



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

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3 **Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol**
4 **for randomised controlled trial**
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Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol for randomised controlled trial

Abstract

Introduction: Like many countries Malaysia is facing an increase in numbers 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 is to evaluate the effectiveness of personalized feedback alone and in combination with peer support in promoting and maintaining physical activity in comparison to 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 health care clinic in Malaysia. The participants will be randomized into 3 groups for a 12-week intervention with a follow-up at 24 weeks 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. This study protocol has been registered with the Malaysian National Medical Research Registry and

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3 with the Current Controlled Trial Ltd (<http://www.controlled-trials.com/ISRCTN71447000/>).

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5 The findings of this study will be presented at international conferences and published in peer-
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8 reviewed journals.
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12 **Trial registration:** Current Controlled Trial Ltd ISRCTN71447000
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14 15 16 17 **Article focus**

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20 • The primary objective of this study is to establish the effectiveness of personalized feedback
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22 alone and in combination with peer support to promote and maintain physical activity in
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24 elderly Malays with type 2 diabetes.
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27 28 29 **Key messages**

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32 • Peer support is potentially a cost-effective adjunct approach for on going diabetes self-
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34 management support in primary care setting.
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37 38 39 **Strength and limitations**

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42 • This study will be the first randomized controlled trial in the region of Southeast Asia to
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44 promote physical activity using personalized feedback and peer support in elderly Asian
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46 people.
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49 • The role of on going peer support to promote adherence to physical activity could be
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51 evaluated in this study with the follow-ups evaluation post intervention.
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54 • The recruitment is targeted to elderly Malays from a community in Malaysia, which limits
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56 the generalizability of this study.
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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most prevalent non-communicable diseases (NCDs) in both developed and developing countries,[1]. It is associated with significant morbidity, mortality and increased healthcare cost,[2,3]. In 2010, about a third of people with diabetes was over 60 years old,[4]. The greatest increase in the prevalence is expected to occur in Asia and Africa due to the joint trends of urbanization 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 elderly, especially with NCDs benefit from regular physical activity,[9–12]. However, 52%-80% of 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 fitness,[21] 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

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3 term,[23,24]. The lack of on-going educational support and attention to behaviour change
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5 principles are often contributing factors to the short-term positive changes in health status. The
6
7 increasing number of attendees to primary care clinics and shortage of healthcare professionals
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9 trained in self-management approaches also contribute to these sub-optimal approaches to T2DM
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11 management.
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15 Peer support has emerged as a relatively low cost approach that can be used in
16
17 conjunction with healthcare professional support to assist in the management of T2DM. On-
18
19 going support through peer mentors empowers patients with T2DM to self-manage their
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21 condition,[25–27]. Peer mentors are people “... who successfully coped with the same condition
22
23 and can be a positive role model” (p. i26),[28]. Interventions incorporating peer mentors
24
25 improved glycaemic control,[19,26] self-efficacy,[27], and self-care behaviour,[20,25,27].
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27 However, the role of peer support for elderly with T2DM in promoting physical activity is not
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29 well documented in the literature especially in South East Asia.
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35 In 2010, Malaysia was ranked in the top ten countries in the world for diabetes
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37 prevalence, with 11.6% of the 17 million people aged 20 to 79 years with diabetes,[1]. The
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39 prevalence of diabetes in Malaysia increased from 8.2% in 1996 to 14.9% in 2006,[29]. The
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41 highest prevalence is among people aged 60-64 years at 26.1%. Furthermore, elderly with T2DM
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43 have low levels of physical activity than younger patients (41.5% vs. 25.3%),[31]. Those who
44
45 were less active have poorer glycaemic control.
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49 Malaysia is a multi-ethnic population comprising the Malay (50.7%), Chinese (23.1%),
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51 Indian (6.9%) and other Bumiputera (11.0%) people (indigenous people) as the major groups
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53 within the total population of 28 million. Malay people have the second highest prevalence of
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55 T2DM at 11.9%,[29] and had worse glycaemic and cardio-metabolic controls,[30]. Moreover,
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3 they have the lowest prevalence of recommended adequate exercise than the other ethnic
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5 groups,[32].
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8 The rapid increased in the incidence of T2DM and a shift towards an ageing population
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10 over the last decade,[33] warrants the need for an intervention program to promote physical
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12 activity and improve the health status of elderly with T2DM in Malaysia. With the limited
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14 healthcare resources, peer support and feedback about physical activity behaviour in the
15
16 management of T2DM may prove to be a cost effective approach. Furthermore, targeting elderly
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18 Malays is appropriate in view of the low prevalence of adequate exercise and poorer glycaemic
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20 control in this group in Malaysia. Hence, the objective of this trial is to evaluate the relative
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22 effectiveness of personalized feedback about physical activity patterns alone and in combination
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24 with peer support to promote and maintain physical activity compared to usual care.
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31 **METHODS AND ANALYSIS**

32 **Study design**

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34 A three-arm randomised controlled trial over 36 weeks will be conducted. Participants will be
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36 randomised into the three groups:
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- 40 1. Personalized feedback about physical activity patterns (PF).
 - 41 2. Personalized feedback about physical activity patterns combined with peer support (PS).
 - 42 3. Control group, usual care (CG).
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48 All groups will receive usual diabetes care. The usual care involves a multidisciplinary team
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50 approach and comprises care by the primary care practitioners, diabetes educator, nutritionist,
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52 and shared care with the endocrinologist and ophthalmologist when required,[34]. The
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54 management includes education about lifestyle modification, medication and self-care.
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3 Before this trial was designed a qualitative focus group was conducted to identify socio-
4 culturally appropriate barriers and motivations to physical activity in the Malay community. In
5 addition, the receptiveness towards the use of pedometer, activity diary and receiving support
6 from peer mentors was explored. These results were used to design the personalized feedback
7 and were incorporated into the training programme for the peer mentors to facilitate the delivery
8 of personalized feedback to their peers.
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20 **Study setting and participants**

21 Participants will be recruited from an urban public primary health care clinic in Malaysia. It is
22 staffed by a family physician with a team of healthcare providers. The clinic provides outpatient
23 care, maternal and child health care and has an ambulance and emergency services with in-house
24 pharmacy, laboratory and radiological imaging facilities. About 800 to 1,000 patients attend the
25 clinic everyday, most have non-communicable diseases and a third are ≥ 60 years,[35]. Elderly
26 Malay adults aged ≥ 60 years diagnosed with T2DM, registered with the clinic and on regular
27 follow-up care were invited to participate in this study.
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41 **Determination of sample size**

42 A sample size was estimated for this study taking into account the desired statistical significance
43 level set at 5%, and the power of the study set at 80%, which allows an overall type I error rate
44 of less than 0.05 and a false-negative rate of less than 0.20, respectively. In this study, the
45 primary outcome is a pedometer determined physical activity. The sample size is calculated
46 based on the difference in daily step counts in an intervention delivered by peer mentors to
47 promote physical activity in adults with T2DM,[20]. They showed an improvement in the step
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counts a day from $4,099 \pm 2,152$ (pre-intervention) to $7,976 \pm 4,118$ (post-intervention). The sample size was calculated using the G*Power version 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 placing a notice on the study at the clinic. 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 Table 1.

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 problem status using a validated Single Global Screening Question,[37] cognitive function using a validated Elderly Cognitive Assessment Questionnaire,[38] and measurements of blood pressure, and visual acuity. The fasting blood glucose (FBG), and urine micro albumin 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 allocated into three groups using a computed random numbers generator based on blocked randomisation. Each block comprises a 1:1:1 allocation to allow equal distribution of participants into the three groups.

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]. Bandura defined behaviour as a dynamic process that involves interaction between the person, behaviour and the environment,[39]. Behaviour change is more likely when a person believes in his or her own capability to change (self-efficacy) and values the outcome (outcome expectation). Behaviour capability is supported by goal setting, capacity building and self-monitoring. 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]. Furthermore, 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 enhanced to ensure behaviour change.

This current study aimed to promote physical activity in sedentary elderly through personalized feedback and peer support. The study participants need to adopt a new behaviour (regular walking activity) and the confidence to adopt the behaviour can be influenced through the personalized feedback and peer support. The personalized feedback received concerning the participants' personal performance accomplishments would motivate them to continue engaging in regular walking. Moreover, actually performing the walking activity would strengthen their self-efficacy. In the peer support groups, self-efficacy can be strengthened via the experiences

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3 and accomplishments of their peer mentors in engaging in regular walking. The participants
4 would be able to learn from others' experiences and be motivated to change their behaviour
5 and/or maintain the new behaviour. Furthermore, the fears and uncertainties, which may be
6 accompanied in initiating the regular walking activity, could be alleviated through the social
7 supports they will receive from their peer mentors and peers. Hence, the regular walking can be
8 enhanced via personalized feedback or combined with the support from the peer mentors, which
9 will allow better accomplishment and confidence in the intended activity.
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20 Both the PF and PS groups will undergo a 12-week intervention designed to promote
21 physical activity through walking activity with a follow-up at 24-weeks and 36-weeks. Figure 1
22 summarises the flow of participants during this study. The participants are encouraged (1) to
23 perform regular brisk walking in graded approach towards the recommended duration, frequency
24 and intensity and (2) to document these activities in a diary. A pedometer determined physical
25 activity pattern will be estimated and clinical assessments and completion of questionnaires
26 (measuring the primary and secondary outcomes) will be performed at four intervals: at baseline,
27 at 12-weeks (the end of the intervention) and a follow up at 24-week and 36-week for all the
28 three groups.
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44 Personalized Feedback on Physical Activity (PF)

45 The research team will provide structured written feedback on each participant's physical
46 activity patterns. The participant's activity patterns will be described based on the calculation of
47 minutes spent walking in a week from the daily step counts entered in the activity diary. The
48 readings will be plotted on a graph. This feedback will be provided as a printed material at each
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3 month for three months. The participant will be provided with a written plan in their activity
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5 diary.
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10 Peer Support (PS)

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12 Participants in this group also will receive a structured written feedback on their physical activity
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14 patterns from the research team and support from their peer mentors. A peer mentor will be
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16 involved with a group of 3 to 5 participants from the point of enrolment in the trial. The aim of
17
18 the peer mentors is to motivate the participants to participate in physical activity and adhere to
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20 the activity. The peer mentors will motivate their peers based on the structured written feedback
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22 on the physical activity patterns through three face-to-face contacts over the 12- weeks. In
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24 addition, peer mentors will provide support on physical activity through three telephone contacts
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26 during the intervention period. During these sessions, the peer mentors will discuss the
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28 participant's identified perceived barriers and motivations to physical activity and encourage
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30 participants to be empowered to self-manage their diabetes by increasing their physical activity
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32 to the recommended level.
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41 *Peer Mentor*

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43 The protocol for the peer mentors includes recruitment, training, and supervision. The clinic's
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45 doctors will conduct the recruitment of peer mentors by circulating a notice about the study to
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47 potential peer mentors. A peer mentor is a volunteer with ≥ 5 years of T2DM, engaged in regular
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49 physical activity, has HbA1c $< 8\%$ and living in the community of the study location. Other
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51 inclusion criteria for a peer mentor include owning a mobile telephone, being willing to attend a
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53 two-day training and complying with the study protocol. The peer mentors agree to a 9-month
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3 commitment to the study project, adhere to the scheduled meeting and provide support on
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5 promoting and maintaining physical activity.
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8 A two-day training will be conducted for the peer mentors. The training conducted for the
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10 peer mentors is aimed to improve the ability of the peer mentors to provide support to the
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12 participants via face-to-face and telephone contacts. The content of the training was adapted
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14 from a peer support training manual by Safford et al (2011) that included diabetes self-
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16 management, physical activity, stress management in diabetes, and methods of
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18 communication,[41,42]. The training comprised interactive discussions, simulations and role-
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20 plays. The training will be conducted for two days at the clinic. Incentives will be provided for
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22 the peer mentors that include: 1) a certificate for completing peer mentor training, 2) cost of
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24 transportation, and 3) prepaid telephone top-ups. The peer mentors will attend two fortnightly
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26 and two-monthly de-briefing meetings over the course of 12 weeks. The aim of these meetings is
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28 to facilitate and support the peer mentors in performing their task. The research team will
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30 conduct on going supervision for the peer mentors throughout the study period at the monthly
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32 clinic visits with their peers. This will allow the researcher to provide feedback to the peer
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34 mentors on their performance and measures to improve them.
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43 **Study outcome measures**

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45 The primary outcome of this study is level of physical activity. The physical activity will be
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47 measured objectively using a pedometer and subjectively using the Physical Activity Scale for
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49 the Elderly (PASE) and an activity diary,[43,44]. A validated Yamax Digi-Walker® CW
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51 700/701 pedometer that measures step count will be used during their waking hours over 7 days
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53 measured at four intervals: at baseline, at 12-weeks and a follow up at 24-week and 36-week for
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3 all the three groups,[45,46]. The participants are instructed to record the total daily step counts in
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5 an activity diary. The pedometer also has a memory recall for 2 weeks to allow the researchers to
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7 recover the step counts in cases where the participants do not record their step counts in the
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9 activity diary.
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12 The Physical Activity Scale for the Elderly is a valid and reliable 12-item scale and
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14 consists of questions related to leisure time, household and work related activities during a
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16 period of 7 days. It also provides information on sitting activity. The PASE scores are calculated
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18 from the frequency and weight values (an activity coefficient known as PASE weight) for each
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20 of the 12 types of activities. The activities include walk outside home, light sport/recreational
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22 activities, moderate sport/recreational activities, strenuous sport/recreational activities, muscle
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24 strength/endurances exercises, light housework, heavy housework, home repairs, lawn work or
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26 yard care, caring for another person and work for pay or as a volunteer. Item scores are added to
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28 reveal the total PASE score for each study participants.
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34 A daily activity diary is provided to the participants to record the step counts from the
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36 pedometer, types and durations of physical activity done at baseline, daily for 12 weeks (during
37
38 the intervention period), and at 24-weeks and 36-weeks of follow-up. The average daily step
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40 counts will be estimated based on at least three days' pedometer readings,[19]. The activity diary
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42 has additional information for participants in the intervention groups, which includes safe
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44 physical exercise practices and the talk test (a validated method of measuring exercise
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46 intensity),[47–49]. In addition, an exercise program schedule, tables to record walking activity
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48 together with the level of intensity and duration of the activity were added to the intervention
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50 groups' diary. A graph to provide feedback on participants' physical activity achievements was
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52 also incorporated in the diary.
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The secondary outcomes will be measured include metabolic variables (such as glycosylated haemoglobin level (HbA1c) and lipid profile), blood pressure, 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, CA, USA) and the fasting lipid profile is analysed using the Beckman DxC800 general chemistry analyser (Beckman Coulter, Fullerton, CA, USA).

Blood pressure (BP) is measured with an average of two readings taken with the participant rested, seated and arm supported. Smoking or ingestion of caffeine within 30 minutes of measurement is disallowed. Measurements are taken in both arms and the higher reading is taken as the systemic BP,[50]. Cardiorespiratory fitness (assesses aerobic endurance) is measured using the 6 min walk test, where the participant walks for 6 minutes and the distance in metres is recorded. The protocol adheres to the requirements of the American Thoracic Society guideline,[51]. The participant's balance is measured using the Timed Up and Go test,[52,53].

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,[55]. The body fat percentage is measured using a

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3 TANITA[®] Inner Scan body composition monitor BC-581. No strenuous exercise, caffeine or
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5 food intake is allowed before the test to ensure adequate hydration.
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8 General health status measures include health related quality of life (HRQoL) and
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10 psychological wellbeing. The HRQoL will be measured using a validated generic 12-item Short
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12 Form Health Survey (SF-12), a self report non-disease specific scale evaluating physical and
13
14 mental health status with a 4-week recall,[56]. The raw health domain scales will be transformed
15
16 using the SF-12 software. The mean composite scores of the physical component summary and
17
18 mental component summary will be used for comparison in this study and a higher score is
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20 indicative of better quality of life.
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24 A 12-item General Health Questionnaire (GHQ-12), a validated tool to screen
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26 psychological disorders in a non-psychiatric clinical setting will be used,[57]. It has 12 questions
27
28 about general level of happiness, depression, anxiety, and sleep disturbances over the past 4
29
30 weeks. Each item is scored by four responses using binary scoring method (0 to 1). The two least
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32 symptomatic answers score 0 and the two most symptomatic answers score 1. Scores of four or
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34 more indicate a high level of psychological distress.
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38 The perceived social support of the study participants will be measured using the
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40 Multidimensional Scale of Perceived Social Support,[58]. It is a 12-item validated self-report
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42 measure of the availability and adequacy of perceived social support. They are divided into 3
43
44 subscales based on the source of social support: family, friends and significant others. Total
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46 score in each subscale is divided with 4 items from the subscale. Higher scores suggest higher
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48 perceived social support.
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52 The Self-Efficacy for Exercise Scale is a 9- item scale that focus on "... self-efficacy
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54 expectations related to the ability to continue exercise in the face of perceived
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3 barriers”(p.155),[59] and has been validated in elderly,[60]. The statements on perceived barriers
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5 are based on the confidence to exercise 3 times a week for 20 minutes. The final score ranges
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7 from 1 to 10 and higher scores indicate a higher strength of self-efficacy for exercise.
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10 11 12 **Data analysis**

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14 Descriptive analysis of the demographic characteristics of the participants, medical history and
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16 baseline variables will be reported using means and standard deviations for continuous variables
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18 and as frequencies and percentages for categorical data. Cross tabulation for categorical variables
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20 and ANOVA for continuous variables will be conducted to determine the homogeneity of the
21
22 characteristics of the participants at baseline. Linear mixed models will be used to determine the
23
24 effect of the intervention within the groups across the study periods (at baseline, 12 weeks, 24
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26 weeks, and 36 weeks) and the differences between the three groups across the study periods.
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28 Data will be analysed using the Statistical Package for Social Sciences (SPSS) version 20.0.
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36 37 **ETHICS AND DISSEMINATION**

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39 Participants' safety to participate in unsupervised regular physical activity was ensured through
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41 screening of risk factors for unsafe participation. In addition, participants in the intervention
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43 group will be advised on safe exercise practices and proper measures to prevent exercise related
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45 injury during enrolment. Furthermore, brisk walking is promoted in this study, which has a low
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47 risk and a safe form of physical activity.
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51 Details of relevant referral procedure in case of any untoward events are included in the
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53 participants' information sheet and the research team will monitor for such events during the
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55 monthly visits to the clinic. Participant requiring assistance will be referred to their attending
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3 doctors for further evaluation. The six minutes walk test and timed up and go assessments
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5 required during this study will be conducted in the clinic with a medical personnel on standby.
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8 The Monash University Human Research Ethics Committee (CF11/1018 – 2011000524)
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10 and the Malaysian Ministry of Health Medical Research Ethics Committee (NMRR-10-1107-
11
12 7328) approved this study. This trial is supported by Monash University Sunway Campus Major
13
14 Grant (M-GPH-MG-68). The development of study protocol, data collection and analysis of data
15
16 is not influenced by funding sources and the decision on presenting or publishing the study
17
18 findings is solely the decision of the research team.
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24 **DISCUSSION**

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26 This study will be the first randomised controlled trial in Malaysia to promote physical activity
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28 in elderly with T2DM. In 2010, the cost of treating T2DM was a significant burden for the
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30 community and the government of Malaysia where 16% (£ 370, 000) of the total health
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32 expenditure was spent on the management of T2DM,[1]. This trial will be conducted in a real
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34 world setting in a primary care clinic. This will allow better transferability and generalizability of
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36 such an intervention to other primary care settings and for other NCDs. This study will have a
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38 follow up period at 36 weeks after the intervention, which allows the measurement of adherence
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40 to the new behaviour. It is important to measure the sustainability of behaviour change after the
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42 intervention is completed.
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48 The involvement of peer support in the delivery of care for elderly with T2DM in this
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50 trial promotes community empowerment in chronic disease management. If successful, the trial
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52 will provide evidence for the use of peer mentors to provide on-going support to elderly with
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54 T2DM to augment the care provided by healthcare professionals. This approach is potentially a
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3 low cost way of addressing staffing shortages in primary care centres in Malaysia and has the
4 potential to reduce financial strains on the health care system. The peer mentors will receive
5 training to prepare them as peer supporters, and will have meetings with the other peer mentors,
6 clinic staff and research team. This will provide an avenue for support and sharing of experiences
7 to facilitate their role as peer mentors. It is hope that this trial will not only help to improve the
8 health of the patients and the delivery of healthcare of the selected clinic, but to become a model
9 to promote healthy lifestyles in primary care setting and the community at large.
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22 **Authors' contributors** SGS, CB and SY conceived the project. All authors participated in its
23 design and methodological development. SGS drafted the initial manuscript. All authors
24 commented on the drafts and approved the final manuscript. SY and CB contributed to the
25 procurement of funding. SGS will coordinate the data collection and the involvement of the peer
26 mentors; and will lead the statistical analysis of the data.
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38 University Sunway Campus Major Grant [M-GPH-MG-68]. This trial protocol is registered with
39 the Current Controlled Trial Ltd, registration number ISRCTN71447000.
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48 **Competing interests** None
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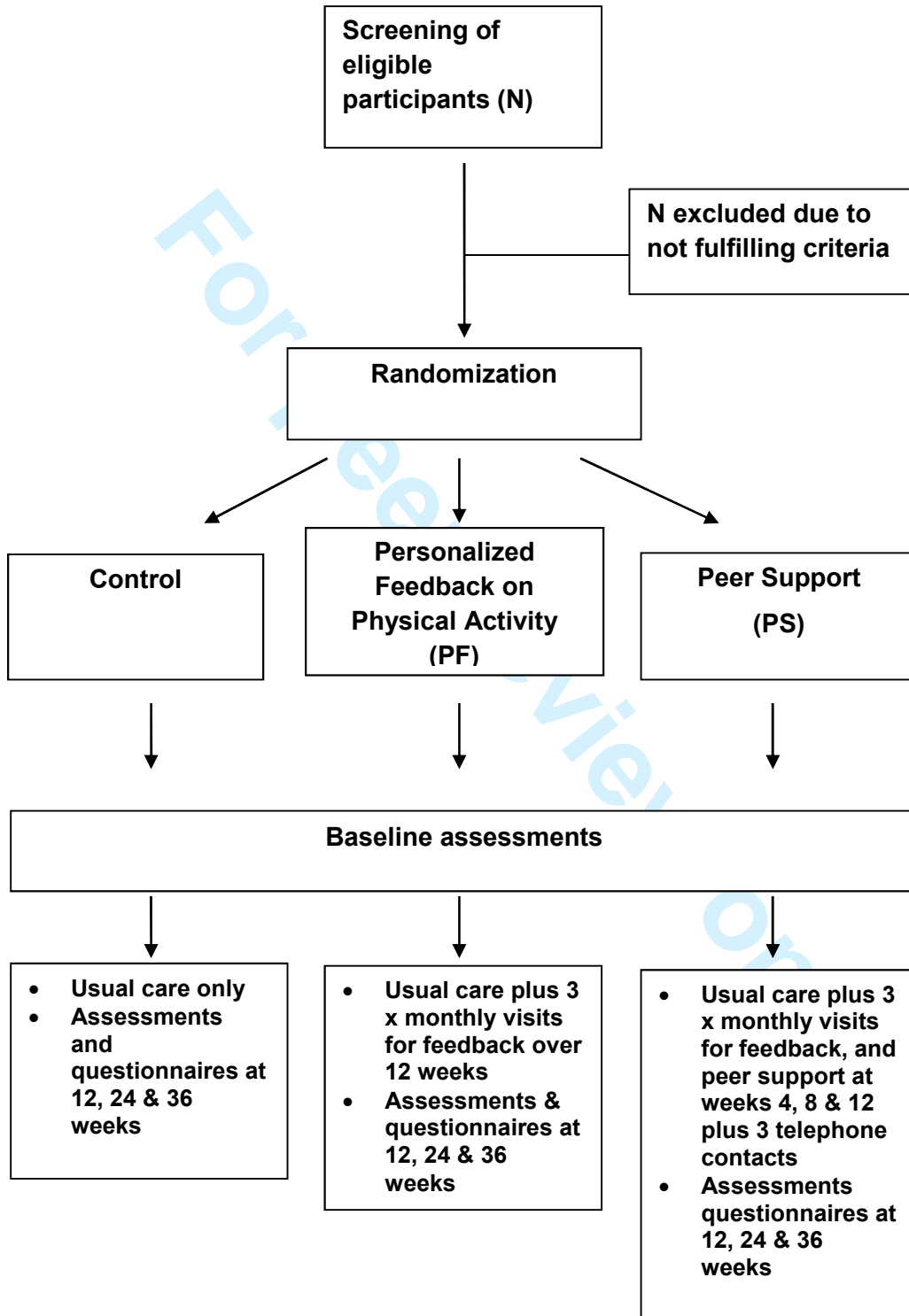
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Figure 1 - Flow of participants during this study



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Table 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 increase dose of medication in the last two months
 3. Presence of cognitive impairment (ECAQ < 7)
 4. Had uncontrolled hypertension (blood pressure \geq 180/100 mmHg)
 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
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Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol for randomised controlled trial

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002119.R1
Article Type:	Protocol
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Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Diabetes and endocrinology, General practice / Family practice, Geriatric medicine
Keywords:	DIABETES & ENDOCRINOLOGY, GERIATRIC MEDICINE, PRIMARY CARE

SCHOLARONE™
Manuscripts

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3 **Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol**
4 **for randomised controlled trial**
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46 **Keywords:** type 2 diabetes mellitus, physical activity, personalized feedback, peer support,
47 elderly Malays
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53 **Word count: 4,000**
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Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol for randomised controlled trial

Abstract

Introduction: Like many countries Malaysia is facing an increase in numbers 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 is to evaluate the effectiveness of personalized feedback alone and in combination with peer support in promoting and maintaining physical activity in comparison to 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 health care clinic in Malaysia. The participants will be randomized into 3 groups for a 12-week intervention with a follow-up at 24 weeks 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

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3 findings of this study will be presented at international conferences and published in peer-
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5 reviewed journals.
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8 **Trial registration:** This study protocol has been registered with the Malaysian National Medical
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10 Research Registry and with the Current Controlled Trial Ltd ([http://www.controlled-
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14 trials.com/ISRCTN71447000/](http://www.controlled-
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12 trials.com/ISRCTN71447000/)).

15 16 17 18 **Article focus**

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20 • The primary objective of this study is to establish the effectiveness of personalized feedback
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22 alone and in combination with peer support to promote and maintain physical activity in
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24 elderly Malays with type 2 diabetes.
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27 28 29 **Key messages**

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31 • Peer support is potentially a cost-effective adjunct approach for on going diabetes self-
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33 management support in primary care setting.
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37 38 39 **Strength and limitations**

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41 • This study will be the first randomized controlled trial in the region of Southeast Asia to
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43 promote physical activity using personalized feedback and peer support in elderly Asian
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45 people.
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49 • The role of on going peer support to promote adherence to physical activity could be
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51 evaluated in this study with the follow-ups evaluation post intervention.
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54 • The recruitment is targeted to elderly Malays from a community in Malaysia, which limits
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56 the generalizability of this study.
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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most prevalent non-communicable diseases (NCDs) in both developed and developing countries,[1]. It is associated with significant morbidity, mortality and increased healthcare cost,[2,3]. In 2010, about a third of people with diabetes was over 60 years old,[4]. The greatest increase in the prevalence is expected to occur in Asia and Africa due to the joint trends of urbanization 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 elderly, especially with NCDs benefit from regular physical activity,[9–12]. However, 52%-80% of 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 fitness,[21] 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

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3 term,[23,24]. The lack of on-going educational support and attention to behaviour change
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5 principles are often contributing factors to the short-term positive changes in health status. The
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7 increasing number of attendees to primary care clinics and shortage of healthcare professionals
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9 trained in self-management approaches also contribute to these sub-optimal approaches to T2DM
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11 management.
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14 Peer support has emerged as a relatively low cost approach that can be used in
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16 conjunction with healthcare professional support to assist in the management of T2DM. On-
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18 going support through peer mentors empowers patients with T2DM to self-manage their
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20 condition,[25–27]. Peer mentors are people “... who successfully coped with the same condition
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22 and can be a positive role model” (p. i26),[28]. Interventions incorporating peer mentors
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24 improved glycaemic control,[19,26] self-efficacy,[27], and self-care behaviour,[20,25,27].
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26 However, the role of peer support for elderly with T2DM in promoting physical activity is not
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28 well documented in the literature especially in South East Asia.
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34 In 2010, Malaysia was ranked in the top ten countries in the world for diabetes
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36 prevalence, with 11.6% of the 17 million people aged 20 to 79 years with diabetes,[1]. The
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38 prevalence of diabetes in Malaysia increased from 8.2% in 1996 to 14.9% in 2006,[29]. The
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40 highest prevalence is among people aged 60-64 years at 26.1%. Furthermore, elderly with T2DM
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42 have low levels of physical activity than younger patients (41.5% vs. 25.3%),[31]. Those who
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44 were less active have poorer glycaemic control.
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48 Malaysia is a multi-ethnic population comprising the Malay (50.7%), Chinese (23.1%),
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50 Indian (6.9%) and other Bumiputera (11.0%) people (indigenous people) as the major groups
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52 within the total population of 28 million. Malay people have the second highest prevalence of
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54 T2DM at 11.9%,[29] and had worse glycaemic and cardio-metabolic controls,[30]. Moreover,
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3 they have the lowest prevalence of recommended adequate exercise than the other ethnic
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6 groups,[32].
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8 The rapid increased in the incidence of T2DM and a shift towards an ageing population
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10 over the last decade,[33] warrants the need for an intervention program to promote physical
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12 activity and improve the health status of elderly with T2DM in Malaysia. With the limited
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14 healthcare resources, peer support and feedback about physical activity behaviour in the
15
16 management of T2DM may prove to be a cost effective approach. Furthermore, targeting elderly
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18 Malays is appropriate in view of the low prevalence of adequate exercise and poorer glycaemic
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20 control in this group in Malaysia. Hence, the objective of this trial is to evaluate the relative
21
22 effectiveness of personalized feedback about physical activity patterns alone and in combination
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24 with peer support to promote and maintain physical activity compared to usual care.
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32 **METHODS AND ANALYSIS**

33 **Study design**

34
35 A three-arm randomised controlled trial over 36 weeks will be conducted. Participants will be
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37 randomised into the three groups:
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- 40 1. Personalized feedback about physical activity patterns (PF).
 - 41 2. Personalized feedback about physical activity patterns combined with peer support (PS).
 - 42 3. Control group, usual care (CG).
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48 All groups will receive usual diabetes care. The usual care involves a multidisciplinary team
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50 approach and comprises care by the primary care practitioners, diabetes educator, nutritionist,
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52 and shared care with the endocrinologist and ophthalmologist when required,[34]. The
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54 management includes education about lifestyle modification, medication and self-care.
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4 Before this trial was designed, a qualitative focus group was conducted to identify socio-
5
6 culturally appropriate barriers and motivations to physical activity in the Malay community. The
7
8 receptiveness towards the use of pedometer, activity diary and receiving support from peer
9
10 mentors was also explored. These results were used to design the personalized feedback and
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12 were incorporated into the training programme for the peer mentors to facilitate the delivery of
13
14 personalized feedback to their peers.
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17 18 19 20 **Study setting and participants**

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22 Participants will be recruited from an urban public primary healthcare clinic in Malaysia. It is
23
24 staffed by a family physician with a team of healthcare providers. The clinic provides outpatient
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26 care, maternal and child healthcare, and ambulance and emergency services with in-house
27
28 pharmacy, laboratory and radiological imaging facilities. About 800 to 1,000 patients attend the
29
30 clinic everyday, most have NCDs and a third are ≥ 60 years,[35]. Elderly Malay adults aged ≥ 60
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32 years diagnosed with T2DM, registered with the clinic and on regular follow up care were
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34 invited to participate in this study.
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41 42 **Determination of sample size**

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44 A sample size was estimated for this study taking into account the desired statistical significance
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46 level set at 5%, and the power of the study set at 80%, which allows an overall type I error rate
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48 of less than 0.05 and a false-negative rate of less than 0.20, respectively. In this study, the
49
50 primary outcome is a pedometer determined physical activity. The sample size is calculated
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52 based on the difference in daily step counts in an intervention delivered by peer mentors to
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54 promote physical activity in adults with T2DM,[20]. They showed an improvement in the step
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counts a day from $4,099 \pm 2,152$ (pre-intervention) to $7,976 \pm 4,118$ (post-intervention). The sample size was calculated using the G*Power version 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 Table 1.

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] and measurements of blood pressure, and visual acuity. The fasting blood glucose (FBG), and urine micro albumin 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

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3 three to create the randomisation schedule. The principal author will conduct assignment of
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5 interventions.
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10 **The intervention**

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12 This study incorporated constructs of the Social Cognitive Theory (SCT) to promote change in
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14 behaviour from sedentary behaviour to being physically active,[39,40]. Bandura defined
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16 behaviour as a dynamic process that involves interaction between the person, behaviour and the
17
18 environment,[39]. Behaviour change is more likely when a person believes in one's own
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20 capability to change (self-efficacy) and values the outcome (outcome expectation). Behaviour
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22 capability is supported by goal setting, capacity building and self-monitoring. Self-efficacy can
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24 be influenced by personal mastery experiences, which is the ability to accomplish a behavioural
25
26 change through perseverant efforts based on one's personal experiences,[40]. It can be
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28 strengthened through social persuasion (being informed by others verbally that one is capable in
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30 mastering the new behaviour), vicarious experience (learning from other's experiences – seeing
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32 how others have succeeded by perseverant efforts), and physiological and emotional states
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34 (relying on one's physiological and emotional responses to the activity to judge one's abilities).
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36 According to SCT, a supportive social environment must be established and self-efficacy
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38 enhanced to ensure behaviour change.
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46 This current study aimed to promote physical activity in sedentary elderly through
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48 personalized feedback and peer support. The study participants need to adopt a new behaviour
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50 (regular walking activity) and the confidence to adopt the behaviour can be influenced through
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52 the personalized feedback and peer support. The personalized feedback received concerning the
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54 participants' personal performance accomplishments would motivate them to continue engaging
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3 in regular walking. Moreover, actually performing the regular walking would strengthen their
4 self-efficacy. In the peer support groups, self-efficacy can be strengthened via the experiences
5 and accomplishments of their peer mentors in engaging in regular walking. The participants
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10 would be able to learn from others' experiences and be motivated to change their behaviour
11 and/or maintain the new behaviour. Furthermore, the fears and uncertainties, which may be
12 accompanied in initiating the regular walking, could be alleviated through the social supports
13 they will receive from their peer mentors and peers. Hence, the regular walking can be enhanced
14 via personalized feedback or combined with the support from the peer mentors, which will allow
15 better accomplishment and confidence in the intended activity.
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25 Both the PF and PS groups will undergo a 12-week intervention designed to promote
26 physical activity through walking activity with a follow-up at 24-weeks and 36-weeks. Figure 1
27 summarises the flow of participants during this study. The principal author (a family physician)
28 will provide the exercise prescription. The participants are encouraged (1) to perform regular
29 brisk walking in graded approach towards the recommended duration, frequency and intensity
30 and (2) to document these activities in a diary. A pedometer determined physical activity pattern
31 will be estimated and clinical assessments and completion of questionnaires (measuring the
32 primary and secondary outcomes) will be performed at four intervals: at baseline, at 12-weeks
33 (the end of the intervention) and a follow up at 24-week and 36-week for all the three groups.
34 Participants will have scheduled dates to return at each interval with a follow-up telephone calls.
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Personalized Feedback on Physical Activity (PF)

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 (PS)

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 to 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 self-manage 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

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3 potential peer mentors. A peer mentor is a volunteer with ≥ 5 years of T2DM, engaged in regular
4 physical activity, has HbA1c $< 8\%$ and living in the community of the study location. Other
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6 criteria for a peer mentor include owning a mobile telephone, being willing to attend a two-day
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8 training and complying with the study protocol. The peer mentors agree to a 9-month
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10 commitment to the study project, adhere to the scheduled meeting and provide support on
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12 physical activity and undergo outcome assessments as their peers.
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17 A two-day training will be conducted for the peer mentors. The training conducted for the
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19 peer mentors is aimed to improve the ability of the peer mentors to provide support to the
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21 participants via face-to-face and telephone contacts. The content of the training was adapted
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23 from a peer support training manual by Safford et al (2011) that included diabetes self-
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25 management, physical activity, stress management in diabetes, and methods of
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27 communication,[41,42]. The training comprised interactive discussions, simulations and role-
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29 plays. The training will be conducted for two days at the clinic. The peer mentors will attend two
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31 fortnightly and two-monthly de-briefing meetings over the course of 12 weeks. The aim of these
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33 meetings is to facilitate and support the peer mentors in performing their task. The research team
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35 will conduct on going supervision for the peer mentors throughout the study period at the
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37 monthly clinic visits with their peers. This will allow the researcher to provide feedback to the
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39 peer mentors on their performance and measures to improve them. Incentives will be provided
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41 for the peer mentors that include: 1) a certificate for completing peer mentor training and as peer
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43 mentors, 2) transportation honorariums at every visit, and 3) monthly prepaid mobile telephone
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45 top-ups.
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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,[43,44]. 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-week and 36-week for all the three groups,[45,46]. 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 cases where the participants do not record their step counts in the activity diary.

The Physical Activity Scale for the Elderly 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-weeks 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

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3 has additional information for participants in the intervention groups, which includes safe
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5 exercise practices and the talk test (a validated method of measuring exercise intensity),[47–49].
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8 Furthermore, an exercise program schedule, tables to record walking activity together with the
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10 level of intensity and duration of the activity were added to the intervention groups' diary. A
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12 graph to provide feedback on participants' physical activity achievements was also incorporated
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14 in the diary.
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17 The secondary outcomes will be measured include metabolic variables (such as
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19 glycosylated haemoglobin level (HbA1c) and lipid profile), blood pressure, cardiorespiratory
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21 fitness, balance, body composition, general health status (health related quality of life and
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23 psychological wellbeing), perceived social support and self-efficacy for exercise. The HbA1c
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25 and fasting lipid profile is part of usual care,[34] performed at the clinic's in-house clinical
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27 laboratory. The HbA1c is analysed using the Bio-Rad D-10 high performance liquid
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29 chromatography (Bio-Rad Laboratories, CA, USA) and the fasting lipid profile is analysed using
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31 the Beckman DxC800 general chemistry analyser (Beckman Coulter, Fullerton, CA, USA).
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37 Blood pressure (BP) is measured with an average of two readings taken five minutes
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39 apart with the participant rested, seated and arm supported. Smoking or ingestion of caffeine
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41 within 30 minutes of measurement is disallowed. Measurements are taken in both arms and the
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43 higher reading is taken as the systemic BP,[50]. Cardiorespiratory fitness (assesses aerobic
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45 endurance) is measured using the 6 min walk test, where the participant walks for 6 minutes and
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47 the distance in metres is recorded. The protocol adheres to the requirements of the American
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49 Thoracic Society guideline,[51]. The participant's balance is measured using the Timed Up and
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51 Go test,[52,53].
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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,[55]. 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,[56]. 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,[57]. 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 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.

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The perceived social support of the study participants will be measured using the Multidimensional Scale of Perceived Social Support,[58]. It is a 12-item validated self-report measure of the availability and adequacy of perceived social support. They are divided into 3 subscales based on the source of social support: family, friends and significant others. Total score in each subscale is divided with 4 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"(p.155),[59] and has been validated in elderly,[60]. The statements on perceived barriers are based on the confidence to exercise 3 times a week for 20 minutes. 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 ANOVA 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 weeks, 24 weeks, 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) version 20.0.

ETHICS AND DISSEMINATION

Participants' safety to participate in unsupervised regular physical activity was ensured through 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. Participant requiring assistance will be referred to their attending doctors for further evaluation. The six minutes 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 generalizability of such an intervention to other primary care settings and for other NCDs. This study will have a

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3 follow up period at 36 weeks after the intervention, which allows the measurement of adherence
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5 to the new behaviour. It is important to measure the sustainability of behaviour change after the
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7 intervention is completed.
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11 The involvement of peer support in the delivery of care for elderly with T2DM in this
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13 trial promotes community empowerment in NCDs management. If successful, the trial will
14
15 provide evidence for the use of peer mentors to provide on-going support to elderly with T2DM
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17 to augment the care provided by healthcare professionals. This approach is potentially a low cost
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19 way of addressing staffing shortages in primary care centres in Malaysia and has the potential to
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21 reduce financial strains on the healthcare system. The peer mentors will receive training to
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23 prepare them as peer supporters, and will have meetings with the other peer mentors, clinic staff
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25 and research team. This will provide an avenue for support and sharing of experiences to
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27 facilitate their role as peer mentors. It is hope that this trial will not only help to improve the
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29 health of the patients and the delivery of healthcare of the selected clinic, but to become a model
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31 to promote healthy lifestyles in primary care setting and the community at large.
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39 **Authors' contributors** SGS, CB and SY conceived the project. All authors participated in its
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41 design and methodological development. SGS drafted the initial manuscript. All authors
42
43 commented on the drafts and approved the final manuscript. SY and CB contributed to the
44
45 procurement of funding. SGS will coordinate the data collection and the involvement of the peer
46
47 mentors; and will lead the statistical analysis of the data.
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54
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2
3 University Sunway Campus Major Grant [M-GPH-MG-68]. The development of study protocol,
4 data collection and analysis of data is not influenced by funding source. The decision on
5
6 presenting or publishing the study findings and the authority over all research related activities
7
8 are solely of the research team. This trial protocol is registered with the Current Controlled Trial
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10 Ltd, registration number ISRCTN71447000.
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18 **Competing interests** None
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Figure 1 - Flow of participants during this study

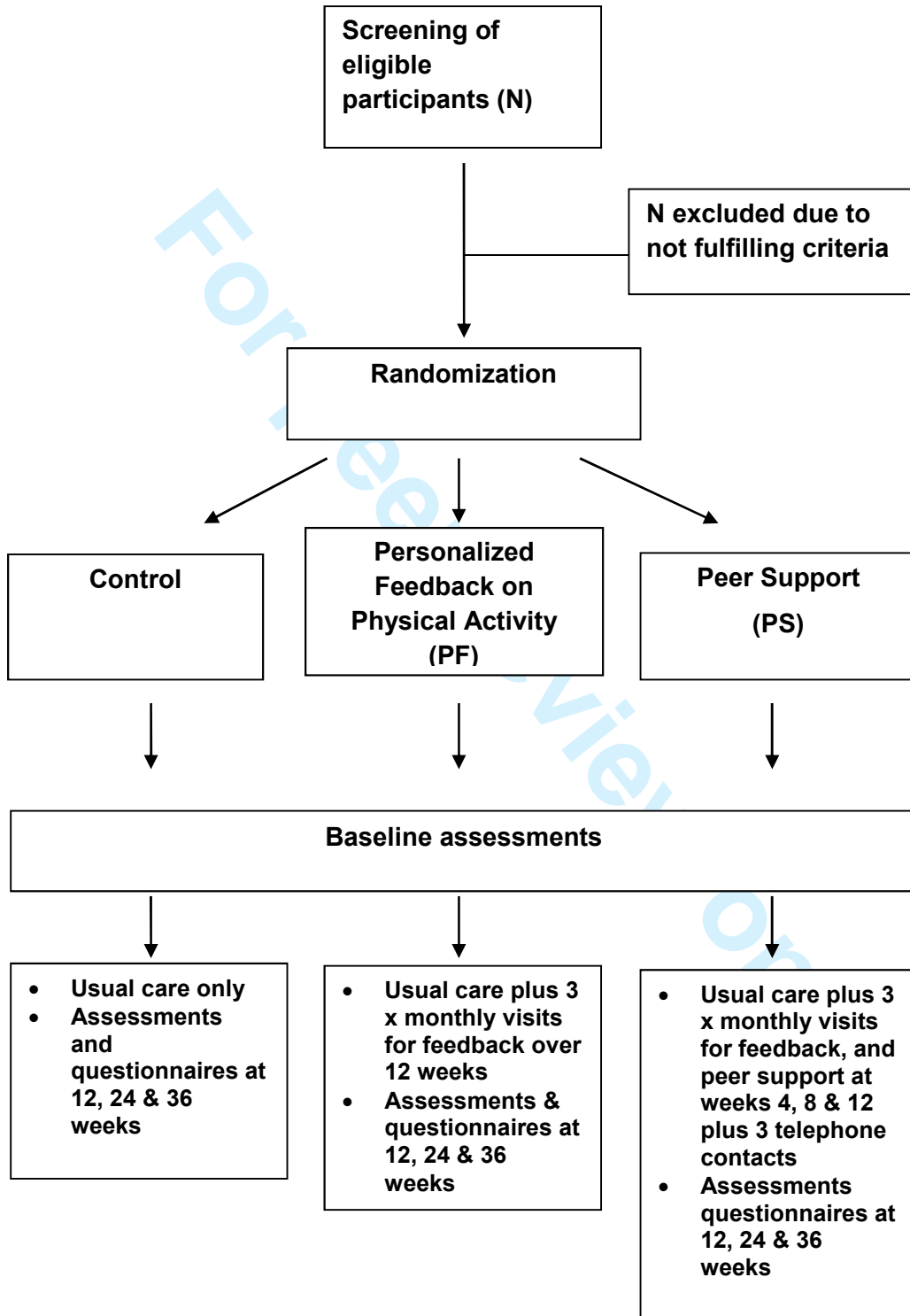


Table 1 – List of participant’s selection criteria

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 increase dose of medication in the last two months
 3. Presence of cognitive impairment (ECAQ < 7)
 4. Had uncontrolled hypertension (blood pressure \geq 180/100 mmHg)
 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
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3 **Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol**
4 **for randomised controlled trial**
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46 **Keywords:** type 2 diabetes mellitus, physical activity, personalized feedback, peer support,
47 elderly Malays
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53 **Word count: 4,000**
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Promoting physical activity in sedentary elderly Malays with type 2 diabetes: A protocol for randomised controlled trial

Abstract

Introduction: Like many countries Malaysia is facing an increase in numbers 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 is to evaluate the effectiveness of personalized feedback alone and in combination with peer support in promoting and maintaining physical activity in comparison to 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 health care clinic in Malaysia. The participants will be randomized into 3 groups for a 12-week intervention with a follow-up at 24 weeks 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

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3 findings of this study will be presented at international conferences and published in peer-
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5 reviewed journals.
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8 **Trial registration:** This study protocol has been registered with the Malaysian National Medical
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10 Research Registry and with the Current Controlled Trial Ltd ([trials.com/ISRCTN71447000/](http://www.controlled-</u>
11 <u><a href=)).
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14 15 16 17 18 **Article focus**

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20 • The primary objective of this study is to establish the effectiveness of personalized feedback
21 alone and in combination with peer support to promote and maintain physical activity in
22 elderly Malays with type 2 diabetes.
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28 29 30 **Key messages**

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32 • Peer support is potentially a cost-effective adjunct approach for on going diabetes self-
33 management support in primary care setting.
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39 40 **Strength and limitations**

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42 • This study will be the first randomized controlled trial in the region of Southeast Asia to
43 promote physical activity using personalized feedback and peer support in elderly Asian
44 people.
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48 • The role of on going peer support to promote adherence to physical activity could be
49 evaluated in this study with the follow-ups evaluation post intervention.
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53 • The recruitment is targeted to elderly Malays from a community in Malaysia, which limits
54 the generalizability of this study.
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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most prevalent non-communicable diseases (NCDs) in both developed and developing countries,[1]. It is associated with significant morbidity, mortality and increased healthcare cost,[2,3]. In 2010, about a third of people with diabetes was over 60 years old,[4]. The greatest increase in the prevalence is expected to occur in Asia and Africa due to the joint trends of urbanization 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 elderly, especially with NCDs benefit from regular physical activity,[9–12]. However, 52%-80% of 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 fitness,[21] 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

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3 term,[23,24]. The lack of on-going educational support and attention to behaviour change
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5 principles are often contributing factors to the short-term positive changes in health status. The
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7 increasing number of attendees to primary care clinics and shortage of healthcare professionals
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9 trained in self-management approaches also contribute to these sub-optimal approaches to T2DM
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11 management.
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15 Peer support has emerged as a relatively low cost approach that can be used in
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17 conjunction with healthcare professional support to assist in the management of T2DM. On-
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19 going support through peer mentors empowers patients with T2DM to self-manage their
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21 condition,[25–27]. Peer mentors are people “... who successfully coped with the same condition
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23 and can be a positive role model” (p. i26),[28]. Interventions incorporating peer mentors
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25 improved glycaemic control,[19,26] self-efficacy,[27], and self-care behaviour,[20,25,27].
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27 However, the role of peer support for elderly with T2DM in promoting physical activity is not
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29 well documented in the literature especially in South East Asia.
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34 In 2010, Malaysia was ranked in the top ten countries in the world for diabetes
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36 prevalence, with 11.6% of the 17 million people aged 20 to 79 years with diabetes,[1]. The
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38 prevalence of diabetes in Malaysia increased from 8.2% in 1996 to 14.9% in 2006,[29]. The
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40 highest prevalence is among people aged 60-64 years at 26.1%. Furthermore, elderly with T2DM
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42 have low levels of physical activity than younger patients (41.5% vs. 25.3%),[31]. Those who
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44 were less active have poorer glycaemic control.
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49 Malaysia is a multi-ethnic population comprising the Malay (50.7%), Chinese (23.1%),
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51 Indian (6.9%) and other Bumiputera (11.0%) people (indigenous people) as the major groups
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53 within the total population of 28 million. Malay people have the second highest prevalence of
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55 T2DM at 11.9%,[29] and had worse glycaemic and cardio-metabolic controls,[30]. Moreover,
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3 they have the lowest prevalence of recommended adequate exercise than the other ethnic
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6 groups,[32].
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8 The rapid increased in the incidence of T2DM and a shift towards an ageing population
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10 over the last decade,[33] warrants the need for an intervention program to promote physical
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12 activity and improve the health status of elderly with T2DM in Malaysia. With the limited
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14 healthcare resources, peer support and feedback about physical activity behaviour in the
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16 management of T2DM may prove to be a cost effective approach. Furthermore, targeting elderly
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18 Malays is appropriate in view of the low prevalence of adequate exercise and poorer glycaemic
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20 control in this group in Malaysia. Hence, the objective of this trial is to evaluate the relative
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22 effectiveness of personalized feedback about physical activity patterns alone and in combination
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24 with peer support to promote and maintain physical activity compared to usual care.
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32 **METHODS AND ANALYSIS**

33 **Study design**

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35 A three-arm randomised controlled trial over 36 weeks will be conducted. Participants will be
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37 randomised into the three groups:
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- 40 1. Personalized feedback about physical activity patterns (PF).
 - 41 2. Personalized feedback about physical activity patterns combined with peer support (PS).
 - 42 3. Control group, usual care (CG).
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48 All groups will receive usual diabetes care. The usual care involves a multidisciplinary team
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50 approach and comprises care by the primary care practitioners, diabetes educator, nutritionist,
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52 and shared care with the endocrinologist and ophthalmologist when required,[34]. The
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54 management includes education about lifestyle modification, medication and self-care.
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Before this trial was designed, a qualitative focus group was conducted to identify socio-culturally 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 personalized feedback and were incorporated into the training programme for the peer mentors to facilitate the delivery of personalized feedback 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 1,000 patients attend the clinic everyday, 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 false-negative 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 $4,099 \pm 2,152$ (pre-intervention) to $7,976 \pm 4,118$ (post-intervention). The sample size was calculated using the G*Power version 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 Table 1.

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] and measurements of blood pressure, and visual acuity. The fasting blood glucose (FBG), and urine micro albumin 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

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3 three to create the randomisation schedule. The principal author will conduct assignment of
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5 interventions.
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10 **The intervention**

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12 This study incorporated constructs of the Social Cognitive Theory (SCT) to promote change in
13 behaviour from sedentary behaviour to being physically active,[39,40]. Bandura defined
14 behaviour as a dynamic process that involves interaction between the person, behaviour and the
15 environment,[39]. Behaviour change is more likely when a person believes in one's own
16 capability to change (self-efficacy) and values the outcome (outcome expectation). Behaviour
17 capability is supported by goal setting, capacity building and self-monitoring. Self-efficacy can
18 be influenced by personal mastery experiences, which is the ability to accomplish a behavioural
19 change through perseverant efforts based on one's personal experiences,[40]. It can be
20 strengthened through social persuasion (being informed by others verbally that one is capable in
21 mastering the new behaviour), vicarious experience (learning from other's experiences – seeing
22 how others have succeeded by perseverant efforts), and physiological and emotional states
23 (relying on one's physiological and emotional responses to the activity to judge one's abilities).
24 According to SCT, a supportive social environment must be established and self-efficacy
25 enhanced to ensure behaviour change.
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46 This current study aimed to promote physical activity in sedentary elderly through
47 personalized feedback and peer support. The study participants need to adopt a new behaviour
48 (regular walking activity) and the confidence to adopt the behaviour can be influenced through
49 the personalized feedback and peer support. The personalized feedback received concerning the
50 participants' personal performance accomplishments would motivate them to continue engaging
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3 in regular walking. Moreover, actually performing the regular walking would strengthen their
4 self-efficacy. In the peer support groups, self-efficacy can be strengthened via the experiences
5 and accomplishments of their peer mentors in engaging in regular walking. The participants
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7 would be able to learn from others' experiences and be motivated to change their behaviour
8 and/or maintain the new behaviour. Furthermore, the fears and uncertainties, which may be
9 accompanied in initiating the regular walking, could be alleviated through the social supports
10 they will receive from their peer mentors and peers. Hence, the regular walking can be enhanced
11 via personalized feedback or combined with the support from the peer mentors, which will allow
12 better accomplishment and confidence in the intended activity.
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15 Both the PF and PS groups will undergo a 12-week intervention designed to promote
16 physical activity through walking activity with a follow-up at 24-weeks and 36-weeks. Figure 1
17 summarises the flow of participants during this study. The principal author (a family physician)
18 will provide the exercise prescription. The participants are encouraged (1) to perform regular
19 brisk walking in graded approach towards the recommended duration, frequency and intensity
20 and (2) to document these activities in a diary. A pedometer determined physical activity pattern
21 will be estimated and clinical assessments and completion of questionnaires (measuring the
22 primary and secondary outcomes) will be performed at four intervals: at baseline, at 12-weeks
23 (the end of the intervention) and a follow up at 24-week and 36-week for all the three groups.
24 Participants will have scheduled dates to return at each interval with a follow-up telephone calls.
25 Transportation honorariums are provided at each visit. If the participants withdraw from the
26 study, the baseline data or last visit outcomes data will be used for analysis.
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Personalized Feedback on Physical Activity (PF)

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 (PS)

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 to 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 self-manage 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

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3 potential peer mentors. A peer mentor is a volunteer with ≥ 5 years of T2DM, engaged in regular
4 physical activity, has HbA1c $< 8\%$ and living in the community of the study location. Other
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6 criteria for a peer mentor include owning a mobile telephone, being willing to attend a two-day
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8 training and complying with the study protocol. The peer mentors agree to a 9-month
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10 commitment to the study project, adhere to the scheduled meeting and provide support on
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12 physical activity and undergo outcome assessments as their peers.
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18 A two-day training will be conducted for the peer mentors. The training conducted for the
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20 peer mentors is aimed to improve the ability of the peer mentors to provide support to the
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22 participants via face-to-face and telephone contacts. The content of the training was adapted
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24 from a peer support training manual by Safford et al (2011) that included diabetes self-
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26 management, physical activity, stress management in diabetes, and methods of
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28 communication,[41,42]. The training comprised interactive discussions, simulations and role-
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30 plays. The training will be conducted for two days at the clinic. The peer mentors will attend two
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32 fortnightly and two-monthly de-briefing meetings over the course of 12 weeks. The aim of these
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34 meetings is to facilitate and support the peer mentors in performing their task. The research team
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36 will conduct on going supervision for the peer mentors throughout the study period at the
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38 monthly clinic visits with their peers. This will allow the researcher to provide feedback to the
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40 peer mentors on their performance and measures to improve them. Incentives will be provided
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42 for the peer mentors that include: 1) a certificate for completing peer mentor training and as peer
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44 mentors, 2) transportation honorariums at every visit, and 3) monthly prepaid mobile telephone
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46 top-ups.
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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,[43,44]. 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-week and 36-week for all the three groups,[45,46]. 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 cases where the participants do not record their step counts in the activity diary.

The Physical Activity Scale for the Elderly 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-weeks 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

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3 has additional information for participants in the intervention groups, which includes safe
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5 exercise practices and the talk test (a validated method of measuring exercise intensity),[47–49].
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8 Furthermore, an exercise program schedule, tables to record walking activity together with the
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10 level of intensity and duration of the activity were added to the intervention groups' diary. A
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12 graph to provide feedback on participants' physical activity achievements was also incorporated
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14 in the diary.
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17 The secondary outcomes will be measured include metabolic variables (such as
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19 glycosylated haemoglobin level (HbA1c) and lipid profile), blood pressure, cardiorespiratory
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21 fitness, balance, body composition, general health status (health related quality of life and
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23 psychological wellbeing), perceived social support and self-efficacy for exercise. The HbA1c
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25 and fasting lipid profile is part of usual care,[34] performed at the clinic's in-house clinical
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27 laboratory. The HbA1c is analysed using the Bio-Rad D-10 high performance liquid
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29 chromatography (Bio-Rad Laboratories, CA, USA) and the fasting lipid profile is analysed using
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31 the Beckman DxC800 general chemistry analyser (Beckman Coulter, Fullerton, CA, USA).
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37 Blood pressure (BP) is measured with an average of two readings taken five minutes
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39 apart with the participant rested, seated and arm supported. Smoking or ingestion of caffeine
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41 within 30 minutes of measurement is disallowed. Measurements are taken in both arms and the
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43 higher reading is taken as the systemic BP,[50]. Cardiorespiratory fitness (assesses aerobic
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45 endurance) is measured using the 6 min walk test, where the participant walks for 6 minutes and
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47 the distance in metres is recorded. The protocol adheres to the requirements of the American
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49 Thoracic Society guideline,[51]. The participant's balance is measured using the Timed Up and
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51 Go test,[52,53].
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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,[55]. 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,[56]. 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,[57]. 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 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.

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The perceived social support of the study participants will be measured using the Multidimensional Scale of Perceived Social Support,[58]. It is a 12-item validated self-report measure of the availability and adequacy of perceived social support. They are divided into 3 subscales based on the source of social support: family, friends and significant others. Total score in each subscale is divided with 4 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"(p.155),[59] and has been validated in elderly,[60]. The statements on perceived barriers are based on the confidence to exercise 3 times a week for 20 minutes. 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 ANOVA 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 weeks, 24 weeks, 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) version 20.0.

ETHICS AND DISSEMINATION

Participants' safety to participate in unsupervised regular physical activity was ensured through 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. Participant requiring assistance will be referred to their attending doctors for further evaluation. The six minutes 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 generalizability of such an intervention to other primary care settings and for other NCDs. This study will have a

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3 follow up period at 36 weeks after the intervention, which allows the measurement of adherence
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5 to the new behaviour. It is important to measure the sustainability of behaviour change after the
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7 intervention is completed.
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11 The involvement of peer support in the delivery of care for elderly with T2DM in this
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13 trial promotes community empowerment in NCDs management. If successful, the trial will
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15 provide evidence for the use of peer mentors to provide on-going support to elderly with T2DM
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17 to augment the care provided by healthcare professionals. This approach is potentially a low cost
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19 way of addressing staffing shortages in primary care centres in Malaysia and has the potential to
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21 reduce financial strains on the healthcare system. The peer mentors will receive training to
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23 prepare them as peer supporters, and will have meetings with the other peer mentors, clinic staff
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25 and research team. This will provide an avenue for support and sharing of experiences to
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27 facilitate their role as peer mentors. It is hope that this trial will not only help to improve the
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29 health of the patients and the delivery of healthcare of the selected clinic, but to become a model
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31 to promote healthy lifestyles in primary care setting and the community at large.
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39 **Authors' contributors** SGS, CB and SY conceived the project. All authors participated in its
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41 design and methodological development. SGS drafted the initial manuscript. All authors
42
43 commented on the drafts and approved the final manuscript. SY and CB contributed to the
44
45 procurement of funding. SGS will coordinate the data collection and the involvement of the peer
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47 mentors; and will lead the statistical analysis of the data.
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54
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3 University Sunway Campus Major Grant [M-GPH-MG-68]. The development of study protocol,
4 data collection and analysis of data is not influenced by funding source. The decision on
5 presenting or publishing the study findings and the authority over all research related activities
6 are solely of the research team. This trial protocol is registered with the Current Controlled Trial
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13 Ltd, registration number ISRCTN71447000.

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18 **Competing interests** None
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Figure 1 - Flow of participants during this study

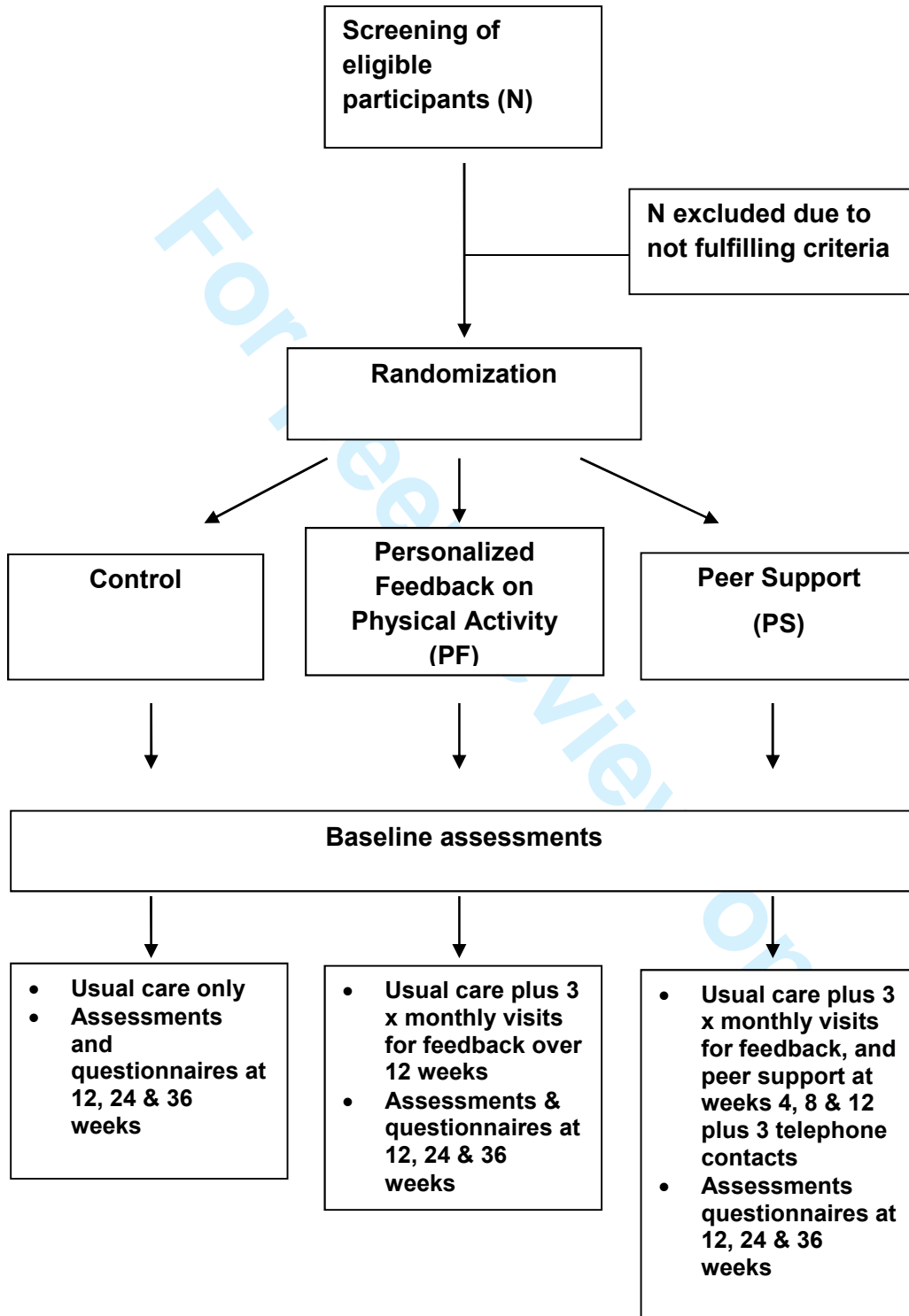


Table 1 – List of participant’s selection criteria

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 increase dose of medication in the last two months
 3. Presence of cognitive impairment (ECAQ < 7)
 4. Had uncontrolled hypertension (blood pressure \geq 180/100 mmHg)
 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
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