


Nutrition and lifestyle behaviour peer support for  
Malaysian adults with metabolic syndrome (PERSUADE)

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## Summary

The outlook of a community-based intervention targeting nutrition and lifestyle behaviour modification among adults with metabolic syndrome (MetS) has not been fully explored. We describe the protocol of the development and three-month RCT of PERSUADE; a group-based community peer support intervention for Malaysian adults with MetS. The primary aim is to evaluate the effect of the peer support intervention on the clinical outcomes MetS components followed by improvements in the participants' dietary practices, physical activity levels and lifestyle behaviours. The PERSUADE module will be constructed using the Health Belief Model (HBM) to address relevant health messages from the appropriate guidelines and recent literature evidence on MetS among Malaysian adults. Following that, a minimum sample of 96 Malaysian adults with MetS will be randomised, either to the control group, who will receive one-time standard nutrition and lifestyle advice or the intervention group, who will participate in a three-month peer support program using the PERSUADE module. The participants will be followed up for three months post-intervention with data collection scheduled at baseline, 3-month and 6-month. PERSUADE is a peer support program developed with the aim improvement in nutrition and lifestyle behaviours among adults with MetS. The program constructed using information obtained from the published clinical and dietary guideline in Malaysia.

## Introduction

In Malaysia, non-communicable diseases such as cardiovascular diseases are the major cause of mortality, accounting for 70–80% of deaths, and its long-term complications are creating a major health burden for people by reducing the quality of life and increasing the healthcare cost to the society (1). Metabolic syndrome (MetS) is the clustering of three or more risk factors that increases the risk of developing type 2 diabetes and cardiovascular diseases and its increasing prevalence throughout the country is now recognized as a major health problem (2). The development of effective strategies for modifying antecedent conditions and risky behaviours, such as abdominal obesity, poor dietary habit and physical inactivity, is in a high priority to aid MetS management and prospective prevention endeavour in Malaysia.

There is a close relationship between MetS and poor lifestyle behaviour (3). Several lifestyle behaviours have been identified as predictors to MetS in Malaysia; poor dietary habit, food insecurity, poor food hygiene, physical inactivity and poor sleeping pattern (4). Hence, lifestyle intervention is seen as the most sustainable approach to the management and prevention step for MetS in Malaysia. However, there is currently only one lifestyle intervention studied among elderly with MetS (5) in Malaysia despite its increasing prevalence. Furthermore, a yearly increase in lifestyle-related non-communicable diseases in this country (4) calls for a need to develop a community-based campaign to promote an adoptable and sustainable healthy lifestyle program among Malaysian adults.

PERSUADE is a three months evidence-based community nutrition and lifestyle behaviour peer support program. The program brought together the existing clinical practice and medical nutrition therapy guidelines in the development process of its peer intervention modules. Furthermore, Health Belief Model (HBM) (6) will be incorporated in the content development of peer modules as its theoretical background. Consequently, the contents were further refined to suit local context using

input gathered from literature evidence synthesis and a qualitative study on motivation and barriers of healthy lifestyle. Eventually, the feasibility of this intervention is designed to be studied as a RCT for Malaysian adults with MetS with the aim to improve clinical outcome of MetS components. PERSUADE is aiming for an overall improvement in the MetS clinical outcomes in participants of the peer intervention group, besides investigating the impact of the peer intervention on the dietary practices, lifestyle behaviours, physical activity and health related quality of life.

## Methodology

### Study Design

This three-month RCT was designed to explore the feasibility of PERSUADE in community settings. The design was in accordance to the recommendations of the CONSORT statement for randomised trials of non-pharmacologic treatment (7). Based on Chronic Care Model (8) and the HBM (6) we developed a hypothetical framework of the study. This framework is constructed to form a theoretical design approach while addressing the patient activation concept in peer support (9) (Figure 1).

Four parent peer intervention modules are designed based on the information gathered from the published national practice guidelines and reported evidence of MetS in Malaysia. The flowchart detailing PERSUADE development and feasibility study is presented in Figure 2. The delivery of this intervention package through peer support program is expected to improve the clinical outcome of MetS components among participants' following their changes in dietary practices, physical activity levels and lifestyle behaviours. Furthermore, adoption of healthy dietary practices and lifestyle behaviours is expected to be reflected on the anthropometric outcomes and health related quality of life.

### Study Aims

The primary aim of our study is to evaluate the effect of a three-month peer support intervention on the clinical outcome of MetS components as compared to the control group. Furthermore, this study aims to determine the impact of the peer support intervention on dietary practices (nutrient intake, food frequency score), physical activity levels and lifestyle behaviours (smoking, alcohol consumption and sleeping habit) compared to the control group.

### Ethics Approval

The study has received ethics approval from Monash University Human Research Ethics Committee (CF16/56 - 2016000022).

## Study Sample

### Sample Size and Power Calculation

The estimated sample size based on earlier similar study (10) on one the study variables, fasting plasma glucose at 95% confidence and 80% power of an anticipated fall in FPG of 1.5 to 1.8 mmol/L. Using an equation to detect changes in a standard parallel-group trial and a 20% drop out rate, the calculated minimum required sample size is 48 participants for each group thus the totalling 96 for both randomized arm.

### Recruitment Process

A series of health screening camp were organised around Kulai district located in the south of Malaysia. Johor state was specifically selected due to high prevalence of MetS as reported in Malaysia Adults Nutrition Survey (MANS) (11) (12), Metabolic Syndrome Study Malaysia (MSSM) (13) and National Health and Morbidity Survey 2015 (NHMS) (14). The eligibility screening and recruitment of study participants were conducted in four low to middle income neighbourhoods. The research team provide assistance on identifying potential study participants according to the eligibility criteria (Table 1). If an individual is found to eligible to participate, they will be requested to complete the baseline questionnaire after consenting for their participation.

### Randomisation and Treatment Allocation

Eligible adults who have consented to participate are matched for age, sex and ethnicity as baseline. To minimised contamination, participants were randomised to either intervention or control group based on their location.

### *Control Group*

Participants in the control group will receive a one-time personalised nutrition and lifestyle advised based from the Malaysian Dietary Guideline 2010 (15). They will be assured to be followed up twice for the next six month. During this session, participants will be required to set realistic health goals particularly on their anthropometric measures, blood biomarkers, dietary practice and physical activity levels.

### *Intervention Group*

Participants residing in the location selected to be intervene will to form at minimum 4 peer groups. This group will receive a continuous three-months, peer-led nutrition and lifestyle behaviour intervention through a series of peer gathering. Two participants from each peer group will be selected as the peer leader (PL). PL will be trained to deliver the content of PERSUADE modules and will be responsible to run a weekly peer gathering with their respective groups for the following three months.

## Randomisation and Blinding

This study is an open label parallel randomized-controlled trial hence both the research team and participants will not be blinded. However, as the randomisation will be made based on participants location, contamination of participants was minimised.

## Development of Peer Modules

A stepwise formative research was conducted to initiate the development of an evidence-based, community-specific and culturally-sensitive peer support program. This formative step aimed to assess the need of a sustainable lifestyle intervention, to form a behavioural change objective matrix, to develop a community-relevant interventional content and finally to elucidate the most sustainable delivery method for the targeted peer population.

### Evidence-based Module

The formative research initiated by reviewing the objectives and lifestyle recommendations set in the National Strategic Plan for Non-Communicable Diseases 2010-2014 (16), Malaysian Clinical Practice Guidelines (CPG) for Primary and Secondary Prevention of Cardiovascular Disease 2017 (17) and Malaysian Dietary Guideline 2010 (15) which are the three key guidelines informing the peer modules. Furthermore, to address component specific recommendations, the peer modules were added with inputs from several other clinical practice and MNT guidelines namely, Malaysian CPG for Type 2 Diabetes Mellitus 2015 (18), Malaysian CPG for Management of Dyslipidemia 2017 (19), Malaysian CPG for Management of Obesity 2004 (20), Malaysian CPG Management of Hypertension 2013 (21), Malaysian Medical Nutrition Therapy (MNT) for Type 2 Diabetes 2005 (22), Malaysian MNT for Hyperlipidemia 2005 (23), and Malaysian MNT Hypertension 2005 (24). This is to ensure that the module is thoroughly developed in line with the published national guidelines. Additionally, published studies on MetS in Malaysia were systematically reviewed. In this review, the nutrition and lifestyle behaviour risk factors will be explored to which those may explains the notably increase of MetS prevalence in Malaysians. The review is regarded as crucial as the risk factors affecting different population were found to be distinctive (25). Eventually, four behavioural change objective themes were determined and elaborated according to the conceptual model to form a matrix containing respective change objectives as well as self-efficacy skills needed to achieve it (Table 2).

### Community-relevant Approach

PERSUADE behavioural change matrix is used as the backbone of its content development. Each modules is carefully developed using respective HBM constructs. For instance, in first module; *Metabolic Syndrome*, contents were developed to deliver the information on risk and susceptibility of MetS. Furthermore, the module is integrated with the information on the self-efficacy skills of measuring waist circumference as the most important risk of MetS. To make PERSUADE to be a community-relevant intervention, internal and surface makeover of contents were done on each module. These makeover is done using the input obtained from the focus group discussion done among Malaysian adults with MetS. During the internal makeover, contents is revised to reflects the

social, psychological, environmental and cultural influences on individuals' health behaviours. Especially that in Malaysia it spread differently across racial populations (26), a holistic understanding how the target audience perceives the disease, its risk and its susceptibility is crucial as these perceptions may influence specific health behaviours. Following that, during the surface makeover step, the content is ensured to match characteristics of the community; low-to-middle income population. As a whole, the PERSUADE module contents health were created by acknowledging the social and behavioural context of the target population.

### Intervention Poster Design

Since PERSUADE is designed for low to middle class community with limitation in technology reach, literacy and affordability, each peer modules objectives will be addressed out using an infographic poster as a stimulus for a peer discussion. Poster design and health information to be highlighted in the posters are discussed in a research panel comprising of a nutritionist, a public health expert, and a layman. The information is aimed to improve peer knowledge, giving them the ability to acknowledge their own barriers and motivations of adopting healthy nutrition and lifestyle behaviours. To increase peer engagement and enhance understandability, poster will include appropriate visual aids such photographs and illustrations. Relevant self-efficacy skills were also included to making the poster as an interactive stimulus for peer gathering sessions. Other than that, to initiate peer discussion, a list of Frequently Asked Question (FAQ) sheet will be provided together with the posters. This FAQ contains factsheets of frequent queries on MetS as gathered earlier from focus group discussions. Following that, all materials will be prepared in two languages, Bahasa Melayu and English to make it more inclusive.

### Peer Leader Selection

As an elaboration to the study flowchart (Figure 2), the intervention group will form a minimum number of eight peer groups with two PL will be selected from each group on voluntarily basis. PL will be trained for the all four modules and an extra module; health promotion. This module aimed at assessing appointed PL for leadership, health educator role, and understanding of the PERSUADE modules. All PL attended a two-days training session on focussing on leadership and communication skills. On top of that, a practical approach will be used, including physical, nutritional, and psychological aspects of a lifestyle change as included in all four PERSUADE modules. PL will be trained to engage with their peers in conversations about the issues of concern, seeking to promote health-enhancing knowledge and skills. The goal for each peer group is to be able to identify potential barriers and determinants of lifestyle improvement and subsequently take actions to reduce their CVD risk. At the end of PL training, a simple post-questionnaire will be distributed among them to indicate validity and adequateness of their knowledge and skills on all peer modules.

Respective PL will distribute the posters among their peer group every week to initiate discussion of relevant topics based on the weekly objectives. In order to maximise the participation, regular reminder about the next peer gathering sessions and short health message through text were regularly sent by PL. Peers will then have to keep the poster and returned it to the PL at the end of three months as a measure of compliance to the peer support program. Besides, peers are also encouraged to distribute the poster as a health promotion steps among the community.

## Outcome Assessment

All assessments will be conducted at during designated peer gathering sessions by the research team and assisted by trained PL (Table 3).

### Primary Outcome – Metabolic Syndrome Biomarkers

Anthropometric measurements (body mass index, waist circumference and percentage of body fat) and blood pressure are taken during each follow-up sessions based on the WHO Protocol (27). Blood clinical outcomes will be screened using rapid finger-prick testing method; glucometer (B Braun Omnitest®3, Germany) and blood lipid profile meter (Cardiocheck® PA, Germany), as it is an accurate and sensitive method to cater a community setting intervention (28). Besides, a bio-impedance body composition analyser (InBody® H2OB Analyser, Korea) will be used to estimate fat and muscle percentage of the participants.

### Secondary Outcome – Dietary Pattern, Physical Activity Levels and Lifestyle Behaviour

A three days 24-hour dietary recall is used to analyse the nutrient intake. The recall will be done in a week timeframe with three non-consecutive days will be randomly selected (29). Physical Activity levels are measured using the validated short-form International Physical Activity Questionnaire (IPAQ) (30) while a short questionnaire on sleeping pattern, smoking and alcohol intake is used to elucidate lifestyle behaviour.

### Process Evaluation

A questionnaire will be developed and validated to measure the self-efficacy change of all peers at two levels; individual and peer group. Adherence to the intervention is assessed by the number of posters collected by all participants at the end of the peer support period. Other than that, PL is responsible to record all peer attendance throughout the three months period. Eventually, the participants' satisfaction of the intervention will be assessed by self-administered questionnaire at post-intervention.

### Other Measurements

The socio-demographic characteristics of all participants will be recorded in a structured questionnaire at baselines. Participants' quality of life will also be recorded using a validated questionnaire (31, 32).

### Statistical Analysis

Diet and nutrition data will be analysed using Axxya Systems Nutritionist Pro™ Diet Analysis while all statistical analyses are performed with IBM® SPSS® Statistics 23.0. Descriptive methods will be used to demonstrate to describe participant characteristics and the consistency of both groups. Independent t-test or Chi Square will be used to evaluate baseline characteristics of peer intervention

participants compared to control, overall significance of improvement across clinical outcome measures. As this is a RCT involving repeated measures, the ANOVA repeated measures model is applied to observe significant differences between and within the study groups. This includes change in clinical measures of MetS component from baseline, end of trial (3rd month) and follow up (6th month). The magnitude of change in both primary and secondary outcome measures will be estimated and the given 95% confidence intervals with the p value 0.05 was taken as the level of significance.

## Discussion

PERSUADE community peer support program is intended to 'activate' a few individuals to be PL within the intervened community whom are able promote improvements on healthy nutrition and lifestyle behaviour among adults with MetS. This "activation" will eventually contribute to the prevention and management of the lifestyle-related diseases.

### Community-specific and culturally-sensitive design

PERSUADE content development is designed to be evidence-based using information gathered from a systematic review of available guidelines and published literature on prevalence and risk factors of MetS in Malaysia. Interestingly, the HBM framework allows PERSUADE to be designed as a culturally sensitive health promotion program. The framework allows PERSUADE program components to be designed in a manner that incorporated community-specific characteristics, such as beliefs, norms, values, and behaviour patterns, which shapes up the community social and environmental influences as shown in a the previous interventional model (33). Consequently, the characteristics of the community can be carefully matched with the intervention materials hence acknowledging the social and behavioural context of the target population. Additionally, a holistic understanding on how the target community perceives the severity and risk of MetS thus influence their lifestyle and health behaviours is emphasised by a qualitative analysis of focus group discussion that was recuperated as a part of PERSUADE intervention development. As a result, PERSUADE is carefully designed to address the need and acknowledge the readiness of behavioural change by reinstate the community health knowledge gap thus endowed a better module delivery method.

### Peer Empowerment

The concept of peer empowerment was first introduced in 1997 by Olsson et al. (34) and since then a number of intervention on chronic diseases has been developed based on it. The empowerment of PL is reported to be capable of sustaining an evidence-based community-sustained nutrition and lifestyle behaviour intervention program for a large group of individuals residing within a close-knit community (35). The outlook of the peer support program is expected to be a low-in-cost thus sustainable prevention step in combating the rising prevalence of MetS due to its attempt to improve the concomitant lifestyle behaviour rather than focussing on any pharmacological approach (36). However, this empowerment of the peers will only be effective when peers acquired great understanding of the health message of the intervention materials thus can actively promote it within



and across their community as found in previous studies (37-39). Hence, PERSUADE is carefully designed to consider appropriate channel of intervention that is easily executed, intervention materials that used a common and simple language, lifestyle advices that is affordable and executable, and finally selection of program settings that are accessible and are familiar to and preferred by the target community (40).

### Applicability in Low-to-middle Income Population

The RCT of PERSUADE will be conducted in four low-to-middle class neighbourhoods in Johor which means the participants may be of a lower socioeconomic background than average Malaysians. This is not the exact representation of the entire population as the access to health providers, high quality food availability, health-supportive infrastructure and health knowledge levels are different in the urban as compared to the rural (41, 42). Hence, we are aiming for a better response in these areas due to a higher prevalence of MetS, absent of prevention measures and poor management among individuals with lower socioeconomic background (43). The applicability of peer support in these communities were shown to be well facilitated by the influence of lay health person, simplicity of health message, ability to collective set realistic health goals and the most important is that it is low in cost (43-45). Hence, it will be interesting to investigate responses from those with lower socio-economic status to a peer-led community health program. Eventually, PERSUADE can be an initiative peer support model to be implemented at the low socioeconomic community and suburban area for evaluation of its feasibility and cost-effectiveness. If successful, it can be a precursor for policy makers to initiate more rigorous promotion of such community peer-based programs to other parts of the country.

### Process Evaluation

Furthermore, PERSUADE combines the HBM concept in a peer support framework. The use of theoretical construct in this study allows the outcome evaluation to be supplemented by an adjunct process evaluation. The process evaluation will measure the degree of knowledge delivered and received, fidelity of acquired skills and its implementation as well as the participants' acceptability and satisfaction with the program. Similar to all peer-based interventions, this trial's reach is highly dependent on the participants' compliance based on the peer attendance rates and usability of PERSUADE materials. Collectively, these measures will enable us to resolve any enhancers and barriers of a peer-based program if the program were to be harnessed in other settings and context.

As a conclusion, PERSUADE is a three months community peer support nutrition and lifestyle behaviour peer support intervention for Malaysian adults with MetS. Peer support is a cost-effective, straightforward and sustainable measure to combat lifestyle-related diseases. Thus, a feasibility study among Malaysian adults is designed as RCT to elucidate its acceptance and effectiveness. As PERSUADE modules were theoretical, evidence-based and community-specific, the overall improvement in metabolic risk profile is greatly expected prior to nutrition and lifestyle behaviour improvement.

Table and Figures

Figure 1: Conceptual framework of PERSUADE peer support program

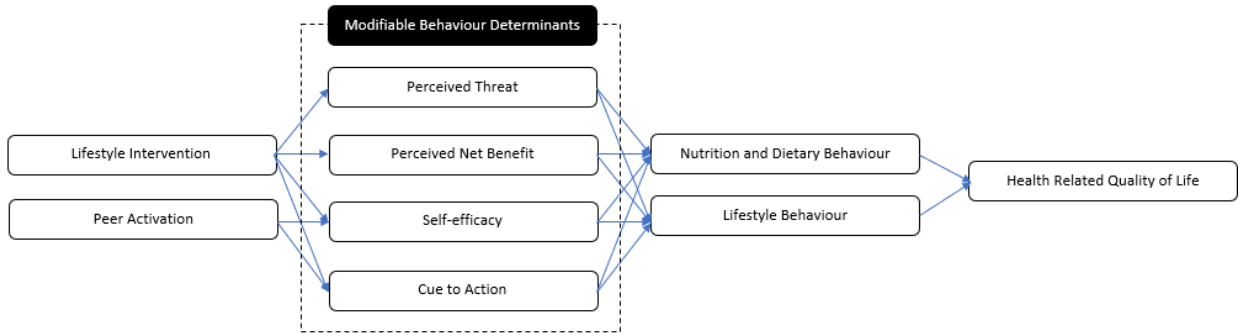


Figure 2: PERSUADE peer support program randomised controlled trial flow chart

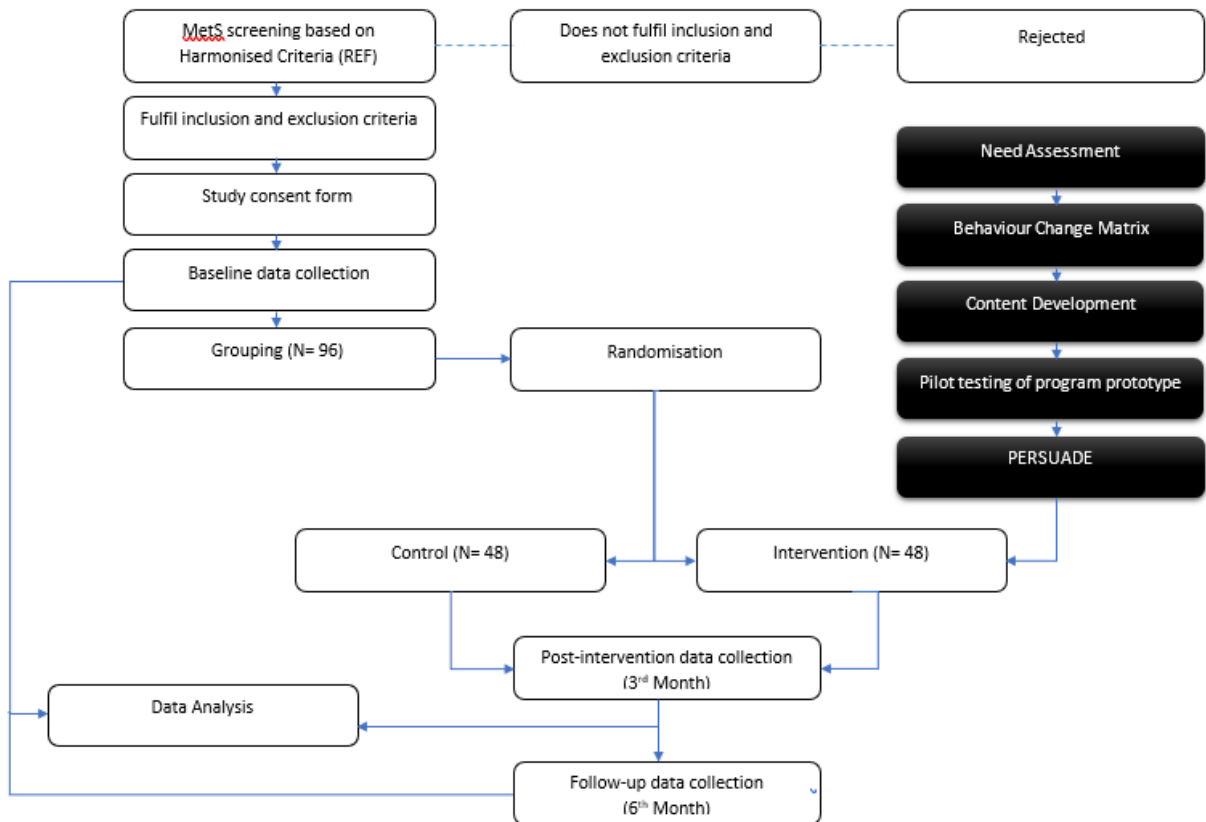


Table 1: PERSUADE inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Physically healthy men and women who are $\geq 18$ years old.	Pregnant, lactating or intend to become pregnant during the study period.
Literate with a fair command of Bahasa Melayu and/or English.	Diagnosed with Type 1 Diabetes Mellitus (T1DM)
Have been confirmed of having MetS according to Harmonised Criteria (46, 47).	Any predisposing condition compromising the quality of life or ability to participate according to protocol.
Willing to attend weekly peer gathering sessions.	Reported severe complications (chronic heart disease, cerebrovascular disease, diagnosed HIV/AIDS, cancer, emphysema, chronic liver or kidney disease) that would affect the participants' ability to follow the participation in peer activity.

Table 2: PERSUADE behavioural change matrix

No	Behavioural Theme	Behavioural Change Objectives	Delivery Approach	Self-efficacy Skills
1	MetS and its components	To understand MetS, its risk factors and disease severity.	An infographic to show the clustering of MetS components and premature death due to cardiovascular diseases	To be able to determine MetS based on the Harmonised criteria.
				To be able to measure waist circumference to detect abdominal obesity
2	Good Dietary Habit	To eat a variety of foods within your recommended intake.	An infographic to introduce Malaysian Food Pyramid and different classes of macronutrients	To be able to prepare meals according to "Pangan Sihat Malaysia" concept
		To prepare foods healthily with adequate amount of salt, sugars and condiments.	An infographic on daily serving sizes of main food class	To be able to estimate food quantity using household measures and palm estimation.
		To drink plenty of water daily.	An infographic on the importance of hydration	To be able to estimate the minimum amount of water required based on body weight
		To make effective use of nutrition information on food labels.	An infographic on Nutrition Information Panel and Food Health Claims	To be able to read and understand NIP hence to limit the intake of processed food
3	Cardiorespiratory Fitness	To be physically active every day.	An infographic on Physical Activity Pyramid	To be able to plan weekly workout schedule
		To understand physical inactivity and sedentary habits.	An infographic on sedentariness	To be able to incorporate movement in daily live (i.e. walking steps, stairs climb)

		To understand sleeping pattern and adequate rest.	An infographic on adequate sleeping pattern	To understand the importance of adequate rest and night sleep as well as naps in between
		To manage stress effectively	An infographic on everyday stress and its complications	To be able to acknowledge the presence of daily stress and seek help if necessary
4	Health Monitoring	To maintain body weight in a healthy range.	An infographic on BMI and Body Fat Percentage	To be able to calculate BMI and measure waist circumference
		To go for a blood screening every six week.	An infographic on good and bad cholesterol.	To have an increased awareness on how frequent to check blood pressure, lipid profile and fasting glucose
		To identify and set a personal health goals	An infographic on healthy life style	To be able to set realistic health goals in term of body weight, waist circumference and weekly diet and physical activity planning

Table 3: PERSUADE outcome assessment

Outcome	Instrument
Socio-demographic information	A brief sociodemographic questionnaire is use to collect basic details (i.e. age, marital status, ethnicity, educational status, occupation, personal and household income, family size and number of years of residence in current location).
Lifestyle characteristics	A brief questionnaire will inquire on participants' smoking habit, alcohol consumption and sleeping pattern. A validated health-related quality of life (HRQOL) questionnaire will be used to determine subject's fulfilment of life.
Physical Activity	International Physical Activity Questionnaire (IPAQ) will be used to determine the level of physical activity of the participants.
Anthropometry	A height scale, body tape and bio-impedance machine will be used to measure participants' height, weight, waist and hip circumferences and body composition.
Nutrition and diet	A semi-food frequency questionnaire (SFFQ) and 3 days 24H food recall will be used to record the participants' nutrients and dietary intake.
Blood biomaker	Finger prick rapid method will be used to detect participants' fasting blood sugar levels and fasting lipid profile.

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