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Promoting physical activity in sedentary elderly Malays with type 2 diabetes: a protocol for randomised controlled trial

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ABSTRACT

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Dr Shariff-Ghazali Sazlina; drsazsg@gmail.com **Introduction:** Like many countries Malaysia is facing an increase in the number of people with type 2 diabetes mellitus diabetes (T2DM) and modifiable lifestyle factors such as sedentary behaviour are important drivers of this increase. The level of physical activity is low among elderly Malay people. In Malaysia, strategies to promote physical activity in elderly Malay people with T2DM are not well documented in the research literature. This paper discusses an intervention to increase physical activity in elderly Malay people with T2DM. The aim of our study was to evaluate the effectiveness of personalised feedback alone and in combination with peer support in promoting and maintaining physical activity in comparison with usual care.

Methods and analysis: A three-arm randomised controlled trial will be conducted among sedentary Malay adults aged 60 years and above with T2DM attending an urban primary healthcare clinic in Malaysia. The participants will be randomised into three groups for a 12-week intervention with a follow-up at 24 and 36 weeks to assess adherence. The primary outcome of this study is pedometer-determined physical activity. Glycaemic and blood pressure control, body composition, cardiorespiratory fitness, balance, lipid profile, health-related quality of life, psychological wellbeing, social support and self-efficacy for exercise are the secondary measures. Linear mixed models will be used to determine the effect of the intervention over time and between groups.

Ethical and dissemination: The Monash University Human Research Ethics Committee and the Malaysian Ministry of Health's Medical Research Ethics Committee approved this protocol. The findings of this study will be presented at international conferences and published in peer-reviewed journals.

Trial registration: This study protocol has been registered with the Malaysian National Medical Research Registry and with the Current Controlled Trial Ltd (http://www.controlled-trials.com/ISRCTN71447000/).

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most prevalent non-communicable diseases (NCDs) in developed as well as

ARTICLE SUMMARY

Article focus

The primary objective of this study was to establish the effectiveness of personalised feedback (PF) alone and in combination with peer support (PS) to promote and maintain physical activity in elderly Malays with type 2 diabetes.

Key messages

 PS is potentially a cost-effective adjunct approach for ongoing diabetes self-management support in a primary care setting.

Strength and limitations of this study

- This study will be the first randomised controlled trial in the region of Southeast Asia to promote physical activity using PF and PS in elderly Asian people.
- The role of ongoing PS to promote adherence to physical activity could be evaluated in this study with the follow-up evaluation postintervention.
- The recruitment is targeted to elderly Malays from a community in Malaysia, which limits the generalisability of this study.

developing countries.¹ It is associated with significant morbidity, mortality and increased healthcare cost.² ³ In 2010, about one-third of people with diabetes were over 60 years of age.⁴ The greatest increase in the prevalence is expected to occur in Asia and Africa due to the joint trends of urbanisation and lifestyle changes.¹

Regular physical activity in the management of T2DM is effective in improving glucose homeostasis and reducing risk of diabetes complications and mortality.^{5–8} Recommendations suggest that the elderly, especially with NCDs, benefit from regular physical activity.^{9–12} However, 52–80% of the elderly were inactive,^{13–15} especially with T2DM.¹⁶ Interventions to promote physical activity in people with T2DM are many but few specifically focussed on elderly as most studies included participants aged ≥40 years and did not examine age effects.^{17–22}

Feedback to promote behavioural change is one of the frequently used interventions. Motion sensor devices (accelerometer or pedometer) and exercise log were used as feedbacks to increase physical activity.^{17–22} They served as motivational tools and allow self-monitoring of the intended behaviour change, hence empowering patients to self-care. These studies reported improvements in daily step counts, metabolic controls,¹⁹ cardiorespiratory fitness²¹ and reductions in anthropometric measurements.²¹

Self-management is an important aspect in the multidimensional management of T2DM. Patients need to address various health behaviours such as physical activity, healthy eating and blood sugar monitoring to manage their condition. In T2DM, healthcare professionals often provide self-management education; however, the effect on health status often is short term.^{23 24} The lack of ongoing educational support and attention to behaviour change principles are often contributing factors to the short-term positive changes in health status. The increasing number of attendees to primary care clinics and shortage of healthcare professionals trained in self-management approaches also contribute to these suboptimal approaches to T2DM management.

Peer support has emerged as a relatively low-cost approach that can be used in conjunction with healthcare professional support to assist in the management of T2DM. Ongoing support through peer mentors empowers patients with T2DM to self-manage their condition.^{25–27} Peer mentors are people '... who successfully coped with the same condition and can be a positive role model' (ref. ²⁸, p i26). Interventions incorporating peer mentors improved glycaemic control,^{19 26} selfefficacy²⁷ and self-care behaviour.^{20 25 27} However, the role of peer support for elderly with T2DM in promoting physical activity is not well documented in the literature especially in South East Asia.

In 2010, Malaysia was ranked among the top 10 countries in the world for diabetes prevalence, with 11.6% of the 17 million people aged 20–79 years with diabetes.¹ The prevalence of diabetes in Malaysia increased from 8.2% in 1996 to 14.9% in 2006.²⁹ The highest prevalence is among people aged 60–64 years at 26.1%. Furthermore, elderly with T2DM have low levels of physical activity than younger patients (41.5% vs 25.3%).³⁰ Those who are less active have poorer glycaemic control.

Malaysia is a multiethnic population comprising the Malay (50.7%), Chinese (23.1%), Indian (6.9%) and other Bumiputera (11%) people (indigenous people) as the major groups within the total population of 28 million. Malay people have the second-highest prevalence of T2DM at 11.9%,²⁹ and had worse glycaemic and cardiometabolic controls.³¹ Moreover, they have the lowest prevalence of recommended adequate exercise than the other ethnic groups.³²

The rapid increased in the incidence of T2DM and a shift towards an ageing population over the last

decade³³ warrants the need for an intervention program to promote physical activity and improve the health status of elderly with T2DM in Malaysia. With the limited healthcare resources, peer support and feedback about physical activity behaviour in the management of T2DM may prove to be a cost-effective approach. Furthermore, targeting elderly Malays is appropriate in view of the low prevalence of adequate exercise and poorer glycaemic control in this group in Malaysia. Hence, the objective of this trial is to evaluate the relative effectiveness of personalised feedback about physical activity patterns alone and in combination with peer support to promote and maintain physical activity compared to usual care.

METHODS AND ANALYSIS Study design

A three-arm randomised controlled trial over 36 weeks will be conducted. Participants will be randomised into the three groups.

- 1. Personalised feedback (PF) about physical activity patterns.
- 2. PF about physical activity patterns combined with peer support (PS).
- 3. Control group (CG), usual care.

All groups will receive usual diabetes care. The usual care involves a multidisciplinary team approach and comprises care by the primary care practitioners, diabetes educator, nutritionist and shared care with the endocrinologist and ophthalmologist when required.³⁴ The management includes education about lifestyle modification, medication and self-care.

Before this trial was designed, a qualitative focus group was conducted to identify socioculturally appropriate barriers and motivations to physical activity in the Malay community. The receptiveness towards the use of pedometer, activity diary and receiving support from peer mentors was also explored. These results were used to design the PF and were incorporated into the training programme for the peer mentors to facilitate the delivery of PF to their peers.

Study setting and participants

Participants will be recruited from an urban public primary healthcare clinic in Malaysia. It is staffed by a family physician with a team of healthcare providers. The clinic provides outpatient care, maternal and child healthcare, and ambulance and emergency services with in-house pharmacy, laboratory and radiological imaging facilities. About 800 to 1000 patients attend the clinic daily, and most have NCDs and a third are ≥ 60 years.³⁵ Elderly Malay adults aged ≥ 60 years diagnosed with T2DM registered with the clinic and on regular follow-up care were invited to participate in this study.

Determination of sample size

A sample size was estimated for this study taking into account the desired statistical significance level set at 5%, and the power of the study set at 80%, which allows an overall type I error rate of less than 0.05 and a falsenegative rate of less than 0.20, respectively. In this study, the primary outcome is a pedometer-determined physical activity. The sample size is calculated based on the difference in daily step counts in an intervention delivered by peer mentors to promote physical activity in adults with T2DM.²⁰ They showed an improvement in the step counts a day from 4099±2152 (preintervention) to 7976±4118 (postintervention). The sample size was calculated using the G*Power V.3.1.3 software.³⁶ Hence, to detect a difference in the step counts a day, a minimum of 17 participants in each group is required to detect 80% power and maintaining a two-sided significance level at 5%.

Recruitment and randomisation process

The recruitment process will be conducted in two phases. The first phase involves strategies to achieve adequate participant enrolment, which will include placing notices on the study at the clinic, through personal communication with the patients by the clinic staff and contacting potential patients via telephone. The second phase involves a screening process conducted by the researcher to determine eligibility and safety to participate based on the inclusion and exclusion criteria. The inclusion and exclusion criteria during the screening process are illustrated in box 1.

Box 1 List of participant's selection criteria

Inclusion criteria

- 1. Aged 60 years and above
- 2. Diagnosed with T2DM at least for 1 year
- 3. Participating in regular follow-up; at least 2 visits in the last 12 months
- 4. Sedentary lifestyle

5. No acute medical illness in the last 6 months

Exclusion criteria

- 1. Fasting blood glucose >13 mmol/l
- 2. Had recent adjustment in the treatment regime needing increased dose of medication in the last 2 months
- 3. Presence of cognitive impairment (ECAQ <7)
- Had uncontrolled hypertension (blood pressure ≥180/ 100 mm Hg)
- 5. Presence of coronary artery syndrome
- 6. Presence of hemiparesis or hemiplegia
- 7. Has advanced osteoarthritis
- 8. Presence of psychiatric disorders (such as depression, anxiety, psychosis)
- 9. Has complications of diabetes (such as proliferative retinopathy, renal impairment)
- 10. Presence of uncontrolled respiratory conditions (such as asthma or chronic obstructive pulmonary disease)
- 11. Known hearing impairment
- 12. Known visual impairment (visual acuity worse than 6/18 after optical correction)
- 13. Lives in residential homes

The screening process involves a health assessment using a structured case report form. The assessments include socio demographic profiles, medical history, sedentary lifestyle status, hearing assessment using a validated Single Global Screening Question,³⁷ cognitive function using a validated Elderly Cognitive Assessment Questionnaire,³⁸ measurements of blood pressure (BP) and visual acuity. The fasting blood glucose, and urine microalbumin or urine albumin, will be collected based on secondary data from the primary care health clinic's patient registry.

Prior to enrolment, detailed description of the study will be provided to eligible participants and written consent will be obtained. *Eligible participants will be sequentially numbered and allocated into three groups using a computer generated blocked randomisation of three to create the randomisation schedule. The principal author will conduct assignment of interventions.*

The intervention

This study incorporated constructs of the Social Cognitive Theory (SCT) to promote change in behaviour from sedentary behaviour to being physically active.^{39 40} Bandura³⁹ defined behaviour as a dynamic process that involves interaction between the person, behaviour and the environment. Behaviour change is more likely when a person believes in one's own capability to change (self-efficacy) and values the outcome (outcome expectation). Behaviour capability is supported by goal setting, capacity building and selfmonitoring. Self-efficacy can be influenced by personal mastery experiences, which is the ability to accomplish a behavioural change through perseverant efforts based on one's personal experiences.⁴⁰ It can be strengthened through social persuasion (being informed by others verbally that one is capable in mastering the new behaviour), vicarious experience (learning from other's experiences-seeing how others have succeeded by perseverant efforts) and physiological and emotional states (relying on one's physiological and emotional responses to the activity to judge one's abilities). According to SCT, a supportive social environment must be established and self-efficacy must be enhanced to ensure behaviour change.

This current study aimed to promote physical activity in sedentary elderly through PF and PS. The study participants need to adopt a new behaviour (regular walking activity) and the confidence to adopt the behaviour can be influenced through the PF and PS. The PF received concerning the participants' personal performance accomplishments would motivate them to continue engaging in regular walking. Moreover, actually performing the regular walking would strengthen their self-efficacy. In the PS groups, self-efficacy can be strengthened via the experiences and accomplishments of their peer mentors in engaging in regular walking. The participants would be able to learn from others' experiences and be motivated to change their behaviour and/or maintain the new behaviour. Furthermore, the fears and uncertainties, which may be accompanied in initiating the regular walking, could be alleviated through the social supports they will receive from their peer mentors and peers. Hence, the regular walking can be enhanced via PF or combined with the support from the peer mentors, which will allow better accomplishment and confidence in the intended activity.

Both the PF and PS groups will undergo a 12-week intervention designed to promote physical activity through walking activity with a follow-up at 24 and 36 weeks. Figure 1 summarises the flow of participants during this study. The principal author (a family physician) will provide the exercise prescription. The participants are encouraged (1) to perform regular brisk walking in graded approach towards the recommended duration, frequency and intensity and (2) to document these activities in a diary. A pedometer-determined physical activity pattern will be estimated and clinical assessments and completion of questionnaires (measuring the primary and secondary outcomes) will be performed at four intervals: at baseline, at 12 weeks (the end of the intervention) and a follow-up at 24 and 36 weeks for all the three groups. Participants will have scheduled dates to return at each interval with a follow-up telephone calls. Transportation honorariums are provided at each visit. If the participants withdraw

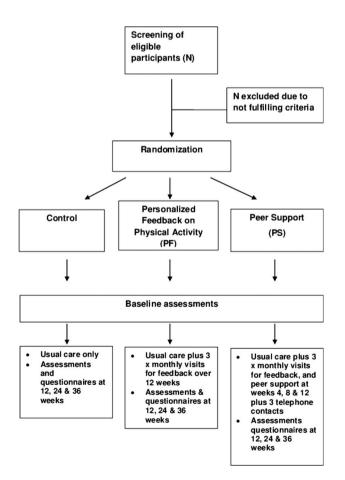


Figure 1 Flow of participants during this study.

from the study, the baseline data or last visit outcomes data will be used for analysis.

PF on physical activity

The research team will provide structured written feedback on each participant's physical activity patterns. The participant's activity patterns will be described based on the calculation of the weekly step counts and minutes spent walking entered in the activity diary. The readings will be plotted on a graph. This feedback will be provided as a printed material at each month for three months. The participant will be provided with a written plan in their activity diary.

Peer support

Participants in this group also will receive a structured written feedback on their physical activity patterns from the research team and support from their peer mentors. A peer mentor will be involved with a group of 3-5 participants from the point of enrolment in the trial. The aim of the peer mentors is to motivate the participants to participate in physical activity and adhere to the activity. The peer mentors will motivate their peers based on the structured written feedback on the physical activity patterns through three face-to-face contacts over the 12 weeks. In addition, peer mentors will provide support on physical activity through three telephone contacts during the intervention period. During these sessions, the peer mentors will discuss the participant's identified perceived barriers and motivations to physical activity and encourage participants to be empowered to selfmanage their diabetes by increasing their physical activity to the recommended level.

Peer mentor

The protocol for the peer mentors includes recruitment, training and supervision. The clinic's doctors will conduct the recruitment of peer mentors by circulating a notice about the study to potential peer mentors. A peer mentor is a volunteer with \geq 5 years of T2DM, engaged in regular physical activity, has glycosylated haemoglobin level (HbA1c) <8% and living in the community of the study location. Other criteria for a peer mentor include owning a mobile telephone, being willing to attend a 2-day training and complying with the study protocol. The peer mentors agree to a 9-month commitment to the study project, adhere to the scheduled meeting and provide support on physical activity and *undergo outcome assessments as their peers*.

A two-day training will be conducted for the peer mentors. The training conducted for the peer mentors is aimed to improve the ability of the peer mentors to provide support to the participants via face-to-face and telephone contacts. The content of the training was adapted from a PS training manual by Cherrington *et al* that included diabetes self-management, physical activity, stress management in diabetes and methods of communication.⁴¹ The training comprised interactive

discussions, simulations and role-plays. The training will be conducted for two days at the clinic. The peer mentors will attend two fortnightly and two-monthly debriefing meetings over the course of 12 weeks. The aim of these meetings is to facilitate and support the peer mentors in performing their task. The research team will conduct ongoing supervision for the peer mentors throughout the study period at the monthly clinic visits with their peers. This will allow the researcher to provide feedback to the peer mentors on their performance and measures to improve them. Incentives will be provided for the peer mentors that include: (1) a certificate for completing peer mentor training and as peer mentors, (2) transportation honorariums at every visit and (3) monthly prepaid mobile telephone top-ups.

Study outcome measures

The primary outcome of this study is level of physical activity. The physical activity will be measured objectively using a pedometer and subjectively using the Physical Activity Scale for the Elderly (PASE) and an activity diary.⁴² ⁴³ A validated Yamax Digi-Walker CW 700/701 pedometer that measures step count will be used during their waking hours over 7 days measured at four intervals: at baseline, at 12 weeks and a follow-up at 24 and 36 weeks for all the three groups.⁴⁴ ⁴⁵ The participants are instructed to record the total daily step counts in an activity diary. The pedometer also has a memory recall for 2 weeks to allow the researchers to recover the step counts in the activity diary.

The PASE is a valid and reliable 12-item scale and consists of questions related to leisure time, household and work-related activities during a period of 7 days. It also provides information on sitting activity. The PASE scores are calculated from the frequency and weight values (an activity coefficient known as PASE weight) for each of the 12 types of activities. The activities include walk outside home, light sport/recreational activities, moderate sport/recreational activities, strenuous sport/recreational activities, muscle strength/endurances exercises, light housework, heavy housework, home repairs, lawn work or yard care, caring for another person and work for pay or as a volunteer. Item scores are added to reveal the total PASE score.

A daily activity diary is provided to the participants to record their step counts from the pedometer, types and durations of physical activity done at baseline, daily for 12 weeks (during the intervention period) and at 24 and 36 weeks of follow-up. The average daily step counts will be estimated based on at least three days' pedometer readings.¹⁹ The activity diary has additional information for participants in the intervention groups, which includes safe exercise practices and the talk test (a validated method of measuring exercise intensity).^{46–48} Furthermore, an exercise program schedule, tables to record walking activity together with the level of

intensity and duration of the activity were added to the intervention groups' diary. A graph to provide feedback on participants' physical activity achievements was also incorporated in the diary.

The secondary outcomes will be measured include metabolic variables (such as HbA1c and lipid profile), BP, cardiorespiratory fitness, balance, body composition, general health status (health-related quality of life and psychological wellbeing), perceived social support and self-efficacy for exercise. The HbA1c and fasting lipid profile is part of usual care,³⁴ performed at the clinic's in-house clinical laboratory. The HbA1c is analysed using the Bio-Rad D-10 high-performance liquid chromatography (Bio-Rad Laboratories, Hercules, California, USA) and the fasting lipid profile is analysed using the Beckman DxC800 general chemistry analyser (Beckman Coulter, Fullerton, California, USA).

BP is measured with an average of two readings taken 5 min apart with the participant rested, seated and arm supported. Smoking or ingestion of caffeine within 30 min of measurement is disallowed. Measurements are taken in both arms and the higher reading is taken as the systemic BP.⁴⁹ Cardiorespiratory fitness (assesses aerobic endurance) is measured using the 6 min walk test, where the participant walks for 6 min and the distance in metres is recorded. The protocol adheres to the requirements of the American Thoracic Society guide-line.⁵⁰ The participant's balance is measured using the Timed Up and Go test.^{51 52}

Measurements of body composition include body mass index (BMI), waist circumference and percentage of body fat. A 6-monthly calibrated TANITA weighing scale and a wall-mounted stadiometer will be used to measure the participants' weight and height, respectively, to calculate the participant's BMI. Waist circumference is measured with the participant standing mid-stance and the measurement taken midway between the inferior margin of the last rib and the iliac crest in a horizontal plane using a measuring tape. Measurement is taken to the nearest 0.1 cm at the end of a normal expiration.⁵³ The body fat percentage is measured using a TANITA Inner Scan body composition monitor BC-581. No strenuous exercise, caffeine or food intake is allowed before the test to ensure adequate hydration.

General health status measures include health-related quality of life (HRQoL) and psychological wellbeing. A validated generic 12-item Short Form Health Survey (SF-12), a self-report non-disease-specific scale evaluating physical and mental health status with a 4-week recall will measure the HRQoL.⁵⁴ The raw health domain scales will be transformed using the SF-12 software. The mean composite scores of the physical component summary and mental component summary will be used for comparison and a higher score is indicative of better quality of life.

A 12-item General Health Questionnaire (GHQ-12), a validated tool to screen psychological disorders in a non-psychiatric clinical setting, will be used.⁵⁵ It has 12

questions about general level of happiness, depression, anxiety and sleep disturbances over the past 4 weeks. Each item is scored by four responses using the binary scoring method (0 to 1). The two least symptomatic answers score 0 and the two most symptomatic answers score 1. Scores of four or more indicate a high level of psychological distress.

The perceived social support of the study participants will be measured using the Multidimensional Scale of Perceived Social Support.⁵⁶ It is a 12-item validated self-report measure of the availability and adequacy of perceived social support. They are divided into three subscales based on the source of social support: family, friends and significant others. Total score in each subscale is divided with four items from the subscale. Higher scores suggest higher perceived social support.

The Self-Efficacy for Exercise Scale is a 9-item scale that focus on "... self-efficacy expectations related to the ability to continue exercise in the face of perceived barriers" (ref. ⁵⁷, p 155), and has been validated in elderly.⁵⁸ The statements on perceived barriers are based on the confidence to exercise three times a week for 20 min. The final score ranges from 1 to 10 and higher scores indicate a higher strength of self-efficacy for exercise. *The research team will assess all the study outcomes.*

Data analysis

Descriptive analysis of the demographic characteristics of the participants, medical history and baseline variables will be reported using means and standard deviations for continuous variables and as frequencies and percentages for categorical data. Cross tabulation for categorical variables and analysis of variance for continuous variables will be conducted to determine the homogeneity of the characteristics of the participants at baseline. Linear mixed models will be used to determine the effect of the intervention within the groups across the study periods (at baseline, 12, 24 and 36 weeks) and the differences between the three groups across the study periods. Data will be analysed using the Statistical Package for Social Sciences (SPSS) V.20.0.

ETHICS AND DISSEMINATION

Participants' safety to participate in unsupervised regular physical activity was ensured through a screening of risk factors for unsafe participation. The participants in the intervention group will be advised on safe exercise practices and proper measures to prevent exercise-related injury during enrolment. Furthermore, brisk walking is promoted in this study, which has a low risk and a safe form of physical activity.

Details of relevant referral procedure in case of any untoward events are included in the participants' information sheet and the research team will monitor for such events during the monthly visits to the clinic. Participants requiring assistance will be referred to their attending doctors for further evaluation. The 6 min walk test and timed up and go assessments in this study will be conducted in the clinic with a medical personnel on standby.

The Monash University Human Research Ethics Committee (CF11/1018–2011000524) and the Malaysian Ministry of Health Medical Research Ethics Committee (NMRR-10–1107–7328) approved this study. This trial is supported by Monash University Sunway Campus Major Grant (M-GPH-MG-68).

DISCUSSION

This study will be the first randomised controlled trial in Malaysia to promote physical activity in elderly with T2DM. In 2010, the cost of treating T2DM was a significant burden for the community and the government of Malaysia where 16% (£370 000) of the total health expenditure was spent on the management of T2DM.¹ This trial will be conducted in a real-world setting in a primary care clinic. This will allow better transferability and generalisability of such an intervention to other primary care settings and for other NCDs. This study will have a follow-up period at 36 weeks after the intervention, which allows the measurement of adherence to the new behaviour. It is important to measure the sustainability of behaviour change after the intervention is completed.

The involvement of PS in the delivery of care for elderly with T2DM in this trial promotes community empowerment in NCDs management. If successful, the trial will provide evidence for the use of peer mentors to provide ongoing support to elderly with T2DM to augment the care provided by healthcare professionals. This approach is potentially a low-cost way of addressing staffing shortages in primary care centres in Malaysia and has the potential to reduce financial strains on the healthcare system. The peer mentors will receive training to prepare them as peer supporters, and will have meetings with the other peer mentors, clinic staff and research team. This will provide an avenue for support and sharing of experiences to facilitate their role as peer mentors. It is hope that this trial will not only help to improve the health of the patients and the delivery of healthcare of the selected clinic, but to become a model to promote healthy lifestyles in primary care setting and the community at large.

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Contributors SGS, CB and SY conceived the project. All authors participated in its design and methodological development. SGS drafted the initial manuscript. All authors commented on the drafts and approved the final manuscript. SY and CB contributed to the procurement of funding. SGS will coordinate the data collection and the involvement of the peer mentors and will lead the statistical analysis of the data.

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presenting or publishing the study findings and the authority over all research related activities are solely of the research team.

Competing interests None.

Ethics approval Monash University Human Research Ethics Committee [CF11/1018 – 2011000524] and the Malaysian Ministry of Health Medical Research Ethics Committee [NMRR-10-1107-7328].

Provenance and peer review Not commissioned; internally peer reviewed

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