EXIT INTERVIEW SCHEDULE – PROGRAM NON-COMPLETERS**

**Vietnam Physical Activity and Nutrition (VPAN) Program**

**Target group: Non-completers**

**Objectives**

**1. To identify the participants' perceptions to the VPAN program**

**2. To identify reason for non-involvement in the VPAN program**

**Interviewer Introduction**

*Good morning/afternoon. My name is \_\_\_\_\_*

You are selected for this interview because you didn't complete the VPAN. I am going to ask you a series of questions about the program and its materials. We need to know what worked and what didn't work so that we can improve the program, so please try to be as honest as possible with your responses.

**Questions**

**(To identify the participants' perceptions to the VPAN program)**

- 1. What did you think about the VPAN program overall?*
- 2. What did you think of the VPAN program materials overall? (e.g. booklet, resistance band)*
- 3. Do you have any suggestions to improve the program materials?*
- 4. What did you think of the VPAN program activities? (e.g. walking group, education sessions)*
- 5. Do you have any suggestions to improve the program activities?*

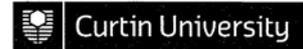
**(To identify reason for non-involvement in VPAN program)**

- 6. What stopped your involvement in the program?*

7. *What could we have done to encourage you stay with the program?*
8. *What would be your ideal physical activity program?*
9. *What would be your ideal nutrition program?*
10. *Are there any other comments you would like to make about the VPAN program?*

**Thank you very much for your time!**

## APPENDIX G: ETHICS



### Memorandum

<b>To</b>	Professor Andy H. Lee, School of Public Health
<b>From</b>	Professor Peter O'Leary, Chair Human Research Ethics Committee
<b>Subject</b>	Protocol Approval <b>HR 139/2014</b>
<b>Date</b>	10 July 2014
<b>Copy</b>	Mr Van Dinh Tran School of Public Health Dr Tony James School of Public Health Professor Peter Howat School of Public Health Dr Jonine Jancey School of Public Health

Office of Research and Development  
Human Research Ethics Committee

**TELEPHONE** 9266 2784  
**FACSIMILE** 9266 3793  
**EMAIL** [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au)

Thank you for providing the additional information for the project titled "*A Community-Based physical activity and nutrition intervention for adults with Metabolic Syndrome in Vietnam*". The information you have provided has satisfactorily addressed the queries raised by the Committee. Your application is now **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 139/2014**. *Please quote this number in any future correspondence.*
- Approval of this project is for a period of four years **10-07-2014 to 10-07-2018**.
- Your approval has the following conditions:
  - i) Annual progress reports on the project must be submitted to the Ethics Office.
- **It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.**

#### Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website [https://research.curtin.edu.au/guides/ethics/non\\_low\\_risk\\_hrec\\_forms.cfm](https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm) contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (If a serious or unexpected adverse event occurs)

Yours sincerely

Professor Peter O'Leary  
Chair Human Research Ethics Committee

**Vietnam Physical Activity and Nutrition (VPAN) Project**

**Consent Form**

You have been invited to participate in this study because you are a Hanam province resident aged between 50 and 65 years. Please read the information document carefully and ask any questions you wish. Do not sign this informed consent form unless you fully understand the nature of the study and the commitment you may need to make over the next 6 months.

I, ....., agree to participate in the above study.  
I have read and understood the Participant Information Sheet given to me.

I understand the requirements for participation in this study. I have been given the opportunity to ask questions about the study. I fully understand that I may withdraw from the study at any time without any negative consequences.

Signed ..... Date .....

Name of witness .....

Signature of witness ..... Date .....