

# 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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## 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 (≈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

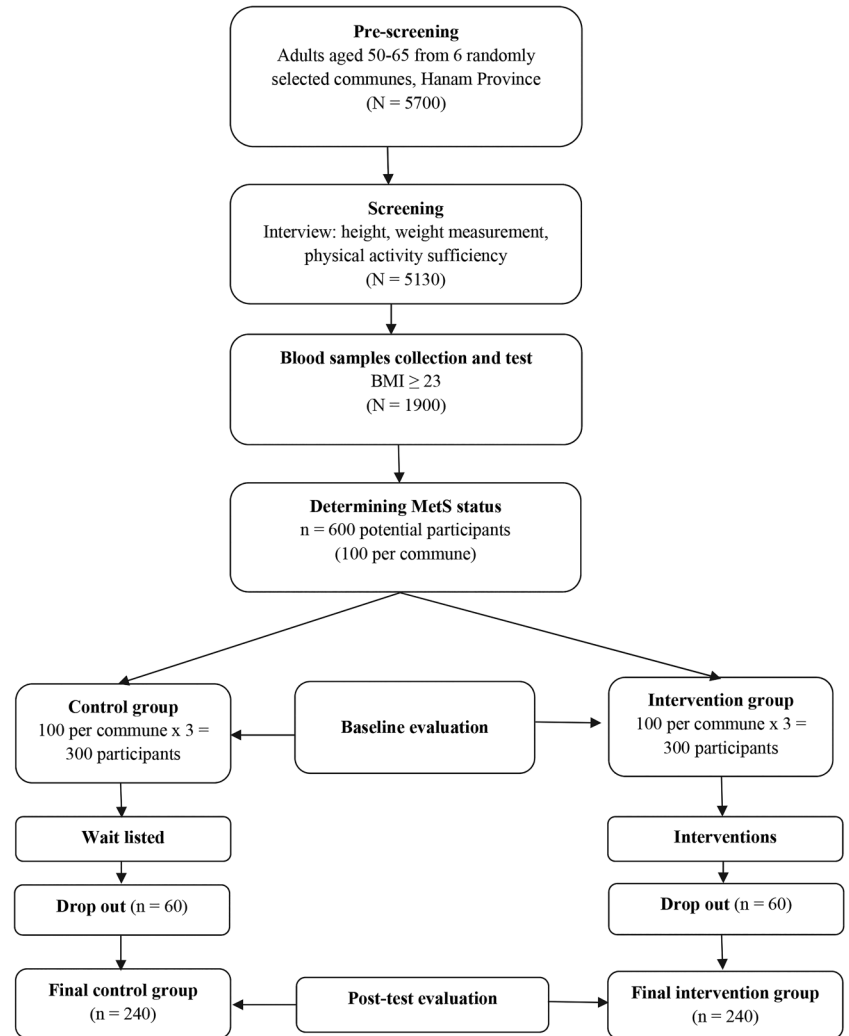
#### Description

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.

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**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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