PROMOTING PHYSICAL ACTIVITY IN SEDENTARY OLDER MALAYS WITH TYPE 2 DIABETES MELLITUS

A thesis submitted for the degree of Doctor of Philosophy

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ABSTRACT

Type 2 diabetes mellitus (T2DM) in older people is becoming a global health problem. In Malaysia, the overall prevalence of diabetes has increased by almost 200% in a decade. Among the different ethnic groups, the Malays are reported to have the poorest control for glycaemia and other cardiovascular risk factors. Lifestyle interventions such as regular physical activity are important in the management of T2DM. Despite the many health benefits of regular physical activity, participation remains low, especially among people with T2DM. This study was conducted in three phases to explore the current situation regarding promoting physical activity in older people with T2DM.

In Phase 1, a systematic review was conducted to review the scientific evidence on interventions promoting physical activity in older people with T2DM. The review found 21 studies (18 randomised controlled trials and three quasi-experimental studies) from eight countries that investigated physical activity in people with T2DM. Strategies that increased physical activity levels in people with T2DM were evident, but most of the studies focused on middle-aged rather than on older people and none were conducted in Asia. Also, these strategies varied markedly between studies and most incorporated health behaviour theories and multiple approaches to facilitate and maintain behaviour change. Further, there was a lack of well-designed trials. More studies with interventions of satisfactory methodological quality promoting physical activity in older people are required.

Phase 2 reported in this thesis was a qualitative focus group study that aimed to explore the perceptions of physical activity, and the motivators for and barriers to physical activity in older Malays with T2DM. This study found that older Malays with T2DM viewed physical activity as an important aspect of the self-care management of diabetes. The conventional perceptions regarding the definition of physical activity, and the motivators for and barriers to physical activity were intertwined with social rules, and cultural and spiritual expectations in this Malay community. Spiritually related activities emerged as a theme in defining physical activity and its barriers. Therefore, emphasis on regular physical activity that not only improves glycaemic control but also allows the continuation of religious obligations is important for older Malays with T2DM.

Phase 3 was a randomised controlled trial conducted to determine the effectiveness of personalised feedback about physical activity patterns alone and in combination with peer support,

in addition to the usual diabetes care on physical activity levels, cardiovascular diseases risk factors, functional status, quality of life and psychosocial wellbeing. Strategies that included the constructs of social cognitive theory in personalised feedback about physical activity patterns combined with peer support assisted older Malays with T2DM to change their physical activity behaviour. The outcomes of this study could be used to inform the development of physical activity interventions for older Malays in primary care and community settings. Such interventions have the potential to improve the health of older people in Malaysia and reduce the health care burden due to diabetes related complications. This would facilitate the nation's vision to promote active and productive ageing in Malaysia.

GENERAL DECLARATION

In accordance with Monash University Doctorate Regulation 17/Doctor of Philosophy and Master of Philosophy (MPhil) regulations, the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institutions and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except when due reference is made in the text of the thesis.

The Monash University Human Research Ethics Committee (MUHREC) approved this study [qualitative focus group study on 28 March 2011 (Project No. CF 10/3191-2010001702) and randomised controlled trial on 15 August 2011 (Project No. CF 11/1018-2011000524)], and Monash University Sunway Campus Major Grant funded this study (Project Code: M-GPH-MG-68).

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PUBLICATIONS AND CONFERENCE PRESENTATIONS ARISING FROM THE THESIS

Published article

1. Sazlina SG, Browning C, Yasin S. Promoting physical activity in sedentary elderly Malays with type 2 diabetes mellitus: A protocol for randomised controlled trial. BMJ Open 2012; 2: e002119. doi: 10.1136/bmjopen-2012-002119.

2. Sazlina SG, Browning C, Yasin S. Interventions to promote physical activity in older people with type 2 diabetes mellitus mellitus: A systematic review. Frontiers in Public Health 2013; 1. doi: 10.3389/fpubh.2013.00071.

Articles under review

1. Sazlina SG, Browning C, Yasin S. The cultural perspectives of physical activity and its barriers in older Malays with type 2 diabetes mellitus. Journal: BMC Public Health.

2. Sazlina SG, Browning C, Yasin S. Effectiveness of primary care based personalised feedback about physical activity patterns alone or in combination with peer support in sedentary older Malays with type 2 diabetes: randomised controlled trial. Journal: PLOS One.

Articles to be submitted

1. Sazlina SG, Brwoning C, Yasin S. Does the effect of walking activity intervention reduce during Ramadan in older Malays with type 2 diabetes?

Presentation at conferences

1. Sazlina SG, Brwoning C, Yasin S. Healthy Ageing: Effectiveness of primary care based personalised feedback about physical activity patterns alone or in combination with peer support in sedentary older Malays with type 2 diabetes. WONCA Asia Pacific Regional Conference 2014, Borneo Convention Centre Kuching, Sarawak, Malaysia on 21-24 May 2014.

2. Sazlina SG, Browning C, Yasin S. Promoting physical activity in sedentary older Malays with diabetes: The preliminary results. XXXII World Congress of Sports Medicine, Roma Caveliari, Rome, Italy on 26 – 30 September, 2012.

3. Sazlina SG, Browning C, Yasin S. The cultural perspective of physical activity and its barriers in older Malays with type 2 diabetes mellitus. 1st World Congress on Healthy Ageing, Kuala Lumpur Convention Centre, Malaysia on 19-22 March 2012.

4. Sazlina SG, Browning C, Yasin S. Promoting Physical Activity in Older people with Diabetes. 9th Asia/Oceania Regional Congress of Gerontology & Geriatrics, Melbourne Convention and Exhibition Centre, Australia on 2-4 November 2011.

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LIST OF ABBREVIATIONS

BMI	Body mass index
BP	Blood pressure
CG	Control group
CRF	Case report form
CVD	Cardiovascular disease
FGD	Focus group discussion
GHQ-12	General Health Questionnaire-12 items
HbA1c	Glycosylated haemoglobin
HDL-C	High-density lipoprotein cholesterol
LDL-C	Low-density lipoprotein cholesterol
LMM	Linear mixed modelling
MCS	Mental Component Summary
METs	Metabolic equivalent of tasks
MSPSS	Multidimensional Scale for Perceived Social Support
NCDs	Non communicable diseases
PCS	Physical Component Summary
PF	Personalised feedback about physical activity patterns alone
PS	Personalised feedback about physical activity patterns combined with peer support
RCT	Randomised controlled trial
SEES	Self-Efficacy for Exercise Scale
SF-12	Short form health survey-12 items
T2DM	Type 2 diabetes mellitus mellitus
WC	Waist circumference

THESIS OUTLINE

Chapter 1 outlines the background information to the research project, the theoretical framework and the rationale for the study. The aims, research objectives, questions and hypotheses are outlined.

Chapter 2 provides a critical systematic review of relevant literatures on interventions promoting physical activity in older people with type 2 diabetes mellitus (Phase 1 of the research project).

Chapter 3 presents the second phase of the research project (qualitative focus group study) that provides the perceptions of physical activity among older Malays with type 2 diabetes mellitus. This chapter provides the purpose and specific objectives of the qualitative focus group study, an overview of the methods used, and presents and discusses the findings from the focus group discussions, and the strength and limitations of the qualitative focus group study.

Chapter 4 outlines the methods employed in the third phase of the research project (randomised controlled trial) according to the Consolidated Standard of Reporting Trials (CONSORT) guideline.

Chapter 5 describes the randomised controlled trial participants' characteristics, which included recruitment and retention, baseline comparison between participants who completed and discontinued the study, baseline comparison of participants in the different groups, trends in the modification of medications related to diabetes care, adherence to study protocol and adverse events because of the intervention.

Chapter 6 describes the findings on the effectiveness of the randomised controlled trial intervention between the three treatment groups across the study period on the primary and secondary outcomes.

Chapter 7 contains the main discussion on the findings of the randomised controlled trial with reference to the initial objectives and hypotheses, and strength and limitations of the randomised controlled trial.

Chapter 8 presents the conclusions and strength and limitations of the research project, implications for practice and policy and recommendations for future research.

CHAPTER 1 INTRODUCTION

The world population is ageing as a result of increased life expectancy, lower fertility and better health care services (1). Population ageing is occurring in all regions and countries, with the fastest increase in developing countries. This will influence society's economic and social structures, as well as the health care system. With greater longevity, more people are at risk of developing chronic non-communicable diseases (NCDs) such as hypertension, type 2 diabetes mellitus (T2DM), stroke and coronary heart disease (2,3). As a result, the health care burden in most nations will increase. Globally at present, these diseases are the leading causes of death (4).

The increasing prevalence of T2DM among older people is a growing public health concern worldwide, including in Malaysia (2,5). The greatest increase is expected in Asia and Africa because of urbanisation and changes in lifestyle. Globally, about 106 million people aged 60 years and above have T2DM (6). By the year 2030, it is projected that about 200 million older people will have T2DM. T2DM causes significant morbidity, disability and mortality among older people. Its impact will increase health care costs to the patient, the community and the nation (7,8). Hence, measures must be taken to improve the health care of older people with T2DM.

Regular physical activity is an important self-management behaviour that aids older people with T2DM to manage their diabetes (9). It improves glucose homeostasis and reduces the risk of diabetes related morbidity and mortality (10,11). Increasingly recommendations suggest that older people will benefit from regular physical activity, especially in the presence of chronic non-communicable diseases such as T2DM (12–14). Despite the evidence of the health benefits from regular physical activity, older people with T2DM remain inactive or sedentary (15). Sedentary behaviour is a predictor of poor glycaemic control (16). Prolonged sitting or lying down is associated with increased risk of cardiovascular events (17) and diminished physical functions in older people (18). In addition, older people are at high risk of poly-pharmacy and associated geriatric syndromes (such as depression, falls and cognitive impairment), which could worsen their functional status (19). Therefore, understanding strategies that promote physical activity and developing an intervention that could increase the physical activity levels among older people with T2DM is important to improve their independence and quality of life.

The focus of this thesis is promoting physical activity in older Malays with T2DM within a primary health care setting. This thesis has three phases: Phase 1: a systematic review; Phase 2: a qualitative focus group; and Phase 3: a randomised controlled trial (RCT). The systematic review (as presented in Chapter 2) was performed to gain understanding of the current situation on interventions promoting physical activity among older people with T2DM. To promote participation in and adherence to regular physical activity, understanding of the perceived motivators for and barriers to physical activity among older Malays with T2DM is essential. Therefore, a qualitative focus group study (as described in Chapter 3) was conducted to inform the design of the randomised controlled trial by exploring the perceptions of physical activity among older Malays with T2DM. The findings from the focus groups were incorporated into the design of the RCT's intervention and training of peer mentors as discussed in Chapters 3 and 4. The RCT was aimed to assess whether physical activity can be promoted through personalised feedback alone or in combination with peer support in sedentary older Malays with T2DM receiving the usual diabetes care. The methods of the RCT are presented in Chapter 4. The findings of the RCT are presented in Chapters 5 and 6, and discussed and concluded in Chapter 7. Chapter 8 provides a conclusion for the overall findings of this thesis.

This chapter describes the current scenarios in Malaysia about population ageing, T2DM, physical activity and management recommendations for older people with T2DM. This chapter also describes the barriers to and motivators for physical activity in older people. The health care system in Malaysia and how it services older people with diabetes is also described. A discussion of Social Cognitive Theory, which provides the theoretical framework for this study, is also included in this chapter. The rationale for this thesis, and the study objectives, research questions and hypotheses are presented at the end of this chapter.

1.1 The ageing population in Malaysia

The world population has increased rapidly from 2.5 billion in 1950 to 6.9 billion in 2010 (20). This growth has been attributed to changes in the fertility rate and mortality rates, as well as improved public health services (21). The world population aged 60 years and above in 2011 was 650 million, and it is projected to reach 2 billion by 2050 (22). In addition, it is estimated that the number of older people living in the lower and middle-income countries will increase to 80% by 2050 compared with 60% in 2005.

Malaysia is also experiencing an increase in ageing population as shown in Figure 1.1. The proportion of the younger population (aged less than 15 years) has decreased over the past 10 years.

In 2010, the younger population comprised 27.6% of the population compared with 33.3% in 2000 (23). In addition, the median age of the Malaysian population increased from 23.6 years in 2000 to 26.2 years in 2010. In national policies, Malaysia defines older people as those aged 60 years or above, in accordance with the United Nations' definition (21). The population of older Malaysian was 2.25 million (7.4%) in 2010 compared with 1.40 million (6.3%) in 2000 (23,24). It is projected that by 2050, 23.8% of the population will be 60 years old and above. In addition, life expectancy has increased for both Malaysian men and women (25). Life expectancy for men has increased from 68.9 years in 1990 to 71.7 years in 2007. Similarly, women's life expectancy has increased from 73.5 years in 1990 to 76.5 years in 2007. These trends indicate a transition of the age structure towards an ageing population in Malaysia.

Malaysia has 13 states and three federal territories (23). It is a multi-ethnic country comprising four main ethnic groups: Malays who comprise 54.6% of the population, and sizeable numbers of Chinese (24.6%), Indians (7.3%) and the indigenous *Bumiputera* (12.8%) groups. Malays forms the largest community and with the indigenous people known as the *Bumiputera* or "sons of the land". The official religion of Malaysia is Islam (61.3%) which is practised by the Malays (26). Given the multi-ethnic population, religious freedom is practised. The other religions embraced are Buddhism (19.8%), Christianity (9.2%) and Hinduism (6.3%). The official language in Malaysia is Bahasa Malaysia, known as the Malay language, which is the native language of the Malays.

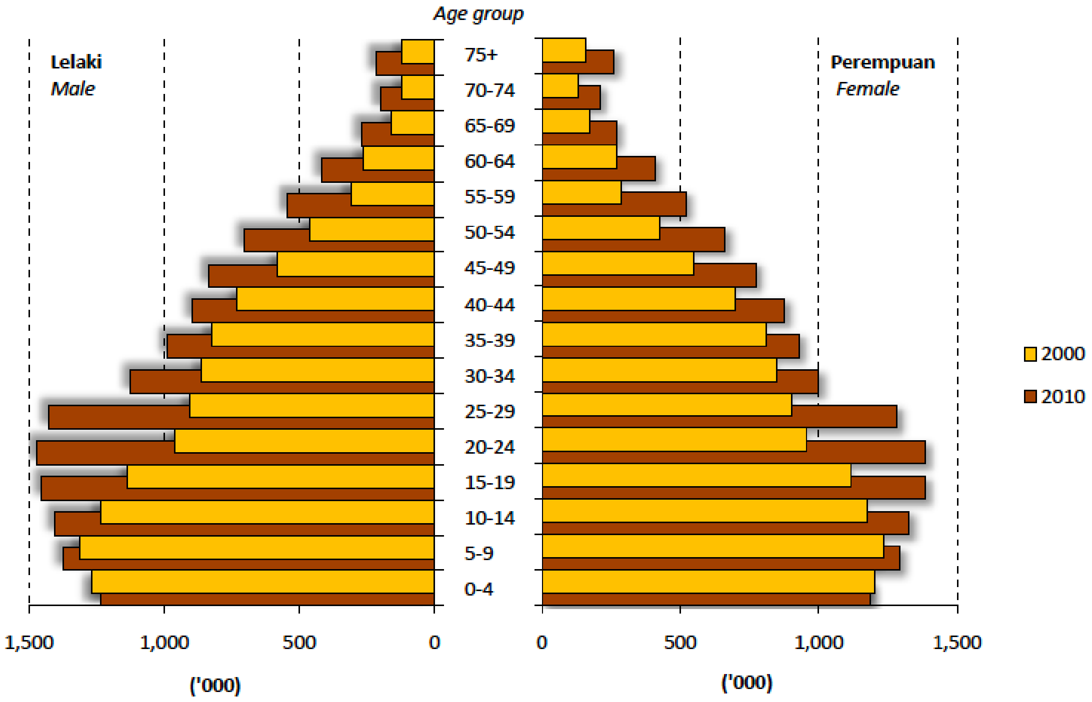

Figure 1.1: Population pyramid by sex and age group in Malaysia, 2000 and 2010

(Source: Department of Statistics, Malaysia, 2010) (23)

Within Malaysia, the rate of growth of the older population varies according to states and urbanisation. Two-thirds of the 16 states have more than 7.5% of their total population aged 60 years and above (23). A variation in the distribution of older people in urban and rural areas is also evident. More older people live in the urban areas (65.7%) in contrast to a few decades ago where rural areas had a larger proportion of older people (23,27). In the past few decades, there has been a migration towards the urban areas by the young rural population in pursuit of better job opportunities. On retirement, they have continued to live in the urban areas, as they have settled their family and homes there. Population ageing has occurred in parallel with rapid urbanisation and industrialisation and improved health life expectancy (21). Therefore, there is a need for urgent planning to address the needs of the growing ageing population, such as the development of aged-friendly community care, social and financial securities, as well as accessibility to health care services.

The transition towards an ageing population will have an impact not only on Malaysia's economic and social structures but also on its health care system (28). With longevity, more people are at risk of developing chronic non-communicable diseases such as hypertension, T2DM and dyslipidaemia (2,3). As a result, the health care burden will increase as these conditions lead to significant cardiovascular diseases, especially coronary heart disease and stroke. These diseases were the leading causes of death in Malaysia in 2008 (29). In addition, the presence of chronic non-communicable diseases among older people is associated with lower health related quality of life (30), which could reduce independence and healthy productive ageing, which are the goals of successful ageing for many nations.

1.2 Type 2 diabetes mellitus in Malaysia

The increasing prevalence of type 2 diabetes mellitus (T2DM) is a significant problem worldwide (5). In the year 2010, 285 million (6.4%) adults had diabetes, and this is expected to increase to 439 million (7.7%) by 2030 (6). Type 2 diabetes mellitus causes significant morbidity and mortality, and it is associated with increased health care costs to the patient and the community (7,8). An estimated 100% increase in the global cost of diabetes from USD 376 billion to USD 490 billion from 2010 to 2030 is predicted (5). The greatest increase in the proportion of people with diabetes is expected to occur in Asia and Africa as a result of trends in urbanisation and lifestyle changes. It is estimated that there will be a 69% increase in the number of adults living with diabetes by 2030 in the lower and middle-income countries (6).

Malaysia was ranked tenth in the world for the percentage of adults living with diabetes (11.6%) in 2010. This is higher than Singapore (10.2%), Japan (5.0%), the U.S.A. (10.3%), the United Kingdom (3.6%) and Australia (5.7%) (6). The overall prevalence of diabetes has increased from 8.2% in 1996 to 14.9% in 2006 among those aged 30 years and older (31). The prevalence increases with age and about a third of people aged 60 years and above have T2DM, with the highest proportion in the age group 60 to 64 years (26.1%). The increased prevalence was observed across the different ethnic groups in Malaysia. The highest prevalence was in Indians (19.9%), followed by Malays (11.9%), Chinese (11.4%) and the indigenous Bumiputera (6.0%).

Glycaemic control among Malaysian adults with T2DM remains poor (defined as glycosylated haemoglobin (HbA1c) of 7.0% and more). The proportion of people over 18 years old with HbA1c of 7.0% and above in both primary and tertiary care centres is between 59.0% and 80.0% (32–35). The proportion of people aged 60 years and above with HbA1c of 7.0% and above is 56.3% (36). Adult Malaysians with poor glycaemic control lack diabetes related knowledge and often demonstrate inadequate self-care practices (37). Among the different ethnic groups, the adult Malays were most likely to have poor glycaemic control (HbA1c $\geq$ 7.0%) and have more cardiovascular risk factors than other races (38). Older Malays were more likely to be overweight and obese (39) and this could be related to higher insulin resistance leading to poor glycaemic control. Furthermore, the Malaysian Adult Nutrition Survey in 2002 reported that the proportion of adult Malays engaging in adequate exercise was lower than that of the Chinese and Indian ethnic groups (40). This could be contributing to their poorer glycaemic control. The Malays and indigenous Bumiputera were the least likely to use modern medications, which could also contribute to poor glycaemic control (41). More Malays use complementary and alternative medicine either alone or with modern medications compared with other ethnic groups.

The high proportion of people with poor glycaemic control leads to significant morbidity, disability and mortality, increasing health care costs (8,42). In 2010, USD 600,000 (16.0%) of the Malaysian health expenditure was spent on diabetes, with the greatest expenditure on people aged 60 years old and above (42). This is expected to increase further to USD 1 million by 2030. Furthermore, older people are at increased risk of higher rates of cardiovascular and coronary events (43). Therefore, strategies to prevent or delay diabetes related complications and mortality in improving the quality of life of older people with T2DM are imperative. Self-care management including interventions that comprise healthy diet, weight control, regular physical activity and avoiding tobacco use is ideal in reducing T2DM related morbidity and mortality.

1.3 Physical activity, peer support and personalised feedback

Regular physical activity is one of the recommendations in the management of T2DM according to all guidelines globally (9,10,44–46). Regular physical activity, which includes aerobic exercise such as brisk walking, improves glucose homeostasis and reduces the risk of diabetes related morbidity and mortality (10,11). In addition, physical activity increases insulin sensitivity and reduces intra abdominal fat distribution. Increasingly recommendations suggest older people will benefit from regular physical activity especially in the presence of chronic non-communicable diseases such as T2DM (10,12–14). Furthermore, older people with diabetes who are less active have poorer glycaemic control than those involved in higher levels of physical activity (47). For older people it is recommended that they adopt regular physical activity of moderate intensity for 30 to 45 minutes at least five days in a week or on most days; or an accumulation of 150 minutes of physical activity in a week to achieve health benefits (12,48). The recommendation of moderate intensity physical activity is the metabolic equivalent of tasks (METs) between 3 and 6 (49).

Despite the increasing evidence on the health benefits from regular physical activity and exercise, many people remain inactive or sedentary. The worldwide prevalence of people who do not engage in the recommended regular physical activity ranges between 49.0% and 70.0% (50–52). In these studies, a higher proportion of women and people over 65 years of age are physically inactive (50,52–55). In Malaysia, the overall prevalence of physical inactivity is similar to that of other countries, ranging from 31.3% to 43.7% (40,56). Malaysian adults spent most of their time in sitting position (40.8% of the day) and in a sleeping or lying down position (33.1% of the day), compared with time engaging in regular physical activity (0.6% of the day) (40). In addition, women are more physically inactive than men in Malaysia. Among the different ethnic groups, the Malays have lowest prevalence of adequate exercise at 12.4%, compared with the Chinese (17.0%) and Indian (16.0%) ethnic groups (40). The prevalence of physical inactivity also increases with age, and many older people with chronic non-communicable diseases (78.4%) do not engage in regular physical activity as recommended (30).

The definition of sedentary behaviour or physical inactivity also varies across different studies (57–60). The American College of Sports Medicine defined sedentary behaviour as “a way of living or lifestyle that requires minimal physical activity and that encourages inactivity through limited choices, disincentives, and/or structural or financial barriers” (13) (p.1511). Some studies define sedentary or inactive lifestyles as those in which the time spent performing physical activity that is less than that recommended by guidelines (57,59,60), while other studies define inactivity on the basis of daily pedometer counts of less than 8,800 steps/day (58,61). The RCT in the current thesis defines sedentary lifestyle as engaging in less than 150 minutes a week of physical actitvity (12,13) and a pedometer was not used as a measure on account of limited resources.

Adherence to regular physical activity among adults with T2DM is also low. In both developed and developing countries, the proportion of adults with T2DM who engage in the recommended physical activity is between 3.0% and 56.0% (14,62–65). In Malaysia, only 33.3% of adults with T2DM engage in the recommended level of physical activity (37,47). Moreover, older people with T2DM are more likely to engage in low levels of physical activity (47,66). However, the recommended level of physical activity varies across these studies, making comparisons difficult. All studies recommended that physical activity should consist of at least 30 minutes a day of moderate to vigorous intensity activity. However, only one study defined the recommended frequency as five days or more in a week (66) while others recommended at least three days a week. This could reflect the guidelines in place when these studies were conducted.

A major reason for non-participation in regular physical activity is perceived barriers to physical activity (47,63,67–69). Most of these are related to personal issues such as poor health, lack of energy, lack of time, no motivation and fear of injury. Among people with diabetes, fear of exercise causing hypoglycaemia is a barrier and is reported most by those aged 60 years and older (69). Family obligation is also perceived as a barrier especially in women (63,68,70). The need to look after children or grandchildren, and doing household chores hinder participation in regular physical activities. Other barriers are related to the physical environment such as perception of not being safe, poor weather and lack of facilities (47,69,70).

Older people who reported fear of injury, unsafe environment or poor health as perceived barriers are less likely to be physically active (67). Moreover, people with a high level of physical activity reported fewer barriers to physical activity. The total number of perceived barriers reported is positively correlated with body mass index and systolic blood pressure among people with diabetes (63). Perceived barriers to physical activity vary among those of different ethnicities and cultural backgrounds (63,67,68). In an Australian study, the Vietnamese reported personal issues as barriers while the Macedonian and Croatian participants described the physical environment as a barrier (67). In addition, the Anglo Celtics and Italians in Australia reported fewer barriers than the Macedonians and Croatians. Cultural issues pertaining to women also pose as barriers to physical activity in some countries (63,67). Women of Arab and Pakistani descendant are not allowed to show their body shape to the opposite sex when wearing sports attire or attend public places. A lack of women-only facilities was therefore reported as discouraging women from engaging in regular physical activity. Feeling embarrassed about exercising in front of others is also among the perceived barriers to exercise (63,67).

Exploring the perceived motivators for physical activity or exercise is as important as identifying the barriers. Understanding these motivators will aid in counselling older people, especially those with T2DM, to initiate and maintain regular physical activity for health benefits. The motivators for people with T2DM to engage in regular moderate intensity physical activity include health, understanding the importance of physical activity for their medical condition, and improved physical and mental wellbeing (47,70). Family support has also been identified as a motivator. In some communities, the family is a source of motivation for people with diabetes to be healthy, so they could continue to provide care for their family members (70). In older people, the motivators for physical activity include the physical benefits of exercise such as increased strength and flexibility, reduced pain (related to osteoarthritis), and improved social interaction (71). So, understanding the barriers to exercise and what motivates people to exercise can facilitate the development of socio-culturally appropriate interventions to promote and maintain regular physical activity in older people, especially in the presence of T2DM. The current thesis uses focus group discussions to help inform the design of the physical activity intervention in this thesis, and these are presented in Chapter 3.

Interventions to promote physical activity in people with T2DM and in older people have been studied widely, and will be presented in Chapter 2 of this thesis. Over the past decade, there has been a growing literature on the role of peer support in the management of T2DM (61,72–82). Strategic approaches to promote best practice in peer support programmes have been developed by the World Health Organization (83) and Peers for Progress (84), with the key functions of peer support including "assistance in applying disease management and prevention plans in daily life, emotional and social support, linkage to clinical care and ongoing support" (84) (p.i64). However, there is limited evidence on the effect of peer support in promoting physical activity in general and in older people with T2DM (77). The current literature on peer support is focused on diabetes self-management education and support. In some studies, peer coaches or mentors provided peer support to patients with diabetes. Peer coaches or mentors are "individuals who successfully coped with the same condition and can be a positive role model" (85) (p.i26). Studies involving peer coaches or mentors have shown positive results such as improvement in glycaemic control (61,73,75,78–80,82), self efficacy (74,75), social support (73,80) and self-care behaviour that include physical activity (58,74,81,82). In studies measuring the frequency of contact with peer mentors, most recommended weekly contacts during the study period (58,74,81). Adherence rates to peer contact vary. In one study, the majority of the participants only had one contact over a 24-week period (81), while other studies had more than 50% of suggested contact over the study period (58,74). The frequency of contacts with peer mentors was positively correlated with the glycaemic control (79,80). The intervention was found to be equally effective when delivered by either health professionals or peer coaches/mentors, which suggests that peer support does have an adjunct role in health care delivery (58,75,82).

The role of feedback in promoting physical activity also has been studied in T2DM patients and in older people in general (60,86–93). In most studies, motion-sensor devices such as a pedometer and a physical activity log were used to provide feedback to increase participants' levels of physical activity. This is a form of personalised visual feedback that involves self-monitoring, and the devices were used as motivational tools (94). However, little is known about the effect of other types of feedback mechanisms in promoting physical activity, such as personalised contextualised feedback that includes goal setting and plans of action. Such feedback could strengthen self-efficacy and promote behaviour change. This thesis evaluates a physical activity intervention for older people with T2DM that incorporates feedback and peer support to increase physical activity.

1.4 The health care system for diabetes patients in Malaysia

Malaysia aims to become a high-income country by the year 2020 with one of its missions being to achieve the quality of life of an advanced nation (25). To achieve this, the focus is to ensure access to quality health care and to promote healthy lifestyles. The strategies proposed to accomplish these outcomes include: 1) to establish a comprehensive health care system and recreational infrastructure; 2) to encourage health awareness and healthy lifestyle activities; 3) to empower the community to plan or conduct individual wellness programmes (taking responsibility for their own health); and 4) to transform the health sector to increase efficiency and effectiveness of the delivery system. This is consistent with the aim of the current study, which is to encourage healthy lifestyle activities by empowering older people to be responsible for their own health.

The Malaysian health care system is provided by both the public and private sectors. Private health care facilities consist of private hospitals, private medical practitioner (GP) clinics, clinics in factories and industries, and clinics run by non-governmental organisations. The Ministry of Health (MoH) together with the other non-MoH governmental organisations such as the Ministry of Defence, Department of Aborigines, Ministry of Women, Family and Community Development, and Ministry of Higher Education represent the public health care system. The health care facilities under the Ministry of Health comprise the public secondary and tertiary hospitals, and the primary health care clinics under the public health facilities. A seamless referral system exists linking the different levels of care in the public system. In Malaysia, the public health care system is funded from central taxation. Civil servants including their spouses, children aged less than 21 years and parents, are entitled to seek medical treatment at any public hospital or clinics without being charged (95). In medical teaching hospitals and clinics, and the National Heart Institute, civil servants and their dependants pay a minimum fee. Malaysian citizens aged 60 years and above are exempted from registration and consultation fees (usually RM 1.00 at the primary health care clinics and RM 5.00 at a hospital’s outpatient clinics; RM 1.00 = AUD 0.33 on 1 May 2014) at all public primary health care and hospital clinics. These fees include fees for consultation and counselling, laboratory and imaging investigations, and treatments and medications provided at outpatient services.

In 2008, more of the population utilized public health care facilities (93.6%) than private facilities (6.4%) (96). Among the attendees at the public facilities, 54.4% received care from the Ministry of Health's primary heath care clinics while others receive care from the outpatient clinics of the Ministry of Health's hospitals or special medical institutions, or the non-Ministry of Health public facilities. In the public sector, care for diabetes patients is provided by the primary health care clinics and/or the hospital's medical outpatient clinics. Most diabetes patients are seen at primary health care clinics, however, determining the setting of this present study (97).

In the primary health care clinics, diabetes care is managed by the family physicians and medical and health officers, supported by diabetes specialised nurses and nutritionists. The diabetes care team in the hospitals comprises the internal medicine physicians or endocrinologist, medical officers, a diabetes nurse educator and dieticians. The usual diabetes care provided in all public facilities includes lifestyle modification (diet and exercise), medications and education to encourage self-care (44). In the primary health care clinics, diabetes patients typically visit the clinic every three or four months in a year; some may be seen at a more frequent intervals depending on their disease control. Cardiovascular disease control surveillance is conducted annually. Patients receive care from medical and health officers and will be seen by family physicians if the diabetes becomes uncontrolled or they develop complications. Complicated or uncontrolled patients also receive shared care with the hospital's specialists (depending on the need for sub-specialised care). The nutritionists who provide education on healthy diet and dietary prescriptions visit the primary health care clinics at monthly interval.

However, there is no structured diabetes education programmes in these clinics. Usually, the attending doctors provide diabetes education during the five- to ten-minute consultations. Some patients do not receive dietary prescription as the nutritionist only attends the clinic once a month. The patients do not receive a formal education on the role of physical activity in diabetes. Usually they receive advice to increase their physical activity levels from their attending doctors during the brief five- to 10-minute consultation. In recent years the number of attendees at the public primary health care clinics has increased. The overall attendance of older people at Malaysian public health care clinics for health conditions including T2DM has doubled from 400,000 in 2007 to 800,000 in 2008 (97). The increased workload, time constraints and lack of personnel may detract from efforts to improve ongoing diabetes education in these clinics. Peer support could be a cost effective adjunct to care for people with T2DM. Therefore, there is a need to evaluate its role in a Malaysian setting.

1.5 Theoretical framework

This thesis incorporates constructs of Social Cognitive Theory (SCT) to promote change from sedentary behaviour to being physically active (98–100). Bandura (98) defined behaviour as a dynamic process that involves interaction between the person, behaviour and the environment. Health behaviour change is more likely when a person believes in his or her own capacity to change (self-efficacy) and values the outcome expectancies as a result of personal action (100). Self-efficacy is influenced through personal *mastery experiences*, where a person persistently attempts to master challenging tasks despite difficulties (99). In addition, self-efficacy 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 through perseverance), and physiological and emotional states (relying on one's physiological and emotional responses to the activity to judge one's capacity). According to SCT, a supportive social environment must be established and self-efficacy enhanced to ensure behaviour change. The behavioural capability is also supported by goal setting, capacity building and self-monitoring support (100). Goal setting and other decisional processes set the stage for personal change that is influenced by perceived motivators for and barriers to an intended behaviour. Figure 1.2 summarises the theoretical framework of this study.

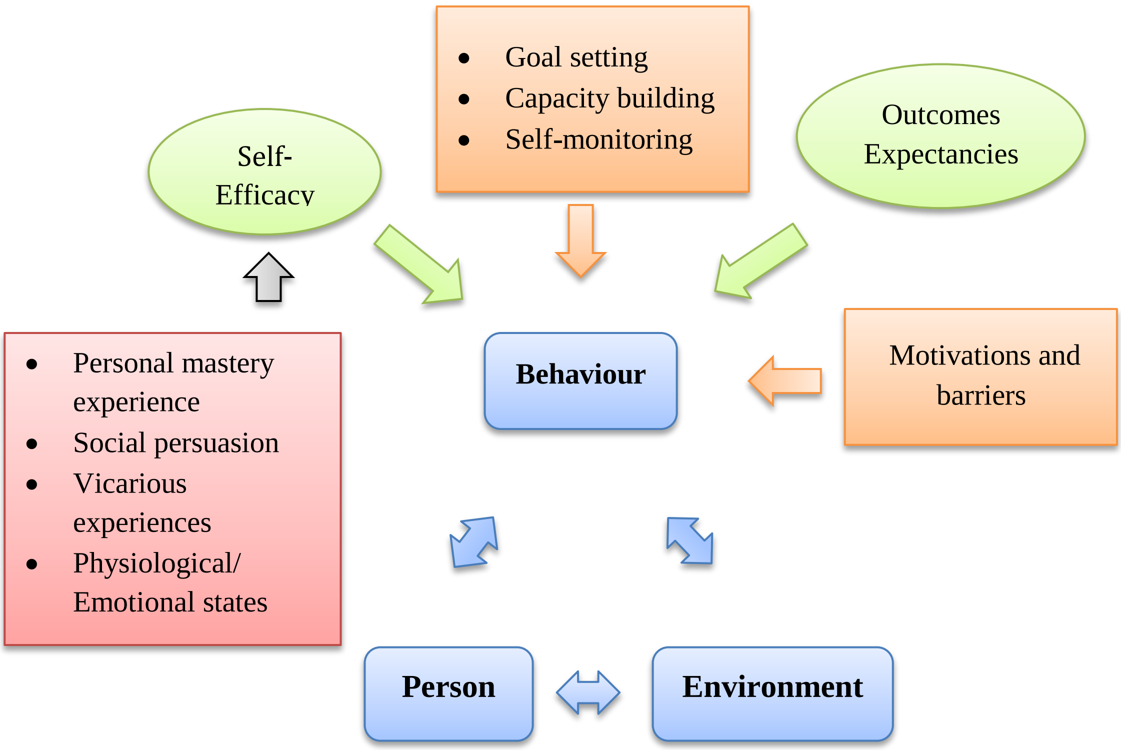

Figure 1.2: Theoretical framework

(Source: Bandura, 1986) (98)

An aim of this current study is to promote physical activity in sedentary older people through personalised feedback alone or in combination with peer support, and specifically to increase walking activity and improve glycaemic control and related risk factors in older Malays. The study participants need to adopt a new behaviour, which is regular walking activity. The confidence to adopt this new behaviour can be influenced by personalised feedback and peer support. However, the feedback needs to be tailored to the participants' identified barriers to and motivators for physical activity. It is assumed the personalised feedback about the participants' personal performance accomplishments will motivate them to continue engaging in regular walking activity. Also, performing the walking activity will strengthen their self-efficacy. In the peer support group, self-efficacy can be strengthened through the experiences and accomplishments of their peer mentors in engaging in regular walking activity. It is assumed that participants would be able to learn from others' experiences and be motivated to change their behaviour and/or preserve the new behaviour. Furthermore, the fears and uncertainties that may accompany starting regular walking activity can be alleviated through the social support received from peer mentors and peers. Therefore, the study tests whether regular walking activity can be enhanced by personalised feedback alone or in combination with support from peer mentors.

1.6 Rationale for the study

There is still dearth of information on promoting physical activity among older people with T2DM especially in South East Asia. This is of concern because there is increasing evidence that older people especially those with T2DM, will benefit by being physically active and that sedentary behaviour should be discouraged (12). Furthermore, the intervention approach to promoting physical activity among older people differs from that appropriate to younger adults, especially in the presence of chronic non-communicable diseases and disability because of age-related changes, and increased susceptibility to hypoglycaemia (12,101).

Identification of the perceived motivators for and barriers to physical activity would aid in promoting physical activity behaviours in sedentary older people with T2DM. Also, the increasing evidence for the positive role of peer support in a diabetes care team may promote self-care management and improve metabolic control among people with T2DM, and ease the burden on health care resources. The role of peer support for older people with T2DM in promoting and maintaining physical activity is not well documented in the literature. In addition, while providing feedback to people to improve their levels of physical activity has been documented in the literature, little is known about the effect of feedback using goal setting and plan of actions in promoting and maintaining physical activity.

Promoting physical activity for the management of T2DM in older people is relevant in Malaysia. The rapid increase in the incidence of T2DM and a shift towards an ageing population warrants the need for an intervention programme to improve the functional status of older people with diabetes. Older people with T2DM have low levels of physical activity, and those who are less active have poorer glycaemic control. In addition, older Malay people with T2DM were chosen as the study sample because Malays have a high prevalence of T2DM and have poorer glycaemic and metabolic control, as well as having the lowest prevalence of adequate physical activity compared with the Chinese and Indian ethnic groups. There are limited health care resources (both human and financial) in Malaysia to provide ongoing diabetes self-management education and support. Peer support and personalised feedback for physical activity in the management of people with T2DM may prove to be a cost-effective approach.

In this study, an urban primary health care clinic in the state of Selangor was selected (see Figure 1.3). Selangor is the most populous of the 16 states of Malaysia, with approximately 5.4 million inhabitants out of the total national population of 28.3 million (23). The state capital is Shah Alam, with an area of 290.3 square km and a population of 646,890 (102). It has 56 residential sectors and was granted city status in the year 2000 on account of its rapid economic development. The ethnic groups in Shah Alam comprise 71.1% Malays, 16.7% Chinese, 11.2% Indians and 0.1% other ethnic groups. About 2.4% of its population are people aged 65 years and above.

Figure 1.3: Map of Selangor in Malaysia

Selangor has nine administrative districts, with 55 public primary health care clinics out of a total 846 clinics in Malaysia (103). Among these, 18 are in the urban areas. The public primary health-care clinics are called community polyclinics, and are community-based clinics under the Ministry of Health. According to the Malaysian Third National and Health Morbidity Survey in 2006, the residents in the state of Selangor had the highest prevalence of physical inactivity (52.1%), and urban adults (45.6%) were found to be more inactive compared to their rural counterparts (40.1%) (31). In addition, more diabetes patients receive care from the primary health care clinics than in private clinics. This is the rationale for selecting an urban primary health care clinic in Selangor as the setting for this study.

Out of the 18 urban polyclinics in the state, Shah Alam Community Polyclinic was selected for this study. This is because the clinic has a community programme for older people linked to a senior citizens' club in Shah Alam, while none of the other urban clinics in Selangor has such a linkage. Engagement with this club could provide an avenue for future programmes from this study to be extended into the community. The Shah Alam Community Polyclinic is staffed by a family physician with a team of medical and health officers, assistant medical officers, registered staff nurses, and community nurses (97). In-house pharmacists, medical laboratory technicians, a radiographer, and a visiting physiotherapist, occupational therapist and nutritionist also support the polyclinic. The polyclinic provides comprehensive multidisciplinary care, which includes outpatient care, maternal, and child health care, and has ambulance and emergency services. In addition, it offers services for cardiovascular screening, adolescent and geriatric care, community health promotion and wellness with a focus on self-examination, healthy eating, physical exercise, smoking cessation and healthy mind.

1.7 Thesis objectives and research questions and hypotheses

The study in this thesis has three phases: Phase 1, a systematic review; Phase 2, a qualitative focus group study and Phase 3, a randomised controlled trial. The following objectives guided this study. From these objectives, related research questions and hypothesis were developed.

Phase 1 – Systematic review

1. Objective:
    - To systematically review the scientific evidence on interventions promoting physical activity in older people with T2DM.

2. Research question:
    - What are the current strategies employed in interventions promoting physical activity in older people with T2DM?

Phase 2 – Qualitative focus group discussions

1. Objectives:
    - To explore the socio-cultural perceptions of physical activity and motivators for and barriers to physical activity in the older Malay community with T2DM.
    - To pilot the use of the pedometer and activity diary keeping.

2. Research questions:
    - How do older Malays with T2DM define physical activity and what are the perceived motivators for and barriers to physical activity in the older Malay community with T2DM?
    - How receptive are older Malays to the use of pedometers and activity diaries?

Phase 3 – Randomised controlled trial

1. Objective:
    - To determine the effectiveness of an intervention that incorporates personalised feedback about physical activity patterns alone and in combination with peer support, in addition to the usual diabetes care, on the levels of physical activity, cardiovascular diseases risk factors, functional status, quality of life and psychosocial wellbeing in older Malays with T2DM.

2. Research questions and hypotheses:

This study set out to test the research hypotheses to answer research questions 2.6 to 2.10.

2.1 What is the level of physical activity among sedentary older Malays with T2DM based on daily pedometer readings (primary outcome), weekly duration and frequency of structured physical activity, Physical Activity Scales for the Elderly (PASE) scores and PASE daily activities while seated?

2.2 What are the cardiovascular disease risk factors among sedentary older Malays with T2DM as measured by glycosylated haemoglobin (HbA1c), blood pressure (BP), weight, body mass index (BMI), waist circumference, body fat percentage, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides?

2.3 What is the functional status among sedentary older Malays with T2DM as measured by six-minute walk test (cardiorespiratory fitness), and timed up and go test (balance)?

2.4 What is the quality of life among sedentary older Malays with T2DM as measured by physical component summary (PCS) and mental component summary (MCS) scores of SF-12 Health Survey?

2.5 What is the psychosocial wellbeing among sedentary older Malays with T2DM as measured by General Health Questionnaire-12 (GHQ-12), Multidimensional Scale for Perceived Social Support (MSPSS) and Self Efficacy for Exercise Scale (SEES)?

2.6 Is there a difference in the levels of physical activity of sedentary older Malays with T2DM across the study period between the personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care groups?

Research hypothesis 2.6:

There will be a significant difference in the levels of physical activity between the three groups (personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care) across the study period on the following measures:

a) Daily pedometer readings (primary outcome)
b) Weekly duration of structured physical activity
c) Weekly frequency of structured physical activity
d) PASE scores
e) PASE daily activities while seated

2.7 Is there a difference in cardiovascular disease risk factors of sedentary older Malays with T2DM across the study period between the personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care groups?

Research hypothesis 2.7:

There will be a significant difference in cardiovascular disease risk factors between the three groups (personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care) across the study period on the following measures:

a) HbA1c
b) Systolic blood pressure
c) Diastolic blood pressure
d) Weight
e) Body mass index
f) Waist circumference
g) Body fat percentage
h) Low-density lipoprotein cholesterol (LDL-C)
i) High-density lipoprotein cholesterol (HDL-C)
j) Triglycerides

2.8 Is there a difference in functional status of sedentary older Malays with T2DM across the study period between the personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care groups?

Research hypothesis 2.8:

There will be a significant difference in functional status between the three groups (personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care) across the study period on the following measures:

a) Six minute walk test

b) Timed up and go test

2.9 Is there a difference in the quality of life of sedentary older Malays with T2DM across the study period between the personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care groups?

Research hypothesis 2.9:

There will be a significant difference in the quality of life between the three groups (personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care) across the study period on the following measures:

a) SF-12 physical component summary scores

b) SF-12 mental component summary scores

2.10 Is there a difference in the psychosocial well being of sedentary older Malays with T2DM across the study period between the personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care groups?

Research hypothesis 2.10:

There will be a significant difference in the psychosocial wellbeing between the three groups (personalised feedback on physical activity patterns alone (PF) and in combination with peer support (PS) and usual diabetes care) across the study period on the following measures:

a) General Health Questionnaire-12

b) Multidimensional Scale for Perceived Social Support (significant others)

c) Multidimensional Scale for Perceived Social Support (family)

d) Multidimensional Scale for Perceived Social Support (friends)

e) Self-Efficacy for Exercise Scale

CHAPTER 2 SYSTEMATIC REVIEW: INTERVENTIONS PROMOTING PHYSICAL ACTIVITY IN OLDER PEOPLE WITH TYPE 2 DIABETES MELLITUS

This chapter describes the first phase of this thesis, which is a systematic review. It includes the search methods and strategies to identify relevant studies, the data extraction and synthesis, and discusses the findings of the selected studies. A manuscript on this systematic review, entitled: "Interventions to promote physical activity in older people with type 2 diabetes mellitus: A systematic review", has been published in *Frontiers in Public Health* 2013 Dec;1. doi: 10.3389/fpubh.2013.00071(see Appendix A.1).

Type 2 diabetes mellitus (T2DM) is one of the most common chronic non-communicable diseases (NCDs) globally, especially in the developing countries (5). Its prevalence continues to grow with changes in lifestyle and increased obesity among all ages including older people. Current estimates indicate a growing burden of T2DM both worldwide and in Malaysia, which is the setting for the study reported in this thesis (6). Therefore, globally there has been an emphasis on the role of lifestyle factors such as regular physical activity in offsetting the increasing prevalence of T2DM. Indeed, regular physical activity is one of the key elements in the management of T2DM. Many people with T2DM, especially older people remain sedentary or inactive despite many health benefits of physical activity (10,11). A systematic review of the literature was conducted to gain a deeper understanding of the evidence on promoting physical activity in older people with T2DM and to compare and evaluate such interventions.

2.1 Methods

A systematic review using the qualitative synthesis method was conducted to retrieve and review the findings of previous literature on interventions promoting physical activity in older people with T2DM. The process started with a search question: What are the interventions that are successful in promoting physical activity in older people with T2DM? The question was formulated using the PICOS (Participant, Intervention, Control, Outcomes, Study design) approach as shown in Table 2.1. The objective, characteristics of the study, contents of the intervention, targeted outcome and major findings for each of the selected studies were assessed in this review.

Table 2.1: Formulating the search question

Question	Element	
Who are the group of patients?	Participants	Adults aged ≥60 years with T2DM
What intervention to evaluate?	Intervention	Approaches promoting physical activity
What is the main or usual alternative?	Comparison	Usual care, waitlist
What could the intervention offer?	Outcomes	Level of physical activity
What is (are) the study design(s)?	Study design	Randomised controlled trial, quasi-experimental design

This qualitative systematic review described the criteria for study selection and the search methods for identification of studies, detailed qualitative synthesis of the selected studies and the discussion of the findings. In this review, physical activity was used instead of exercise, as exercise is a subset of physical activity. Physical activity is defined as "body movement that is produced by the contraction of skeletal muscles and that increases energy expenditure", while exercise is "planned, structured, and repetitive movement to improve or maintain one or more components of physical activity" (13) (p.1511).

2.1.1 Criteria for study selection

The criteria for considering studies in this review included types of study, types of participants, types of interventions and types of outcome measures.

Types of study

All randomised controlled trials and quasi-experimental designs comparing different strategies to promote sedentary older people with T2DM to engage in regular physical activity were considered in this review. Studies that include self-management of diabetes and combined lifestyle (diet and physical activity) were also included. Review articles were not included.

Types of participants

Studies that included older people aged 65 years and above with T2DM and living in the community were considered for this review. Those that included people with type 1 diabetes mellitus and impaired glucose tolerance were not included in the review. However, studies reporting combined results for T2DM and impaired glucose tolerance were included if the analysis of these results were conducted separately.

Types of interventions

This review included studies with interventions to promote physical activity among adults. The interventions may include one or a combination of:

- One-to-one or group counselling or advice
- Self-directed or prescribed physical activity
- Supervised or unsupervised physical activity
- Ongoing one-to-one support
- Telephone support
- Written motivation support material
- Self-monitoring using a pedometer or accelerometer

Interventions that promoted physical activity in order to achieve a secondary goal such as weight reduction were also included. Interventions conducted by one or combinations of intervention providers were considered. The intervention providers could be health care providers (physician, nurse, health educator, dietitian, counsellor), exercise specialists, peer coaches/mentors and/or community health workers. No restrictions were applied about the type and contents of the control group. The interventions could be compared with a no-intervention control, a group assigned to a waiting list, attention control (receiving attention such as the usual diabetes care matched to length of intervention) or a minimal intervention control group.

Types of outcome measures

The primary outcome measured in the selected studies was change in the level of physical activity. At least one of the outcomes must describe change in physical activity levels (such as change in amount or quantity of physical activity). The change in physical activity could be self-reported (using questionnaire) and/or based on pedometer and/or accelerometer readings between baseline, post-intervention and follow-ups. The levels of physical activity could be expressed as estimated total energy expenditure, total minutes of physical activity, achieving recommended threshold for physical activity, and daily step counts. Studies with changes in cardiovascular disease risk factors (such as blood pressure and anthropometric measurements) and biochemical markers (glycosylated haemoglobin, lipid profile) related to T2DM were included.

2.1.2 Search methods for identification of studies

The search was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (104). The process of this search method included describing the data sources, search strategy, data extraction and quality assessment.

Data sources and search strategy

The studies were searched electronically using the following databases: OvidMEDLINE, PubMed, EMBASE, SPORTDiscus and CINAHL. The reference lists of reviewed articles and included studies were hand searched for other potentially eligible studies using the selection criteria described earlier. Other potentially eligible studies were sought through experts in the field. Published systematic reviews on physical activity were used as a source of randomised controlled trials. Peer-reviewed published articles between years 2000 and December 2012 were used. Because of limited resources for translation, only articles published in English were considered. No attempts were made to contact authors for additional information, but cross-referencing on related previously published studies was performed to obtain additional information. As an example, the search strategy used for OvidMEDLINE is described in Table 2.2. Comparable searches were made for the other databases (see Appendix B.1 – B.4). In addition, searches through a local library for archived articles from the South East Asian region using the previously described selection criteria were also conducted.

Table 2.2: Search strategy for OvidMEDLINE

Dates 2000 – Dec 2012	
1	Physical activity.mp
2	Exp Exercise/
3	Exp Walking/
4	Exp Physical Exertion/
5	Exp Sports/
6	Exp Lifestyle/
7	Exp Physical fitness/
8	Strength training.mp
9	Exp Resistance training/
10	Aerobics.mp
11	Physical$.mp
12	Exercis$.mp
13	Sport$ .mp
14	Aerobic$.mp
15	Walk$.mp
16	Lifestyle$.mp
17 (or/1-16)	
18	Exp Diabetes mellitus, type 2/
19	Exp Diabetes mellitus/
20 (or/18-19)	
21	Exp Health Education/
22	Exp Patient Education/
23	Exp Health Promotion/
24	Promot$.mp
25	Educat$.mp
26	Program$.mp
27 (or/21-26)	
28 (17 and 20 and 27)	
29 (limit 28 to (English language and All aged 65 and over and RCT or quasi-experimental)	

Note: RCT=Randomised controlled trial

Data extraction and quality assessment

The titles and abstracts of every study retrieved from the search were reviewed following the criteria for study selection to determine if full-text articles were required for further evaluation. Each full-text article retrieved was evaluated systematically according to: 1) the study's objective(s); 2) targeted health behaviour (physical activity, self-management, or combined physical activity and nutrition); 3) characteristics (study design, participants' age, behavioural theoretical model, and sample size); 4) contents of the intervention (intervention strategies, intervention provider, length of intervention and follow-up contacts); 5) targeted outcome(s); and 6) major results. The nature of this qualitative systematic review meant that the data and outcomes extracted from the selected studies were not combined and re-analysed.

Each selected article was further evaluated for methodological quality. A list of 13 criteria was used to assess the quality of selected articles' methodology and its scoring method was adopted from a systematic review on internet-based physical activity interventions (105), as presented in Table 2.3. All criteria were scored as "yes", "no", or "unclear", resulting in a summary score between 0 and 13. A good methodological quality of study was considered if two thirds or more of the criteria were fulfilled that gave a summary score of 9 or higher.

Table 2.3: Criteria of methodology quality

1.	Were the eligibility criteria specified?
2.	Was the method of randomisation described?
3.	Was the random allocation concealed? (i.e. Was the assignment generated by an independent person not responsible for determining the eligibility of the patients?)
4.	Were the groups similar at baseline regarding important prognostic indicators?
5.	Were both the index and the control interventions explicitly described?
6.	Was the compliance or adherence with the interventions described?
7.	Was the outcome assessor blinded to the interventions?
8.	Was the dropout rate described and were the characteristics of the dropouts compared with the completers of the study?
9.	Was a long-term follow-up measurement performed (outcomes measured $\geq$ 6 months after randomization)?
10.	Was the timing of the outcome measurements in both groups comparable?
11.	Was the sample size for each group described by means of a power calculation?
12.	Did the analysis include an intention-to-treat analysis?
13.	Were point estimates and measures of variability presented for the primary outcome measures?

2.2 Results

2.2.1 Study selection

The initial search identified 696 potential articles from the databases search and another 25 were found through cross-referencing. After removing duplicates, 556 articles were assessed based on titles and abstracts against the selection criteria. A total of 520 studies were excluded because they were not on physical activity or T2DM, their designs were not RCT or quasi-experimental, or the measured outcomes did not include the levels of physical activity. Of the 36 full-text articles retrieved for further evaluation, 21 were included in the final qualitative synthesis. Fifteen studies were excluded. Ten of the studies' interventions did not promote physical activity, two studies were not an RCT or quasi-experimental design, one did not include people aged 65 years and above, one was not on T2DM and one had a comparison group using walking aids. Figure 2.1 describes the PRISMA flow diagram for the study selection.

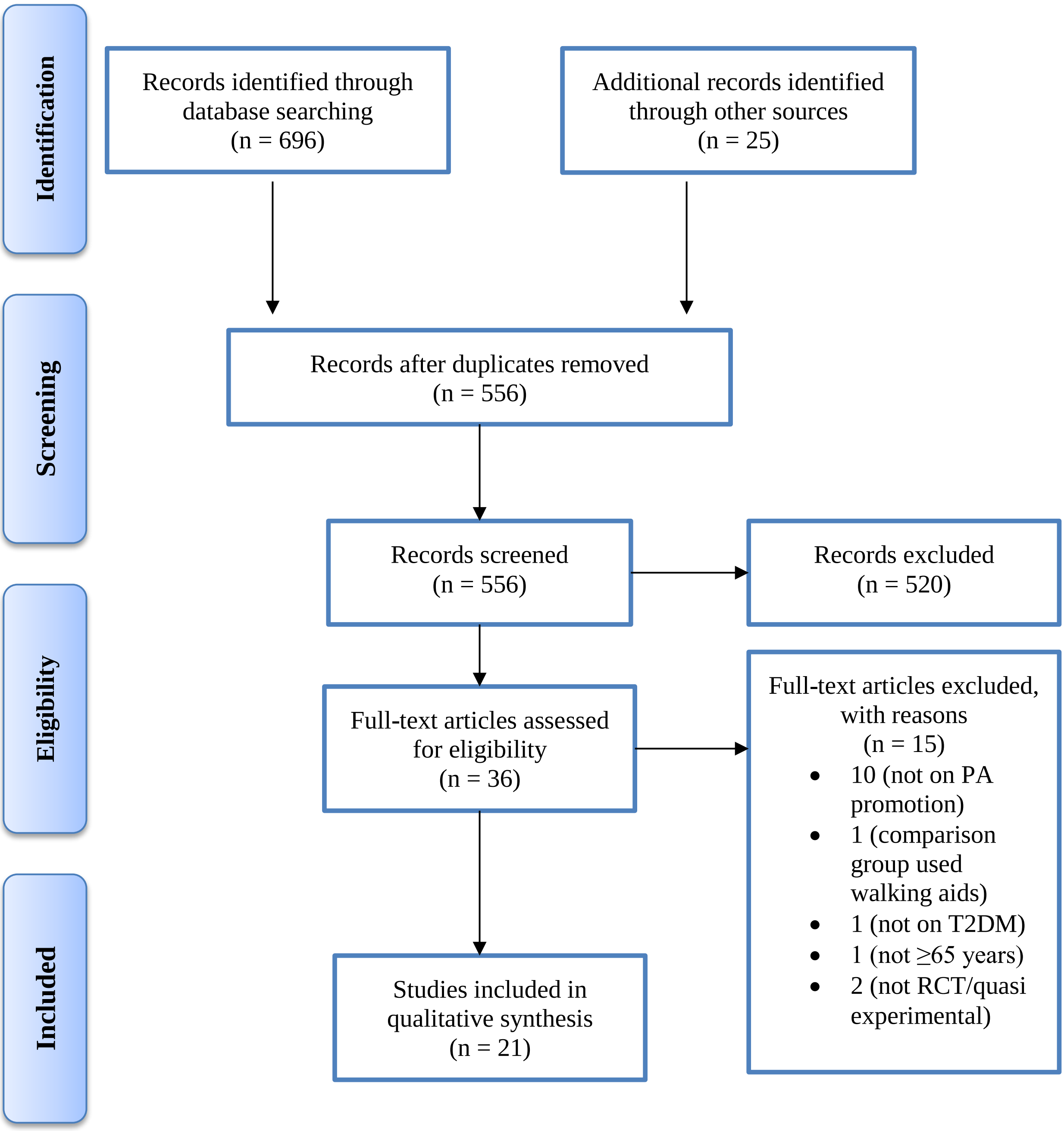

Figure 2.1: PRISMA flow diagram for study selection

2.2.2 Data extraction and synthesis

All articles were published between the years 2000 and 2012, with the majority (90.5%) published after the year 2005. All were published in the English language.

Selected studies and participants

Table 2.4 describes the characteristics of the selected studies and participants. Out of the final 21 studies selected for the review, 18 were randomised controlled trials (RCT) (57,59,60,87,90,92,106–117). Three studies were three-arm RCTs (90,106,117) and one was a pilot RCT (59). Another three of the 21 studies were quasi-experimental designs (58,86,118). Ten studies were conducted in North America (Canada and the United States) (58,59,107,109,110,113–115,117,118), nine studies were conducted in Europe (Italy, the United Kingdom, Belgium, the Netherlands and Norway) (57,87,90,92,106,108,111,112,116), and two were conducted in Australia (60,86). No studies from the Asian region conducted interventions to promote physical activity in adults with T2DM.

Most of these studies were conducted in a clinical setting such as primary health care clinics (59,106,107,109,110,113–115,117) or outpatient clinics in tertiary care centres (57,58,87,92,108,111,112,118). About half of the selected studies' interventions focused on physical activity (57–60,87,90,92,106,108,111–113,116), and others on self-management of diabetes (86,107,109,110,114,115,117,118). The length of the interventions varied between two weeks and five years. Most often the chosen length of intervention was either 12 weeks (87,106,110,118), 16 weeks (58,112), 24 weeks (60,92,108,116), or a year (90,109,111,114,117). Only three studies had post-intervention follow-ups ranging between 20 weeks to one year (86,87,108).

At first, articles with people aged 65 years and above were filtered; however, the search of the databases also captured articles with participants in younger age groups. Only one study specifically studied older people aged 65 to 80 years (107). Therefore, for this review, all studies that included participants aged 18 years and above, as well as 65 years and above, with T2DM were included. One study specifically included postmenopausal women (114) and another included participants with impaired glucose tolerance (86). Two studies had women only as participants (114,117), while three targeted adults of specific ethnic minority groups (109,110,117). Eight studies targeted adults who were either inactive (57–59,90,112) or sedentary (60,111) at enrolment. Of these studies, three provided a definition of inactivity, but the definition varied widely (57–59) and one defined sedentary behaviour (60). Two studies specifically included participants who were overweight, with a body mass index of 25–35 kg/m^2 (106,108).

The types of physical activity prescribed in these studies were also diverse. In some studies the prescribed physical activity described by the authors was specific. These included unsupervised walking (58,60,86,92,106–108,118), a supervised group-based walking exercise (112), and supervised aerobic and resistance training (111). However, in some studies the participants were given a choice of physical activity. The participants either built on their present physical activity level (57,87,110,113,115), targeted moderate intensity physical activity, (59,109,114,116) or chose the intensity of the physical activity based on their present chronic diseases' condition (90,117). Most of the studies adopted a self-directed regime targeting towards the recommended levels of physical activity. Only two had a supervised physical activity regime: one offered a walking group led by personal exercise trainers (112) while another offered supervised aerobic and resistance training (111).

Table 2.4: Characteristics of selected studies and participants

Study/ Country	Study design	Setting	Targeted health behaviour	Length of intervention/ Follow up (weeks/years)	Age	No. of participants randomised	Types of participants	Description of physical activity
De Greef et al, 2011 (106), Belgium	3 arm RCT	Primary health care	Physical activity	12 weeks/-	≤80 years	67 (CG: 24; IG by general practitioner: 22; IG by behavioural expert: 21)	Overweight (25–35 kg/m^2) with T2DM, HbA1c ≤12%, no physical limitations	Walking
Kirk et al, 2009 (90) , UK	3 arm RCT	Multifaceted	Physical activity	1 year/ -	Age not stated	134 (CG: 35; IG consultation by person: 47; IG consultation by written form: 52)	Inactive (?), with T2DM, in contemplation or preparation stage of behaviour change	Choice of moderate to vigorous PA
Keyserling et al, 2002 (117), USA	3 arm RCT	Primary health care	Self management	1 year/ -	≥40 years women	200 (CG: 67; IG Clinical+ Community based intervention: 67; IG Clinical based intervention: 66)	African American women with T2DM	Choice of non weight bearing, mild or moderate intensity PA
Weinstock et al, 2011 (107), USA	RCT	Primary health care	Self management	5 years/-	65-80 years	1650 (CG: 813; IG: 837)	Older adults with T2DM from underserved areas	Walking
De Greef et al, 2011 (108), Belgium	RCT	Tertiary care	Physical activity	24 weeks/ 1 year	35-75 years	92 (CG: 32; IG: 60)	Overweight (25–35 kg/m^2), ≥6 months of T2DM, HbA1c ≤12%, no physical limitations	Walking
Toobert et al, 2011 (109), USA	RCT	Primary health care	Self-management	1 year/ -	30-75 years	280 (CG: 138; IG: 142)	Adults of Latina ethnicity, with ≥6 months of T2DM	Moderate PA

Note: RCT=randomised controlled trial; Multifaceted=media, primary health care, tertiary care, diabetes programs; CG=control group; IG=intervention group; T2DM=type 2 diabetes mellitus mellitus; HbA1c=glycosylated haemoglobin; PA=physical activity; (?)=no description provided.

Study/ Country	Study design	Setting	Targeted health behaviour	Length of intervention/ Follow up (weeks/years)	Age	No. of participants randomised	Types of participants	Description of physical activity
Wisse et al, 2010 (57), Netherlands	RCT	Tertiary care	Physical activity	2 years/ -	Age not stated	74 (CG: 36; IG: 38)	With T2DM, on insulin treatment, inactive (PA ≤160 min/week)	Build on present level of PA
Negri et al, 2010 (112), Italy	RCT	Tertiary care	Physical activity	16 weeks/ -	50-75 years	59 (CG: 21; IG: 39)	Inactive (?), ≥2 years of T2DM, HbA1c 6.5% - 9.9%	Group based walking exercise
Osborn et al, 2010 (110), USA	RCT	Primary health care	Self management	12 weeks / -	≥18 years	118 (CG: 59; IG: 59)	Puerto Rican ethnicity, ≥1 year of T2DM	Build on present level of PA
De Greef et al, 2010 (87), Belgium	RCT	Tertiary care	Physical activity	12 weeks/ 1 year	35-75 years	41 (CG: 21; IG: 20)	T2DM ≥6 months, no medical or physical limitations	Build on present level of PA
Balducci et al 2010 (111), Italy	RCT	Tertiary care	Physical activity	1 year/ -	40-75 years	606 (CG: 303; IG: 303)	With T2DM, sedentary lifestyle (?), no contraindications to physical activity	Supervised group aerobic & resistance training
Dutton et al, 2008 (113), USA	RCT	Primary health care	Physical activity	4 weeks/ -	≥18 years	85 (CG: 39; IG: 46)	With T2DM, able to participate in moderate intensity activity	Build on present level of PA
Bjørgaas et al, 2008 (92), Norway	RCT	Tertiary care	Physical activity	24 weeks/ -	<80 years	69 (CG: 37; IG: 31)	With T2DM, no complications and no limitation of walking	Walking
Toobert et al, 2007 (114), USA	RCT	Primary health care	Self management	1 year/ -	<75 years women	279 (CG: 116; IG: 163)	T2DM ≥6 months, post menopausal, not disabled	Moderate PA
Engel et al, 2006 (60), Australia	RCT	Community	Physical activity	24 weeks/ -	50-70 years	57 (CG: 30; IG: 24)	With T2DM, sedentary (≤30 min/week of PA)	Walking

Note: RCT=randomised controlled trial; Multifaceted=media, primary health care, tertiary care, diabetes programs; CG=control group; IG=intervention group; T2DM=type 2 diabetes mellitus mellitus; HbA1c=glycosylated haemoglobin; PA=physical activity; (?)=no description provided.

Study/ Country	Study design	Setting	Targeted health behaviour	Length of intervention/ Follow up (weeks/years)	Age	No. of participants randomised	Types of participants	Description of physical activity
King et al, 2006 (115), USA	RCT	Primary health care	Self management	8 weeks/ -	≥25 years	335 (CG: 161; IG: 174)	T2DM ≥6 months, able to participate in moderate intensity PA	Build on choice of present level of PA
	RCT	?	Physical activity	24 weeks/ -	Age not stated	70 (CG: 35; IG: 35)	With T2DM, in contemplation or preparation stage of behaviour change	Moderate PA
Allen et al, 2008 (59), USA	Pilot RCT	Primary health care	Physical activity	8 weeks/ -	>18 years	52 (CG: 25; IG: 27)	With T2DM, not on insulin, inactive (<3 days/week of PA), HbA1c >7.5%	Moderate PA
Diedrich et al, 2010 (118), USA	Quasi experimental	Tertiary care	Self management	12 weeks/ -	23-89 years	53 (CG: 26; IG: 27)	With T2DM	Walking
Tudor-Locke et al, 2009 (58), Canada	Quasi experimental	Tertiary care	Physical activity	16 weeks/ -	40-70 years	220 (Intervention by professionals: 157; Intervention by peers: 63)	With T2DM, inactive (walks <8800 steps/day) with no contraindication to walking	Walking
Furber et al, 2008 (86), Australia	Quasi experimental	Community	Self-management	2 weeks/ 20 weeks	Age not stated	226 (CG: 105; IG: 121)	With T2DM or impaired glucose tolerance	Walking

Note: RCT=randomised controlled trial; Multifaceted=media, primary health care, tertiary care, diabetes programs; CG=control group; IG=intervention group; T2DM=type 2 diabetes mellitus mellitus; HbA1c=glycosylated haemoglobin; PA=physical activity; (?)=no description provided.

Characteristics of interventions

Table 2.5 presents the characteristics of the interventions promoting physical activity and the control conditions. The interventions used in each study vary markedly. Most studies delivered their interventions either in a group (58,86,87,109,110,114) or using one-to-one counselling or advice (57,59,60,90,92,107,108,111,113,115,116,118). Two studies used combined group and one-to-one counselling (112,117), while one compared the effects of one-to-one counselling to group counselling (106). Other intervention strategies included printed or written prescription (90,113), information and communication technology (ICT) such as a telemedicine intervention via videoconference (107) and interactive CD-ROM technology (115), and personalised feedback (58,59,86,87,92,106,108,118). Most studies used devices such as pedometer readings as personalised feedback (58,86,87,92,106,108,118) and one used a printed graph from the participants' continuous blood glucose monitoring as a feedback mechanism (59).

One or more health care providers including physicians, psychologists, diabetes educators, dietitians, exercise physiologists, physiotherapists and community diabetes advisors, delivered the interventions of the studies (57,58,86,87,106–112,114,115,117,118). In five studies, the research team delivered the interventions alone or with other health care providers (59,60,90,92,113,116). Four studies used peers and other health care providers to deliver their intervention strategies (58,109,114,117).

All the studies' participants had at least one contact with the intervention provider. As part of support and motivation to adopt physical activity, eight studies contacted the participants on 2 or more occasions in the first four weeks of the intervention (57,58,108,109,111,112,114). Some studies offered follow-ups throughout the period of intervention as part of the motivational and relapse prevention strategies using one (or a combination) of the following approaches: one-to-one or group meetings (57,60,87,107,109,111,114,117), telephone calls (57,59,90,108,115–117) and/or written motivational messages such as a tailored health newsletter (115). The participation rate in the studies was reasonable, ranging between 69.9% and 95.7% (mean 84.75±SD8.59%); however, participants who complied with the intervention ranged widely between 33.3% and 96.0% (mean 66.56±SD18.99%) as reported in only eight studies (58,86,87,111,112,114,115,117).

Most studies incorporated one or a combination of health behaviour theories or models in their interventions. The most commonly adopted health behaviour theory was social cognitive theory (58,86,106,108,109,113,115,118). Other theories or models incorporated were the trans theoretical model (90,113,116), goal system theory (109,114,115), social ecological theory (109,114,115), self-efficacy theory (59), behavioural change theory (117), and an information-motivation-behavioural skills model (110). Half of the selected studies compared interventions to promote physical activity with control groups receiving either standard diabetes care alone (57,106–110,114), or in combination with additional physical activity counselling/education (87,111) or information on lifestyle recommendations for diabetes on physical activity and nutrition (112,115,117). Ten studies compared interventions where the main difference was either the treatment procedures used to promote physical activity (59,60,86,90,92,113,116,118) or the person delivering the intervention (58), but the number of contacts between the participants and intervention providers did not differ.

Effectiveness of interventions

The outcome measures and results of interventions promoting physical activity are presented in Table 2.5. The primary outcome in most studies was either physical activity level alone or in combination with other health outcomes such as glycosylated haemoglobin (HbA1c), blood pressure, lipid profile, anthropometric measurements and cardiorespiratory fitness. The level of physical activity was measured objectively using a pedometer and/or an accelerometer in four studies (58,59,87,117) or in combination with a questionnaire in four studies (90,106,108,116). Eleven studies assessed physical activity subjectively using a questionnaire (57,86,107,109–111,113–116,118), although the questionnaires used varied between studies. The unit of measurement to represent the physical activity levels also varied. Three studies used a self-reported activity log (60,92,112) and another three used indirect measures of physical activity such as VO_2 peak or VO_2 maximum (92,111,116). Based on self-reported scales and activity logs, changes in energy expenditure on the performed physical activities were estimated in six studies (57,92,111,112,114,115). In ten studies, the level of physical activity was based on the questionnaire's total score or on relative change of either duration, frequency and/or intensity of physical activity (60,86,90,92,107,109,110,113,116,118).

The health outcomes measured included cardiovascular disease (CVD) risk factors such as HbA1c, fasting blood glucose, blood pressure, anthropometric measurements (weight, body mass index, waist circumference and body fat) and lipid profile (57–60,87,90,92,106,107,109–112,116–118), cardiorespiratory fitness (six-minute walk test, indirect VO_{2max}) (111,112,116), and flexibility (111,114). In one study physical activity level was the secondary outcome because the primary outcome was HbA1c (111). In studies that focused on self-management or combined physical activity and nutrition, other outcomes measured included nutrition or diet (109,110,114,115,117), self-care (107,109), quality of life (57,114), and social support (107,109,114).

Ten of the 12 studies reported a significant positive change in the level of physical activity when compared to the controls (87,106–109,111,112,114,115,117). Of these studies, four reported improvements in HbA1c level (106,109,111,112), two showed improvements in other CVD risk factors (blood pressure, waist circumference and lipid profile) (106,111) and one reported improved distance walked in six minutes (112). Two studies did not show any significant changes in either the level of physical activity or the CVD risk factors (57,110). Across 10 studies, the intervention and comparison groups differed in treatment procedure. Most studies showed no differences between groups on the levels of physical activity or CVD risk factors (58,60,90,92,113). Four studies reported differences between the intervention and comparison groups (59,86,116,118). Three studies showed significant improvements in the levels of physical activity (59,86,116) while one did not (118). Two studies reported improvements in the levels of HbA1c (59,116), and three showed improvements in the CVD risk factors (systolic and diastolic blood pressure, and body mass index) (59,116,118).

Table 2.5: Characteristics and results of interventions

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
De Greef et al, 2011 (106)	IG 1: 3x15 min individual counselling by general practitioner (GP); IG 2: 3x90 min cognitive-behavioural group session; Counselling sessions (goal setting, decisional balance, relapse prevention) Pedometer as feedback	Standard diabetes care	Social cognitive theory	General practitioner vs. Clinical psychologist	Pedometer (steps/day), IPAQ: Housekeeping & gardening activities, leisure-time walking, total PA, MVPA (min/day)	Weight, BMI, WC, Cholesterol, FBG, HbA1c	95.5%	IG 2 increased steps/day (+837±688) than IG 1 and (+313±493) CG ($P<0.05$) and total PA & MVPA min/day ($p<0.05$) than IG1 & CG; IG1 improved WC (-1.4cm), HbA1c (-0.32%) and total cholesterol (+7.2 mg/dl) than IG2 & CG ($p<0.05$)	Significant positive findings for level of PA, HbA1c, WC and total cholesterol
Weinstock et al, 2011 (107)	Standard care augmented by a telemedicine intervention via one-to-one home videoconference every 4–6 weeks over 5 years	Standard diabetes care	-	Diabetes educator, Primary care providers	Diabetes Self-Care Activities for assessment of PA (level of PA)	BMI, BP, HbA1c, ADL, Self-Care Activities Comorbidity, Social Support	-	IG had lower rate of decline in physical activity ($P=0.013$) and higher activity level ($P=0.003$) than CG	Significant positive findings for level of PA but not for health outcomes

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
De Greef et al, 2011 (108)	One-to-one cognitive behavioural counselling; Pedometer as feedback (target: 10,000 steps/day); 7 x telephone support (goal setting, self-monitoring, self-efficacy, problem solving, social support & relapse prevention)	Standard diabetes care	Social cognitive theory, Motivational interviewing	Clinical psychologist	Pedometer (steps/day) Accelerometer: total, light and MVPA and sedentary (min/day), IPAQ: total, light and MVPA (min/day)	-	95.7%	Post-intervention: IG improved (+2744steps/ day,$p<0.001$), total PA (+23 min/day, $p< 0.001$) and decreased sedentary behaviour (-23 min/day, $P< 0.05$) After 1 year: (+1872steps/day, $p<0.001$), total PA (+11 min/day, $p< 0.001$) and decreased sedentary behaviour (-12 min/day, $P< 0.001$)	Significant positive findings for level of PA
Toobert et al, 2011 (109)	24 x weekly then 12 x fortnightly next group counselling & support on Mediterranean diet, stress management, 30 min/day PA & problem solving	Standard diabetes care	Social cognitive theory, Goal systems, Social ecological theory	Registered dietitian, Exercise physiologist, Stress-management instructor, trained lay group leaders	IPAQ: total PA (day/week)	Problem solving, Self-care, Social support, Nutrition, BMI, BP, HbA1c, Lipids	78% at 6 months	IG improved in day/week exercised ($P<0.05$), calories from fat ($P<0.01$), practice of stress management ($P<0.001$) and HbA1c ($P<0.01$) than CG	Significant positive findings for level of PA, fat intake, stress management and HbA1c

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Wisse et al, 2010(57)	Regular structured personalized exercise (target: 160 min/week moderate intensity) First 6 weeks: 2 x1 hour consultation, 2 x15 min telephone calls. Over 2 years: 1 x 30 min consultation alternate with 1x15 min telephone calls every 6 weeks	Standard diabetes care	-	Physio-therapist, Physicians	Tecumseh/ Minnesota scale: leisure time activities (MET/week)	Quality of life (W-BQ12 scale) BP Weight HbA1c FBG Lipids	82.4%	Leisure time activities increased for IG (33±4 MET/week from 15±3 MET/week) and CG (39±6 MET/week from 23±5 MET/week) (p=0.171)	No significant findings for level of PA or health outcomes
Osborn et al, 2010 (110)	1 x 90 min group diabetes self-care counselling using motivation and behavioural skills; No physical activity prescription	Standard diabetes care	Information-motivation-behavioral skills model	Clinic's medical assistants Dietitian, Diabetes educator, Psychologist	PA subscale of Summary of Diabetes Self-Care Activities (SDSCA), frequency of PA in past 7 days)	Diet subscale of SDSCA, HbA1c, BMI	77.1%	No group difference on PA scores (p=0.230) and HbA1c (p=0.760). ? BMI results	No significant findings for level of PA or health outcomes

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Toobert et al, 2007 (114)	24 x weekly then 12 x fortnightly next group counselling & support on Mediterranean diet, stress management, 30 min/day PA & problem solving	Standard diabetes care	Social cognitive theory, Goal systems, Social ecological theory	Dietitian, Exercise physiologist, Stress-management instructor, trained lay group leaders	CHAMPS (kcal/kg/hour of moderate intensity PA)	Diet, Flexibility, Stress management, Social support, Problem solving, Self-efficacy, Depression, Quality of life	85.0%	IG had greater kcal/kg/hour of moderate intensity PA ($P<0.01$), min/day of stress management practice ($P<0.001$), reduced calories of saturated fat ($P<0.001$) & sit-reach % score ($P<0.05$) than CG	Significant positive findings for level of PA, saturated fat intake, stress management and flexibility
De Greef et al, 2010 (87)	5 x 90 min cognitive behavioural group sessions, pedometer as feedback (target: ≥10,000 steps/ day); with social support & self-monitoring. Booster session to discuss social support & relapse prevention	Standard diabetes care and one single group education on effects of PA on diabetes care	Motivational interviewing, Cognitive behavioural	Exercise coaches, Clinical psychologist	Pedometer (steps/day), Accelerometer: total PA, light PA, MVPA and sedentary time (min/day)	Weight, BMI, HbA1c, BP	90.3% at week 12 87.8% at 1 year	IG increased 2502 steps/day ($P<0.05$), and decreased in sedentary behaviour ($P<0.05$) post-intervention than CG; No difference between groups on accelerometer's PA level & clinical parameters; At 1 year: no group differences on all parameters	Significant positive findings for level of PA, not for health outcomes post-intervention; No significant findings for level of PA or health outcomes at 1 year

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Balducci et al 2010 (111)	2 x supervised exercise (aerobics & resistance training) sessions/ week (150 min/week of moderate intensity), 4 x structured individual exercise counselling (once every 3 months) to encourage any types of PA	Exercise counselling as part of standard diabetes care	-	Exercise specialist, Diabetologist	Minnesota Leisure time PA questionnaire (MET hour/week)	HbA1c, Lipids, BP, Cardiorespiratory fitness (indirect VO_{2max}), Flexibility	92.9%	IG MET hour/week (20.0±0.9, P<0.001) was higher than CG; IG improved in HbA1c level (−0.30%, P<0.001), systolic BP (−4.2 mmHg, P=0.002) and diastolic BP (−1.7mmHg, P=0.03) HDL-C (+3.7 mg/dL, P<0.001) and LDL-C (−9.6 mg/dL, P=0.003); WC (−3.6 cm, P<0.001)	Significant positive findings for level of PA, HbA1c, BP, HDL-C, LDL-C and WC
Negri et al, 2010 (112)	3x45 min/week supervised walking group (targeting moderate intensity) Had one individual and one group counselling	Standard lifestyle recommendations	-	Personal exercise trainer	Activity log (MET hour/week)	HbA1c, FBG, Lipids, 6 min walk test	86.4%	IG increased in MET hour/week (P=0.008), reduced HbA1c (-0.37%, P=0.01), and increased distance walked in 6 minutes (P=0.001) compared with CG	Significant positive findings for level of PA, HbA1c and 6 minute walk test

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
King et al, 2006 (115)	One-to-one self management counselling (goal-setting & barriers problem solving) with interactive CD-ROM; Weekly PA; 2 x telephone calls & a tailored health newsletter	A 90 min. visit at enrolment for an interactive computerized health risk appraisal; brief generic health counselling; no subsequent follow-up	Goal system theory, Social cognitive theory, Social ecological theories	Health coaches (clinics' staff)	CHAMPS questionnaire (kcal/kg/hour and total caloric expenditure/ week)	Dietary pattern, Psychosocial (results not presented in this study)	92.2%	IG increased in all PA ($P<0.01$), moderate PA ($P=0.001$) and strength training ($P<0.001$) than CG	Significant positive findings for level of PA
Keyserling et al, 2002 (117)	First 6 months: 4 x individual clinic based counselling (IG1) or combined with 2 group sessions & 6 telephone calls from peer counsellors (IG2); Target: 30 min/day moderate intensity PA; Second 6 months: IG2 received 6 telephone calls & 1 group session	Received mailed pamphlet on PA, nutrition and diabetes	Behaviour change theory	Primary care physicians, Community diabetes advisor (peer counsellors)	Accelerometer (kcal/day)	Dietary intake, HbA1c, Lipids	85.5%	IG2 ($P=0.0055$) and IG1 ($P=0.029$) had higher mean kcal/day than CG	Significant positive findings for level of PA, not for health outcomes and dietary intake

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Diedrich et al, 2010 (118)	8 hours of Diabetes Self Management Education (DSME) programmes, pedometer use & individual goal setting & self-monitoring; Target: daily PA ≥10,000 steps/day	8 hours of Diabetes Self Management Education (DSME) programs	Social cognitive theory	Diabetes nurse, Dietitian	Paffenbarger PA questionnaire (higher scores = better level of PA)	HbA1c, BP, BMI, Body fat	62.0%	IG significantly reduced diastolic BP (P=0.024) compared with CG; Effect over time: IG reduced in HbA1c (P=0.020) & body fat (P=0.037) and CG reduced in HbA1c (P=0.005) & weight (P<0.001)	Significant positive findings for diastolic BP; not for PA between groups; Time effect is observed for HbA1c, body fat and weight
Kirk et al, 2009 (90)	A written self instructional workbook; a 12 week walking plan (Target: 30 min/day on most days); goal setting & relapse prevention (IG1) or combined with 2x30 min one-to-one consultation (IG2); Both received 3 x telephone calls	Received a two-page information leaflet on PA as part of standard diabetes care; Received 3 x 5-10 min follow-up telephone calls (at month 1, 3 & 6)	Trans theoretical model	Research team	Accelerometer (hour/day), 7-day Recall questionnaire	HbA1c, BMI, WC, BP, Lipids	86.6%	No significant difference between groups or the effects over time on the measured outcomes	No significant findings for level of PA or health outcomes

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Furber et al, 2008 (105)	2 hour group education session on self care & nutrition (goal setting & self-monitoring); one group education on PA & 10 min on pedometer use; Set own PA goals	2 hour group education session (on self care and nutrition); One 15 min of group education on PA	Social cognitive theory	Diabetes nurse educator, Dietitian	Active Australia survey on PA: total PA, walking, moderate intensity PA (min/week)	-	92.9% at week 2 81.4% at week 20	IG had higher mean min/week for walking & % achieving recommended PA level post-intervention than CG; No difference between groups at week 20	Significant positive findings for level of PA
Dutton et al, 2008 (113)	One-to-one tailored print-based PA (self-efficacy, goal setting, social support, problem solving); Setting own PA goals	Diabetes specific dietary tip sheet advice, no advice on PA	Trans theoretical model, Social cognitive theory	Research team	7-day PA recall for MVPA (min/week); Physical activity stage of change	-	94.0%	No significant difference between groups on physical activity level	No significant findings for level of PA
Allen et al, 2008 (59)	One individual counselling on glucose monitoring; Glucose chart as feedback; One reinforcement telephone call	One individual diabetes education; one reinforcement telephone call	Self efficacy theory	Research team	Accelerometer: light, moderate, vigorous and sedentary activities (min/day)	BP BMI HbA1c Self-efficacy for exercise behaviour	88.5%	IG decreased in light/sedentary activity min/day ($P < 0.05$), and decreased HbA1c ($P < 0.05$) & BMI ($P < 0.05$) compared with CG	Significant positive findings for level of PA, HbA1c and BMI

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Bjørgaas et al, 2008 (92)	2 one-to-one sessions with study nurse for goal setting; pedometer as motivational and self-monitoring tool to increase physical activity Target: steps increment based on previous visit's mean number of steps achieved	2 one-to-one sessions with study nurse for goal setting to increase the average daily time spent walking from one visit to another, guided by the logbook	-	Research team	Exercise testing using VO_{2peak} (L/min)	HbA1c, FBG, Lipids	69.6%	No significant difference between the groups on the measured outcomes; Effect over time: CG increased in VO_{2peak}	No significant findings for level of PA or health outcomes; CG had increased VO_{2peak} over time
Engel and Lindner, 2006 (60)	Health related coaching on diabetes education, behaviour change & psychosocial support; pedometer as feedback; self selected walking goals; 6 x one-to-one contacts with interventionist	Health related coaching on diabetes education, behaviour change & psychosocial support; 6 x one-to-one contacts with interventionist	-	Research team	Activity log (min/day of walking activity)	HbA1c Weight BMI BP Cardiorespiratory fitness (shuttle test)	88.0%	No significant difference between groups on all outcomes; Effect over time: both IG and CG significantly increased walking time, reduced weight & WC, and increased cardiorespiratory fitness	No significant findings for level of PA or health outcomes; Significant effects over time for PA, weight, WC and cardiorespiratory fitness

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

Study	Description of intervention group	Description of control/ comparison group	Theory/ Model	Intervention provider(s)	Physical activity outcomes	Additional/ Secondary outcomes	Retention rate	Important results	Conclusion
Kirk et al, 2003 (116)	One-to-one exercise consultation (target: 30 min moderate PA on most days) with exercise leaflet; Included social support, goal setting & relapse prevention; 2 x follow-up telephone calls	Exercise leaflet as part of standard diabetes care; 2 x follow-up telephone calls	Trans theoretical model, Motivational theory, Cognitive behavioural strategies	Research team	7-day PA recall: sleep and light, moderate, hard, very hard, and strengthening and flexibility activities (min/week), accelerometer (activity counts/week)	Cardiorespiratory fitness (indirect VO_{2max}) Stage and processes of change, BP, BMI HbA1c, Lipids profile, Fibrinogen	90.0%	IG improved moderate activity (P<0.001), activity count/week (P<0.001), total exercise duration & peak gradient (P<0.005), HbA1c (P=0.02), & systolic BP (P=0.02) than CG	Significant positive findings for level of PA, HbA1c and systolic BP
Tudor-Locke et al, 2009 (58)	4 x group sessions on goal setting, self-monitoring & problem solving; pedometer as feedback; self-directed behaviour change (target: 10,000 steps/day); delivered by health care professionals	4 x group sessions on goal setting, self-monitoring & problem solving; pedometer as feedback; self-directed behaviour change (target: 10,000 steps/day): delivered by peers	Social cognitive theory	Diabetes educator vs. Peers (trained individuals with T2DM who are physically active)	Pedometer (steps/day)	Weight, WC, Resting HR, BP	75.0%	No significant difference between the groups on the measured outcomes; Effect over time: Both IG & CG significantly increase in steps/day, weight, WC and BP	No group difference on PA level and other outcomes; significant time effects on PA, weight, WC and BP

Note: IG=intervention group; CG=control or comparison group; PA=physical activity; IPAQ=International Physical Activity Questionnaire; MET= metabolic equivalent tasks; CHAMPS=Community Healthy Activities Program for Seniors; BMI=body mass index; WC=waist circumference; FBG=fasting blood glucose; HbA1c=glycosylated haemoglobin; BP=blood pressure; LDL-C=low density lipoprotein cholesterol; HDL-C=high density lipoprotein cholesterol; MVPA=moderate-to-vigorous physical activity

2.2.3 Studies' methodological quality

The methodological quality of the selected studies is summarised in Table 2.6. Studies were assessed based on the 13 quality criteria as described in the methods section (105). Only six of the 21 studies fulfilled nine or more criteria of methodological quality implying good quality studies (87,90,109,111,114,117). All studies provided a clear description of the eligibility criteria. All the RCTs described that participants were randomised into groups. The randomisation process was explained explicitly in 11 studies (59,87,90,106,108,109,111,113,114,116,117). Of the 11 studies, four did not elaborate on the concealment of group assignment (106,108,109,116). Two studies used clustered randomisation, where the unit of randomisation was the participating clinic (111) and participating physician (114), while others randomised patients.

All studies reported that their groups were similar at baseline on the measured outcomes and provided detailed description of their interventions. Only eight studies reported on participant compliance with the intervention (58,86,87,111,112,114,115,117). These included attendance to counselling or support sessions (58,86,87,114,117), exercise sessions (111,112), use of a pedometer (86) and minutes spent using an interactive CD-ROM (115). Five studies stated that their outcome assessments were conducted by independent and blind assessors (57,90,107,109,110). Another five studies made comparisons between participants completing and discontinuing the study (58,87,92,114,118).

About half of the studies had outcome assessment at six months or more after randomisation (57,60,87,90,92,107–109,111,114,116,117). Of these, nine described powered sample size estimation (87,90,106,108,109,111,114,116,117). Only three studies reported using intention-to-treat analysis (90,109,112). Of the remaining studies, three had less than 20% loss to follow-up (92,110,118).

Table 2.6: Methodological quality of selected studies

Criteria	De Greef et al, 2011 (106)	Weinstock et al, 2011 (107)	De Greef et al, 2011 (108)	Toobert et al, 2011 (109)	Wisse et al, 2010 (57)	Diedrich et al, 2010 (118)	Negri et al, 2010 (112)	Osborn et al, 2010 (110)
Specification of eligibility criteria	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Description of randomization methods	Yes	Unclear	Yes	Yes	Unclear	NA	No	Unclear
Random assignment performed by independent person	No	Unclear	No	No	Unclear	NA	No	Unclear
Groups similar at baseline on outcomes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sufficient description of interventions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Description of compliance with interventions	No	No	No	No	No	No	Yes	No
Blinding of outcome assessor	No	Yes	No	Yes	Yes	No	No	Yes
Description of dropout rate plus comparison of dropouts and completes	No	No	No	No	No	Yes	No	No
Outcome assessment ≥ 6 months after randomization	No	Yes	Yes	Yes	Yes	No	No	No
Timing of assessments comparable	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Description of sample size calculation	Yes	No	Yes	Yes	No	No	No	No
Intention-to-treat analysis	No	No	No	Yes	No	No	Yes	No
Presentation of point estimates and variability measures	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total number of criteria fulfilled	**6**	**8**	**8**	**10**	**7**	**6**	**7**	**6**

Note: NA = not applicable due to quasi-experimental study design

Criteria	De Greef et al, 2010 (87)	Balducci et al, 2010 (111)	Kirk et al, 2009 (90)	Tudor-Locke et al, 2009 (58)	Furber et al, 2008 (86)	Dutton et al, 2008 (113)	Allen et al, 2008 (59)	Bjørgaas et al, 2008 (92)
Specification of eligibility criteria	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Description of randomization methods	Yes	Yes	Yes	NA	NA	Yes	Yes	Unclear
Random assignment performed by independent person	Yes	Yes	Yes	NA	NA	Yes	Yes	Unclear
Groups similar at baseline on key outcomes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sufficient description of interventions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Description of compliance with interventions	Yes	Yes	No	Yes	Yes	No	No	No
Blinding of outcome assessor	No	No	Yes	No	No	No	No	No
Description of dropout rate plus comparison of dropouts and completes	Yes	No	No	Yes	No	No	No	Yes
Outcome assessment ≥ 6 months after randomization	Yes	Yes	Yes	No	No	No	No	Yes
Timing of assessments comparable	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Description of sample size calculation	Yes	Yes	Yes	No	No	No	No	No
Intention-to-treat analysis	No	No	Yes	No	No	No	No	No
Presentation of point estimates and variability measures	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total number of criteria fulfilled	**11**	**10**	**11**	**7**	**6**	**7**	**7**	**7**

Note: NA = not applicable due to quasi-experimental study design

Criteria	Toobert et al, 2007 (114)	Engel & Lindner, 2006 (60)	King et al, 2006 (115)	Kirk et al, 2003 (116)	Keyserling et al, 2002 (117)
Specification of eligibility criteria	Yes	Yes	Yes	Yes	Yes
Description of randomization methods	Yes	Unclear	Unclear	Yes	Yes
Random assignment performed by independent person	Yes	Unclear	Unclear	Unclear	Yes
Groups similar at baseline on key outcomes	Yes	Yes	Yes	Yes	Yes
Sufficient description of interventions	Yes	Yes	Yes	Yes	Yes
Description of compliance with interventions	Yes	No	Yes	No	Yes
Blinding of outcome assessor	No	No	No	No	No
Description of dropout rate plus comparison of dropouts and completes	Yes	No	No	No	No
Outcome assessment ≥ 6 months after randomization	Yes	Yes	No	Yes	Yes
Timing of assessments comparable	Yes	Yes	Yes	Yes	Yes
Description of sample size calculation	Yes	No	No	Yes	Yes
Intention-to-treat analysis	No	No	No	No	No
Presentation of point estimates and variability measures	Yes	Yes	Yes	Yes	Yes
Total number of criteria fulfilled	**11**	**6**	**6**	**8**	**10**

2.3 Discussion and conclusions

2.3.1 Summary of main results

From this review, it appears that the number of well-designed trials on interventions promoting physical activity in older people with T2DM is small. Further, and of particular relevance to this thesis, no studies were reported from the Asian region. Half of the reviewed studies focused on physical activity and others were on self-management of diabetes or combined lifestyle approaches (nutrition and physical activity). The chosen length of intervention varied ranging between two weeks and five years. Three studies had follow-up measurements post-intervention. Regardless of the chosen length of intervention, some studies did show changes in the levels of physical activity over time and differences between different groups while other studies did not. Only seven studies targeted sedentary or inactive participants (57–60,90,111,112). The definition of sedentary or inactivity varied across studies and only three studies reported changes in physical activity levels (59,111,112). In other studies, the participants were asked to build on their present physical activity. These participants may therefore be physically active at recruitment, and this may influence the observed outcomes.

Interventions promoting physical activity

In ten of 12 studies with positive findings for physical activity level compared to controls, the intervention groups had follow-up contacts with the intervention provider more than once during the period of intervention (87,106–109,111,112,114,115,117). In addition, five of these studies had a long period of intervention of at least one-year duration (107,109,111,114,117) and one of these studies had supervised physical activity sessions with the intervention provider (111). The effects of follow-up contacts with the intervention providers could influence the positive outcomes in these studies. Also, these studies reported long-term effects of the interventions for the levels of physical activity but not for glycaemic control.

Among the 10 studies that differed in the treatment procedure but not the number of contacts between the participants and intervention provider, five reported no group differences for physical activity and health outcomes (58,60,90,92,113). This could be because both the intervention and comparison groups in these studies received follow-up support and counselling that incorporated goal setting and problem solving skills. Further, three of these studies reported that both the intervention and comparison groups had significant improvements across the study period for physical activity levels, glycaemic and other CVD risk factors control, and cardiorespiratory fitness (58,60,118). The lack of observed group differences could be explained by the role of follow-up support and not the intervention in itself.

Level of physical activity was measured as the primary outcome in all studies except one. Most studies from this review used a single physical activity outcome measure in a self-reported physical activity scale. Only seven studies used objective measures obtained from wearable motion sensor devices (accelerometer and/or pedometer). Furthermore, self-reported physical activity scales lack validity in measuring physical activity and are found to be inferior to wearable motion sensor devices (119,120).

Promoting physical activity requires an understanding of the principles of health behaviour models or theories of behaviour change. Fourteen studies incorporated one or more health behaviour theoretical models in their interventions. The constructs of social cognitive theory such as self-efficacy and social support are most often used in the design of the interventions used in the studies included in this review. These studies showed positive results not just in promoting physical activity (59,86,106,108,109,114,115) but also in improving glycaemic control (59,106,109). However, this review could not provide evidence to recommend the most suitable health behaviour theories or models for future interventions. For future studies, the objectives of a study and the interventions should guide the choice of the most relevant theories or models to be incorporated in an intervention.

Role of feedback in promoting physical activity

This review found that more studies evaluated the role of feedback in promoting physical activity in adults with T2DM than other strategies that promote physical activity. There are various types of feedback to promote physical activity behaviour change (94). Feedback can be generic where general information relevant to the participant population is used. Another type of feedback is targeted: the information provided is tailored to general characteristics but relevant to the specific participants. Personalised feedback is based on personal information provided by the participant using some type of assessment method. Personalised feedback can be further divided into simple, visual and contextualised feedback. Simple feedback involves providing verbal reminders and advice on improving physical activity. Visual feedback involves providing relevant personal performance in a written form to increase physical activity. Contextualised feedback, on the other hand, is aimed at providing tailored goal setting and a plan of action. In most of the studies in this review, pedometer readings were used as visual feedback to increase participants' levels of physical activity through self-monitoring and motivation (58,60,86,87,92,106,108,118). However, mixed results were observed in changing both the levels of physical activity and HbA1c. Only one study used a printed graph to feedback on the participants' performance, which resulted in a change in physical activity and HbA1c levels (59). However, little is known on the effect of the other types of feedback mechanisms in promoting physical activity.

Role of peer support in promoting physical activity

There was increasing evidence that peer support contributes to the management of T2DM resulting in improved glycaemic control, self-efficacy for diabetes self-management and social support (61,72–76,78–82). However, these studies focused on the diabetes self-management education and support. The present review also found that interventions with peer support reported significant improvements in physical activity levels (109,114,117) and glycaemic control (109). Previous studies on self-management of diabetes found that glycaemic control is positively correlated with the frequency of contacts with peer coaches or mentors (79,80). However, in these studies, peer support was not evaluated as an intervention by itself as the intervention providers also included a team of other health care providers. Only one study from this review showed that the intervention delivered by either health professionals or peer coaches or mentors were equally effective in improving the level of physical activity as well as CVD risk factors control, but the long term effect is unknown because the study did not have a follow-up measurement post-intervention (58).

2.3.2 Applicability of evidence

This review identified 21 studies (18 RCTs and three quasi-experimental designs) that promoted physical activity in people with T2DM. These studies were conducted in eight countries but none from the Asian region. Most studies had participants in the middle-age groups and only one recruited participants aged 65 years and above. The methodological quality of the selected studies in this review varied. Only six studies (all RCTs) were rated as good quality. The quality of the selected studies in this review is limited by a lack of intention-to-treat analysis as only three studies perform this. The studies with low quality have weaknesses of inadequate description of the randomisation methods; no information on random assignment performed by an independent person, insufficient description of sample size estimation and lack of information on whether an independent assessor evaluated the main outcome measures. Poor methodological approaches in trials are associated with bias (121).

The review demonstrated significant diversity in the interventions exists making comparisons between studies difficult; any conclusions must therefore be made with caution. Both one-to-one and group sessions improved physical activity levels. However, most of these studies incorporated constructs from health behaviour theories with strategies such as problem solving, self-monitoring and social support in their interventions. It is assumed that these studies incorporated multiple constructs of health behaviour theories and strategies to facilitate behaviour change and maintenance (122). However, overall interventions promoting physical activity with follow-up contacts during the study period did increase the level of physical activity as well as improve control of glycaemia and other CVD risk factors.

The levels of physical activity of the participants differed at randomisation. This made it difficult to arrive at definitive conclusions about the effectiveness of these interventions. Only a third of the studies targeted sedentary or inactive participants. Participants who were already physically active were more likely to comply with physical activity interventions and maintain a healthy lifestyle than those who were sedentary or inactive (123). Most studies used a single physical activity outcome measure, mainly self-reported scales, and most lacked an objective measure of physical activity. Self-reported scales were used to calculate energy expenditure, total scores of scales and oxygen consumption to measure change in the level of physical activity. This could lead to less precise measurement and misclassification of the level of physical activity. An objective measure of physical activity is thus necessary to establish the effect of intervention in a trial, as it would allow a uniform measurement of physical activity level.

In this current review, health-care providers delivered most of the studies' interventions. They may be more motivated to deliver the interventions than might be observed in a non-trial setting. In addition, the participants in most of these studies had to undergo extensive screening prior to randomisation. Those who finally participated in these studies were therefore likely to be highly motivated. Another limitation in interpreting the evidence of the effectiveness of the interventions is that the contents of the control or comparison intervention varied widely across studies. In some studies participants in the control group received only usual standard diabetes care or more general information about lifestyle changes. But in some studies, participants received additional counselling about physical activity and some had multiple counselling sessions on diabetes self-care management. A number of studies did provide feedback, goal setting and social support to the control or comparison groups similar to the intervention group.

The roles of feedback and peer support in promoting physical activity in people with T2DM is evident but the studies are limited. Only one study evaluated the effectiveness of peer support on pedometer-determined physical activity, but no assessment was made on the glycaemic control. Besides, the participants recruited in that study were middle-aged, and the study was conducted in a developed nation. More studies are therefore needed to evaluate interventions promoting physical activity in sedentary older people with T2DM, particularly in the South East Asian regions.

2.3.3 Strength and limitations of review

An important strength of this review is the search methods for identification of studies was conducted according to PRISMA guidelines, which involved thorough search through multiple major databases and studies' quality assessments. But, there are limitations of this review. Only peer-reviewed papers published in recent years (i.e. from year 2000) and published in English were included in the data extraction. As a consequence, there is a possibility of selection bias. In addition, even though the searches were done thoroughly through multiple major databases with cross-referencing, there is a possibility that some relevant papers were not included because of the inclusion criteria used for this current review. In this review, only one reviewer assessed the studies' eligibility, which may contribute to risk of assessment bias.

2.3.4 Conclusions and recommendations

In conclusion, the interventions promoting physical activity, the outcome measure for levels of physical activity, and the methodological quality differed widely across the studies included in this review. Studies with interventions promoting physical activity that compared outcomes with outcomes of standard diabetes care do show significant increase in the levels of physical activity in people with T2DM. Further, ongoing follow-up support seems to contribute to increasing levels of physical activity. However, these studies were restricted to middle-aged people with T2DM in Western countries and none involved any of the Asian ethnic groups.

In addition, very few studies had follow-up assessment post-intervention to allow evaluation of the sustainability of the effects of the interventions promoting physical activity. Peer support for adults with T2DM has potential in promoting physical activity but the evidence is scarce. Furthermore, the role of contextualized feedback has not been evaluated as a single component of an intervention. Objective measures of physical activity such as the data obtained from a pedometer or an accelerometer are needed to allow a valid classification of the level of physical activity. Therefore, further exploration of these areas is warranted when developing interventions promoting physical activity in older people with T2DM.

2.4 Summary

Based on the systematic review conducted, little is known about what works to promote physical activity in older people with T2DM. No quality RCTs or quasi-experimental studies in this area were found for the region of South East Asia. However, from the limited evidence presented in this present review, feedback and peer support do contribute to improving the level of physical activity, and to a lesser extent improve the level of HbA1c and reduce other CVD risk factors. These approaches may have a significant role and may be feasible in promoting and maintaining physical activity in older people with T2DM in Malaysia. A randomised controlled trial promoting physical activity using feedback alone and in combination of peer support was therefore conducted as Phase 3 of this thesis, as described in Chapter 4. However, in order to design the intervention arms of the proposed RCT, a qualitative focus group study was conducted (Phase 2 of the thesis) to examine the perceptions of physical activity in older Malays with T2DM. This study is described in the Chapter 3.

CHAPTER 3 QUALITATIVE FOCUS GROUP DISCUSSION: THE CULTURAL PERSPECTIVES ON PHYSICAL ACTIVITY AND MOTIVATORS FOR AND BARRIERS TO PHYSICAL ACTIVITY

This chapter describes the purposes, methods and findings of the qualitative focus group study (Phase 2 of this thesis). A manuscript on the findings of this study entitled: "Physical activity: Perspectives of older Malays with type 2 diabetes in Malaysia" has been submitted for publication and is currently under review.

3.1 Background

Despite the known health benefits of regular physical activity, older people with T2DM remained sedentary or inactive (47,124). In Malaysia, the prevalence of physical inactivity increases with age and many older people with chronic non-communicable diseases including T2DM (78.4%) do not engage in regular physical activity as recommended (30). A major factor that influences non-participation in physical activity is perceived barriers. These include personal, health and environmental barriers (67–69,125,126). Furthermore, the perceived barriers to physical activity vary among different ethnic and cultural groups despite their living in the same environment (67,126).

Exploring the perceived motivators for regular physical activity is as important as exploring those barriers. The motivators for people with T2DM who engaged in regular physical activity are to be healthy, understanding the importance of physical activity for their medical condition, and improved physical and mental wellbeing (47,70). Understanding these motivators will aid in counselling older people, and especially those with T2DM, to initiate and maintain regular physical activity for health benefits.

Definitions of physical activity and its motivators and barriers have been reported in the literature, but few studies have explored the cultural contributions to perceptions of physical activity among older people with T2DM (125). Studies have shown that perceived barriers vary among people from different cultures even when they inhabit the same environment (67,126). Furthermore, there are no studies that have explored this area in the Malay community. In Malaysia, there is limited published work on perceptions of physical activity and the factors that influence it. In order to design an appropriate physical activity intervention for older Malays it is necessary to address the possible cultural issues in relation to adopting and maintaining physical activity behaviour in this group. Therefore, exploring the perceptions of physical activity and the factors that influence engagement in physical activity in the Malay community would facilitate the design of an appropriate intervention to promote physical activity in older Malays with T2DM.

3.2 Objectives

The purpose of this qualitative focus group study was 1) to explore the perceptions of physical activity and to identify factors that influence engagement in physical activity among older Malays with T2DM, and 2) to pilot the use of the pedometer and activity diary keeping. Specifically, the study addressed the following research questions:

1. How do older Malays with T2DM perceive physical activity?
2. What are the perceived motivators for and barriers to physical activity among these older people?
3. What are the sources of motivations for older Malays with T2DM?
4. How receptive are older Malays on the use of pedometers and activity diaries?

3.3 Methods

The Monash University Human Research Ethics Committee (CF10/3191 – 2010001702) and the Medical Research Ethics Committee, Ministry of Health, Malaysia (NMRR-10-1107-7328) approved the methods and materials constructed for this qualitative study (see Appendix C.1 and C.2).

3.3.1 Study setting and design

This study was conducted in an urban primary health care clinic in Shah Alam, Selangor. Selangor is the most populous state in Malaysia with 19.3% of the national population of 28.3 million (23). It is reported to have the highest prevalence of physical inactivity at 52.1% in 2006 (56). People living in the urban areas were more inactive (45.6%) than their rural counterparts (40.1%). The Shah Alam Community Polyclinic in Section 7, Shah Alam was selected because this clinic served patients in the urban area. It also has in their register over 4,000 patients with T2DM from diverse socio-economic background. The ethnic composition of Shah Alam comprises 71.1% Malays, 16.7% Chinese, 11.2% Indians and 0.1% other ethnic groups. The participants were asked about their preferred meeting place for the focus group discussions (FGDs) and most suggested the clinic. They believed it was the most convenient meeting point since they were living in various parts of the 56 residential sections of Shah Alam.

A qualitative focus group methodology was chosen for this study. The FGDs allowed exploration of perceptions, thoughts, feelings and experiences of the older participants about physical activity with a focus on the motivators for and barriers to physical activity through group interaction (127,128). The participants were able to relate their experiences and reactions among other older Malays with similar backgrounds (129). Also, the trustworthiness of the findings could be assessed based on the participants' responses that arise through the group interaction.

3.3.2 Participants and recruitment

The participants were recruited on the basis that they were 60 years and older, diagnosed with T2DM and were community-dwellers. The Malays have the lowest prevalence of physical activity at 12.4% compared with other ethnic groups (40). Also, a higher proportion of Malays with type 2 diabetes have poor glycaemic control and other cardiovascular disease risk factors compared with the other ethnic groups in Malaysia (38). The recruitment was conducted between September and October 2011. A purposive sampling method (130) was used to recruit 25 participants by placing a notice about the study at the clinic (see Appendix D) and through personal communication with the patients by the clinic staff. The participants were screened using a screening questionnaire (see Appendix E). Older Malay patients with T2DM were not included if they had speech disorders (dysarthria or dysphasia), hearing difficulties, cognitive impairment, mobility impairment, or were very ill on day of recruitment.

A research assistant compiled a list of those who agreed to participate and contacted these patients by telephone to arrange a date to attend the FGD. All participants in this study received an explanatory statement about this study (see Appendix F). All participants provided informed verbal and written consent to participate, and consent to be audiotaped was also obtained from them (see Appendix G). They also completed a brief socio-demographic profile (see Table 3.1 for the participants' characteristics). Unequal numbers of men and women were recruited in this study because of the difficulty in recruiting women. Most women were busy with family obligations and were not able to attend the FGD.

Table 3.1: Characteristics of focus group participants

Characteristics	Men (N=18)	Women (N=7)
Age range (years)	60 – 77	60 - 73
Mean age ± SD (years)	65.9 ± 4.3	65.3 ± 4.2
Marital status		
Married	18 (100%)	3 (42.9%)
Widow/widower	0	4 (57.1%)
Highest education		
Primary	5 (27.8%)	2 (28.6%)
Secondary	11 (61.1%)	4 (57.1%)
Tertiary	2 (11.1%)	1 (14.3%)
Working status		
Not working	15 (83.3%)	6 (85.7%)
Working	3 (16.7%)	1 (14.3%)
Living arrangement		
Lives with spouse	4 (22.2%)	2 (28.6%)
Co-reside with children	14 (77.8%)	5 (71.4%)
Mean monthly gross household income ± SD (RM)	1,750.00 ± 1,242.98	1,342.85 ± 1,688.05
Mean duration of diabetes ± SD (years)	12.2 ± 9.2	15.0 ± 12.9
Engaged in regular exercise	7 (38.9%)	2 (28.6%)

Note: SD = standard deviation; RM = Ringgit Malaysia (RM 1= AUD 0.33 on 1 May 2014)

3.3.3 Focus group guide and procedure

The focus group guiding questions were adapted from Kolt (68) because they were based on previous literature on perceptions on physical activity in older people. Also, Kolt included self-efficacy theory, a health behaviour construct used in the Phase 3 of this thesis as described in Chapter 4. The focus group interview schedule was back translated from English to Malay and then back to English (see Appendix H). All the questions were arranged from general to specific. Because the participants in the focus groups have T2DM, a question on diabetes care was included. The focus group guiding questions consisted of open-ended questions about measures to achieve good diabetes control, the meaning of physical activity, motivators for and barriers to physical activity, and sources of motivations. Participants were also asked about their receptiveness to the use of a pedometer, the charting of an activity diary and receiving support from their peers.

This study aimed to access a range of perspectives that may vary by gender (men and women), socioeconomic status (lower and higher socioeconomic groups), and levels of physical activity (sedentary lifestyle and regular physical activity). Sedentary lifestyle was defined as engaging in less than 150 minutes of moderate intensity activity per week (12). Regular physical activity was defined as engaging in 150 minutes per week of at least moderate intensity activity. Four FGDs were conducted in the Malay language with five to seven participants per group (see Table 3.2 for group characteristics). An attempt was made for the focus groups to be representative by gender and socio-economic status, but this did not prove possible as most of the participants who attended the FGDs were men and had low monthly gross household income.

Table 3.2: Characteristics of focus groups

Characteristics	Focus Groups			
	1 (N=7)	**2 (N=5)**	**3 (N=7)**	**4 (N=6)**
Sex				
Men	4 (57.1%)	4 (80.0%)	5 (71.4%)	5 (83.3%)
Women	3 (42.9%)	1 (20.0%)	2 (28.6%)	1 (16.7%)
Highest education				
Primary	1 (14.3%)	1 (20.0%)	3 (42.9%)	2 (33.3%)
Secondary	5 (71.4%)	4 (80.0%)	3 (42.9%)	3 (50.0%)
Tertiary	1 (14.3%)	0	1 (14.3%)	1 (16.7%)
Monthly gross household income				
≤ RM 1,500	6 (85.7%)	3 (60.0%)	3 (42.9%)	3 (50.0%)
> RM 1,500	1 (14.3%)	2 (40.0%)	4 (57.1%)	3 (50.0%)
Regular exercise				
Yes	1 (14.3%)	3 (60.0%)	1 (14.3%)	4 (66.7%)
No	6 (85.7%)	2 (40.0%)	6 (85.7%)	2 (33.3%)

The FGDs were conducted in a meeting room at the clinic's non-patient care area; the room has an oval table and chairs. I moderated all the FGDs as my first language is Malay and I also speak English fluently. I have received training in focus group methodology from involvement in previous qualitative researches with the Institute of Gerontology, Universiti Putra Malaysia. Also, I have received certification for 10-day qualitative research methods training with Prof. Sharan Merriam of the University of Georgia, U.S.A. All the FGDs were conducted in a conversational manner. The FGDs were initiated with a general discussion about healthy lifestyle in diabetes care and later moved to the topics related to physical activity. An assistant moderator (a trained research assistant) aided me in taking detailed notes on the order of speakers, made observations about the discussion, and recorded field notes including facial expression, comments and interpersonal interactions that occurred during the FGDs (129). The participants were encouraged to ask questions and share information not sought during the FGDs.

On average, the focus group interviews lasted between 1 and 1.5 hours. All the focus groups were audiotaped, transcribed verbatim and translated. All the recordings were in Malay and were transcribed verbatim in Malay. All the non-verbal communication and the emotional context of the interview captured during the FGDs were included in the transcripts (131). The transcripts were translated word-for-word from Malay to English. In instances where literal translation could not adequately convey the intended meaning of the participants, contextual meaning was used to produce a meaning-based translation (132). The transcripts reflected the actual words, emotions and nonverbal cues used by the participants. The transcripts were translated from Malay into English and then back to Malay to check their accuracy.

3.3.4 Data analysis

The data were analysed using a thematic analysis as described by Braun and Clarke (133). The six phases described by Braun and Clarke were applied in developing the codes and themes for this study. These phases include "1) familiarising with the data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) producing the report." (133)(p.87). The data analysis started during the data collection. The FGDs were conducted on four different days about a week apart. After each FGD, I immediately transcribed the recording in Malay. I read and reread through the transcript carefully to gain familiarity with the data, which allowed me to identify initial codes manually. I continually explored for emerging codes in all the transcripts during subsequent FGDs. This allowed me to review the interview from the initial group, to either confirm or refute the emerging codes during subsequent FGDs (134). This process was to ensure that data saturation was reached, where additional data collection was redundant and revealed no new codes and themes (135,136). Also, this helped to determine the sample size needed for this study. Data saturation was achieved at the end of the fourth focus group with the 25 participants.

I translated all the transcripts from Malay to English (as I needed to report the data in English) and a colleague from the linguistics department back-translated the transcripts to Malay to check the quality of the translation. I organised my data using QSR NVivo 8 qualitative data analysis software (137). I constantly compared the codes to each other iteratively in the transcripts and organised the data accordingly. From the data, emerging codes and themes were identified through line-by-line reading. Also, my supervisors read the translated transcripts and crosschecked the analysis in my presence. The emerging themes were combined into overarching themes that reflected commonalities among them and I grouped the themes into categories that reflected the specific aims of this qualitative study. Face validity of the data is important and was determined through member checks or respondent validation done in real time (129,134). Identified issues related to the topic being discussed were clarified and verified with the participants immediately during each focus group.

3.4 Results

The participants in the FGDs found the topic was important and relevant. This was evident in the enthusiastic and vibrant discussions. The participants in each focus group were comfortable with one another. They freely shared their views and opinions in an amiable environment despite the differences in gender and socio-economic status. The findings from the focus groups were examined under five broad categories based on the research questions of this study: 1) defining physical activity in the Malay culture; 2) motivators for physical activity; 3) barriers to physical activity; 4) sources of motivation; and 5) receptiveness towards pedometer use and diary keeping.

3.4.1 Defining physical activity in the Malay culture

Three core themes related to physical activity in the Malay culture emerged during the FGDs. These themes were recreational activities, household chores and body motions.

Recreational activities

The term "physical activity" and "exercise" were used interchangeably during the FGDs. However, men in this study defined exercise as a structured and planned form of physical activity. A 65-year-old physically active man commented: "Exercise is different. When you mow the lawn and do household chores, those are not exercise. Exercise is what you do non-stop until you sweat. It has to be done regularly." Similarly, a 65-year-old physically active man said, "I walk at least for an hour each time and do it four times in a week. It [exercise] must be planned."

The activities described as physical activities included walking, jogging, playing badminton, cycling, swimming and Tai Chi. Participants who were physically active shared these views based on their own experiences:

> “Exercise means you jog, walk, or play badminton. Then you will sweat and feel energetic.” (Aged 72 years, physically active man)

> “Walking is exercise, not running but walking. I walk up and down the hills and in a week I will walk up the hills four times then I will walk down.” (Aged 67 years, physically active man)

> “Tai Chi is exercise and I do Tai Chi. Majority are Malays in the [Tai Chi] group but other races also joins in. We do it every morning.” (Aged 65 years, physically active woman)

Both men and women in the FGDs agreed that walking is the most suitable type of physical activity for older people especially with increasing age.

> ‘‘People our age should just walk. You walk until you feel tired. Don’t run or else you may drop-dead or worry you may trip. You walk for one or two cycles around the park or the lake is more than enough. If you can’t go further then you should stop.” (Aged 67 years, physically active man)

> “When you said exercise it means you have to move. So, walking would be best.” (Aged 63 years, sedentary woman)

Most believed that older people should exercise but it has to be done in moderation and according to one’s capacities. The risks or harms from the exercise do worry them; so, safety when exercising is an issue, which could also act as a barrier to engagement in physical activity.

> “Exercising excessively would not be good for us. It [exercise] has to be in moderation. Do it to what you are capable of. If you do more, you will get tired. So, you do it in moderation.” (Aged 72 years, physically active man)

> “When we have high blood pressure or heart disease that is the worry. So, exercise

according to your ability." (Aged 66 years, physically active man)

> "The exercise must be done according to the capability of the individual. Don't do a timetable that you must exercise 30 minutes each time when you can't. … Reality is you must exercise but according our ability." (Aged 65 years, physically active man)

> "If we can't exercise and we push ourselves it will harm us. We could fall, so we must do what we are capable of." (Aged 60 years, sedentary woman)

> "The worry is when we do more, we will be injured." (Aged 60 years, sedentary man)

Household chores

Although some participants were involved in regular physical activities or exercise, others, especially women, defined physical activities in the form of household chores and instrumental activities of daily living. They conceptualised their daily chores such as sweeping the floor, mopping, washing and cooking as physical activity. Most participants also equated these activities as exercise.

> "For us women, we do household chores and that involves a lot of movements. So, it is like exercise. I do not have a domestic helper so I do everything in the house. I sweep the floor, tidy-up the house, cooking and all… So, my daily activities would be sufficient to replace exercise." (Aged 64 years, sedentary woman)

Some of the men in the FGDs also agreed that household chores are a form of exercise. However, for them it was more in the form of doing yard work. In Malaysia, traditionally some Malay families inherited houses from their deceased parents in their hometown usually located in the rural villages (138). Often families only use these houses for gatherings during festivities or ceremonials of death anniversaries known as *kenduri arwah*. The families will go to their houses during their free time and will spend time cleaning the yard or fixing the house, if necessary.

> "Whenever I go back to my hometown, I will do housework on the empty house for hours. I will mow and sweep the lawn, or do anything that I could." (Aged 67 years, sedentary man)

> "If I go to my hometown, I will mow the lawn, cut the logs and burn the grass. That causes me to sweat. Usually the work will be at least a four hour work, and that is some exercise." (Aged 67 years, physically active man)

Body motion

Some participants described "light exercises" as a form of physical activity. After further elaboration, these "light exercises" were any form of physical activities that were not structured or planned. These involved any form of bodily movements such as movement of the joints and stretching movements. Some of these movements were done over a substantial period of time, but some participants did them only briefly.

> "As long as we move it is light exercise. It does not matter if you are sitting down and doing some movement that can be exercise. Even movement of your wrist like this (showing range of motion of the wrist), or our foot here, it means any movement of our limbs are exercise." (Aged 65 years, sedentary man)

> "It (exercise) has to be the lighter ones like the stretching exercises that you do everyday for 20 minutes. You will see the body is healthier." (Aged 67 years, sedentary man)

> "Light exercise is the one that you do at home. Because of my knee pain, I do exercises while seated. I do this (demonstrating stretching exercises) until 100 (times)." (Aged 62 years, sedentary man)
>
> "Stretching exercises would be the best that is the light one. You could do the pulling-like exercise (demonstrating hands in pulling motion from above the head). Sometimes, if you have frozen shoulder, this could be done while sitting. What I meant is that we do light stretching exercises so we won't be stiff." (Aged 60 years, sedentary man)

Bodily movements made during prayers (known as *solat*) were also described as a form of exercise or physical activity. For example, a 68-year-old physically active woman said: "When you pray there are a lot of movements involved and that is basic exercise." Similarly, a 65-year-old physically active man said: "From the point of view of *solat*, when we *rukuk* (a forward bending movement with arms squared on the knees) and *sujud* (kneeling on with the forehead on the ground) for the few moments it is similar to stretching exercises. As Muslims, we do it [prayers] five times a day."

> "Praying movements is one of the best exercise. Because when we *rukuk* or *sujud* we are doing stretching exercises." (Aged 60 years, sedentary man)

In addition, some participants believed not only that the movements made during prayers equate to exercises, but that the prayers also improved their physical and mental wellbeing.

> "The movements that we do during the prayers have been set by the religion. When we *rukuk* and *sujud,* the blood circulates to the head and to other parts of the body. There are also hand movements as well. Also we feel at peace and this [prayer] improves us mentally and spiritually." (Aged 66 years, physically active man)

> "During the prayers it is really exercise and it rejuvenates our body. The body feels lighter and healthier." (Aged 68 years, physically active man)

Some participants also described walking to the mosque (or *surau)* for the five times a day as a form of exercise.

> "Jogging or walking as an exercise that I can't do. I have no strength. Sometimes my knee aches and I can't do it. I will walk to the *surau,* each [of the five] prayer times and for classes. That is 20 minutes to and back from the *surau* and that is enough exercise." (Aged 73 years, sedentary woman)

It has to be noted that when the participants described walking as exercise, they meant brisk walking. In contrast their description of "non-exercise" walks referred to "normal" walking to achieve a task, such as walking to the shop. Interestingly when describing physical activity, the participants believed that a sedentary lifestyle should be avoided as it could lead to other co-morbidities. They believed that being physically active also involved not being sedentary. In addition, being sedentary was perceived as contributing to diseases.

> "Exercise is about body movements. It's about getting our body moving, walking, or anything that you could do at all times and not be inactive. No muscles should be too tense. You must move in the house, if not, you will be paralyzed and the joints will ache, too."

(Aged 72 years, physically active man)

"I have my illness because I have stopped working. I was sedentary and that was why I have the diseases. I have diabetes and high blood pressure. When I was working, there were a lot of stresses but my blood pressure was not up. So, you can get diseases by being sedentary." (Aged 66 years, physically active man)

"If the exercise is for our diabetes, there should be movements. It [exercise] does help in reducing our sugar. If we remain seated, inactive, then we will get other illness … like cholesterols and the others." (Aged 63 years, sedentary man)

3.4.2 Motivators for physical activity

The three themes that emerged during the focus group discussions on motivators for being physically active were awareness of diabetes, presence of illness or disease, and pleasant outcomes.

Awareness of diabetes

Awareness of what diabetes does to an individual was perceived as a motivation to improve self-care, which included engagement in regular physical exercise. A 60-year-old physically active man said: "I read an article on diabetes and its complications. It says that once you have diabetes, you could only control it. That is why I have changed and I did change [doing more exercise]. Now my sugars are better". Similarly, a 62-year-old sedentary man commented: "You must have awareness on how the illness can be controlled as you can't cure it. Diabetes will have its ups and downs. There is no cure, so you just control it."

"When you have an illness, it will motivate you to get better and you will do things to improve your health. All this while you've been lazy, but now with your illness you need to join a club where there are friends to share your problems. You need to find a friend you can go for walks. If you don't, you still need to walk for your health. You must exercise, take your meds as advised and don't stop doing these." (Aged 65 years, physically active man)

> "Since the doctor told me about my diabetes, I have really looked after my health. My diabetes is now under control. Now it's [sugar level] 5.2 and sometimes more than 4. Although, sometimes it goes up to 7 but it is not often. I do sports and thank to God for giving me the interest in badminton. Since young I was playing badminton until now. I play two to three times in a week. When I think about it [playing badminton] that is what that controls my diabetes." (Aged 70 years, physically active man)

Some participants believed the reason people with diabetes do not engage in self-care is that they lack awareness about diabetes and its consequences. They believed that it is their responsibilities to look after themselves.

> "We have this habit that if we know we are sick and we want to be well we will do it [exercise]. But we won't do anything if we don't care about our illness or not aware of its effects. So, there must be some awareness. Importantly is to create awareness about our illness. We have to look after our illness and not depend on others. If you need others to look after your illness then no one will." (Aged 60 years, sedentary man)

Pleasant outcomes

Among the motivators for continued engagement in regular physical activity or exercise were the positive or pleasant outcomes they have experienced. These motivators were related to the perceived physical and mental functions that were achieved through the exercise. These included greater wellbeing, less joint pains, improved physiological functions (breathing and circulation) and better sleep. In addition, the participants felt a sense of satisfaction as an outcome of physical activity or exercise. The opportunity to socialise was perceived as a positive outcome.

> "The body feels lighter and you feel good. When we don't exercise our body tires easily and you feel sleepy. When you exercise it rejuvenates the energy." (Aged 68 years, physically active man)

> "It [exercise] improves mental health, become more energetic and sleeps better." (Aged 67 years, sedentary man)

> "When we exercise the body aches disappears. We feel lighter with less joint aches. That you can feel with the exercise." (Aged 67 years, physically active man)

> "If your breathing is less efficient, exercise makes it better. You could breath deeper. You will be satisfied after a walk." (Aged 68 years, physically active woman)

> "First, it [exercise] improves the breathing. The blood circulation will improve and the breathing is better. It also improves our mental aspect. When you socialise with others your horizon is widened. The diabetes will also improve. So, will the blood pressure and the cholesterol will come down. Our mental health will also improve. If you don't exercise in a day you will feel restless." (Aged 67 years, physically active man)

3.4.3 Barriers to physical activity

Perceived barriers to physical activity were discussed during the FGDs, and four core themes emerged. These themes were perceptions of ill-health and injury, perceptions of age and age-related functions, family obligations and spiritually related activities.

Perceptions of ill-health and injury

Among the personal barriers to physical activity were health problems and fear of injury. Naturally, most participants shared a common barrier related to their diabetes. Being diabetics, they shared the feeling of easily becoming tired, lack of energy, and symptoms related to diabetes complications (such as neuropathy and diabetic foot problems). These had deterred them from doing any form of physical activity.

> "Our body is not like before with diabetes. Just like what the doctor said [in mimicking voice], 'You must do more exercise!' But sometimes we do feel uncomfortable, weak, tired, and fatigued after the exercise." (Aged 60 years, sedentary man)

> "We are not able to do it [exercise] with diabetes. There is no energy to go for walks." (Aged 64 years, sedentary woman)

> "If our foot hurts, a lot of movements are restricted… I can't even cycle, even walking I can't as my foot hurts. I had to walk less. I used to walk in Section 10. When I tried to walk even half way now, it is slower than before because the foot hurts." (Aged 60 years, sedentary man)

In addition, the perceived fear of injury limits some participants' activities, even more if they need to engage in regular physical exercise. Some participants were demotivated to engage in physical activity because of other people's negative health experiences.

> "My exercise will be the household chores. It will be like mopping and sweeping the floor, and that's all. I can't go out because I am afraid of falling. Sometimes, I do feel dizzy so I am a little scared." (Aged 73 years, sedentary woman)

> "Sometimes we may trip on stones or step on a nail, and we won't feel it. A week later the foot becomes swollen. Actually, there is an ulcer on the sole. Only in a week, not that long actually, it will become a hole on your sole. So, there won't be other choices but to have surgery. That's what happened to my friend. So now I am scared to walk." (Aged 60 years, sedentary man)

Perceptions of age and age-related functions

Among some of the participants, increasing age was perceived as a barrier to physical activity. The participants believed they were weaker with increasing age and were prone to injury. Further, functional changes and co-morbidities such as osteoarthritis that occur with ageing were perceived as barriers to engagement in physical activity.

> "I don't do much exercise. Sometimes I feel weak and I worry I may fall. I am going to be 80, so I don't dare to exercise. If I want to walk I would look at the place first. Have to be careful and not to trip on a stump and fall." (Aged 63 years, sedentary man)

> "When we get older, our activity changes. We become slower, too. So, our movements have become a barrier [to exercise]." (Aged 77 years, sedentary man)

"Of course, I don't have the energy to do it [exercise] as I am much older now. I worry I may fall. So, I am more careful looking after myself now since I am alone and my children live far." (Aged 73 years, sedentary woman)

"I don't exercise because of my knees. So, I can't walk much or far because of the pain. Now I don't take meds for these (showing to his knees). I use to take medications, had gels injected into the joints. Now nothing works. If I exert on it there will be more pain. So, that is my barrier." (Aged 63 years, sedentary man)

"The elderly do not only have diabetes but other problems like knee pain. So, when the legs are weak they worry that they will trip and fall when they exercise. So, the exercise can lead to other problems." (Aged 66 years, physically active woman)

Family obligations

Some participants described their duties to their family's needs is a top priority. Their time will be occupied with the family matters, which restricted the time available for engagement in regular physical exercise. Also, in some families, the participants had to look after dependent grandchildren to help their working adult children with childcare.

"It is the time factor regardless if it is morning or other parts of the day. We have activities like groceries shopping and sending the grandchildren to school and back. So, the time is spent on matters related to family affairs." (Aged 68 years, sedentary man)

"I have to send my spouse and the grandchildren here and there. I thought after retirement, I don't have to do any work. But now I have more chores and it is almost like work looking after the grandchildren. One will say I have to pick her up at the train station while the other one has to be sent to university. It seems that I now have more work driving people around. Well that involves movement but not structured like exercise of course." (Aged 65 years, physically active man)

"It's our attitude on the priorities. Our Malay culture is rooted to family ties. So, our priorities will be related to family affairs or obligations. So, exercise became less of a priority." (Aged 63 years, physically active woman)

> “I have to look after my grandson who is four month-old as my working daughter does not have a [domestic] helper. So, she will drop my grandson early in the morning before going to work and will pick him up later in the evening. So, I do not have time to exercise as looking after him involves bathing, feeding, changing diapers, then of course I will have to do household chores too.” (Aged 60 years, sedentary woman)

Spiritually related activities

A barrier to physical activity among some older Malays was related to spiritual related activities. Priorities in life changed as they grow older, and spiritually related activities took priority. Further, attending the religious classes and congregations allows socialisation, which is important in later life especially to older people who have lost partners.

> “The Malays as a Muslim, when we are older our mission differs. When we were younger and working we have less time to spare for religious knowledge. So, when we have retired we spend more time for religious knowledge and that is our priority. At 7 am, I will go for exercise but when I have religious programmes that will be my priority. So, I will put exercise aside. So, it comes back to what is our priority in your life.” (Aged 66 years, physically active woman)

> “In the morning, I will boil the water and then recite the *Quran* after *Subuh* [dawn] prayer. After sunrise, I will conduct the *Du’ha* [supererogatory] prayer. I will always attend the religious classes that have been my routine and my priority. Every day there are classes and on Wednesdays the *Ustaz* will teach me reciting the *Quran*. So, I don’t have the energy to go for exercise after all this. It is all for the knowledge and learning the *Quran* for *Jannah* [heaven].” (Aged 73 years, sedentary woman)

> “For us Muslims, we want to get closer to *Allah* [God], so we think of death. So we prepare ourselves for death and how to reach *Jannah* [heaven]. In Islam, the illness we have is God given. The events that happen in our lives have been pre-determined by God. There is a blessing with every circumstance. So, exercise is only an additional activity.” (Aged 64 years, sedentary woman)

"I usually read the *Quran* and attend the religious talks. I would walk to classes and my friends will drive me back home. When you are out you socialise with others." (Aged 68 years, sedentary man)

However, not all the participants agreed with this view. Some believed that engagement in physical activity is as important as engagement in spiritually related activities.

"I do not think so. The exercise is still important and we must do it as it is important for our health. We must do it at least three times a week. Sometimes, I do daily but mostly three times a week. But of course we can't neglect the prayers and some religious activities can still be a priority but we must find the time [to exercise]." (Aged 63 years, physically active woman)

3.4.4 Sources of motivation

The participants were asked to share their opinions on the sources of motivation or support to be physically active. The sources of motivation described were their family, doctors and peers. Within the family, their spouses or children were considered a source of motivation. For some participants, their children encouraged their older parents to exercise and became their exercise buddy.

"Our spouse does motivate us to exercise. When I am lazy, my wife like a nurse will persuade me to exercise and she would come along to do it [exercise]. That motivates me." (Aged 66 years, physically active man)

"The kids told me that I must do lots of exercise. It is true that I must exercise for my health. So, now I would [exercise] in the mornings with my daughter. From the house to the lake I would walk. The kids, they don't want me to drive." (Aged 68 years, physically active woman)

Some participants believed that both their doctors and their peers play an important role in motivating older people with diabetes to be active and improve their health. This view was shared by one physically active, 66-year-old man: "Motivation should be from both your peers and the doctors. When you are not well, motivations will come from all that would relieve the illness." To some participants the doctors were perceived as the knowledgeable people who will provide them with accurate advice, while the peers could only share their experience but not advise.

> "As for me the doctor would be better to motivate the older people because they have the knowledge and know the right advice and the more accurate ones. Doctors will know best of what we should do. So, the doctors are better motivators." (Aged 73 years, sedentary woman)

> "When it comes to giving advice, the one that could advise us would be the doctor. The doctors can provide information on how the medications should be taken and what could be done to control the sugar. When we are with friends or peers it would be more of sharing of experiences, not advice." (Aged 62 years, sedentary man)

> "The doctor always said to exercise in my home because I have feet numbness. So I bought a bicycle, the static one and started cycling. The bicycle is still there in my home until today. It has been years now but it helps to control my sugar levels." (Aged 60 years, physically active man)

For some participants, the experiences shared by their peers became a motivation to improve their health. The peers were perceived as individuals with the same disease who had tried various measures to control it, while the doctors may not have personal experience of it. The doctors may just know the "what to do" but not the "how to do". Their peers' experiences mattered to the participants, and were perceived as a source of motivation.

> "But with the doctors when they advise we understand but do not feel motivated. Those who had gone through the whole ordeal [having diabetes] would understand better. So, if they [peers] have done something that makes their sugar go down you would want to try as well. The doctor always said, 'You have to look after your own health.' They gave us the menu to follow but in the end it is up to us to do it or not. We only get information from the doctors but not the motivations. As with our peers they have the disease and they have gone through it and we see them strive with their illness. That is motivation." (Aged 66 years, physically active woman)

For some participants, the experiences of their peers, not only the positive outcomes but the negative ones were used as motivators to avoid complications of diabetes.

> "When you see other's health is better than yours you would ask them what they did. Some of the information you could not get it from your readings. So, we do get more information from our peers, in addition to those advised by the doctors. So, we will be more confident as our peer is able to do it, so will we. That is a motivation." (Aged 66 years, physically active woman)

> "As for me when I see another older person with an illness like diabetes, high blood pressure and yet they look well and happy, I would want to know what they have done. We all have our own meds and when someone says exercise does change their wellbeing, then you would consider it and finds out that it helps. So, with the peers we will be able to share experiences and exchange of opinion. That is a good thing." (Aged 65 years, physically active man)

> "Other than hearing their experiences, when we see those who are a bit unfortunate like they had amputations, it also acts as a reminder to motivate us to improve our health." (Aged 66 years, physically active man)

3.4.5 Receptiveness towards pedometer use and diary keeping

In this study, another purpose of the FGDs was to explore the participants' receptiveness towards the use of some of the study equipment and instruments to be used during the intervention (the pedometer and the activity diary). Most were excited about the use of the pedometer, as it was a novel tool for them. However, they believed there should be a feedback on its use. In addition, some participants believed that it would be better if the pedometer could record steps and store memory for recall.

> "There must be monitoring and feedback on the use and not just wearing it. There must be a feedback every three months or so, for someone to tell us if our readings are ok. It is an indicator to monitor our health. So, whatever we do should be evaluated. If we use a gadget there must be a feedback on its effectiveness." (Aged 60 years, sedentary man)

> "To get feedback we need to record our activities, but those who are lazy will not do it. Then it would be pointless. So, there should be an instrument that will record on its own.

Those who are capable to do will do it [charting of activities]. Usually, only when the appointment is nearing then they will chart it.” (Aged 66 years, physically active woman)

The use of activity diary raised mixed feelings from the focus group participants. Some perceived the diary as an appropriate measure to monitor progress. But, they believed that the health care providers should evaluate the progress and not only the patients. In addition, the diary should be made simple.

> “There must be feedback from the doctor on what we have on the chart if we need to improve on anything… This will be used to explain the status of our health. If not the diary keeping even though done daily would be useless.” (Aged 66 years, physically active man)

> “We will be satisfied in keeping a record but the doctor must evaluate. We can see our own progress from the diary and so will the doctor. This can be used to decide on how to improve it [physical activity level] or maintain the same. So, the doctor could also advise more.” (Aged 68 years, physically active man)

> “For the older people, the diary can be a motivation but it must have everything written and we just check on the boxes. Most older people are lazy to write and some can’t write.” (Aged 66 years, physically active man)

However, some participants believed the diary would increase the burden on some older people, especially those with low literacy. Also, a concern was that their memory would interfere with the diary keeping, and that the diary should be made simple.

> “As for me, when it comes to writing and jotting things down, those are not for the older people. I have difficulty to write it down as I don’t read and write well.” (Aged 68 years, sedentary man)

> “As for me, my memory frequently fails me I may not remember to write it or recall what I did exactly. So, that will be the problem.” (Aged 63 years, sedentary man)

> “Memory is definitely deteriorating with age. Sometimes I forget what I did earlier in the morning. So, I will not write it down.” (Aged 63 years, physically active woman)

"It is good but I can't do the diary. I do not know what and how to write, so I can't chart a diary. I only went to school until year 4 and I could read but very slow." (Aged 73 years, sedentary woman)

The findings from the FGDs are summarised in Table 3.3.

Table 3.3: Summary of focus group discussion findings

Categories	Themes
Defining physical activity in the Malay culture	• Recreational activities • Household chores • Body motions that included spiritual-related activities
Barriers to physical activity	• Perception of ill-health and injury • Perception of age and age-related functions • Family obligations • Spiritual related activities (priority to attend religious classes/activities)
Motivations to physical activity	• Awareness on diabetes • Pleasant outcomes
Sources of motivation	• Family • Physician • Peers
Receptiveness towards pedometer use and diary keeping	Pedometer • Feedback on the use • With memory for recall Diary: • An appropriate measure to monitor progress • Health care provider & patient should evaluate the progress • Make it simple

3.5 Discussion

The older Malays with T2DM in this community viewed physical activity as an important aspect of the self-care management of T2DM. The conventional perceptions concerning physical activity, and motivators for and barriers to physical activities were intertwined with the social rules, and the cultural and spiritual expectations of the Malay community. Physical activity in this Malay community was focused on household chores, recreation and body motions that included spiritually related activities such as praying five times a day and walking to the mosque for prayers. Physically active participants shared having awareness of diabetes and experiencing pleasant outcomes as a result of the exercise motivates them to engage in regular physical activity. The perceived barriers often seem to relate to the participants' health conditions and ageing, which were reinforced by their health beliefs. However, lack of time to engage in physical activity was influenced by the social and cultural expectations, where the utmost priority goes to spiritually related activities and obligations to kin. Nevertheless, the source of motivations came from their family, peers and physicians. The participants were receptive towards the use of the pedometer but had mixed feelings on the use of the activity diary.

In defining physical activity in this Malay community, and similar to previous studies, recreational activities and household chores were commonly perceived as a form of physical activity (67–70,126). The physical activities perceived as recreational activities included walking, swimming, cycling and jogging in studies of older people (67,68) and people with T2DM (69,70). Walking was also perceived as the most suitable type of physical exercise for older people (67,68) and for people with T2DM (69,70). However, for some of these participants, walking may mean "normal" walking to achieve a task such as going to the shops and not as a regular physical exercise. To produce significant health outcomes, older people with T2DM are recommended to achieve the minimum recommended amounts of physical activity (at least 150 minutes a week of moderate intensity activity) if there is no contraindication (12). Also, walking as an exercise has similar risk reduction for coronary heart disease and other cardiovascular events such as stroke, in postmenopausal women (17). Brisk walking at moderate intensity and the accumulation of 150 minutes a week of walking also lowers the risk of both coronary and cardiovascular events, as well as improving glycaemic control. The latter may also be improved by accumulating short bouts of at least 10 minutes a day of physical activity (139). Older people, especially those with chronic non-communicable diseases such T2DM, should therefore be encouraged to engage in walking exercise as it is safe, cheap and has many beneficial outcomes.

Regarding household chores, previous studies on older people (68) and on people with T2DM (69,70,126) reported house cleaning, gardening, cooking and mowing the lawn as physical activities. Similar to our study, yard work was also perceived as a form of physical activity among Mexican Americans with T2DM (70). Malay families traditionally lived in a *kampong* or village located in rural areas (138). After Malaysian independence in 1957, many left their villages to enter the workforce in the cities, where most now have settled down and retired (140). Some of these families, however, have inherited houses in their home villages from their deceased parents. In their free time, they go back to their villages to clean the yard or fix the house, if necessary; such activities were described as yard work in the present study.

The body movements during prayers were perceived as physical activity in our study, and this was consistent with the findings of an Australian study (126). Similarly, Muslim Bosnian women in

Australia also viewed prayers as a form of physical activity, and being physically active was considered a religious obligation. Every aspect of the Malay daily life and culture is encompassed by Islamic practices that are derived from the *Quran* (the holy book of Islam) and *Sunnah* (Prophet Muhammad's deeds, words and indirect commandments) (138,141).

It is compulsory for Muslims to pray five times daily lasting five to 10 minutes each to worship God *(Allah)*. Communal prayers are preferable to solitary prayers and are usually performed in mosques (138). However, the mosque is not just a place for worship; it is also a place for community gathering and learning. *Solat* (prayer) is the pillar of Islamic religion and has to be done at the appropriate times, circumstances and in sequence. The prayer involves physical bodily movements and adopting certain postures. The main postures during prayer include standing *(qiyam)*, bending forward (*rukuk),* kneeling on the floor with forehead touching the ground *(sujud)* and sitting with leg sideways *(tahiyat)* performed as a cycle *(raka'at)* (142). A *raka'at* involves this sequence: standing → bending forward → standing → kneeling →sitting → kneeling → sitting → standing. Also, through the Quran, Islam encourages Muslims to stay healthy through regular physical activity (143). In our study, the prayers were believed to be associated with health benefits. However, the effect of these praying movements on the physiological and psychological functions is unknown because no published study has been done in this area.

Most participants agreed that sedentary behaviour should be avoided, as it was perceived to worsen their health conditions and this is an interesting finding. No study has reported on avoidance of sedentary behaviour as an aspect of physical activity. Sedentary behaviour is a predictor of poor glycaemic control (144,145). In addition, prolonged sitting or lying down for more than 12 hours a day was associated with increased risk of cardiovascular events (17) and diminished physical functions in a cohort of postmenopausal women (18). It is recommended that people with T2DM should avoid sedentary behaviour by undertaking bouts of light intensity physical activity if they are unable to engage in regular moderate intensity physical activity (146). Light intensity physical activity, which was objectively measured, does improve glycaemic control (144). In addition, interruption of sedentary time (engaging in light intensity physical activity) leads to improved body composition (lower waist circumference and body mass index) and triglycerides levels (16). Older people with T2DM should avoid sedentary behaviour. The benefits of walking as a physical exercise at moderate intensity must be emphasised in older patients with T2DM. Some may not be able to reach the recommended target of physical activity to have an impact on their health but it should be highlighted that sedentary behaviour has detrimental effects on their glycaemic control and health in general. In older people with functional limitations, it should be emphasised that some form of physical activity such as light intensity physical activity is better than none at all.

Regarding motivations to physical activity, Mier (70) reported that awareness of having diabetes motivated Mexican American adults with T2DM to be physically active, which was consistent with the findings of the current study. Similarly, Australian women of diverse ethnic origins increased their physical activity because of health concerns (126). When the risk of a disease is made known to an individual and they are aware of the complications due to physical inactivity, older people were motivated to change their behaviour by being more physically active and choosing healthy lifestyles (126). However, lack of knowledge or awareness about diabetes and the benefit of physical activity among older people and people with T2DM may be related to misconceptions about diabetes and physical activity. For example, Lawton (125) found that people with T2DM of Pakistani and Indian origins in the United Kingdom perceived that diabetes caused irreversible functional decline, which was unavoidable and beyond their control. Therefore, older patients with T2DM should be educated about diabetes and self-care management and misconceptions about diabetes and its management should addressed during clinical consultation.

Pleasant outcomes, such as a sense of physical and mental wellbeing experienced as a result of being physically active, were also perceived as a motivator for physical activity in Mexican Americans with T2DM (70). The participants in our study expressed similar experiences. Other studies found that older people perceived social, psychological and health benefits of physical activity and that this had encouraged them to engage in regular physical activity (68,71,147).

That health problems related to diabetes, combined with fear of injury and increasing age, were perceived to cause irreversible ill-effects on health and prevent engagement in regular physical activity, was a phenomenon also observed in the Pakistani and Indian communities with T2DM in the United Kingdom (125). These participants perceived that diabetes irreversibly worsened their health, strength and vitality. In other studies, engagement in regular physical activity was also perceived to worsen diabetes symptoms such as fatigue and tiredness (69,126). In view of the perceived ill-health, engagement in physical activity was believed to increase the risk of injury through falling or fainting (125), risk of hypoglycaemia (69) and muscle soreness (126). This perception may be more intense in the presence of diabetes complications.

However, some participants in the present study agreed that regular physical activity is important in the presence of T2DM, as reported by Caperchione (126). Women of diverse ethnic origins in Australia perceived that their ill-health motivated them to adopt a healthier lifestyle. However, participants in the present study believed that regular physical activity should be done in moderation and according to one’s capacity. Regular physical activity has been shown to improve the physical function and capacity in older people (9,148). Physical activity recommendations promote a gradual and stepwise approach towards recommended physical activity levels to lessen risk of injury, which allows positive reinforcement (12). Increasing age is associated with physical functional decline, and disability, which might influence one’s physical abilities (149). Thus the participants’ perception that excessive or vigorous physical activities could lead to potential injuries especially in the presence of functional deterioration is a valid concern. Risks of vigorous physical activity do exist; the commonest being musculoskeletal injury (150,151) while the most serious inherent risk is a cardiac event in susceptible individuals (152,153). However, these risks need to be assessed alongside the potential benefits of regular physical activity, even in people with chronic non-communicable diseases and in older people (13). With proper pre-participation assessment and counselling, older people with or without chronic diseases can perform regular physical activity safely (9).

Pre-participation screening is recommended to ensure the safety of engaging in regular physical activity. In older people with T2DM it is recommended that they develop a physical activity plan in consultation with their health care providers to allow the therapeutic and risk management issues to be sufficiently considered (9,12,154). Therefore, the physical activity plan should be tailored according older people’s activity abilities, fitness and presence of co-morbidities. Physical activity in older people (especially those who were previously sedentary) should be prescribed gradually over time starting with short periods of low-intensity physical activity and slowly increasing this until they reach the recommended levels (9,12). This approach would not only reduce risk of injury but allows positive reinforcement on the intended behaviour.

Obligations to kin are influenced by the social norms of this Malay community as part of supporting intergenerational relationships, which is also enforced by the teachings of Islam (155). There is the expectation that family members should give priority to helping each other. The responsibility towards their children and grandchildren was regarded as a lifelong commitment in a Malay community reported in a local study (156). In most situations, there is an exchange of both monetary and non-monetary supports that involves exchange of financial, instrumental and emotional support (157). Older parents would receive support from both their co-resident and non co-resident adult children. They in turn provide support to both the co-resident and non co-resident adult children. The role of older people within an extended family is a barrier to physical activity as reported in another study (68). Because the obligations to other family members involves looking after grandchildren and doing the normal domestic duties such as housework and meal preparation, the older Tongans in New Zealand, especially the women, have less time for regular physical activity. Their time is spent in dealing with family matters and family responsibilities and this becomes a barrier to engagement in regular physical activity (63).

Religious or spiritual activities seem to take priority over other activities for some participants in our study, though there were some who some believed that religious or spiritual activities are as important as other activities such as engaging in regular physical activity. There is no study that reports similar findings to the present study to allow comparison. In a Malaysian study of older people's perceptions of healthy ageing spirituality appears to play a central role in the life of older Malay Muslims as they prepare for the life hereafter (156). This provides them with a sense of self-fulfilment and peace of mind. In our study, prayer was viewed as a form of physical activity, something that has also been reported by Caperchione (126). Such devotion to religious or spiritual activities might be considered not to be a barrier to physical activity but rather an opportunity to be active as being physically active is a religious obligation. Therefore, counselling about physical activity for older Muslims should highlight both the maintenance of good health and the ability to engage in religious or spiritual activities.

This study's participants identified their family, peers and physicians as sources of motivation to improve self-care and physical activity. As reported in another study, family members became an important motivator for physical activity (70). The ability to maintain one's health would translate into the ability to help their kin to care for other family members. This reinforces the duties to kin, as this is perceived as an important responsibility in this Malay community. Another source of motivation in this study was their peers (older people with T2DM). The participants shared that they learned from both the positive and negative experiences of others who had the same chronic condition. The negative outcomes (such as amputation of a foot) experienced by others motivated them to improve their health so that they would not suffer the same fate. The physicians were perceived as important motivators to get them physically active, and this was found in other studies (63,68). Physicians were perceived as the clinical experts and participants believed that the management they provided would be accurate and valid. Their advice was greatly valued. However, some participants reasoned that physicians do not experience their patients' disease personally, and may be able to provide advice based on the "what to do" but not the "how to do". The peers were perceived as individuals who have "done it" and could thus share their relevant experiences with others.

The receptiveness towards the use of a pedometer and charting the activity diary were explored. The participants welcomed the use of devices that could monitor their behaviour as long as it would have a positive impact on their health. However, they highlighted that feedback on the use of such device must be provided. Also, both participants and health care providers should monitor the progress or else it would be purposeless. In addition, the device should be user friendly. Regarding charting the step counts in the diary, most said they would not mind doing it but that the process should be simple. Charts were suggested but too much information should not be required and where possible check boxes should be used. Some were concerned that should they forget to chart in the diary, they should have a contingency plan.

Because of the lack of literature on older Malays related to physical activity behaviour, a major strength of this qualitative focus group was that it has provided knowledge on the perceptions of physical activity and the motivators for and barriers to physical activity among older Malays with T2DM. It was an essential initial stage to develop a physical activity promotion program tailored to the values of an ethnic group. This has facilitated the design of the intervention, which was socially and culturally appropriate for this local community of older Malays and grounded in the perceptions of the target population as described in Chapter 4. This qualitative method allowed the researcher to obtain an in-depth understanding into the needs of these older Malays in this sample of the population.

There are some limitations in the current study. An attempt was made to look at the influence of gender on the perceptions of physical activity in this Malay community but the response rate was low from women (28.0%) to allow this observation. The older women who declined to participate in this study said they were busy with family matters. Men and women play different societal and cultural roles in the Malay community (158,159). In a Malay family system, man is regarded as head of household that has been sanctioned by religion (Islam) and customary law. A woman would occupy a subordinate role in the Malay society. Married women would assume the role of a homemaker where household chores and child-care have always been regarded as the women’s responsibilities regardless of their participation in the labour force. This could possibly explain the low participation rate in the current study as obligations to family are a priority for the older Malay women who refused to participate.

The results of this study could not be generalizable to the general population of older people in Malaysia, as Malaysia is a multi-ethnic population. Exploration of the perceived motivators for and barriers to physical activity of the other ethnic groups is warranted as previous studies found that perceived motivators for and barriers to physical activity do vary among those of different ethnicities and cultural background, despite their living in the same environment (63,67,68).

3.6 Applying focus group findings to the design of an intervention to promote physical activity in older Malays with T2DM

While the results of the current study may not be generalisable to all older people in Malaysia, the findings of the FGDs have provided many relevant and salient suggestions in facilitating the design of the intervention to promote physical activity for older Malays with T2DM. The results of this study have been used to design the intervention for the randomised controlled trial in this thesis as described in Chapter 4. Walking activity was chosen as the most suitable type of physical activity that could be performed by older people, as it would be easy, safe and cheap. However, as in any such recommendation the walking activity is to be done in a graded manner. The identified motivators for and barriers to physical activity identified by this qualitative study were included in the clinical report form as part of the personalised problem-solving, goal-setting and feedback to the participants. Also, the motivators for and barriers to physical activity were used as case vignettes and in role-plays to problem solve and to overcome barriers to physical activity in the training of peer mentors in the intervention described in Chapter 4.

The participants valued the opinions of their attending doctors and the experiences of their peers. The doctors continued providing the usual diabetes care to all the participants in the randomised controlled trial (RCT) as described in Chapter 4. The activity diary was improvised with fewer columns and the participants were required to chart the date, time they put on and take off the pedometer, and the daily step counts. The participants in the RCT intervention groups were to circle the options if they performed walking activity, and mark the physical activity intensity. In addition, the pedometer selected has a differently coloured reset button and a memory button to recall the step counts from the previous 14 days, in order to address the issue of participants forgetting to chart the previous days' readings.

CHAPTER 4 RANDOMISED CONTROLLED TRIAL: EFFECTIVENESS OF PERSONALISED FEEDBACK ABOUT PHYSICAL ACTIVITY PATTERN ALONE OR COMBINED WITH PEER SUPPORT IN SEDENTARY OLDER MALAYS WITH TYPE 2 DIABETES MELLITUS

Phase 3 of this thesis is the randomised controlled trial (RCT). This chapter describes the methods of this RCT, and is presented according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (160–162). These include the study setting, design and duration, the interventions, sampling of participants, ethical considerations, and study outcomes and data analysis of this study. The study protocol of this study has been published (see Appendix A.2): Sazlina, S. G., Browning, C. J., & Yasin, S. (2012). Promoting physical activity in sedentary elderly Malays with type 2 diabetes mellitus: a protocol for randomised controlled trial. *BMJ Open*, *2*(6). doi:10.1136/bmjopen-2012-002119.

The RCT was designed based on the findings from the systematic review and the qualitative focus group study as presented earlier in Chapters 2 and 3 of this thesis. Interventions to promote physical activity in people with type 2 diabetes mellitus (T2DM) have been studied. However, there are few studies that used feedback and peer support, and that are focused on older people with T2DM. In addition, the extensive literature search showed that no studies promoting physical activity have been conducted in the Asian region, and none among the Malay community. Therefore, the objective of this RCT was to evaluate the effectiveness of personalised feedback about physical activity patterns alone or in combination with peer support, in addition to the usual diabetes care, on levels of physical activity, cardiovascular diseases risk factors, functional status, quality of life and psychosocial wellbeing.

4.1 Study setting

The present study was conducted in an urban primary health care clinic in the state of Selangor. Residents of Selangor were reported to have the highest prevalence of physical inactivity (52.1%) in Malaysia (31). In addition, urban adults (45.6%) were found to be less active than their rural counterparts (40.1%). The selected clinic was Shah Alam Community Polyclinic in Section 7 in city of Shah Alam because it is the only urban clinic in Selangor that has a community programme for older people that linked with a senior citizens club.

4.2 Study design

A three-arm randomised controlled trial was conducted over 36 weeks, and participants were randomised into three groups, two intervention groups and a control group:

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

Both intervention groups received the usual diabetes care. One of the interventions involved providing personalised feedback on participants' physical activity patterns (PF) by the research team. The other intervention also received the personalised feedback on the physical activity patterns from the research team and received support from their peer mentors (PS). Before the trial was designed, a qualitative focus group study was conducted to identify socio-culturally appropriate motivators for and barriers to physical activity in the Malay community (as described in Chapter 3). In addition, the receptiveness towards the use of a pedometer, activity diary and receiving support from peer mentors were explored. These results were used to design the personalised feedback about physical activity patterns in the two intervention groups (PF and PS). In addition, this information was incorporated into the training programme for the peer mentors to facilitate the delivery of personalised feedback to their peers.

4.3 Study duration

The RCT was conducted from January 2012 to February 2013.

4.4 Intervention

The intervention involved a 12-week individually tailored intervention designed to promote an increase in physical activity level through unsupervised walking activity in older Malays with

T2DM with a follow-up at 24 and 36 weeks. Figure 4.1 summarises the flow of study participants in this RCT. The participants were encouraged to engage in regular brisk walking performed gradually towards the recommended duration, frequency and intensity by doing bouts of at least 10 minutes of walking, accumulated to at least 30 minutes a day for five days or more in a week, or to accumulate 150 minutes a week of walking at moderate intensity. From the qualitative focus group study as presented in Chapter 3, most participants agreed that walking activity would be the most suitable form of regular physical activity for older people. Furthermore, sedentary people could more easily integrate walking into their daily lives than other forms of physical activity (163).

The motivating factor of this RCT that acted as the targeted goal for participants in the intervention groups was to achieve the recommended duration, frequency and intensity of walking activity. The target of the intervention was to achieve at least 150 minutes a week of moderate intensity walking activity (12). The step counts a day was not used as the goal for the intervention, because the pedometer was not intended as a motivating tool to increase level of physical activity. Instead, it was used as an objective measure of physical activity level for all participants in the three groups.

The researcher provided exercise prescriptions to the patients based on ACSM's Exercise is Medicine^{TM} guide (164). This was individually tailored to their needs and preferences to minimise injury. The participants were provided with a walking activity schedule in their physical activity diary (see Appendix I). In the first month, the participants were prepared for progressive exercise training by walking three days a week and gradually increasing the duration of walking activity by five to 10 minutes every week. Once the participants were comfortable with the walking activity, they were instructed to increase the intensity of walking activity from low to moderate as measured by the Talk Test. In the second month of the intervention, the participants were encouraged to increase the frequency of walking activity to four and then fives times each week. The target was to achieve 30 minutes of moderate intensity walking activity on five days a week. In the third month of the intervention, the participants were encouraged to maintain the recommended level of physical activity achieved.

At enrolment, all participants in the intervention groups were provided a guideline on safe physical activity practices and proper measures to prevent exercise related injury. The information in the guideline included use of proper sports attire, to do warm up and cool down exercises before and after an exercise, maintaining good hydration status, alarming symptoms that warrant discontinuation of an exercise, and appropriate environment to exercise (such as exercising in a shady and well-lit area, and on flat surface). This information was incorporated in the activity diary of the participants.

The participants' were taught to monitor their physical activity intensity using the Talk Test during each walking activity (165–167). The Talk Test is an informal, subjective method to estimate appropriate cardiorespiratory exercise intensity. The intensity based on the Talk Test is divided into three categories: 1) low intensity: the participants are able to talk and sing during the activity and are not breathless; 2) moderate intensity: the participants can talk, but not sing, and becoming breathless; and 3) vigorous intensity: the participants are not able to talk without pausing for breath. The Talk Test correlates well with VO_2 measured cardiorespiratory endurance (*r* ranged between 0.88 and 0.97) (166).

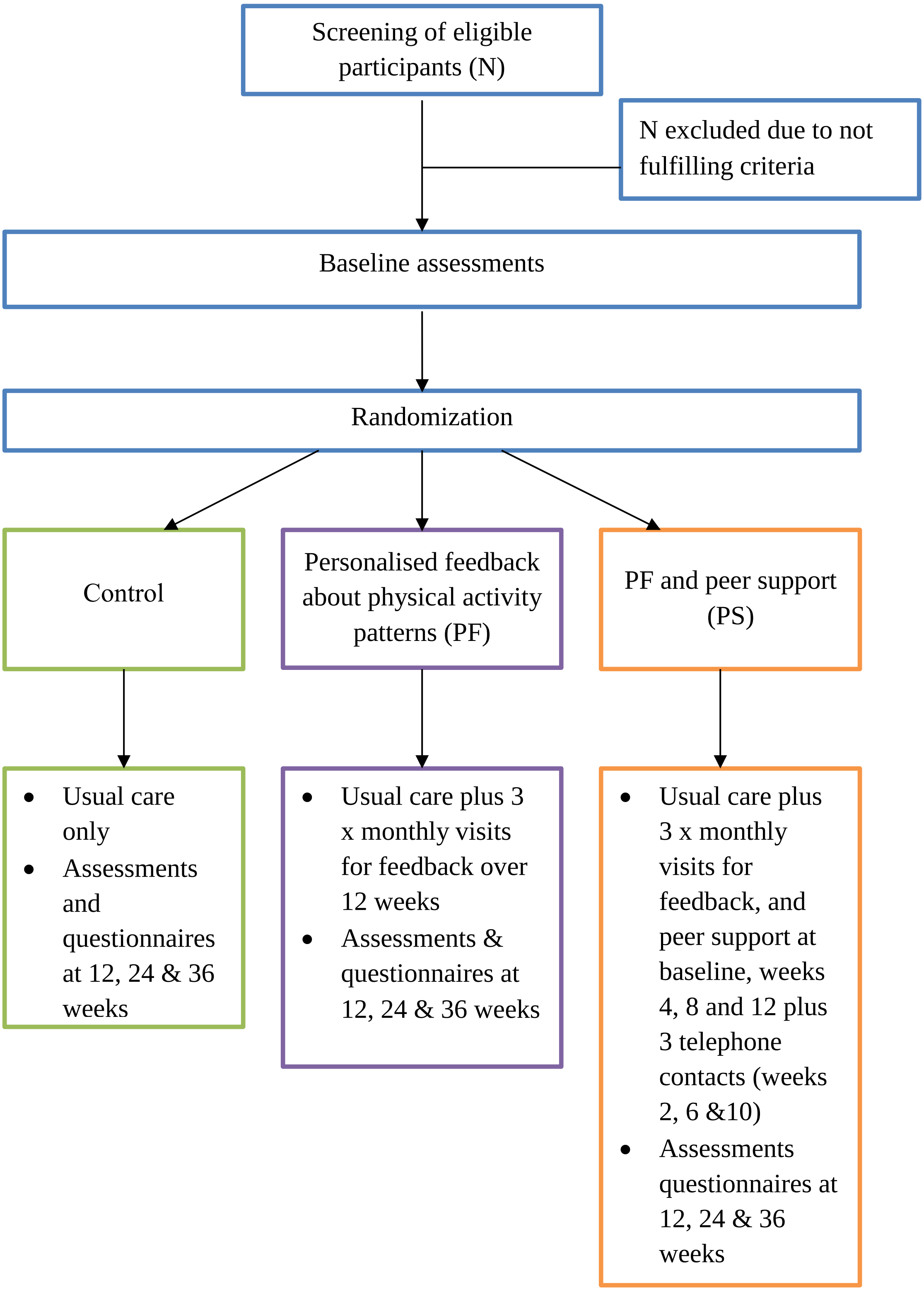

Figure 4.1: Study participants' flow diagram

A pedometer (Yamax Digi-Walker® CW 700/701, Japan) was provided to all participants to be worn during their waking hours while engaging in all activities except during activities that involved water (see Figure 4.2). The pedometer was worn at the waist in line with the mid-point of the thigh. Each participant's stride length was calculated and was set in their individual pedometer.

The participants were trained on the proper placement and use of the pedometer. They were instructed to reset to zero every morning (by pressing the yellow button) before wearing it during the period of assessments. All participants received a telephone call from the research assistant at baseline, week 12, week 24 and week 36 to remind them to wear their pedometers for seven days. They were also reminded to enter the pedometer readings and information on duration and frequency of structured physical activity (if any) into their physical activity diaries.

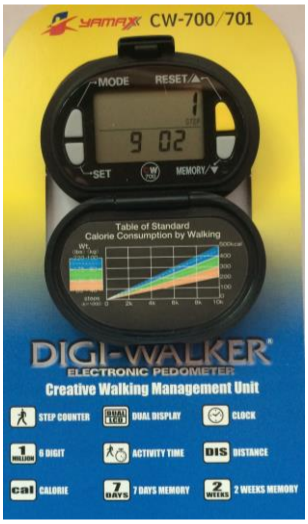

Figure 4.2: Pedometer used in this study (Yamax Digi-Walker® CW 700/701)

Throughout the 12 weeks of intervention, the participants in the PF and PS groups were instructed to record the information on their walking activities (the duration, frequency and intensity of the walking activity) performed in a week into their physical activity diary (see Figure 4.3). At each month during the intervention, the average weekly duration of physical activity was calculated for both the PF and PS groups. Clinical assessments and completion of questionnaires (measuring the primary and secondary outcomes) were performed at four intervals: at baseline, 12-weeks and follow-ups at 24-weeks and 36-weeks.

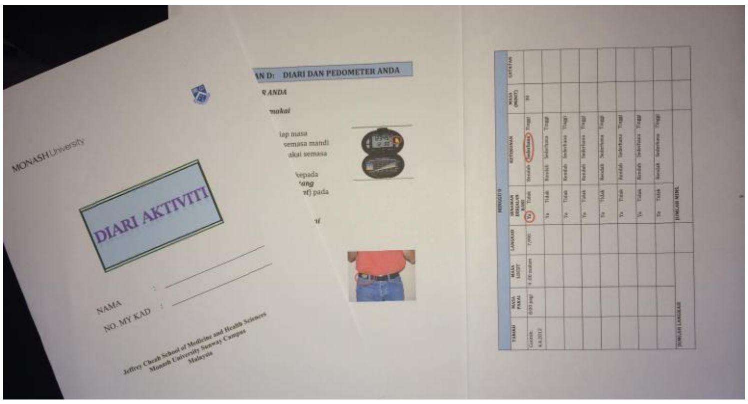

Figure 4.3: Physical activity diary for participants in the intervention groups

4.4.1 Personalised feedback about physical activity patterns (PF)

The participants in this group received a structured personalised feedback and the usual diabetes care. Structured written feedback on each participant's physical activity patterns was provided at the monthly one-to-one session with the researcher during the three clinic visits over the 12 weeks. The feedback was based on the calculated minutes spent walking in a week. The minutes a week of moderate intensity physical activity achieved were plotted onto a graph (see Appendix J), which was incorporated into their physical activity diary. Also, personalised goal setting and plan of action was included in the feedback to the participants. The physical activity plan was discussed with each participant after identifying his or her motivators for and barriers to physical activity. Before the RCT, focus group discussions (FGDs) were conducted to determine the perceived motivators for and barriers to physical activity amog the older Malay community. The identified motivators for and barriers to physical activity from the FGDs were included in the clinical report form as choices for the participants during the monthly visits. These findings were also incorporated in the peer mentors training for the personalised feedback about physical patterns combined with peer support group (details of the intervention are described in the following section).

4.4.2 PF and peer support (PS)

The participants in the peer support group received an intervention delivered by peer mentors and received the usual diabetes care. Participants in this group also received three one-to-one sessions on the structured written feedback on their physical activity patterns from the research team, the same that was provided to the PF group. In addition, they received support from their peer mentors: three group sessions with their peer mentors (at weeks 4, 8 and 12) and three telephone calls (at weeks 2, 6 and 10). Peer mentors are "individuals who successfully coped with the same condition and can be a positive role model" (85) (p. i26).

Peer support programme

The peer support programme for this RCT was developed based on integration of the strategic approaches to promote best practice in peer support programme developed by the World

Health Organization (83) and Peers for Progress (84), needs assessment of older Malays with T2DM (derived from the findings of the qualitative focus group study as described and discussed in Chapter 3) and review of literatures on peer support in adults with T2DM. The key functions of peer support included "assistance in applying disease management and prevention plans in daily life, emotional and social support, linkage to clinical care and ongoing support" (84) (p. i64). In this RCT, the peer mentors were Malay volunteers aged 60 years and above, who have T2DM, lived in the same community as the participants that is in Shah Alam and who were physically active. The aims of the peer mentors were to motivate and to support the participants to engage in walking activity and adhere to the activity. The implementation protocol for the peer mentors included recruitment, training, and supervision.

The clinic's doctors recruited potential peer mentors by circulating a notice about the study (see Appendix K). Potential peer mentors were screened for eligibility based on the inclusion criteria by the research team using a checklist (see Appendix L). The inclusion criteria for a peer mentor included: diagnosed with type 2 diabetes mellitus for more than five years, engages in regular physical exercise, has good glycaemic control with HbA1c < 8%, has a mobile telephone, is willing to attend a two-day training and comply with the study protocol. The peer mentors agreed to a nine-month commitment to the study project, to adhere to the scheduled meeting times and to provide support on promoting and maintaining physical activity. Each peer mentor worked with about three to four participants over the 12-weeks duration of the intervention from the point of enrolment.

The peer mentors motivated their peers based on the structured written feedback about physical activity patterns through three one-to-one contacts over the 12 weeks from enrolment to increase their physical activity level. In addition, peer mentors provided support on increasing the participants' physical activity level through three telephone contacts during the intervention period in-between the monthly meetings. During these sessions, the peer mentors helped the participants to identify motivators for and barriers to physical activity. They also encouraged the participants to be empowered to self-manage their diabetes by increasing their physical activity to the recommended level through walking activity. The peer mentors assisted participants in goal setting and measures to achieve their goals.

The training conducted for the peer mentors was aimed to improve the ability of the peer mentors in providing support to the participants through face-to-face and telephone contacts. The content of the training included diabetes self-management, physical activity, stress management in diabetes, and methods of communication and facilitation (168,169). The training comprised interactive discussions, simulations and role-plays. During these interactive sessions, the research team observed the peer mentors' inherent communication and facilitation skills to assess their competency level in delivering patient-centred support using a checklist adapted from Cherrington (169) (see Appendix M). The goal was to ensure that the selected peer mentors were able to build rapport and provide patient-centred support, and not to overpower their peers. Measures to improve on these skills were feedback to the peer mentors. All peer mentors were competent in communication and facilitation skills at the end of the training.

The findings from the qualitative focus group discussions were incorporated in the training of the peer mentors to facilitate the delivery of support to their peers. The identified motivators for and barriers to physical activity were used as case vignettes and in role-plays to solve problem and overcoming barriers to physical activity in the training of the peer mentors. The training was conducted for two days (total of 15 hours) at the clinic. Incentives for the peer mentors included: 1) a certificate for completing the peer mentor training; 2) cost of transportations during this study; and 3) prepaid mobile telephone top-ups (used during the period of intervention). The content of the peer mentors training is provided in Appendix N.

Besides the training, the peer mentors attended two fortnightly debriefing sessions in the first four weeks of the intervention and another two monthly debriefing sessions over the remaining 8 weeks. The aims of these meetings were to facilitate and to support the peer mentors in performing their task. These meetings also provided an avenue for the peer mentors to clarify certain issues related to their roles. Among the issues discussed included:

1. Fear of intruding into other people's lives and/or privacy.
2. Unsure if they have handled their peers' identified barriers or problems appropriately.
3. Feelings of failure when they have peers who did not reach the recommended physical activity levels.
4. Handling difficult or overpowering peers.

During these debriefing sessions, the issues raised by the peer mentors were discussed through role-plays that were facilitated by the research team. Some of the peer mentors also shared their experiences in tackling some of the feelings of fear and failure. The peer mentors were reminded often in these sessions on their roles and limitations, as highlighted earlier during the training workshop. The research team also conducted ongoing supervision on the peer mentors throughout the study period at the monthly group sessions with their peers. This was to ensure that the delivery of support was standardised. Also, this provided an opportunity for the research team to provide feedback to the peer mentors on their performance and the proper measures to improve them.

4.4.3 Usual diabetes care

Participants in the control group received the usual diabetes care during the intervention period and acted as a comparison group to the two intervention groups. During the 12-weeks intervention, the participants in the control group attended the clinic at monthly intervals to refill their prescriptions. All participants in the three groups received the usual diabetes care from their attending clinic doctors at a three-monthly interval during the study. The usual diabetes care was based on the Malaysian guideline on management of T2DM (44). It involves a multidisciplinary team approach with the patient as the central member, and comprises care by the primary care practitioners, a diabetes nurse educator, a nutritionist, and if needed shared care with an endocrinologist and ophthalmologist. The management includes education on lifestyle change (diet and exercise), medication and self-care. Table 4.1 summarises the main characteristics of each group in this study.

Table 4.1: Main characteristics of each group

Control group	Personalised feedback about physical activity pattern alone (PF) group	PF and in combination with peer support (PS) group
Usual diabetes care	Usual diabetes care	Usual diabetes care
Use of pedometer and diary keeping	Use of pedometer and diary keeping	Use of pedometer and diary keeping
	Received 3 x structured written feedback about physical activity patterns from researcher during 12 weeks period (at weeks 4, 8 & 12)	Received 3 x structured written feedback about physical activity patterns from researcher during 12 weeks period (at weeks 4, 8 & 12)
		Received 3 x one-to-one (at enrolment, and at weeks 4, 8 & 12) and 3 telephone (at weeks 2, 6 & 10) supports from peer mentor during the 12 weeks period

4.5 Sampling of participants

4.5.1 Recruitment, screening and randomisation processes

Participants were recruited from an urban public primary health care clinic in the state of Selangor, Malaysia between January 2012 and April 2012. Older Malay adults aged 60 years and above diagnosed with T2DM, having a sedentary lifestyle, registered and on follow-up care with the clinic were invited to join this study. The participants were selected based on the inclusion and exclusion criteria during the screening process (see Table 4.2).

Table 4.2: List of participants' 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 behaviour
5. No acute medical illness in the last 6 months

Exclusion criteria

1. Had recent adjustment in the treatment regime needing increase dose of medication in the last two months
2. Fasting blood glucose of >13 mmol/L
3. Presence of cognitive impairment (Elderly Cognitive Assessment Questionnaire ≤ 7)
4. Had uncontrolled hypertension (blood pressure ≥180/100 mmHg)
5. Presence of coronary artery syndrome
6. Presence of hemiparesis or hemiplegia
7. Known advanced osteoarthritis or conditions deterring walking activity
8. Presence of psychiatric disorders
9. Has complications of diabetes
10. Presence of uncontrolled respiratory conditions
11. Known hearing impairment
12. Known visual impairment
13. Lives in residential homes

Recruitment for this study was conducted in two phases. The first phase involved placing a notice at the clinic (see Appendix O), through personal communication with the patients by the clinic staff and contacting potential patients through telephone. The second phase was a screening process of potential participants by the researcher to determine the eligibility and safety to participate based on the inclusion and exclusion criteria as described in Table 4.2. The potential participants were screened using a structured case report form (see Appendix P).

The screening involved health assessments that included diabetes history and medical history, sedentary lifestyle status, hearing problem status using a validated Single Global Screening Question (170), cognitive function using a validated Elderly Cognitive Assessment Questionnaire (171), and measurements of fasting blood glucose, blood pressure, and visual acuity. Sedentary lifestyle was defined as engagement in less than 150 minutes a week of moderate intensity physical activity (13); the pedometer was not used at this stage because of limited resources. The potential participants were provided with an explanatory statement with a detailed description of the study (see Appendix Q). Both verbal and written consents were obtained before screening (see Appendix R). Those who did not fulfil the selection criteria were excluded and were not contacted for enrolment in this study.

The diabetes history and medical history were verified using the patient's medical record. The information included duration of T2DM, number of follow-ups with the clinic in the past year, medication history (recent adjustments to medications), history of acute illness in the previous six months, known diabetes complications (such as proliferative retinopathy, renal impairment, diabetic foot), known coronary artery syndrome, known hemiplegia or hemiparesis, known advanced osteoarthritis or conditions deterring them from walking activity, known uncontrolled respiratory conditions (such as asthma or chronic obstructive pulmonary disease) and known psychiatric conditions (such as depression, anxiety or psychosis). In addition, symptoms of the medical conditions were elicited during the screening. Those with a positive symptom of medical conditions (such as chest pain and shortness of breath) were excluded from the study and were referred to their attending doctors for further evaluation.

Hearing was assessed using a Single Global Screening Question (170): "Do you or your family think that you may have hearing loss?" The blood pressure screening was based on the measurement taken on the day of the clinic visit by the clinic's staff. Patients with readings of 180/100 mmHg and more were excluded. Visual acuity was tested using the Snellen chart with a pinhole test or with glasses (for those wearing glasses). This result was obtained from the patients' annual screening by the clinic. Visual impairment was defined as visual acuity of 6/18 or worse with a Snellen chart and pin-hole test (172). To assess sedentary behaviour, the patients were asked: "Are you involved in any physical activity such as brisk walking, tai chi, swimming, badminton or other similar activities at least 30 minutes a day on at least five days in a week?" Those engaging in less than 150 minutes a week of moderate intensity physical activity were defined as adopting sedentary behaviour (12,13). Cognitive function was assessed using a validated Elderly Cognitive

Assessment Questionnaire (ECAQ) (171) to exclude any underlying cognitive impairment. Those who scored ≤ 7 were excluded from the study.

The research assistant contacted eligible participants for enrolment. The research assistant explained the study protocol and written informed consent was obtained from each participant before baseline assessment at enrolment. The baseline assessment comprised clinical assessments and completion of questionnaires (measuring the primary and secondary outcomes of the study), which will be described below under the study outcomes measures (Section 4.7). Before enrolment, potential participants needed to agree to the following requirements (98,99):

- A nine-month commitment to the project;
- To use a pedometer during the period of study as directed by the research team;
- To complete the daily activity diary;
- To attend for clinical assessments and complete a series of questionnaires throughout the study period;
- To perform blood investigations for surveillance of glycaemic control and lipids control;
- To allow telephone calls from the peer mentors (those in the peer support group); and
- To allow access to information from their medical record.

The researcher sequentially numbered the eligible participants and they were allocated into three groups using a computer generated blocked randomisation of three with an allocation ratio of 1:1:1 to create the randomisation schedule (173). The group allocation was concealed from the other research team (the research assistant and clinic's staff) involved in the recruitment and the assessments of outcomes at baseline and every assessment time points. The researcher conducted the assignment of interventions after the baseline assessment. Blinding of the participants was not possible owing to the nature of the intervention as the participants in the intervention groups will know that they will receive personalised feedback only or with peer support. The participants were informed in the explanatory statement that there were three arms of this RCT, so they were aware of other participants receiving other intervention than themselves. As this study was conducted in the same clinic, proper measures to minimise cross-contamination were necessary. Participants from different allocated groups were arranged to attend the clinic for their scheduled visits on different clinic days. In addition, during the training of the peer mentors (who are patients themselves), they were instructed to only share the intervention with their assigned peers.

4.5.2 Determination of sample size

The sample size was estimated for this study considering the desired statistical significance level and the power of the study. A statistical significance level of 5% and 80% power was set for this study that allows an overall type I error rate of less than 0.05 and a false-negative rate (type II error) of less than 0.20. In this study, the primary outcome is pedometer-determined physical activity. The calculated sample size was based on the difference in step counts a day following an intervention delivered by peer mentors to promote physical activity in adults with T2DM (58). The findings from that study showed an improvement in the step counts per day from 4,099 ± SD 2,152 (pre-intervention) to 7,976 ± SD 4,118 (post-intervention). The sample size was calculated using the G*Power version 3.1.3 software (174). To detect a difference in the step counts per day, a minimum of 20 participants in each group were required to detect 80% power, maintaining a two-sided significance level at 5% and accounting for 20% loss to follow-up.

4.6 Ethical considerations

The Monash University Human Research Ethics Committee (CF10/3191 – 2010001702) and Medical Research Ethics Committee, Ministry of Health, Malaysia (NMRR-10-1107-7328) approved the methods and materials constructed for this RCT (see Appendix C.1 and C.3). Both verbal and written consents were obtained from the eligible participants before the conduct of this RCT. Confidentiality of the participants was ensured. The participants were assigned non-identifiable identification codes for data entry and data analysis. All the consent forms, clinical report forms, questionnaires and physical activity diary were stored in a locked filing cabinet accessible only by the researcher and the supervisors. The participants were not identified individually in publications or report writing.

4.6.1 Potential risk, discomforts and inconveniences

In this study, there were minimal potential risks, discomfort or inconveniences from the intervention strategies. The assessments required included a six-minute walk test and a timed up and go test, which were conducted in the clinic. The clinic has emergency facilities with a fully equipped resuscitation trolley and medical personnel on stand-by. The blood investigations required were conducted at a three monthly intervals and the usual safety protocols were employed.

Before participation in the physical activity programme, advice on safe physical activity practices and proper measures to prevent exercise related injury was provided to participants in the intervention groups at enrolment as mentioned earlier, in Section 4.4. In addition, the physical activity promoted in this RCT was brisk walking, which has a low risk and is a safe form of physical activity. In addition, the participants were advised to follow the guideline for physical activity closely to minimise risk, which was incorporated in the physical activity diary of the intervention groups' participants.

The questionnaires used in this study comprised general topics on physical activity practice; health related quality of life, general wellbeing, perceived social support, and self-efficacy for exercise. These questionnaires would not provoke any undesirable events for the participants. Details of the relevant referral procedure in case of any untoward events were included in the participants' information sheet and the researcher monitored for such events during the monthly visits to the clinic. Participants requiring assistance were referred to their attending doctors for further evaluation.

4.6.2 Potential benefits

The potential benefits of the study are listed below.

For the participants:

The participants were assisted in starting regular physical activity leading to a recommended level through a graded approach. In addition, the health assessments performed provided information on their overall health that in return would create or increase awareness of self-care management.

For the peer mentors:

The peer mentors also gained benefits through their participation in this study. These included becoming self-sufficient in managing their own diabetes, and the satisfaction of doing good by helping their peers to increase their physical activity level. In addition, they also created a support network in their community for older people with diabetes.

For the researchers:

The findings from this study will be used to translate the intervention to other non-communicable diseases, other primary care settings and the community as a whole.

4.6.3 Withdrawal from the study

Participation in this study is voluntary, which the study participants could choose not to participate. Their health care would not be compromised and they could withdraw from the study at any point without the need to provide any explanation.

4.7 Study outcome measures

The study outcome measures were divided into primary and secondary outcomes. The primary outcome measured in this RCT was the pedometer-determined physical activity. The secondary outcomes in this study were the self-reported physical activity, cardiovascular disease risk factors, functional status, quality of life and psychosocial wellbeing.

4.7.1 Primary outcome

Pedometer-determined level of physical activity

The primary outcome of this RCT was the pedometer-determined level of physical activity. Physical activity was measured objectively using a pedometer. A reliable and valid pedometer (Yamax Digi-Walker® CW 700/701, Japan) was used to measure the level of physical activity (based on daily step counts) of the RCT participants during their waking hours (175,176). The pedometer measured step counts in a day. The pedometer was not intended as a motivational tool to increase physical activity levels but as an objective measure of physical activity level in this RCT. Therefore, all participants were instructed to record the total daily step counts in a physical activity diary over seven days at baseline, week-12 post-intervention, and week-24 and week-36 follow-ups.

The total step counts recorded were divided by the number of days of assessment (in this study was seven days) to estimate the average step count per day. The step count per day was used as the primary outcome measure in the analyses. However, if the participants did not complete the seven days assessment for some reason, the step counts were estimated using at least three days readings and the average daily step counts was used as the primary outcome measure in the analyses. This approach is consistent with current best practice proposed by Tudor-Locke (177). The average daily step counts was not calculated if the participants had less than three days readings and was imputed as missing data. In addition, the pedometer used in this RCT has a two-week memory recall. This allowed the researcher to recover the daily step counts of the participants over the last one week before the three monthly assessments if they did not record the readings in their physical activity diary.

4.7.2 Secondary outcomes

Self-reported levels of physical activity

In this RCT, the physical activity diary (that provided the duration and frequency of physical activity) and the Physical Activity Scale for the Elderly (PASE) measured the self-reported levels of physical activity.

1. Physical activity diary

A physical activity diary was provided to all participants to record their step counts from the pedometer, and duration and frequency of structured physical activity performed (if any) during the intervention and assessments periods. The participants who engaged in structured physical activity (walking activity) were instructed to grade the intensity of the activity using the Talk Test. The method to measure exercise intensity using the Talk Test was included in the diary. For participants in the intervention groups, the physical activity diary has extra information that included guideline on safe physical activity practices and proper measures to prevent exercise related injury, an exercise programme schedule, tables to chart walking activity with the level of intensity, and duration and frequency of the activity. In addition, a graph to provide personalised feedback about their physical activity achievements at every month during the 12 weeks intervention was incorporated in the diary.

From the diary, the duration and frequency of structured physical activity performed in a week were estimated as minutes per week and days per week of moderate intensity structured physical activity, respectively. Similar to the pedometer readings, if the participants did not complete the seven days recording of the duration and frequency of physical activity, readings from at least five days of recording were used to estimate the mean duration and frequency of structured physical activity per week. However, the duration and frequency of structured physical activity in a week were not estimated if the participants had less than five days readings and this was imputed as missing data.

2. Physical Activity Scale for the Elderly

The Physical Activity Scale for the Elderly is a valid and reliable 12-item scale to measure level of physical activity (178,179), however, no validation study has been conducted for the Malaysian population. It consists of questions related to leisure-time, household and work-related activities during a period of seven days (see Appendix S). The PASE scores are calculated from the frequency and weight values (an activity coefficient known as PASE weight) for each of 12 types of activities. These activities include walking outside the home, light sport or recreational activities, moderate sport or recreational activities, strenuous sport or recreational activities, muscle strength or 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 for each study participants. PASE was measured at four assessment time points, i.e. baseline, post-intervention at week 12, and follow-up at weeks 24 and 36. The scores gained by the participants were used to make comparison between the different study groups across the study period. In this RCT, the researcher also estimated the sedentary behaviour (hours spent in daily activities while seated) and the types of physical activity engaged by the study participants that were not included in the calculation of the PASE scores. This allows for a comprehensive definition of physical activity levels for this RCT.

Cardiovascular disease risk factors

The cardiovascular disease risk factors measured in this RCT included glycosylated haemoglobin (HbA1c), blood pressure, weight, body mass index, waist circumference, body fat percentage and lipids profile.

1. Glycosylated haemoglobin (HbA1c)

The glycosylated haemoglobin (HbA1c) was measured as part of the usual diabetes care at the four assessment time points (post-intervention at week 12, and follow-up at weeks 24 and 36) to determine the glycaemic control of the study's participants. The HbA1c was analysed using the Bio-Rad D-10 high performance liquid chromatography (Bio-Rad Laboratories, CA, USA) by the clinic's in-house clinical laboratory. Glycaemic control was not achieved if HbA1c is ≥ 8% for older people as recommended by the American Diabetes Association (9).

2. Blood pressure (BP)

An average of two blood pressure (BP) measurements was taken with the participant rested, seated and the arm supported using an OMRON HEM-7111 digital automatic blood pressure monitor (OMRON Health Care Co. Ltd., Kyoto, Japan), which was calibrated every six months. Smoking or ingestion of caffeine within 30 minutes of measurement was not allowed (9,44). Blood pressure was considered elevated if the systolic BP was greater than 130 mmHg and/or diastolic BP was greater than 80 mmHg (9).

3. Weight

A six-monthly calibrated TANITA® weighing scale (Tanita Corporation, Tokyo, Japan) was used to measure the participants' weight. The measurement taken for weight was in kilograms and rounded to the nearest 0.1 kg.

4. Body mass index (BMI)

A wall-mounted stadiometer was used to measure the participants' height in metres and rounded to nearest 0.01 m. The body mass index (BMI) was calculated based on the participants' weight and height using the following formula:

$$\mathrm{BMI} = \frac{\text{body weight (kg)}}{[\text{height (m)}]^2}$$

The BMI is classified in Table 4.3.

Table 4.3: Classification of body mass index

Classification	BMI (kg/m^2)
Underweight	< 18.5
Normal range	18.5 - 22.9
Overweight:	≥ 23
Pre-obese	23.0 - 27.4
Obese	≥ 27.5

Source: Clinical Practice Guidelines on Management of Obesity, Malaysia, 2004 (180).

5. Waist circumference (WC)

Waist circumference (WC) was measured with the participant standing mid-stance and the measurement was taken midway between the inferior margin of the last rib and the iliac crest in a horizontal plane using a measuring tape (181). The measurements were taken to the nearest 0.1 cm at the end of a normal expiration. A WC greater than or equal to 90 cm in men and greater than or equal to 80 cm in women is classified as increased risk for cardiovascular disease (180).

6. Body fat percentage

The body fat percentage was measured using a TANITA® Inner Scan body composition monitor BC-581 (Tanita Corporation, Tokyo, Japan). Before the test, strenuous exercise, caffeine or eating large meals was not allowed to ensure adequate hydration level during assessment. The body fat percentage was classified according to gender. Table 3.4 summarises the classification of the body fat percentage.

Table 4.4: Classification of body fat percentage

Classification	Body fat %	
	Men	Women
Normal range	<24.0 %	<36.0 %
Overweight	24.0-28.9 %	36.0-40.9 %
Obese	≥29.0 %	≥41.0 %

Source: Gallagher et al (2000) (182).

7. Fasting lipid profile

The fasting lipid profiles of the study's participants were measured to determine the levels of low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides. The clinic's in-house laboratory analysed the fasting lipid profile using the Beckman

DxC800 general chemistry analyzer (Beckman Coulter, Fullerton, CA, USA). Targets for metabolic control were not achieved if LDL-C was greater than 2.6 mmol/L, triglycerides level was greater than 1.7 mmol/L and HDL-C was greater than1.0 mmol/L in men and greater than 1.3 mmol/L in women, respectively (9).

Functional status

The functional status in this RCT comprised cardiorespiratory fitness (measured by six minute walk test) and dynamic balance (measured by timed up and go test).

1. Cardiorespiratory fitness

The cardiorespiratory fitness, which assessed the participant's aerobic endurance, was measured using the six-minute walk test (183,184). This test requires the participant to walk for six minutes and the distance in metres was recorded. The protocol adhered to the recommendations of the American Thoracic Society Guideline (185). There are no standard cut-off values to interpret the results of the six-minute walk test. However, it is recommended that comparison based on the mean changes in the distance walked to be made following an intervention (184,185).

2. Balance

The participants' balance was assessed using the Timed Up and Go (TUG) test (186,187). Participants were required to get up from a seated position without help (using a chair with sitting height between 44 and 47 cm), walk 3 metres, turn around, walk back and return to seated position. The time was measured in seconds when the participant started to rise from the chair and ended when they were seated. The inter-rater reliability for TUG test is high (r=0.98) (187). Older people taking longer than 14 seconds to complete the TUG test have a high-risk of falls (187). However, in this RCT the changes in the time taken to complete this test were compared to the baseline values to determine the evidence of improvement in balance.

Quality of life

Health related quality of life was measured using the Malay validated version of the generic 12-item Short Form (SF-12) Health Survey, a self-report non-disease specific scale evaluating physical and mental health status with four-week recall (see Appendix T) (188). The scale comprises eight health domains, which produces two summary scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS) scores. The domains of physical functioning, role of physical functioning, bodily pain and general health represent the PCS score. The vitality, social functioning, role of social functioning and mental health domains represent the MCS score. In this RCT, the raw health domain scales were transformed into 0–100 scores using the SF-12 software. An aggregate score for each of the PCS and MCS raw scores was transformed into a mean composite score, which was used for comparison in this study to represent physical health and mental health status, respectively. These were calculated using the SF-12 Health Survey software. A higher score suggests better quality of life. The Cronbach alpha values for the physical health and mental health domains of the Malay language version were 0.67 and 0.66 (189). Permission and license for use has been obtained from Quality Metrics Incorporated, U.S.A.

Psychosocial wellbeing

1. Psychological wellbeing

A 12-item General Health Questionnaire (GHQ-12) was used to evaluate general psychological wellbeing (see Appendix U) (190). This is a validated tool to screen psychological distress in a non-psychiatric clinical setting such as in the community and primary care clinics. A validated Malay language version was used and the Cronbach alpha value is 0.85 (191). It contains 12 questions about general level of happiness, depression, anxiety, and sleep disturbances over the past four weeks. Each item is scored by four responses. The responses were divided into those in which agreement indicated either health or illness. A binary scoring method is used with values of 0 and 1. The two least symptomatic answers score 0 and the two most symptomatic answers score 1. The total score is 12 with a minimum score of 0. Scores of four or more indicates a high-level of psychological distress. Permission and licence for use was obtained from GL Assessment Limited, U.K.

2. Perceived social support

The perceived social support of the study participants was measured using the Multidimensional Scale of Perceived Social Support (MSPSS) (see Appendix V) (192). This is a 12-item self-report measure of the availability and adequacy of perceived social support. The scale comprises three subscales based on the source of social support form either significant others, family or friends. Each item is scored by seven responses. The responses are divided into “agree” (responses 5–7), “neutral” (response 4) or “disagree” (responses 1–3) with the statements. It is a valid and reliable measure of perceived social support in older people with a Cronbach alpha values ranging from 0.87 to 0.94 for the different subscales (193). The validated Malay language version was used and the Cronbach alpha values for the significant others, family and friend subscales are 0.89, 0.91 and 0.90, respectively (194). Each subscale has four items. The total raw scores for each subscale ranged between 4 and 28 and average score is calculated for the final subscale scores. The final subscale scores ranged from 1 to 7 and higher scores suggest higher perceived social support.

3. Self-efficacy for exercise

The participants’ self-efficacy for exercise was measured using the Self-Efficacy for Exercise Scale (SEES) (see Appendix W). It is a nine-item scale that focuses on “… self-efficacy expectancies related to the ability to continue exercise in the face of perceived barriers” (195) (p.155). It has been validated in older people (196), but not in Malay. The statements on perceived barriers are based on the confidence to exercise three times a week for 30 minutes. Each item is scored on a 10 point scale ranging from “0” as “Not confident” to “10” as “Very confident”. The total raw score ranged between 9 and 90, and average score is calculated for the final score. The final scores ranged from 1 to 10 and higher scores indicate higher strength of self-efficacy for exercise.

All the study outcomes were measured at four points: baseline, post-intervention (at week 12), and two follow-ups (weeks 24 and 36) throughout this study. Table 4.5 summarises the outcome measures used in this study.

Table 4.5: Summary of outcome measures of the study

Outcomes	Methods of measurement
Physical activity level	Pedometer (Primary outcome) Physical activity diary Physical Activity Scale for the Elderly
CVD risk factors	
HbA1c	Clinical report form (use secondary data)
Blood pressure	OMRON HEM-7111 digital automated blood pressure monitor
Weight and Body mass index	TANITA weighing scale & stadiometer
Waist circumference	Metric measuring tape
Body fat percentage	TANITA® Inner Scan body composition monitor BC-581
LDL-C, HDL-C, triglycerides	Clinical report form (use secondary data)
Functional status	
Cardiorespiratory fitness	6 minute walk test
Balance	Timed up and go test
Quality of life	12-item Short Form Health Survey (SF-12)
Psychosocial wellbeing	
Psychological wellbeing	12-item General Health Questionnaire (GHQ-12)
Perceived social support	Multidimensional Scale of Perceived Social Support (MSPSS)
Self-efficacy for exercise	Self-Efficacy for Exercise Scale (SEES)

Note: CVD = cardiovascular disease; HbA_{1c} = glycosylated haemoglobin; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol.

Four standard structured case report forms (CRFs) were used to collect and record the data throughout the course of this study (see Appendix X.1. to X.4). These CRFs included enrolment CRF, telephone calls CRF, clinic visits CRF, and post-intervention CRF. The enrolment CRF (see Appendix X.1.) was used to collect baseline data of the study's participants and have five sections as summarised in Table 4.6.

Table 4.6: Summary of enrolment CRF contents

Section A – Demographic profile	• Age (based on the participants' birth date) • Sex • Marital status (single, married or divorced/widowed) • Level of highest education (no formal education, primary education, secondary education or tertiary education) • Occupation (retiree, pensioner, still working or unemployed/housewife) • Living arrangement (with spouse/children, with spouse and children, relatives/friends or alone) • Monthly household income
Section B – Medical history	• Duration of T2DM • Smoking status (current smoker, never smoked or stopped smoking) • Concomitant morbidity (hypertension, dyslipidaemia, asthma, chronic obstructive pulmonary disease, osteoarthritis or others – choices can be more than one) • Treatment modalities (diet, exercise, oral diabetic medications, or insulin – choices can be more than one) • List of medications • Self-blood glucose monitoring Note: The duration of T2DM, concomitant morbidity, and treatment modalities were verified using the participants' medical records
Section C – Clinical information	Health assessments performed: • BP • Weight and height • BMI • Waist circumference • Body fat percentage • 6 minute walk test • Timed up and go test • Results for HbA1c and lipids profile
Section D – Questionnaires	• PASE • SF-12 • GHQ-12 • MSPSS • SEES
Section E – Physical activity related information	• Baseline barriers to physical activity (none, afraid of falling, no time, health problems, busy with religious activities, tired, no interest, no facilities or other reasons) • Baseline motivations to physical activity (none, to be healthy, for better health, family support or other reasons) • Baseline pedometer reading • Walking activity prescription

The telephone calls CRF was used by the peer mentors to collect information from study participants in the peer support group (see Appendix X.2). Three telephone calls were scheduled at week 2, 6 and 10 of the 12-weeks intervention. The CRF comprised information as summarised in Table 4.7.

Table 4.7: Summary of telephone calls CRF content

1.	Perform walking activity	Options: done or not done
2.	Side effects from the walking activity	Options: • None • Leg pain • Fall • Chest pain • Breathlessness • Dizziness • Other reasons (need to specify) • Not applicable
3.	Barriers to physical activity	Options: • None • Afraid of falling • No time • Health problems • Busy with religious activities • Tired • No interest • No facilities • Other reasons (need to specify)
4.	Motivations for physical activity	Options: • None • To be healthy • Family support • Other reasons (need to specify)
5.	Support provided by peer mentors	Filled up by peer mentors

All the participants attended three clinic visits at weeks 4, 8 and 12 during the intervention period. During these visits, a clinic visits CRF (see Appendix X.3) was used to collect information on the participants' walking activity for the intervention groups to provide them with the feedback on their physical activity patterns. During these visits the control group participants also visited the clinic to refill their monthly prescriptions and they received the usual diabetes care from their attending doctors in the clinic. Table 4.8 summarises the content of the clinic visits CRF.

Table 4.8: Summary of clinic visits CRF content

1.	Perform walking activity	Options: done or not done
2.	Frequency and duration of the walking activity	Only applicable if walking activity was performed (obtained from the participants' activity diary)
3.	Pedometer daily step counts	Calculated from the participants' activity diary
4.	Number of contacts with their peer mentors	Based on the telephone calls and clinic visits (only for PS group)
5.	Side effects from the walking activity	Options: • None • Leg pain • Fall • Chest pain • Breathlessness • Dizziness • Other reasons (need to specify) • Not applicable
6.	Barriers to physical activity	Options: • None • Afraid of falling • No time • Health problems • Busy with religious activities • Tired • No interest • No facilities • Other reasons (need to specify)
7.	Motivations for physical activity	Options: • None • To be healthy • Family support • Other reasons (need to specify)
8.	Support provided by peer mentors	Filled up by peer mentors (only for PS group)

After the 12 weeks intervention, all participants were requested to return for post-intervention assessments at week 12, and two follow-up at weeks 24 and 36. A post-intervention CRF (see Appendix X.4) was used to collect information from the participants at these three time points. This CRF has four sections as summarised in Table 4.9.

Table 4.9: Summary of post-intervention CRF content

Section A – Medical history	• Modification of their medications (verified using the participants' medical records) • History of recent illness related to their T2DM requiring doctor's care • History of recent treatment for hypoglycaemia • History of recent hospitalisation due to their T2DM • List of recent medications (verified using the participants' medical records)
Section B – Physical activity	• Information on walking activity, which included information on walking activity, either walking alone or in a group, other walking activities performed (to mosque, shops, school) • Frequency and duration of the walking activity (only applicable if walking activity performed by participants) • Pedometer daily step counts • Number of contacts with their peer mentors (only for PS group) • Side effects from walking activity • Barriers and motivations to physical activity
Section C – Clinical information	Health assessments performed: • BP • Weight and height • BMI • Waist circumference • Body fat percentage • 6 minute walk test • Timed up and go test • Results for HbA1c and lipids profile
Section D – Questionnaires	• PASE • SF-12 • GHQ-12 • MSPSS • SEES
Section E – Physical activity related information	• Baseline barriers to physical activity (none, afraid of falling, no time, health problems, tired, no interest, no facilities or other reasons) • Baseline motivations to physical activity (none, to be healthy, for better health, family support or other reasons) • Baseline pedometer reading • Walking activity prescription

4.8 Data analysis

Data were analysed using the IBM Statistical Package for Social Sciences (SPSS) version 20.0 (IBM Corp. Armonk, NY, USA). The data analysis started with data cleaning. All data and problems (if any) were checked and rectified. Both the research assistant and myself performed the data entry. Double entry was performed for data verification. Identification of data or coding errors and outliers was conducted using descriptive techniques. The data has very few outliers ranging between 0 and 2.0% cases for each variable. Normal distribution of the data was assumed when the Shapiro-Wilk test had a p value ≥ 0.05. Transformation of data was not performed, as the dataset in this study was not highly skewed.

Descriptive analysis of the demographic characteristics of the participants, clinical history and baseline variables were reported using means and standard deviations (SD) or median and inter-quartile range (IQR) for continuous variables (depending on the data distribution), and as frequencies and percentages for categorical data. An analysis to compare between participants who completed and withdrew from the study was made using Chi-square or Exact test (for unbalanced data) for categorical variables and independent t-test for continuous data. Assumptions for independent t-tests were checked, which included: 1) the groups being compared are independent of each other; 2) the data are continuous; 3) the data are normally distributed; and 4) the data are homogeneous. Some of the variables violated these assumptions; so, Mann-Whitney U tests were performed.

The homogeneity of the participants' characteristics at baseline was determined using Chi-square or Exact test (for unbalanced data) for categorical variables and One-way Analysis of Variance (ANOVA) for continuous data. The assumptions for one-way ANOVA were tested and this comprised: 1) a random sample; 2) groups being compared are independent of each other; 3) the data are normally distributed; and 4) the data are homogenous. Kruskal-Wallis tests were performed for variables that violated the assumptions required for one-way ANOVA. All analyses conducted were two-tailed with significant level set at p value <0.05.

In this RCT, participants who withdrew from the study across the different assessment time points contributed the missing data. In addition, nine participants during this study did not complete the recording of the duration and frequency of physical activity with 5.8% of missing data (range: two to four missing data). Missing data were specified as either 1.00 or 99.00. The reasons for withdrawal were not related to adverse events of the interventions or removal by the researcher. The missing data was not imputed and incomplete data analysis using multivariate modelling with likelihood methods was conducted to handle the missing data (197). Therefore, the linear mixed modelling (LMM) employing intention-to-treat analysis (198) was implemented using SPSS MIXED MODELS version 20.0 to determine the effectiveness of the interventions between the groups during this study (at baseline, 12 weeks, 24 weeks, and 36 weeks) on the measured outcomes. In addition, the LMM is more robust for the potential bias from missing data compared with the more conventional methods of imputation for missing data (such as the last observation carried forward) (199). The LMM was performed on account of the repeated measures in this RCT and to address the missing data in this RCT.

A two-level hierarchical model assessed the relative effectiveness of the personalised feedback about physical activity patterns alone (PF) and in combination with peer support (PS) across the study period on the primary and secondary outcomes. The first level units were the repeated observations (at baseline, 12 weeks, 24 weeks, and 36 weeks) nested within the individual treatment group. The second level units were the three treatment groups (PF, PS and control groups). An advantage of LMM is that the type 1 error rate is not inflated. The LMM analysis allows means of an outcome and the relationship between the outcome and independent variables to vary between different level units (200).

In this RCT, the primary outcome was the level of physical activity determined by the daily pedometer readings. The secondary outcomes in this study included the self-reported physical activity levels (measured by the Physical Activity Scale for Elderly (PASE) and physical activity diary (to calculate the weekly duration and frequency of structured physical activity), CVD risk factors (measured by HbA1c, BP, weight, BMI, waist circumference, body fat percentage, LDL-C, HDL-C and triglycerides), functional status (measured by six minute walk test and timed up and go test), health related quality of life (measured by SF-12 Health Survey), and psychosocial status (measured by General Health Questionnaire-12, Multidimensional Scale of Perceived Social Support and Self-Efficacy for Exercise Scale).

An exploratory model building strategy was performed to select the final model as suggested by Hox (201). In the models produced for this RCT, the four assessment time points and three treatment groups were included in the model as the fixed effect factors. There was no random effect in this RCT as the study was conducted in one primary health care clinic and the participants were recruited from the same population. The maximum likelihood method was used to estimate the parameters of the model as it provides more accurate estimates of the fixed regression parameters (202). Each outcome was adjusted for covariates (variables that differed between the groups at baseline, if any) before testing the group differences. Interaction between the change over time and treatment groups were assessed and a plot of interaction was presented for each outcomes. The results of each outcome from the final model were presented as adjusted mean and standard errors for each group at the different assessment time points. Contrast tests were performed on outcomes with significant differences between groups over time. This was done to compare the effects of change over time between the three groups. The baseline assessment time point served as the reference. The results of the contrast tests were presented as standardised estimates (β), standard error (SE) and 95% confidence intervals. The standardised estimates were the regression coefficients on the relationship between the three groups over time and the measured outcomes. Statistical significant was set at p value of less than 0.05.

The assumptions for LMM were checked and fulfilled, which included: 1) linear relationship between residuals of different levels; 2) residuals are normally distributed; 3) equal variances of residuals at each level); 4) no multi-collinearity; and 5) no influential outliers. The models' overall fit was tested using the change in the chi-square likelihood ratio test and the critical values of the chi-square were obtained from Tabachnick and Fidell (200). The statistical significance was set at p values of less than 0.05. The adjusted R squared was calculated to determine the effect size. The effect sizes were reported according to Cohen's definition, R^2=0.14 is small effect size, R^2=0.36 is medium effect size and R^2=0.51 is large effect size (203). In this RCT, two of the secondary outcomes (perceived social support measured with Multidimensional Scale for Perceived Social Support and self-efficacy measured with Self-Efficacy for Exercise Scale) were also potential mediators of physical activity. However, it was beyond the scope of this RCT to evaluate the mediating effects of social support and self-efficacy on account of the insufficient sample size for path analysis.

4.9 Key milestones of the project

No.	Milestones	At confirmation		At present		Comments
		Tentative date	Completed date	Tentative date	Completed date	
1.	Development of study design and protocol		Dec 2010			
2.	Ethics approval and permission from authority		May 2011			Not allowed to start project (another on-going study in the clinic until Aug 2011)
3.	Completion of qualitative focus groups	Sept 2011			Oct 2011	
4.	Completion of peer mentors training	Nov 2011			Mac 2012	Delay in delivery of the pedometers from Japan
5.	Completion of recruitment	Apr 2012			May 2012	
6.	Completion of intervention	Oct 2012			July 2012	
7.	Completion of week 24 follow up	Oct 2012		Oct 2012		
8.	Completion of week 36 follow up	-		Jan 2013		A decision was made to continue the project for 36 weeks in view of Ramadhan
9.	Completion of data analysis	Dec 2012		June 2013		
10.	Submission of thesis	June 2013		May or June 2014		

4.10 Gantt Chart

No	Activities	2010		2011							2012							2013			2014
		July -Oct	**Nov - Dec**	**Jan - June**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**July - Dec**	**Jan**	**Feb - June**	**July - Dec**	**Jan - June**
1	Development of study design and protocol																				
2	Ethic approval and permission from authority (MUHREC and MoH)																				
3	Qualitative focus group discussions																				
	Recruitment																				
	Data collection																				
	Data analysis and interpretation																				
4	Recruitment and training of peer mentors																				
5	RCT																				
	Recruitment																				
	Intervention & data collection																				
	Data management																				
	Data analysis & interpretation																				
6	Report & thesis writing/Publication																				
7	Submission of final report & thesis																				

CHAPTER 5 DESCRIPTION OF PARTICIPANTS' CHARACTERISTICS IN THE RANDOMISED CONTROLLED TRIAL

This chapter describes the study participants of the randomised controlled trial (RCT), their characteristics and scores on the various measures. Included are the participants' recruitment and retention in the study, and their socio-demographic and clinical characteristics with the baseline measured outcomes of the study participants. In accordance with CONSORT guidelines on reporting RCT findings, comparisons between participants who completed and withdrew from the study and determination of the intervention group similarities at baseline on measured outcomes were performed. Programme compliance and implementation of the peer support programme are also described in this chapter.

5.1 Participants' recruitment and retention

A total of 331 Malay patients aged 60 years and above with T2DM were approached and screened to join this study. These patients either responded to a notice about this study at the clinic, or were approached through personal communication by the clinic staff. Out of the 331 patients, 78 patients (23.6%) were excluded because did not meet the study criteria. One hundred and twenty-nine (38.9%) patients declined to participate and 124 (37.5%) were eligible. These 124 participants agreed to join and were invited for enrolment. Of those who agreed to participate, 15 (12.1%) could not be contacted (either wrong phone numbers or unable to reach the patient by telephone after five repeated attempts) and 40 (32.3%) withdrew at enrolment. Table 5.1 summarises the reasons for non-participation after initial screening and recruitment. A total of 69 participants were enrolled for this RCT and underwent baseline assessment.

Table 5.1: Reasons for non-participation after recruitment

	Reasons for non-participation
Not fulfilling study criteria, N=78 (23.6%)	• 20 (25.6%) had fasting blood glucose >13 mmol/L • 20 (25.6%) using walking aids • 9 (11.5%) had no telephones • 8 (10.3%) does regular physical exercise (≥ 150 minutes/week) • 4 (5.1%) had high BP ≥180/100 mmHg • 4 (5.1%) had neurological deficits • 4 (5.1%) had renal impairment • 4 (5.1%) used wheelchair • 3 (3.8%) were visiting their children in Shah Alam • 2 (2.6%) had visual impairment
Refuse to participate, N=129 (38.9%)	• 74 (57.4%) were not interested • 30 (23.2%) had no time • 13 (10.1%) were busy with work • 7 (5.4%) had transportation issues • 5 (3.9%) had family obligations – looking after dependent grandchildren or spouse
Eligible and agreed to participate but did not participate at enrolment, N=55 (16.6%)	• 15 (12.1%) could not be contacted (either wrong phone numbers or unable to reach patient by telephone after five repeated attempts) • 40 (32.3%) withdrew at enrolment: – 19 (47.5%) did not turn up – 16 (40.0%) said they could not commit to the study protocol – 3 (7.5%) had to care for dependent person – 2 (5.0%) said their family were unsupportive

At post-intervention week 12, 61 participants returned for assessments, representing 88.4% retention from baseline. Five participants in the control group, two participants in personalised feedback about physical activity patterns alone (PF) group and one woman in personalised feedback about physical activity patterns combined with peer support (PS) group withdrew from the study. At the week-24 follow-up assessment, 56 participants returned representing 81.2% retention from baseline. Five participants withdrew from the study: one from control group, two from PF group and two from PS group. At completion of the study at week 36, 52 participants remained representing 75.4% retention from baseline. At this follow-up, four participants withdrew from the study: one from the control group and three from the PS group. Overall, a total of seven (41.2%), four (23.5%) and six (35.3%) participants from the control, PF and PS groups, respectively withdrew from this study. This difference was not statistically significant (χ^2=1.09, df=2, p=0.579). Figure 5.1 shows the flow of study participants during this RCT.

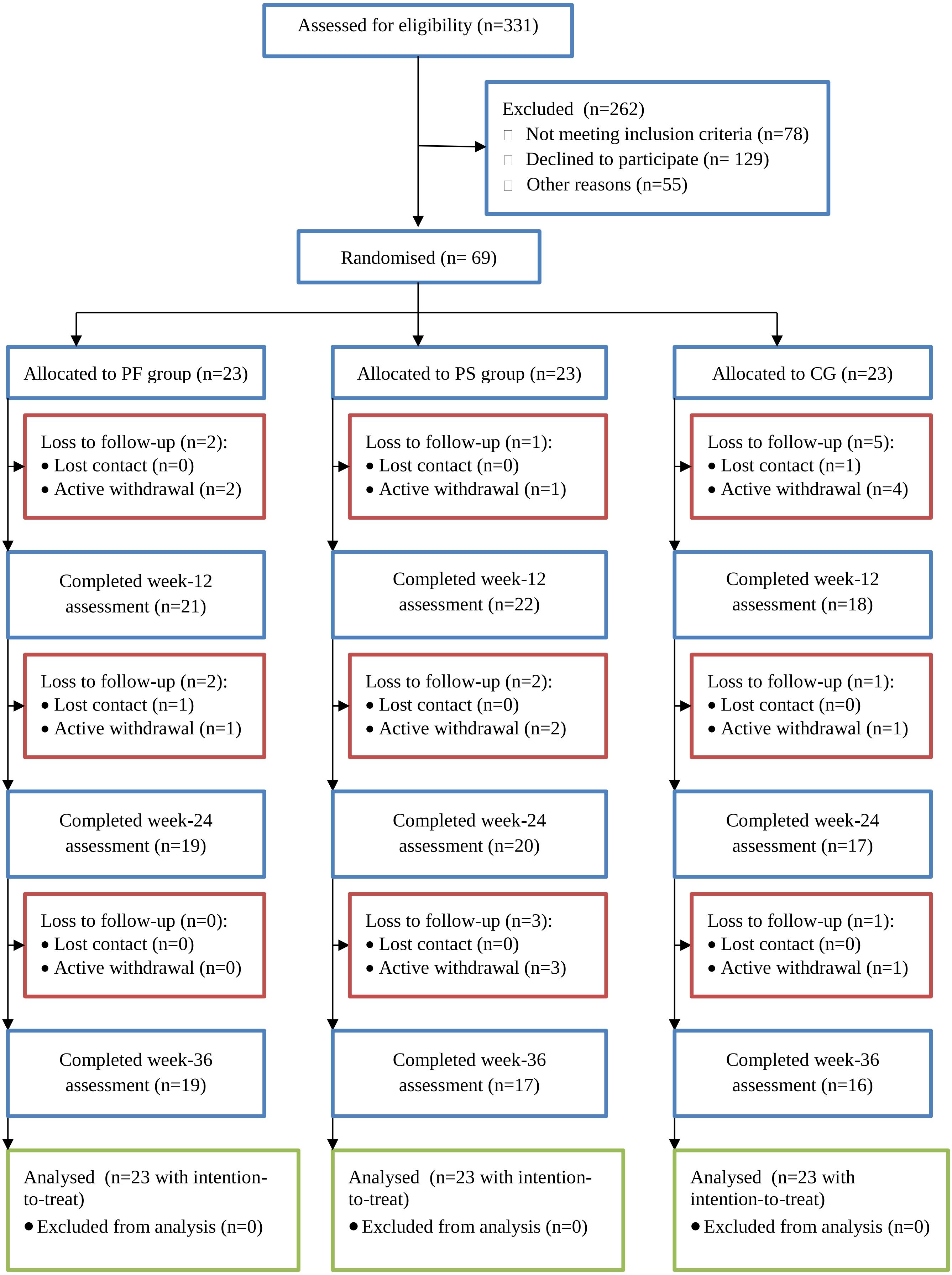

Figure 5.1: Flow of participants through RCT

Three participants, one from each group, could not comply with the study protocol and requested to withdraw. Other participants withdrew for reasons not related to the RCT. Table 5.2 summarises the participants who withdrew from the study and presents the reasons for withdrawal.

Table 5.2: Summary of participants who withdrew from the RCT and reasons for withdrawal

Study intervals	No. of withdrawals	Reasons for withdrawal
Week 12 post-intervention	CG: 5 (2 men, 3 women)	• Unable to commit to study protocol • Transportation issues • Family not supportive with involvement in this study • Sustained sprain ankle due to fall from staircase • Not contactable
	PF: 2 (1 men, 1 women)	• Shifted to another state • Had frozen shoulder
	PS: 1 (woman)	• Looking after newborn grandchild
Week 24 follow-up	CG: 1 (woman)	• Had a fall
	PF: 2 (both women)	• Shifted to another state • Not reachable
	PS: 2 (both women)	• Unable to commit to study protocol
Week 36 follow-up	CG: 1 (man)	• Busy with family obligations
	PF: none	• Shifted to another district
	PS: 3 (1 men, 2 women)	• Unable to commit to study protocol • Looking after dependent husband

Note: CG=control group; PF=personalised feedback on physical activity pattern group; PS=personalised feedback combined with peer support group.

5.2 Characteristics of the RCT participants

The socio-demographic and clinical characteristics with the baseline information about the participants' levels of physical activity, cardiovascular disease risk factors, functional status, quality of life and psychosocial wellbeing are described below.

5.2.1 Socio-demographic and clinical characteristics

Table 5.3 summarises the study participants' socio-demographic and clinical characteristics. Sixty-nine older Malays with type 2 diabetes mellitus (T2DM) were enrolled in this RCT and 52 completed this study at week 36. The participants in this RCT were older Malays with a mean age of 64.59±SD4.49 (range: 60-80 years). Most participants were aged less than 75 years (95.7%).

Most were men (53.6%), married (82.6%), and lived with their spouse and adult children (59.4%), with 52 (75.4%) participants co-resided with their adult children. Only 13 (18.8%) of the married couples did not co-reside with their adult children. The percentage of participants who completed secondary education was 49.3%. The participants' average monthly gross household income was RM3354.64±SD3067.93 (range: RM100.00 to RM11, 000.00), which is above the nation's official poverty level of RM 900.00 (RM 900.00=AUD302.30 on 1 May 2014).

About a third (29.0%) of them were still working and another third (30.4%) were pensioners (civil servants who received a fixed monthly numeration upon retirement). Of the working participants, most (15 or 75.0%) were men: five worked as taxi-drivers, three ran their own businesses, two were bus drivers, two were security guards, two were professional photographers and one worked as a factory supervisor. Among the five women who were still working, three conducted part-time Quran classes, one was a nursing staff member in a tertiary education institution and one managed her own catering company.

The mean duration of diabetes was 9.59±6.47 years (range: two to 32 years). About treatment for T2DM, most of the participants were on a diet plan and oral anti-hyperglycaemic agents (AHA) (73.9%) and 20.3% were on both oral AHA and insulin. Most of the participants (60.9%) were on a combination of sulphonylureas and biguanides (see Figure 5.2). Only 27.5% conducted self-blood glucose monitoring. Most of the participants had co-morbid conditions (95.7%) with 42 (60.9%) had both hypertension and dyslipidaemia, which was reflected by the high percentage of anti-hypertensive agents (82.6%) and lipid lowering agents (71.0%) use. Only 17 (25.8%) had hypertension only and six (9.0%) with dyslipidaemia only, while three (4.3%) had concurrent asthma, two (2.9%) had concurrent chronic obstructive airway disease, and one (1.4%) had concurrent gout. On average, the participants were on 4.58±SD1.54 prescribed medications (range: 0 to 8 prescribed medications). Most had never smoked (76.8%), and half used concurrent complementary and alternative medicine (50.7%), of whom 85.7% used herbal leaves or roots to control their diabetes and/or hypertension.

Table 5.3: Study participants' socio-demographic and clinical characteristics

Characteristics	Mean±SD/Median±IQR	Frequency (%)
Age, years	64.00±IQR7.00	
Sex		
• Men		37 (53.6)
• Women		32 (46.4)
Marital status		
• Married		57 (82.6)
• Single (divorced/widowed)		12 (17.4)
Highest education level		
• Tertiary education		17 (24.6)
• Secondary education		34 (49.3)
• Primary education		14 (20.3)
• No formal education		4 (5.8)
Occupation		
• Still working		20 (29.0)
• Pensioner		21 (30.4)
• Retired		15 (21.8)
• Housewife		13 (18.8)
Living arrangements		
• Lives with spouse or children		26 (37.7)
• Lives with spouse and children		41 (59.4)
• Lives with relatives/friends		2 (2.9)
Co-residency with adult children		
• Yes		52 (75.4)
• No		17 (24.6)
Monthly gross household income, RM	2,000.00±IQR3000.00	
Duration of diabetes, years	9.00±IQR9.50	
Presence of at least one comorbidity		66 (95.7)
Treatment modalities for diabetes		
• Diet alone		1 (1.4)
• Diet and oral AHA(s)		51 (73.9)
• Oral AHA(s) only		3 (4.4)
• Oral AHA(s) and insulin		14 (20.3)
Use of SBGM		19 (27.5)
Use of antihypertensive agent(s)		57 (82.6)
Use of lipids lowering agent(s)		49 (71.0)
Use of aspirin		10 (14.5)
No. of prescribed medications	4.58±SD1.54	
Smoking status		
• Never		53 (76.8)
• Current smoker		3 (4.4)
• Ex-smoker		13 (18.8)
Use of complementary and alternative medicine		
• Yes		35 (50.7)
– Herbal leaves/roots		30 (85.7)
– Nutritional supplements		5 (14.3)
• No		34 (49.3)

Note: SD=standard deviation; IQR=interquartile range; RM=Ringgit Malaysia (RM 1.00=AUD 0.33 on 1 May 2014); AHA=anti-hyperglycaemic agent; SBGM=self-blood glucose monitoring.

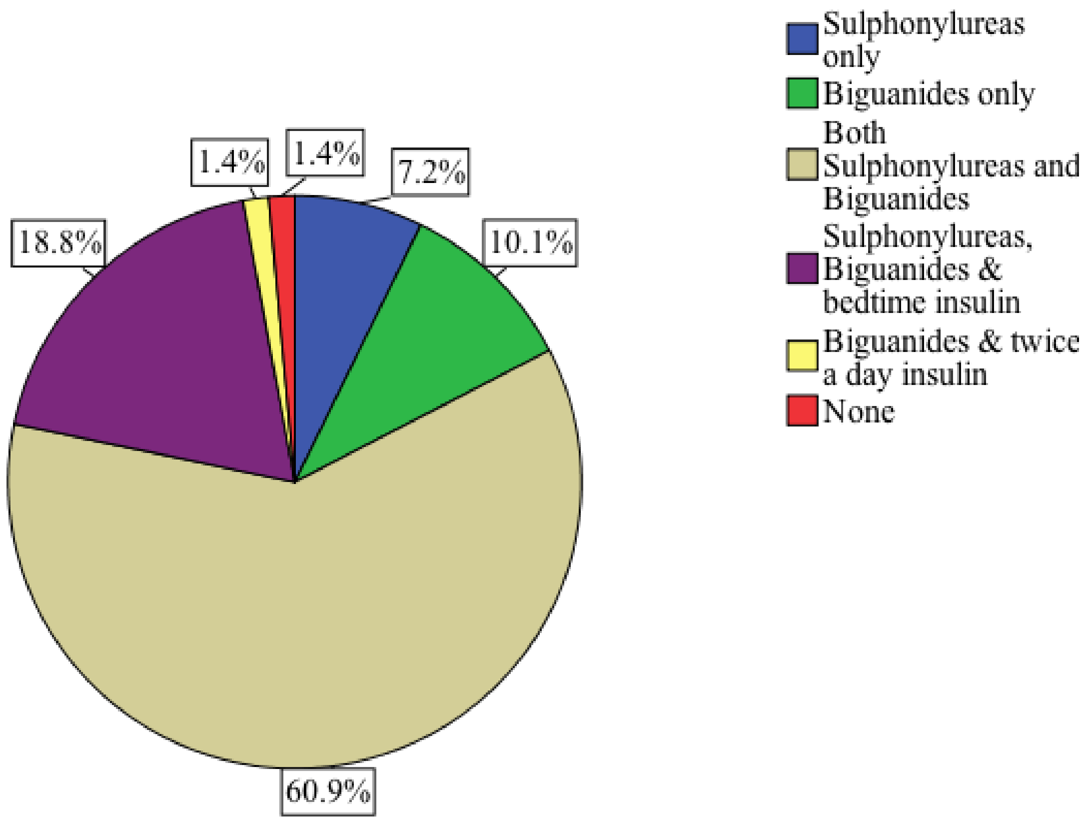

Figure 5.2: Types of anti-hyperglycaemic agents used by RCT participants

5.2.2 Baseline physical activity

Table 5.4 summarises the participants' physical activity profile. At baseline, the participants' mean pedometer steps/day was 3844.87±SD1748.94 steps a day (range: 432 to 7233 steps a day). The mean duration of structured physical activity engaged was 18.25±SD38.99 minutes in a week (range: 0 to 125 min) and the mean frequency of structured physical activity physical activity was 0.51±SD1.09 days in a week (range: 0 to four days) with a median of 0 for both the duration and frequency of structured physical activity. The mean Physical Activity Scale for Elderly (PASE) scores of the participants was 127.58±SD54.28 (range: nine to 239). On average, the participants spent 2.41±SD1.49 hours a day doing activities while seated (range: 0.5 to six hours a day). Almost a quarter (n=15, 21.7%) spent four hours or greater in a day doing activities while seated.

Table 5.4: Study participants' physical activity profile

Characteristics	n (%)/ Mean±SD/ Median±IQR
Daily pedometer mean step counts, steps/day	3844.87±SD1748.94
Duration of physical activity done, minutes/week	0.00±IQR0.00
Frequency of physical activity done, days/week	0.00±IQR0.00
Physical Activity Scale for Elderly (PASE) scores	127.58±SD54.28
Duration of PASE activities while seated, hours/day	2.00±IQR2.00

Note: SD=standard deviation; IQR=interquartile range.

The types of physical activities performed obtained from the Physical Activity Scale for Elderly are described in Table 5.5. About half of the participants (55.1%) reported not engaging in any form of physical activity, while the commonest form of physical activity performed was walking. However, the participants seldom performed the reported physical activity and 18 (58.1%) of the 31 reported that the physical activity they engaged in was not structured physical activity.

Table 5.5: Types of physical activity

Types of physical activity	N (%)
• Walking	19 (27.5)
• Gardening	6 (8.7)
• Jogging	2 (2.9)
• Cycling	3 (4.4)
• Fishing	1 (1.4)
• None	38 (55.1)

Figure 5.3 summarises the types of daily activities while seated from PASE. The most common daily activity done while seated were watching television and reading the newspaper (n=30, 43.5%), followed by watching television (n=20, 29.9%) and watching television and reading Quran (n=6, 8.7%).

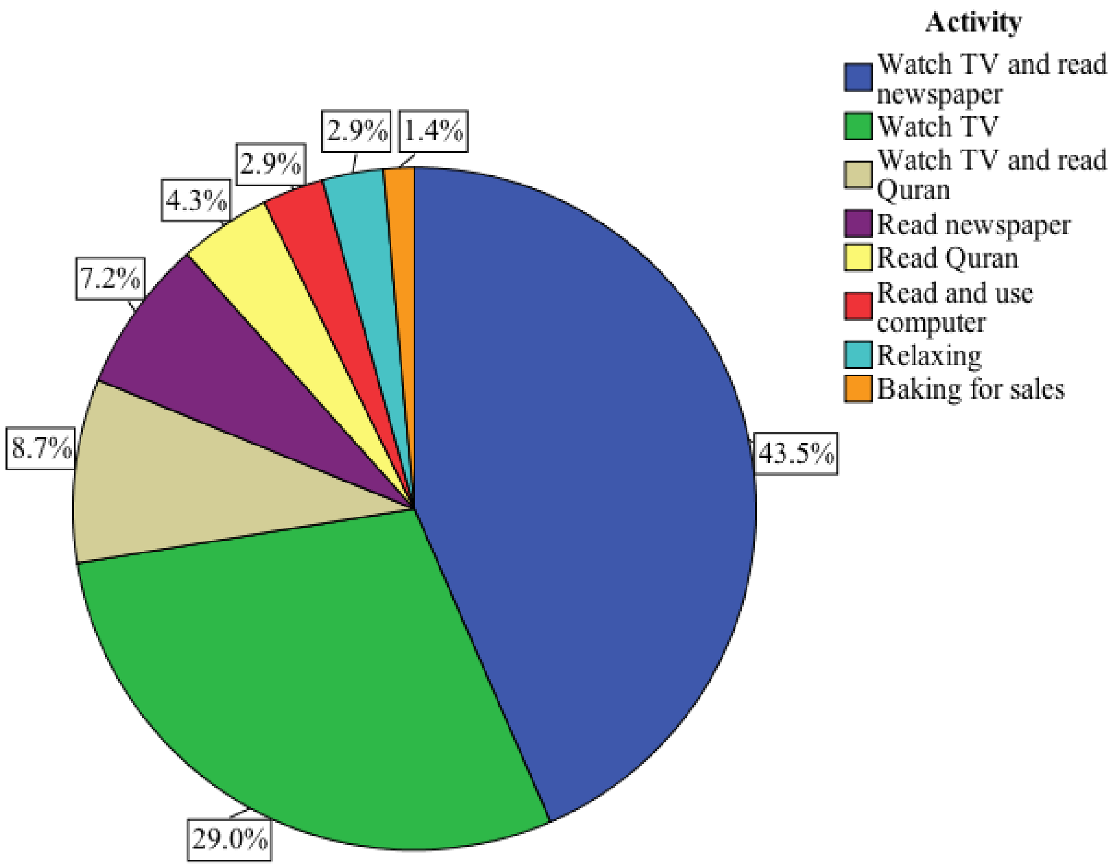

Figure 5.3: Types of daily PASE activities performed while seated

The most common perceived barriers to physical activity reported by the participants' were health problems (n=18, 26.1%). Other reported perceived barriers included laziness (n=13, 18.8%), looking after a dependent person, either spouse or grandchildren (n=7, 10.1%) and being busy with religious activities (n=7, 10.1%). Figure 5.4 summarises the perceived barriers to physical activity in this study.

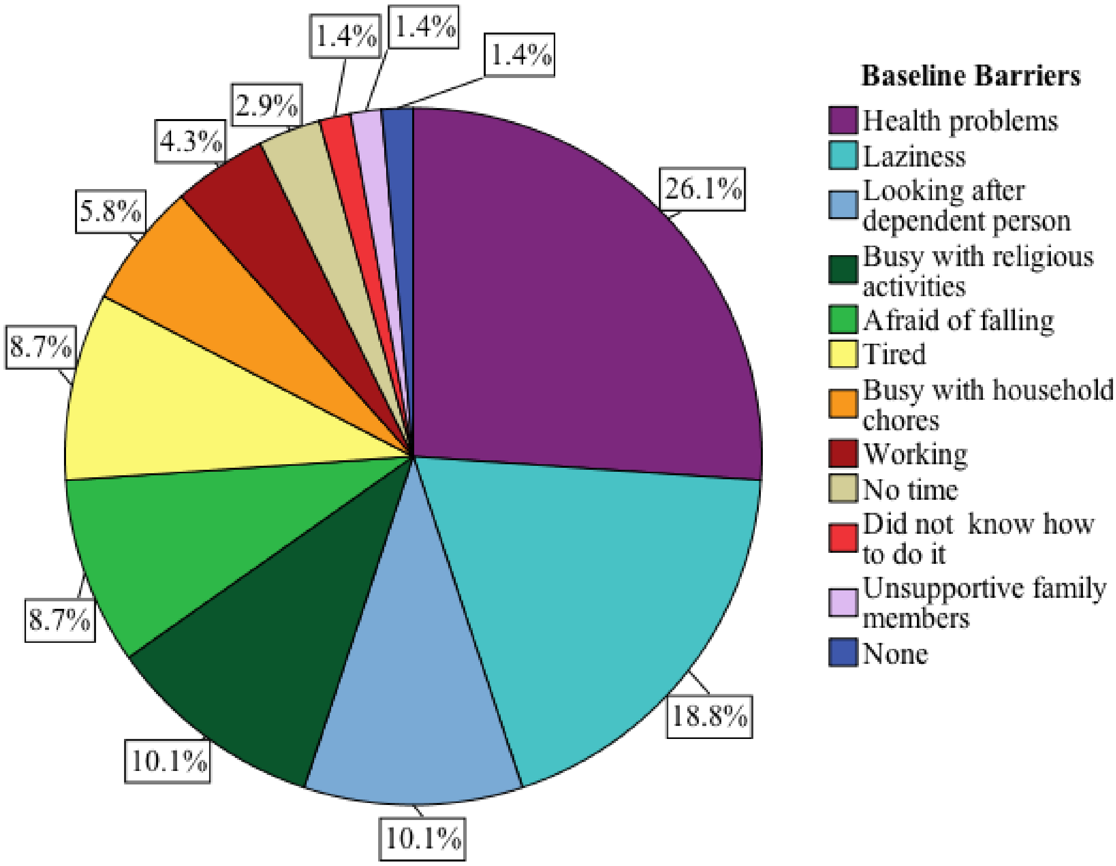

Figure 5.4: Perceived barriers to physical activity

Table 5.6 presents the perceived motivators for physical activity. The majority reported 'for better health' as their main motivator.

Table 5.6: Motivators for physical activity

Reasons	**N (%)**
Motivations	
• For better health	64 (92.8)
• Family support	4 (5.8)
• Better circulation	1 (1.4)

5.2.3 Baseline cardiovascular disease risk factors

The baseline cardiovascular disease (CVD) risk factors of the RCT participants are presented in Table 5.7. The cardiovascular disease risk factors assessed in this RCT included glycosylated haemoglobin (HbA1c), blood pressure, weight, body mass index, waist circumference, body fat percentage, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol and triglycerides. The mean HbA1c of the study participants was 8.48±SD1.61 % (range: 5.8 to 13.9%) and 28 (40.6%) of the participants had HbA1c levels that were less than 8.0%. The participants' baseline mean systolic blood pressure (BP) was 138.30±SD13.32 mmHg (range: 110 to 170 mmHg) and mean diastolic BP was 77.03±SD8.44 mmHg (range: 56 to 94 mmHg). The percentage of participants with BP control less than 130/80 mmHg was 40.6%.

The participants in this RCT had a mean weight of 70.19±SD12.85 kg (range: 41.2 to 107.3 kg) with a mean body mass index (BMI) of 27.65±SD4.60 kg/m^2 (range: 17.5 to 43.0 kg/m^2). Most participants were overweight with BMI greater than 23 kg/m^2 (71.3%). The baseline mean waist circumference (WC) of the participants was 95.72±SD7.81 cm (range: 84 to 117 cm) and 91.16±SD10.38 (range: 68 to 116 cm) for men and women, respectively. Only five (13.5%) men achieved WC less than 90 cm and two (6.3%) women achieved WC less than 80 cm. The mean body fat percentage was 25.86±SD3.73% (range: 18.6 to 34.8%) and 39.56±SD8.08% (range: 21.7 to 55.9), for men and women, respectively. More men (59.5%) achieved target body fat percentage less than 24.0% and only a third of the women (34.4%) achieved target body fat percentage less than 36.0%.

The mean LDL-C of the participants was 3.22±SD0.93 mmol/L (range: 1.4 to 4.6 mmol/L) and 29.0% achieved LDL-C less than 2.6 mmol/L. The men and women baseline mean HDL-C were 1.06±SD0.22 mmol/L (range: 0.7 to 1.7 mmol/L) and 1.13±SD0.22 mmol/L (range: 0.7 to 1.6 mmol/L), respectively. More men (43.2%) achieved target HDL-C than women (15.6%). The baseline mean triglycerides of the participants was 1.72±SD0.88 mmol/L and 58.0% achieved triglycerides less than 1.7 mmol/L.

Table 5.7: Study participants' baseline cardiovascular disease risk factors

Characteristics	Mean±SD/Median±IQR	Frequency (%)
HbA_{1c}, %	8.10±IQR1.90	
Glycaemic controls		
• HbA_{1c} <7.0		8 (11.6)
• HbA_{1c} 7.0 – 7.9		20 (29.0)
• HbA_{1c} ≥8.0		41 (59.4)
Systolic BP, mmHg	138.30±SD13.32	
Diastolic BP, mmHg	80.00±IQR10.00	
BP control <130/80 mmHg		28 (40.6)
Weight, kg	70.19±SD12.85	
BMI, kg/m^2	26.80±IQR5.50	
• Underweight (<18.5)		1 (1.4)
• Normal (18.5 – 22.9)		5 (7.3)
• Pre-obesity (23.0 – 27.4)		36 (32.2)
• Obesity (≥27.5)		27 (39.1)
WC, cm		
• Men	93.00±IQR7.00	
• Women	91.00±IQR15.25	
WC achieving targets		
• Men (<90 cm)		5 (13.5)
• Women (<80 cm)		2 (6.3)
Body fat, %		
• Men	24.90±IQR4.35	
• Women	38.75±IQR1.97	
Categories of body fat %		
Men		
• Normal (<24.0 %)		22 (59.5)
• Overweight (24.0-28.9 %)		13 (35.1)
• Obese (≥29.0 %)		2 (5.4)
Women		
• Normal (<36.0 %)		11 (34.4)
• Overweight (36.0-40.9 %)		10 (31.3)
• Obese (≥41.0 %)		11 (34.4)
LDL-C, mmol/L	3.22±SD0.93	
LDL-C achieving <2.6 mmol/L		20 (29.0)
HDL-C, mmol/L		
• Men	1.00±IQR0.30	
• Women	1.10±IQR0.30	
HDL-C achieving targets		
• Men (>1.0 mmol/L)		16 (43.2)
• Women (>1.3 mmol/L)		5 (15.6)
Triglycerides, mmol/L	1.60±IQR0.90	
Triglycerides achieving <1.7 mmol/L		40 (58.0)

Note: SD=standard deviation; IQR=interquartile range; BP=blood pressure; BMI=body mass index; WC=waist circumference; HbA_{1c}=glycosylated haemoglobin; LDL-C=low-density lipoprotein cholesterol; HDL-C=high-density lipoprotein cholesterol.

5.2.4 Baseline functional status, quality of life and psychosocial wellbeing

The functional status assessment in this study included the six-minute walk test, and the timed up and go test. The SF-12 Health Survey measured the quality of life and the psychosocial wellbeing was measured by General Health Questionnaire-12 (psychological wellbeing), the Multidimensional Scale of Perceived Social Support (social support) and Self-Efficacy for Exercise Scale (self-efficacy) as shown in Table 5.8. The baseline mean distance walked in six minutes was 216.35±64.19 metres (range: 80 to 400 metres) and the mean time taken for the timed up and go test was 9.42±1.69 seconds (range: six to 13 seconds) by the participants. The participants' mean physical component scores and mental component scores of the SF-12 were 44.03±9.90 (range: 18.12 to 57.36) and 57.09±7.512 (range: 36.48 to 73.15), respectively. The mean score for the General Health Questionnaire-12 of the participants at baseline was 0.42±0.69 (range: 0.00 to 4.00). The participants mean scores for the Multidimensional Scale of Perceived Social Support for significant others, family and friends were 5.96±0.80 (range: 2.75 to 7.00), 6.02±0.70 (range: 3.25 to 7.00) and 4.64±1.46 (range: 1.00 to 7.00), respectively. The mean score for Self Efficacy for Exercise Scale of the participants at baseline was 6.64±1.46 (range: 1.00 to 9.00).

Table 5.8: Study participants' baseline functional status, quality of life and psychosocial wellbeing

Characteristics	Mean±SD/Median±IQR
Functional status	
Six minute walk test distance, metre (cardiorespiratory fitness)	216.35±SD64.19
Timed up and go, seconds (balance)	10.00±IQR2.50
Quality of life (Short Form-12)	
• Physical component scores	46.29±IQR15.18
• Mental component scores	57.93±IQR10.46
Psychosocial wellbeing	
General health questionnaire-12 score	0.00±IQR1.00
Multidimensional Scale of Perceived Social Support	
• Significant others	6.00±IQR1.00
• Family	6.00±IQR0.63
• Friends	5.00±IQR2.75
Self-efficacy for exercise scale	6.64±SD1.46

Note: SD=standard deviation; IQR=interquartile range.

5.2.5 Summary

In this study, most of the participants were aged less than 75 years, men, married, co-resided with their adult children and had an average monthly gross household income of RM3,354.64 (equals to AUD 1,140.58). Less than half attained secondary education and a third were still working. On average, the participants had diabetes for 9.59 years and were taking 4.58 prescribed medications. Only about a quarter performed self-blood glucose monitoring. The majority had concurrent hypertension and dyslipidaemia, and were on oral anti-hyperglycaemic agents, anti-hypertensive agents and anti-lipid agents.

At baseline, the average daily pedometer reading was 844 steps and the participants spent about two hours a day on activities while seated. The participants had a baseline mean HbA1c of 8.48% and 40.6% had HbA1c levels less than 8.0%. The participants' baseline mean systolic blood pressure ranged between 110-170 mmHg and mean diastolic BP was between 56–94 mmHg. The mean weight was 70.19 kg, while the mean body mass index was 27.65 kg/m^2. Most participants were overweight with BMI greater than 23 kg/m^2. The baseline mean waist circumference of the participants was 95.72 cm and 91.16 cm for men and women, respectively. The mean body fat percentage was 25.86% for men and 39.56% for women. About half of the men achieved target body fat percentage less than 25.0% and only a third of the women achieved target body fat percentage less than 37.0%. The mean LDL-C of the participants at baseline was 3.22 mmol/L and 29.0% achieved target LDL-C less than 2.6 mmol/L. The men and women baseline mean HDL-C were 1.06 mmol/L and 1.13 mmol/L, respectively. More men achieved target HDL-C of more than 1.0 mmol/L than women achieving the target HDL-C of more than 1.3 mmol/L. The baseline mean triglycerides level of the participants was 1.72 mmol/L and 58.0% achieved triglycerides less than 1.7 mmol/L.

The baseline mean distance walked in six minutes was 216.35 metres and the mean time taken for the timed up and go test was 9.42 seconds by the participants. The participants' mean physical component scores and mental component scores of SF-12 were 44.03 and 57.09, respectively. The mean scores for General Health Questionnaire-12 of the participants at baseline was 0.42. The participants mean score for the Multidimensional Scale of Perceived Social Support from significant others, family and friends were 5.96, 6.02 and 4.64, respectively. The mean score for Self Efficacy for Exercise Scale of the participants at baseline was 6.64.

5.3 Baseline comparison between participants who completed and those who withdrew from the study

Participants who completed and discontinued the study were analysed and compared based on their baseline socio-demographic characteristics, clinical profile, baseline physical activity level, baseline cardiovascular diseases (CVD) risk factors and baseline measures of functional status, quality of life and psychosocial wellbeing.

5.3.1 Comparison between participants who completed and withdrew from the study by socio-demographic characteristics

More women than men discontinued from this study (p=0.021). No significant differences were observed between those participants who completed and those who withdrew on the measures of age, marital status, highest level of education attainment, occupation and monthly gross household income. Table 5.9 summarises these findings.

Table 5.9: Comparison between participants who completed and those who withdrew from the study by socio-demographic characteristics

Characteristics	Status of participants		Mann Whitney U[a] / Chi square test[b]	
	Completed (N=52)	Withdrew (N=17)	z / χ^2	*P* value
Age[a], median±IQR (years)	63.00±5.00	65.00±9.00	-1.59	0.113
Sex[b], n (%)				
• Men	32 (61.5)	5 (29.4)	5.32	0.021*
• Women	20 (38.5)	12 (70.6)		
Marital status[b], n (%)				
• Married	45 (86.5)	12 (70.6)	1.52	0.132
• Single (divorced/widowed)	7 (13.5)	5 (29.4)		
Highest education level[b], n (%)				
• At least secondary education	40 (76.9)	11 (64.7)	3.51	0.245
• Primary education or none	12 (23.1)	6 (35.3)		
Occupation[b], n (%)				
• Still working	18 (34.6)	2 (11.8)	3.25	0.122
• Not working	34 (65.4)	15 (88.2)		
Monthly gross household income[a], median±IQR (RM)	2500.00±3500.00	1500.00±1950.00	-1.25	0.211

Note: IQR=interquartile range; RM=Ringgit Malaysia (RM 1.00=AUD 0.33 on 1 May 2014); *P value <0.05=statistically significant.

5.3.2 Comparison between participants who completed and withdrew from the study by clinical profiles

There was no significant difference between participants who completed or withdrew from the study for the measures of the duration of diabetes, presence of comorbidity, diabetes treatment modalities and the number of types of medications (see Table 5.10).

Table 5.10: Comparison between participants who completed and those who withdrew from the study by clinical history

Characteristics	Status of participants		Mann Whitney U[a]/ Chi square test[b] / t-test[c]	
	Completed (N=52)	Withdrew (N=17)	*z*/ *t* /χ^2	*P* value
Duration of diabetes[a], median±IQR (years)	10.00±9.75	6.00±8.00	-0.64	0.525
Presence of comorbidity[b], n (%)				
• Yes	49 (94.2)	17 (100.0)	1.03	0.570
• No	3 (5.8)	0		
Treatment modalities for diabetes[b], n (%)				
• Diet alone	1 (1.9)	0	3.39	0.349
• Diet and oral AHA(s)	39 (75.0)	12 (70.6)		
• Oral AHA(s) only	1 (1.9)	2 (11.8)		
• Oral AHA(s) and insulin	11 (21.2)	3 (17.6)		
No. of prescribed medications[c], mean±SD	4.42±1.51	5.06±1.56	-1.49	0.140

Note: IQR=interquartile range; SD=standard deviation; AHA=anti-hyperglycaemic agent.

5.3.3 Comparison between participants who completed and those who withdrew from the study by physical activity level

The participants who completed the study had significantly higher Physical Activity Scale for the Elderly (PASE) scores compared to those who withdrew (p=0.003). However, there was no significant difference in the daily step counts, engagement in structured physical activity, duration and frequency of structured physical activity performed in a week, and the hours of daily PASE activities while seated between the participants who completed and those who withdrew from the study as shown in Table 5.11.

Table 5.11: Comparison between participants who completed and those who withdrew from the study by level of physical activity

Characteristics	Status of participants		t-test [a]/ Chi square test [b]/ Mann Whitney U[c]	
	Completed (N=52)	**Withdrew (N=17)**	***t* / z/ χ^2**	***P* value**
Daily pedometer steps[a], mean±SD (steps/day)	4040.87± 1612.29	3245.35± 2051.18	1.65	0.104
Duration of structured physical activity[c], median±IQR (minutes/week)	0.00±0.00	0.00±0.00	-0.17	0.862
Frequency of structured physical activity physical activity[c], median±IQR (days/week)	0.00±0.00	0.00±0.00	-0.06	0.951
Physical Activity Scale for Elderly (PASE) score[a], mean±SD	138.52±53.33	94.12±43.31	0.31	0.003*
Duration of daily PASE activities while seated[c], median±IQR (hours/day)	2.00±2.00	2.00±2.50	-0.59	0.556

Note: SD=standard deviation; IQR=interquartile range; *P value <0.05=statistically significant.

5.3.4 Comparison between participants who completed and those who withdrew from the study by CVD risk factors

Participants who withdrew from this study had greater mean weight (p=0.018) and mean body mass index (p=0.019) than those who completed the study as shown in Table 5.12. In addition, men who withdrew from the study had larger waist circumference (p=0.024) and greater body fat percentage (p=0.002) than those who completed the study. There was no significant difference between participants who completed and withdrew from the study in the mean of glycosylated haemoglobin (HbA_{1c}), systolic blood pressure (BP), diastolic BP, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides. In addition, no difference was observed in the glycaemic control, BP control less than 130/80 mmHg, WC target achieved, targets of body fat percentage achieved, and the controls of LDL-C, HDL-C and triglycerides between those who completed and withdrew from the study.

Table 5.12: Comparison between participants who completed and those who withdrew from the study by CVD risk factors

Characteristics	Status of participants		Mann Whitney U[a]/ Chi square[b] /t-test[c]	
	Complete (N=52)	Withdrew (N=17)	*z*/ *t* /χ^2	*P* value
Mean HbA_{1c}[a], median±IQR (%)	8.20±2.15	8.10±SD1.60	-0.36	0.722
Glycaemic controls[b], n (%)				
• HbA_{1c} <7.0	6 (11.5)	2 (11.8)	0.470	0.847
• HbA_{1c} 7.0 – 7.9	14 (26.9)	6 (35.3)		
• HbA_{1c} ≥8.0	32 (61.5)	9 (52.9)		
Mean systolic BP[c], mean±SD (mmHg)	137.21±12.83	141.65±14.63	-1.20	0.236
Mean diastolic BP[a], median±IQR (mmHg)	80.00±10.00	80.00±19.00	-0.52	0.606
BP control < 130/80 mmHg[b], n (%)	22 (42.3)	6 (35.3)	0.26	0.777
Mean weight[c], mean±SD (kg)	68.12±10.98	76.50±16.17	-2.42	0.018*
Mean BMI[a], median±IQR (kg/m^2)	26.45±3.07	29.30±7.80	-2.35	0.019*
BMI[b], n (%)				
• Underweight (<18.5)	0	1 (5.9)	10.70	0.009*
• Normal (18.5 – 22.9)	5 (9.6)	0		
• Pre-obesity (23.0 – 27.4)	31 (59.6)	5 (29.4)		
• Obesity (≥27.5)	16 (30.8)	11 (64.7)		
Mean WC[a], median±IQR (cm)				
• Men	92.50±5.88	111.00±16.50	-2.21	0.024*
• Women	90.00±12.75	96.00±16.75	-1.41	0.170
WC achieving targets[b], n (%)				
Men	N=32	N=5	0.90	0.588
• <90 cm	5 (15.6)	0		
Women	N=20	N=12	1.28	0.516
• <80 cm	2 (10.0)	0		
Mean body fat[a], median±IQR (%)				
• Men	24.45±3.78	28.80±6.25	-2.89	0.002*
• Women	38.15±7.08	41.70±11.85	-1.21	0.239
Body fat %[b], n (%)				
Men	N=32	N=5		
• Normal (<24.0 %)	20 (62.5)	2 (40.0)	1.70	0.506
• Overweight (24.0-28.9 %)	10 (31.2)	3 (60.0)		
• Obese (≥29.0 %)	2 (6.2)	0		
Women	N=20	N=12		
• Normal (<36.0 %)	7 (35.0)	4 (33.3)	2.68	0.350
• Overweight (36.0-40.9 %)	8 (40.0)	2 (16.7)		
• Obese (≥41.0 %)	5 (25.0)	6 (50)		
Mean LDL-C[c], mean±SD (mmol/L)	3.14±0.95	3.44±0.89	-1.12	0.268
LDL-C <2.6 mmol/L[b], n (%)	16 (30.8)	4 (23.5)	0.33	0.568

Characteristics	Status of participants		Mann Whitney U[a]/ Chi square[b] /t-test[c]	
	Complete (N=52)	**Withdrew (N=17)**	***z*/ *t* /χ^2**	***P* value**
Mean HDL-C[a], median±IQR (mmol/L)				
• Men	1.00±0.30	1.20±0.35	-1.11	0.286
• Women	1.15±0.27	1.10±0.30	-0.16	0.893
HDL-C achieving targets[b]				
Men	N=32	N=5	0.66	0.664
• >1.0 mmol/L	13 (40.6)	3 (60.0)		
Women	N=20	N=12	0.02	1.000
• >1.3 mmol/L	3 (15.0)	2 (16.7)		
Mean triglycerides[a], median±IQR (mmol/L)	1.50±0.90	1.70±1.50	-1.45	0.147
Triglycerides <1.7 mmol/L[b], n (%)	32 (61.5)	8 (47.1)	1.10	0.294

Note: IQR=interquartile range; SD=standard deviation; BP=blood pressure; BMI=body mass index; WC=waist circumference; HbA_{1c}=glycosylated haemoglobin; LDL-C=low-density lipoprotein cholesterol; HDL-C=igh-density lipoprotein cholesterol; *P value <0.05=statistically significant.

5.3.5 Comparison between participants who completed and those who withdrew from the study by functional status, quality of life and psychosocial wellbeing

Those who completed this study had greater distance walked in the six-minute walk test (p=0.001) and greater SF-12 physical component summary scores (p=0.040), and a greater self-efficacy for exercise scores (p=0.017) than those who withdrew from the study. However, participants who withdrew from the study took a longer time to perform the timed up and go test (p=0.021). Table 5.13 summarises the comparison on functional status, quality of life and psychosocial wellbeing measures between participants who completed and withdrew from the study.

Table 5.13: Comparison between participants who completed and those who withdrew from the study functional status, quality of life and psychosocial wellbeing

Characteristics	Status of participants		t-test [a]/ Mann Whitney U [b]	
	Completed (N=52)	Withdrew (N=17)	*t / z*	*P* value
Cardiorespiratory fitness				
• Six minute walk test distance[a], mean±SD (metre)	230.69±61.97	172.47±50.55	3.51	0.001*
Balance				
• Timed up and go[b], median± IQR (seconds)	9.00±2.00	10.00±2.50	-2.31	0.021*
Health related quality of life (Short Form-12)				
• Physical component scores[b], median±IQR	48.27±11.66	45.12±20.64	-2.05	0.040*
• Mental component scores[b], median±IQR	57.09±11.54	59.17±10.56	-1.33	0.183
Psychological wellbeing				
• General health questionnaire-12 score[b], median±IQR	0.00±1.00	0.00±1.00	-0.10	0.920
Multidimensional Scale of Perceived Social Support				
• Significant others[b], median±IQR	6.00±1.00	6.00±0.38	-0.17	0.864
• Family[b], median±IQR	6.00±0.69	6.00±0.50	-0.41	0.681
• Friends[b], median±IQR	5.00±1.94	5.25±3.50	-0.27	0.785
Self-efficacy for exercise scale[a], mean±SD	6.88±1.26	5.91±1.80	2.45	0.017*

Note: SD=standard deviation; IQR=interquartile range; **P* value <0.05=statistically significant.

5.3.6 Summary

Comparison between the participants who completed and those who withdrew from the study was made. Among those who withdrew from this study, most were women. The Malay women hold traditional roles in the family, where obligations to spouse and family takes priority (158). This could contribute to their non-participation in this study. Those who withdrew had lower total Physical Activity Scale for the Elderly (PASE) scores and greater mean weight and body mass index. The men who withdrew from the study had larger waist circumference (WC) and greater body fat percentage than those who completed the study. Participants who withdrew from the study also had lesser distance walked in the six-minute walk test, physical component scores of SF-12 and self-efficacy scale for exercise scores than those who completed the study. They also took longer time to perform the timed up and go test compared to those who completed the study.

5.4 Comparison between participants' baseline characteristics and the different groups

Homogeneity of the data at baseline between the three groups including the participants' socio-demographic characteristics, clinical profiles, levels of physical activity, cardiovascular disease risk factors, functional status, quality of life and psychosocial wellbeing parameters was determined.

5.4.1 Socio-demographic characteristics

The baseline socio-demographic characteristics between the participants in the different groups were compared as shown in Table 5.14. There was no significant difference in the baseline socio-demographic characteristics across the different groups.

Table 5.14: Comparisons of baseline socio-demographic characteristics according to groups

Characteristics	Control group (N=23)	Personalised feedback (PF) (N=23)	PF and Peer support (N=23)	Kruskal Wallis[a] or Chi square test[b]	
				H **(χ^2)**	***P* value**
Age[a], median±IQR (years)	63.00±7.00	63.00±8.00	64.00±7.00	0.19	0.909
Sex[b], n (%)					
• Men	11 (47.8)	14 (60.9)	12 (52.2)	0.82	0.755
• Women	12 (52.2)	9 (39.1)	11 (47.8)		
Marital status[b], n (%)					
• Married	19 (82.6)	20 (87.0)	18 (78.3)	0.61	0.921
• Unmarried	4 (17.4)	3 (13.0)	5 (21.7)		
Highest level of education[b], n (%)					
• At least secondary education	17 (73.9)	16 (69.6)	18 (78.3)	0.45	0.940
• Lower than secondary education	6 (26.1)	7 (30.4)	5 (21.7)		
Working status[b], n (%)					
• Not working	19 (82.6)	13 (56.5)	17 (73.9)	3.94	0.178
• Still working	4 (17.4)	10 (43.5)	6 (26.1)		
Co-residency with children[b], n (%)					
• Yes	19 (82.6)	19 (82.6)	14 (60.9)	3.90	0.179
• No	4 (17.4)	4 (17.4)	9 (39.1)		
Monthly gross household income[a], median±IQR (RM)	2500.00± 2500.00	2000.00± 2000.00	2000.00± 3700.00	0.36	0.836

Note: IQR=interquartile range; RM=Ringgit Malaysia (RM 1.00=AUD 0.33 on 1 May 2014).

5.4.2 Baseline clinical profiles

Diabetes treatment modalities (p=0.007), use of anti-hypertensive agents (p=0.027) and the number of prescribed medications (p=0.006) significantly differed across the different groups. The mean number of types of prescribed medication used was significantly greater in the control group than the personalised feedback group. Higher proportion of the control group (39.1%) was on both oral anti-hyperglycaemic agents and insulin compared with PF (13.0%) and PS (8.7%) groups. There was no significant difference between the different groups for duration of diabetes, use of oral AHA, self-blood glucose monitoring, and use of lipid lowering agents. Table 5.15 summarises the baseline clinical profiles across the different groups.

Table 5.15: Comparison of baseline clinical profiles according to groups

Characteristics	Control group (N=23)	Personalised feedback (PF) (N=23)	PF and Peer support (N=23)	Kruskal Wallis[a] / Chi square[b] /One-way ANOVA[c]	
				H (χ^2)/ F	P value
Duration of diabetes[a], median±IQR (year)	6.00±9.00	10.00±9.00	9.00±11.00	1.53	0.465
Presence of co-morbid conditions[b], n (%)	23 (100.0)	20 (87.0)	23 (100.0)	6.27	0.101
Treatment modalities for diabetes[b], n (%)					
• Diet alone	0	1 (4.3)	0	14.97	0.007*
• Diet and oral AHA(s)	14 (60.9)	19 (82.6)	18 (78.3)		
• Oral AHA(s) only	0	0	3 (13.0)		
• Oral AHA(s) and insulin	9 (39.1)	3 (13.0)	2 (8.7)		
SBGM[b], n (%)					
• Yes	8 (34.8)	7 (30.4)	4 (17.4)	1.89	0.491
• No	15 (65.2)	16 (69.6)	19 (82.6)		
Use of anti-hypertensive agents[b], n (%)	22 (95.7)	15 (65.2)	20 (87.0)	7.87	0.027*
Use of lipid lowering agents[b], n (%)	15 (65.2)	16 (69.6)	18 (78.3)	0.99	0.713
No. of presecribed medications[c], mean±SD	5.13±1.55**	3.78±1.57**	4.83±1.19	5.50	0.006*

Note: IQR=interquartile range; SD=standard deviation; AHA=anti-hyperglycaemic agents; SBGM=self-blood glucose monitoring; **P* value <0.05=statistically significant; ** Post-hoc test significant between groups.

5.4.3 Baseline levels of physical activity

The baseline physical activity level of the participants are summarised in Table 5.16. Comparisons made across the different groups showed no significant difference in the baseline levels of physical activity.

Table 5.16: Comparisons of baseline physical activity level according to groups

Characteristics	Control group (N=23)	Personalised feedback (PF) (N=23)	PF and Peer support (N=23)	One-way ANOVA[a]/Chi square test [b] / Kruskal Wallis [c]	
				F/ χ^2/ H	P value
Mean daily pedometer steps[a], mean±SD (steps/day)	3385.26± 1734.88	4076.13± 1918.68	4073.22± 1559.51	1.20	0.308
Duration of structured physical activity[c], median±IQR (minutes/week)	0.00±0.00	0.00±0.00	0.00±0.00	0.22	0.897
Frequency of structured physical activity[c], median±IQR (days/week)	0.00±0.00	0.00±0.00	0.00±0.00	0.15	0.926
Physical Activity Scale for Elderly (PASE) scores[a], mean±SD	121.87± 41.25	142.00± 62.05	118.87± 56.79	1.24	0.295
Duration of daily PASE activities while seated[c], median±IQR (hours/day)	2.00±1.00	2.00±3.00	2.00±2.00	3.53	0.171

Note: SD=standard deviation; IQR=interquartile range.

5.4.4 Baseline cardiovascular disease risk factors

The baseline CVD risk factors did not differ across the different groups as presented in Table 5.17.

Table 5.17: Comparisons of baseline cardiovascular disease risk factors according to groups

Characteristics	Control group (N=23)	Personalised feedback (PF) (N=23)	PF and Peer support (N=23)	Kruskal Wallis[a] /One-way ANOVA[b]	
				***H*/ *F*□**	***P* value**
HbA_{1c} [a], median±IQR (%)	8.10±2.70	8.30±1.70	8.10±2.00	0.50	0.779
Systolic BP[b], mean ±SD (mmHg)	139.04± 10.68	137.35± 6.42	138.52± 13.32	0.09	0.909
Diastolic BP[a], median±IQR (mmHg)	80.00±10.00	78.00±17.00	80.00±10.00	0.04	0.978
Weight[b], mean±SD (kg)	70.62±13.65	70.02±13.10	69.92±12.34	0.02	0.981
BMI[a], median±IQR (kg/m^2)	26.10±7.00	26.60±4.40	27.00±5.50	0.91	0.636
WC[a], median±IQR (cm)					
• Men	96.00±9.00	94.25±10.00	91.50±4.75	2.13	0.345
• Women	91.00±19.00	90.00±13.00	93.00±16.00	0.41	0.814
Body fat[a], median±IQR (%)					
• Men	26.20±3.00	24.80±5.88	24.90±4.98	0.39	0.820
• Women	37.30±9.28	37.80±7.25	40.60±13.60	3.61	0.165
LDL-C[b], mean±SD (mmol/L)	3.23±1.13	3.11±0.72	3.30±0.94	0.23	0.794
HDL-C[a], median±IQR (mmol/L)					
• Men	1.00±0.40	1.15±0.33	0.95±0.18	2.75	0.253
• Women	1.15±0.42	1.20±0.20	1.10±0.30	0.81	0.668
Triglycerides[a], median±IQR (mmol/L)	1.60±1.40	1.60±1.00	1.40±1.40	2.23	0.327

Note: IQR=interquartile range; SD=standard deviation; BP=blood pressure; BMI=body mass index; WC=waist circumference; HbA_{1c}=glycosylated haemoglobin; LDL-C=low-density lipoprotein cholesterol; HDL-C=high-density lipoprotein cholesterol.

Table 5.18 compared the control of CVD risk factors across the groups. There was no significant difference in the CVD risk controls across the groups in this study.

Table 5.18: Comparisons of baseline CVD risk factors control according to groups

Characteristics	Control group (N=23)	Personalised feedback (PF) (N=23)	PF and Peer support (N=23)	χ^2	P value
Glycaemic control,					
• HbA_{1c} <7.0%	2 (8.7)	3 (13.0)	3 (13.0)	0.54	0.968
• HbA_{1c} 7.0-7.9%	6 (26.1)	7 (30.4)	7 (30.4)		
• HbA_{1c} ≥8.0%	15 (65.2)	13 (56.5)	13 (56.5)		
BP					
• <130/80 mmHg	6 (26.1)	11 (47.8)	11 (47.8)	3.00	0.264
BMI, kg/m^2					
• Underweight (<18.5)	0	0	1 (4.3)	3.29	0.871
• Normal (18.5-22.9)	1 (4.3)	2 (8.7)	2 (8.7)		
• Pre-obesity (23.0-27.4)	14 (60.9)	12 (52.2)	10 (43.5)		
• Obesity (≥27.5)	8 (34.8)	9 (39.1)	10 (43.5)		
Waist circumference					
Men	N=11	N=14	N=12	3.08	0.214
• <90 cm	0	2 (14.3)	3 (25.0)		
Women	N=12	N=9	N=11	1.19	0.553
• <80 cm	1 (8.3)	1 (11.1)	0		
Body fat percentage					
Men	N=11	N=14	N=12	4.81	0.308
• Normal (<24.0 %)	7 (63.6)	8(57.1)	7 (58.3)		
• Overweight (24.0-28.9 %)	4 (36.4)	6 (42.9)	3 (25.0)		
• Obese (≥29.0 %)	0	0	2 (16.7)		
Women	N=12	N=9	N=11	2.34	0.674
• Normal (<36.0 %)	5 (45.7)	4 (44.4)	2 (18.2)		
• Overweight (36.0-40.9 %)	4 (33.3)	2 (22.2)	4 (36.4)		
• Obese (≥41.0 %)	3 (25.0)	3 (33.3)	5 (45.5)		
LDL-C <2.6 mmol/L	8 (34.8)	6 (26.1)	6 (26.1)	0.56	0.843
HDL-C					
Men	N=11	N=14	N=12	2.75	0.253
• >1.0 mmol/L	5 (45.5)	8 (57.1)	3 (25.0)		
Women	N=12	N=9	N=11	2.52	0.283
• >1.3 mmol/L	3 (25.0)	0	2 (18.2)		
Triglycerides <1.7 mmol/L,	13 (56.5)	13 (56.5)	14 (60.9)	0.12	1.000

Note: Chi square test was performed. All results were based on Chi-square or Exact test and described as frequencies and percentages.

BP=blood pressure; BMI=body mass index; WC=waist circumference; HbA_{1c}=glycosylated haemoglobin; LDL-C=low-density lipoprotein cholesterol; HDL-C=high-density lipoprotein cholesterol.

5.4.5 Baseline functional status, quality of life and psychosocial wellbeing

The SF-12 mental component summary score was significantly different between the three groups (p=0.048). No other significant differences in the other variables between the three groups were found as summarised in Table 5.19.

Table 5.19: Comparisons of baseline functional status, quality of life and psychosocial wellbeing according to groups

Characteristics	Control group (N=23)	Personalised feedback (PF) (N=23)	PF and Peer support (N=23)	One-way ANOVA[a] / Kruskal Wallis[b]	
				F* / *H	***P* value**
Functional status					
Cardiorespiratory fitness					
• Six minute walk test distance[a], mean± SD (metre)	196.52± 68.46	236.00± 65.85	216.52± 53.81	2.26	0.113
Balance					
• Timed up and go[b], median±IQR (seconds)	9.00±3.00	10.00±2.00	9.00±2.00	0.48	0.787
Quality of life (Short Form-12)					
• Physical component scores[b], median±IQR	46.74±17.01	49.16±6.91	44.98±16.34	5.89	0.052
• Mental component scores[b], median±IQR	56.09±10.72	56.74±9.98	60.10±10.52	6.07	0.048*
Psychosocial wellbeing					
Psychological wellbeing					
• General health questionnaire-12 score[b], median±IQR	0.00±1.00	0.00±1.00	0.00±0.00	4.91	0.086
Multidimensional Scale of Perceived Social Support					
• Significant others[b], median±IQR	6.00±0.50	6.00±1.25	6.00±0.75	3.95	0.139
• Family[b], median±IQR	6.00±0.75	6.00±0.75	6.00±1.00	1.93	0.380
• Friends[b], median±IQR	5.00±2.75	5.00±1.50	5.50±3.00	0.19	0.910
Self-efficacy for exercise scale[a], mean±SD	6.44±1.86	6.73±0.98	6.75±1.45	0.34	0.714

Note: SD=standard deviation; IQR=interquartile range; **P* value <0.05=statistically significant.

5.4.6 Summary

Diabetes treatment modalities, use of anti-hypertensive agents, the number of types of medications used and the SF-12 mental component summary scores differ significantly across the different groups, while other outcomes did not.

5.5 Trend on the modification of medications related to diabetes care during this study

In this study, data on modification of the medications related to diabetes care was collected at the different assessment time points (at weeks 12, 24 and 36). Across these time points, some participants from each group had their medications modified to achieve better glycaemic and/or CVD risk control. The modifications involved either increment of the medications dosage or adding another type of medication. Table 5.20 summarises the modification of medications in each group across the study period. None of the participants had reduction in the dosage of their medication regimen.

Table 5.20: Summary of modification of medications related to diabetes care across the study period

Medications modified	Week 12			Week 24			Week 36		
	CG (N=18)	**PF (N=21)**	**PS (N=22)**	**CG (N=17)**	**PF (N=19)**	**PS (N=20)**	**CG (N=16)**	**PF (N=19)**	**PS (N=17)**
• Increased oral AHA or insulin dose	4 (22.2%)	4 (19.0%)	-	2 (11.8%)	2 (10.5%)	2 (10.0%)	3 (18.9%)	2 (10.5%)	1 (5.9%)
• Increased anti-hypertensive agents	1 (5.6%)	1 (4.8%)	1 (4.5%)	2 (11.8%)	1 (5.9%)	1 (5.0%)	1 (6.2%)	-	-
• Increased anti-lipid agents	-	-	-	1 (5.8%)	-	-	1 (6.2%)	1 (5.8%)	-
• Add new medications (oral AHA, insulin anti hypertensive agents or anti-lipid agents)	2 (11.1%)	-	-	2 (11.8%)	1 (5.9%)	-	1 (6.2%)	-	-
• No modifications required	11 (61.1%)	16 (76.2%)	21 (95.5%)	10 (58.8%)	15 (77.7%)	17 (85.0%)	10 (62.5%)	16 (83.7)	16 (94.1%)

Note: CG=Control group; PF=personalised feedback about physical activity group; PS=PF combined with peer support group; AHA=anti-hyperglycaemic agents.

From the Pearson's chi-square test, a significant difference between the groups on the modification of medications was observed at week 12 ($\chi^2(2)=7.1$, $p=0.029$). More participants in the control group (38.9%) had their medications modified than those in the PF (23.9%) and PS (4.5%) groups as shown in Figure 5.5.

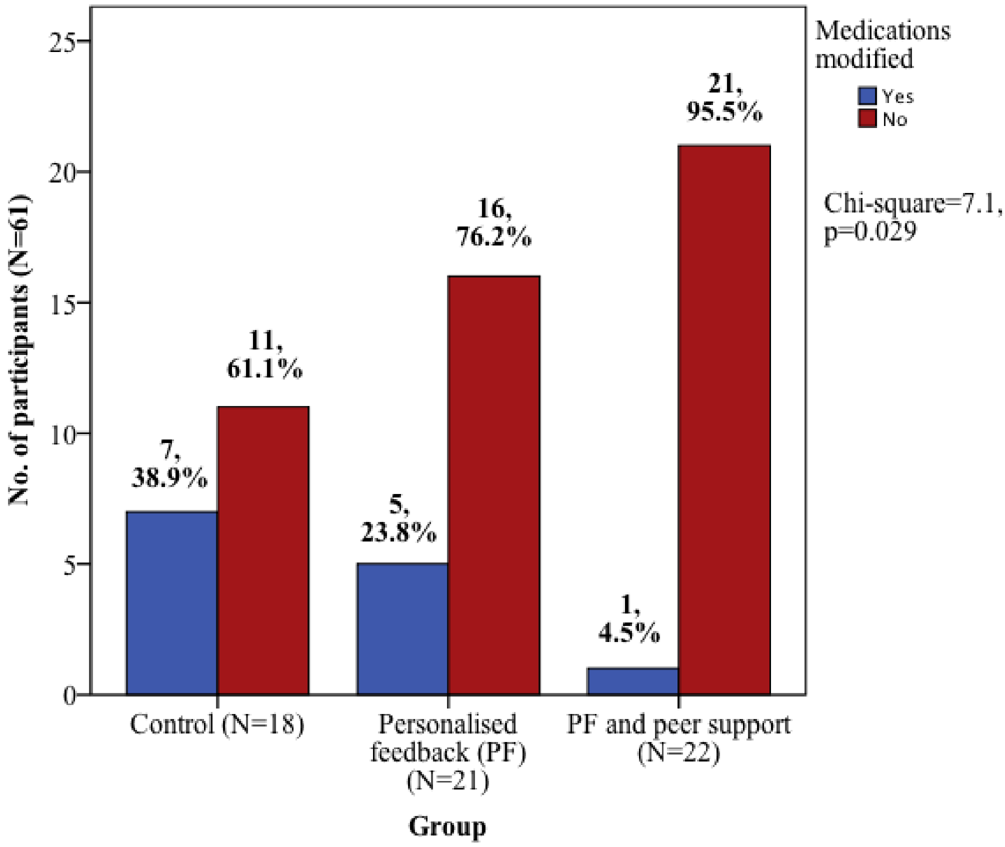

Figure 5.5: Modification of medications at week 12

There was a significant difference between the groups on the modification of medications related to diabetes care at week 36 ($\chi^2(2)=5.2$, $p=0.027$) but not at week 24 ($\chi^2(2)=0.2$, $p=0.185$) as shown in Figures 5.6 and 5.7.

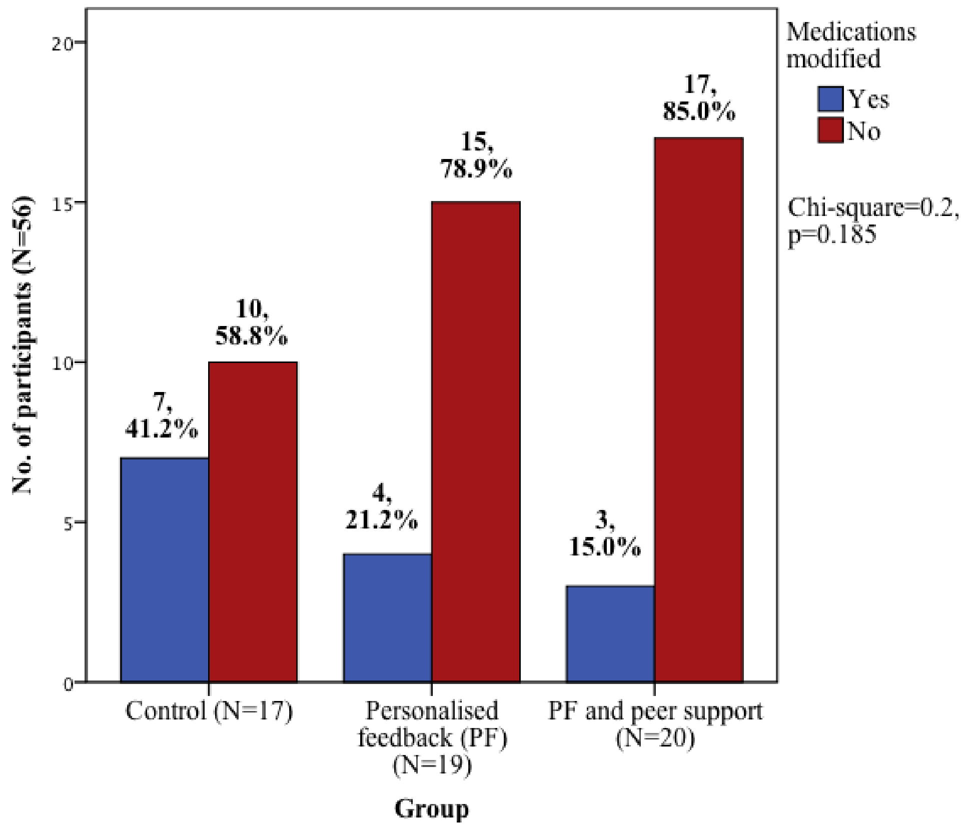

Figure 5.6: Modification of medications at week 24

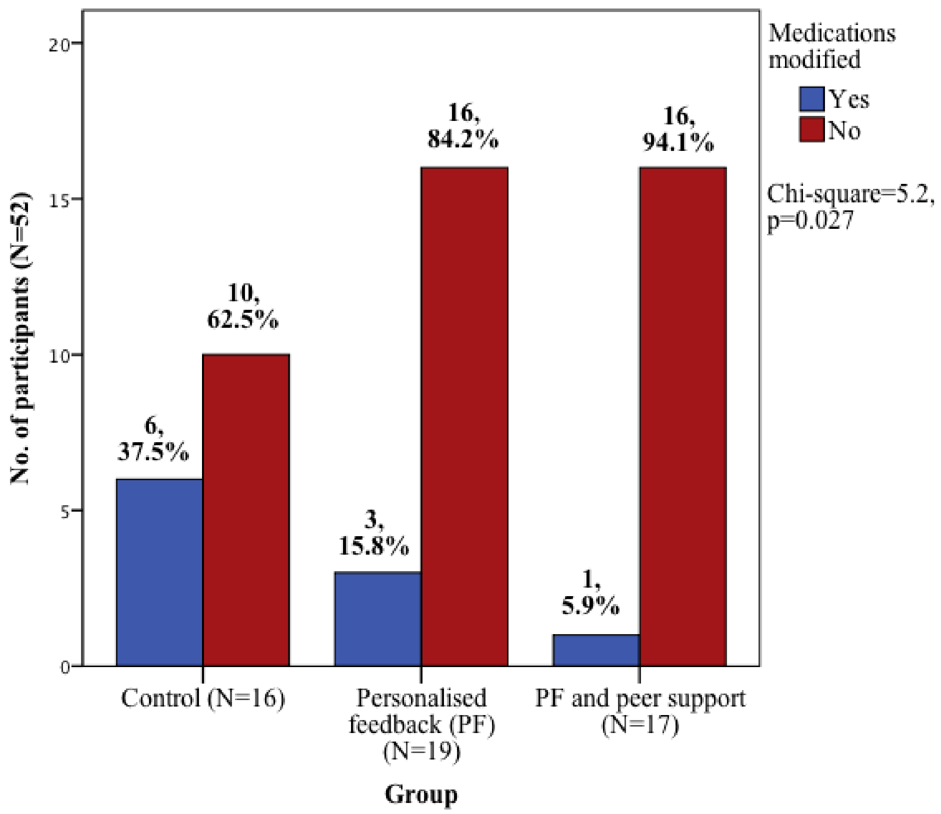

Figure 5.7: Modification of medications at week 36

5.6 Adherence to study protocol

In this RCT, participants had to use the pedometer, chart their physical activity in a diary, and those in the intervention groups were required to exercise. All participants wore the pedometers during the four assessment time points. Over time, the adherence to recording in their physical activity diary declined. During the 12 weeks of intervention, all participants in the PF and PS groups recorded the duration, frequency and intensity of structure physical activity in their diaries. At post-intervention week 12, week 24 and week 36, 59/61 (96.7%), 53/56 (94.6%) and 48/52 (92.3%) participants completed the diary, respectively. For the nine participants who did not adhere to charting of the diary, the daily pedometer readings were obtained from the memory of the pedometer. The information on the weekly duration and frequency of structured physical activity of these participants were imputed as missing data.

During this study, the proportion of participants in the intervention groups who adhere to the exercise prescription also fluctuated. At the completion of this RCT, five (21.7%) participants from the PF group and one (4.3%) participant from the PS group did not engage in the walking activity. The reasons for non-participation included the rainy season, laziness, and being busy with work or with religious activities. Interestingly, four of these participants from the PF group did not walk regularly after the 12 weeks intervention while each from the PF and PS group did not engage in the walking activity at the week-36 follow-up. During this RCT, following the 12 weeks of intervention was the start of the Ramadan month according to the Islamic calendar followed by the festive month of Syawal. During Ramadan, the Muslims fast from dawn to dusk. They fill their days with religious related activities such as attending religious classes, *Tarawih* prayers and reciting and understanding the Quran (*Tadarus*). The month of Syawal marks the festival of Eid-Ul-Fitr, when all sins are forgiven as a reward from the fasting and prayers in Ramadan. Consequently, there is a possibility that the participants became less active on account of religious activities. This could be reflected by the presence the fasting month of Ramadan and the festive month of Syawal during the week-24 follow-up. Furthermore, the follow-up weeks 24 to 36 were during the monsoon season (between November and January), which discourage some of these participants from engaging in walking activity. Two participants did not exercise at 36 weeks of follow-up because they work as taxi-drivers, so they were too busy transporting passengers. Table 5.21 summarises the adherence to study protocol according to groups.

Table 5.21: Adherence to study protocol

Protocol	Week 12		Week 24		Week 36	
	Total	**N (%) of adherence**	**Total**	**N (%) of adherence**	**Total**	**N (%) of adherence**
Use of pedometer						
• CG	18	18 (100.00)	17	17 (100.00)	16	16 (100.00)
• PF	21	21 (100.00)	19	19 (100.00)	19	19 (100.00)
• PS	22	22 (100.00)	20	20 (100.00)	17	17 (100.00)
Physical activity diary charting						
• CG	18	17 (94.40)	17	16 (94.10)	16	14 (87.50)
• PF	21	20 (95.20)	19	17 (89.50)	19	17 (89.50)
• PS	22	22 (100.00)	20	20 (100.00)	17	17 (100.00)
Walking activity prescription						
• CG	18	NA	17	NA	16	NA
• PF	21	21 (100.00)	19	13 (68.40)	19	14 (73.70)
• PS	22	22 (100.00)	20	18 (90.00)	17	16 (94.10)

Note: CG=Control group; PF=personalised feedback about physical activity patterns group; PS=PF combined with peer support group; NA=not applicable.

5.7 Adverse events due to complications and hospitalisations

None of the participants from this RCT sustained any injury or experienced any adverse events because of the intervention. Six (8.7%) participants developed complications during this study (four from control group, and one each from PF and PS groups). The complications comprised falls (two from control group), coronary heart disease (one from control group), renal impairment (one each from the control and PF groups) and carbuncle (one from the PS group). Three participants from the control group and one participant from the PS group required hospitalisation because of the complications. None of these complications were because of the intervention.

5.8 Peer mentors' recruitment, characteristics at enrolment and contacts with the participants

Twenty-five potential peer mentors were approached and 15 (60.0%) agreed to participate. Of these, 13 (52.0%) were men and 12 (48.0%) were women. Ten patients refused to participate and the reasons for refusals were: no time to spare, not interested and shifting to another state. Those who agreed to participate were screened and they attended the two days training workshop. One participant withdrew, as he was busy with a political party involvement.

At enrolment, six peer mentors participated as peer mentors with equal numbers of men and women. Table 5.22 presents the socio-demographic characteristics of the peer mentors at enrolment. Their mean age was 63.50±SD2.66 years (range: 60 to 67 years) and all were married. Most completed secondary education (83.3%), were retired civil servants (66.6%), and lived with their spouse and adult children (66.7%). On average, the monthly gross household income was RM3,050.00±SD1, 911.81 (range: RM 300.00 to RM6, 000.00).

Table 5.22: Socio-demographic characteristics of peer mentors

Characteristics	Mean±SD/Median±IQR	Frequency (%)
Age, years	63.50±SD2.66	
Sex		
• Men		3 (50.0)
• Women		3 (50.0)
Marital status		
• Married		3 (100.0)
Highest education level		
• Tertiary education		1 (16.7)
• Secondary education		5 (83.3)
Occupation		
• Pensioner		1 (16.7)
• Retired		4 (66.6)
• Housewife		1 (16.7)
Living arrangements		
• Lives with spouse or children		2 (33.3)
• Lives with spouse and adult children		4 (66.7)
Monthly gross household income, RM	3,050.00±SD1, 911.81	

Note: SD=standard deviation; IQR=interquartile range; RM=Ringgit Malaysia (RM 1.00=AUD 0.33 on 1 May 2014).

The peer mentors also had similar assessments as the RCT's participants. Table 2.23 summarises the clinical profiles of the peer mentors. The average duration of diabetes was 10.67±SD4.37 years (range: six to 17 years), and number of medication types was 4.00±SD0.89

(range: three to five prescribed medications). All had one or more co-morbidity, on diet and oral anti-hyperglycaemic agents, on anti-hypertensive agents and lipids lowering agents.

Table 5.23: Clinical profiles of peer mentors

Characteristics	Mean±SD/Median±IQR	Frequency (%)
Duration of diabetes, years	10.67±SD4.37	
Presence of at least one co-morbidity		6 (100.00)
Treatment modalities for diabetes		
• Diet and oral AHA(s)		6 (100.00)
Use of antihypertensive agent(s)		6 (100.00)
Use of lipids lowering agent(s)		6 (100.00)
Use of aspirin		1 (16.7)
No. of prescribed medications	4.00±SD0.89	

Note: SD=standard deviation; IQR=interquartile range; AHA=anti-hyperglycaemic agent.

Table 5.24 summarises the outcome variables of the peer mentors at enrolment. On average, the peer mentors had pedometer readings of 10,265.50±SD1,364.11 steps/day (range: 9,054.00 to 12,477.00 steps/day), duration of structured physical activity of 190.83±SD32.00 minutes/week (range: 150.00 to 225.00 minutes/week), frequency of structured physical activity of 5.50±SD0.84 days/week (range: five to seven days/week), Physical Activity Scale for Elderly (PASE) scores of 194.00±SD74.49 (range: 127.00 to 328.00) and duration of PASE activities while seated of 1.33±SD0.52 hours/day (range: 1.00 to 2.00 hours/day).

The CVD risk factor profiles of the peer mentors were mean HbA1c % of 6.90±SD0.51% (range: 5.90 to 7.30%), systolic BP of 138.00±SD8.65 mmHg (range: 127.00 to 148.00 mmHg), diastolic BP of 79.67±SD1.37 mmHg (range: 77.00 to 81.00 mmHg), weight of 69.67±SD13.04 kg (range: 48.70 to 84.00 kg), BMI of 26.90±SD4.85 kg/m^2 (range: 20.50 to 32.50 kg/m^2), and body fat percentage of 31.08±SD9.07% (range: 18.70 to 46.10 %). The lipid profile of the peer mentor were LDL-C of 3.12±SD0.93 mmol/L (range: 2.40 to 4.40 mmol/L), HDL-C of 1.18±SD0.24 mmol/L (range: 0.90 to 1.60 mmol/L), and triglycerides of 1.50±SD0.42 mmol/L (range: 1.20 to 2.30 mmol/L).

On average, the peer mentors' six minutes walk test was 367.00±SD26.04 metres (range: 316.00 to 386.00 metres) and timed up and go test was 9.50±SD0.84 seconds (range: 8.00 to 10.00 seconds). The peer mentors' quality of life was SF-12 physical component summary scores of 44.71±SD6.72 (range: 34.42 to 52.34), and SF-12 mental component summary scores of 51.41±SD7.69 (range: 40.67 to 62.27). The peer mentors' GHQ-12 scores was 0.17±SD0.41 (range: 0.00 to 1.00), MSPSS (significant others) was 6.04±SD0.81 (range: 5.00 to 7.00), MSPSS (family) was 6.17±SD0.68 (range: 5.50 to 7.00), MSPSS (friends) was 5.08±SD0.99 (range: 3.75 to 6.50) and the Self-efficacy Scale for Exercise was 7.13±SD1.18 (range: 5.67 to 9.00).

Table 5.24: Outcome variables of peer mentors at enrolment

Outcomes	Mean±SD/Median±IQR
Physical activity level	
Pedometer-determined PA, steps/day	10, 265.50±SD1, 364.11
Duration of structured PA, minutes/week	190.83±SD32.00
Frequency of structured PA, days/week	5.00±IQR1.25
Physical Activity Scale of Elderly (PASE) scores	194.00±SD74.49
Duration of daily PASE activities while seated, hours/day	1.33±SD0.52
Cardiovascular disease risk factors	
HbA1c, %	6.90±SD0.51
Systolic BP, mmHg	138.00±SD8.65
Diastolic BP, mmHg	80.00±IQR1.00
Weight, kg	69.67±SD13.04
BMI, kg/m^2	26.90±SD4.85
Body fat, %	31.08±SD9.07
LDL-C, mmol/L	2.70±IQR1.85
HDL-C, mmol/L	1.18±SD0.24
Triglycerides, mmol/L	1.35±IQR0.58
Functional status	
Six minute walk test, metres	378.00±IQR29.50
Timed up and go, seconds	10.00±IQR1.25
Quality of life	
SF-12 Health Survey physical component summary scores	44.71±SD6.72
SF-12 Health Survey mental component summary scores	51.41±SD7.69
Psychosocial wellbeing	
General Health Questionnaire -12	0.00±IQR0.25
Multidimensional Scale for Perceived Social Support (significant others)	6.04±SD0.81
Multidimensional Scale for Perceived Social Support (family)	6.17±SD0.68
Multidimensional Scale for Perceived Social Support (friend)	5.08±SD0.99
Self-Efficacy for Exercise	7.13±SD1.18

Note: SD=standard deviation; IQR=interquartile range; PA=physical activity; BP=blood pressure; BMI=body mass index; LDL-C=low-density lipoprotein cholesterol; HDL-C=high-density lipoprotein cholesterol.

There were six peer support groups with three groups for each gender. Each of the peer mentors was assigned three to four peers from the PS group. The participants in the PS group received support from their peer mentors during intervention. The participants had three one-to-one and three telephone scheduled contacts during the 12 weeks intervention period. On average, each one-to-one session lasted about 1 to 1.5 hours and the mean duration spent on the telephone call was 7.73±SD1.83 minutes and median of 7.20±IQR 2.15 (range: 5.90 to 11.20 minutes).

During the 12 weeks of the intervention, the participants had a mean of 6.59±SD1.50 contacts and a median of 7.00±IQR1.00 contacts (range: three to 11 contacts) with their peer mentors. Of the 22 participants who returned for the week-12 post-intervention visit, 18 (81.82%)

participants had six or more contacts with their peer mentors. Four participants (18.18%) did not have all the six scheduled contacts during the intervention because the peer mentors could not reach them through telephone after three attempts.

From week-12 post-intervention to the follow-up week 36, there was no scheduled contact between the participants in the PS group and the peer mentor. However, when the researcher asked about contacts with their peer mentors outside the study protocol schedule, the participants had contacts with their peers and peer mentors during the six months post-intervention. From the week-12 post-intervention to follow-up week 24, the participants had a mean of 1.58±SD0.77 and median of 1.00±IQR1.00 contacts (range: 1.00 to 4.00 contacts) with their peer mentors. Through informal communication with the participants and the peer mentors, the unscheduled contacts came from meetings during Ramadan and Syawal. For the women, they got together at the religious classes and at the mosque during the *Tarawih* prayers. As for the men in the PS group most of their contacts came after Ramadan where some of them did the walking activity together at the Lake Shah Alam, which has a walking track.

At week 24 to week 36, the participants had a mean of 0.91±SD0.24 and median of 1.00±0.00 contacts (range: 0 to 1.00 contacts) with their peer mentors. Through informal communication with the participants and the peer mentors, the contacts was either meeting at the religious classes for the women or at the lake for the men. Interestingly, the participants and the peer mentors became acquainted and had developed their own social network outside the study. Unfortunately, this RCT only captured the number of contacts the participants had with their peer mentors but not among themselves.

5.9 Overall summary of findings

In this study, most of the participants were older people aged less than 70 years, men, married, attained secondary education and co-reside with their adult children, with an average gross monthly household income above the nation’s poverty level. The participants’ mean duration of diabetes was 9.59±6.47 years, ranging from two to 32 years. Most of them were on oral anti-hyperglycaemic agents and had co-morbid hypertension and dyslipidaemia. Only a fifth of the participants performed self-blood glucose monitoring and on average, the study participants were on five prescribed medications.

Before enrolment, the average daily pedometer steps was 3844.87±SD1748.94 steps/day, less than a fifth of the participants engaged in regular structured physical activity and about a quarter spent four hours or more on daily activities while seated, mostly watching the television up to six hours a day. Most reported their health problems deterred them from being physically active, though the most commonly reported motivator for physical activity was for better health. On average, the participants' baseline mean HbA1c level was of poor control. The mean systolic and diastolic blood pressures were within the normal limits. At baseline, most of the study participants did not achieve the targets of body mass index, waist circumference, body fat percentage, and lipid profile.

At baseline, the participants had low cardiorespiratory fitness with normal balance and psychological wellbeing. Unfortunately, there are no Malaysian population norms for the SF-12 physical component summary and mental component summary scores, Multidimensional Scale of Perceived Social Support scores and Self Efficacy for Exercise Scale scores to allow comparison. Therefore, in this study the differences in scores from baseline were used to determine improvements of these secondary outcomes.

In this study, 17 participants (24.6%) were lost to follow-up, and 41.2%, 23.5% and 35.3% of participants were from the control, PF and PS groups respectively. Only three participants could not comply with the study protocol because of time constraints, and requested to withdraw from the study. Most of the participants who withdrew from this study were women, had larger waist circumferences, greater body fat percentage and took longer to get up and go from a chair. At baseline, the diabetes treatment modalities, use of anti-hypertensive agents, the number of types of medications used and baseline SF-12 mental component summary scores were significantly different across the three groups, while other outcomes did not vary across the groups. In addition, a comparison between the groups on modification of the participants' medications across the study period was performed. There were significant differences between the groups on the modifications of medications at week 12 and week 36. More participants in the control group had their medications modified by their attending doctors than participants in the PF and PS groups. More participants in the control group had complications requiring hospitalisation during the course of this study. However, there were no reported adverse events due to the intervention. Interestingly, the participants in the PS group developed their own social network with their peers and peer mentors outside the study.

It is necessary to highlight the fact that differences between those who completed and discontinued this RCT and participants in the PS group who conferred outside scheduled meetings could affect the validity of this RCT. These issues are addressed as a limitation in interpreting the RCT findings in the discussion section in Chapter 7. The differences in some of the clinical information measured in this RCT between the three groups at baseline are addressed in the analysis by controlling for these variables as covariates to the primary and secondary outcomes measured. This is described in Chapter 6 where the analyses to determine the effectiveness of the RCT interventions on the measured outcomes are presented.

CHAPTER 6 FINDINGS OF PERSONALISED FEEDBACK ABOUT PHYSICAL ACTIVITY PATTERN ALONE AND IN COMBINATION WITH PEER SUPPORT INTERVENTIONS

The effectiveness of personalised feedback about physical activity pattern alone and in combination with peer support interventions, in addition to the usual diabetes care on the primary and secondary outcomes of this RCT is presented in this chapter. The study participants were randomly allocated into three groups: 1) control group (CG), who received the usual diabetes care as did the other groups; 2) personalised feedback about the pattern of physical activity (PF) group; and 3) personalised feedback about the pattern of physical activity combined with peer support (PS) group. The primary outcome of this RCT was the pedometer-determined physical activity level and the secondary outcomes included self-reported physical activity, cardiovascular disease risk factors, functional status, quality of life and psychosocial wellbeing.

Linear mixed modelling using intention-to-treat analysis was applied to determine the effectiveness of interventions across the different assessment time points (baseline, week 12 post-intervention, and week 24 and week 36 follow-ups). The following assumptions were checked and fulfilled: 1) linear relationship between residuals of different levels; 2) residuals were normally distributed; 3) equal variances of residuals at each level; 4) absence of multi-collinearity; and 5) no influential outliers. All analyses were controlled for variables that differed between groups at baseline, namely, diabetes treatment modalities, number of prescribed medications, use of antihypertensive agents and baseline SF-12 mental component summary scores.

6.1 Primary outcome

The primary outcome of this study was the pedometer-determined level of physical activity, which was represented by the daily pedometer readings. The daily pedometer readings were presented as pedometer steps/day. A significant difference in the pedometer steps/day between the groups over time (F (6, 173.85)=4.10, p=0.001; final model χ^2 (11)=91.41, p<0.001; adjusted R^2=0.212) with a small to medium effect size was observed. The hypothesis 2.6 (a) that there would be a significant difference in the pedometer steps/day between the groups across the study period was supported. Table 6.1 compares the daily pedometer readings between the three groups across the study period. All the assumptions were checked and fulfilled.

Compared with baseline, the PF group showed significantly greater pedometer steps/day at follow-up week 24 (β=2093.18±SE666.89 steps/day, p=0.002) than the control group. The PS group also showed significantly greater daily pedometer readings from baseline at post-intervention week 12 (β=2265.85±SE642.93 steps/day, p=0.001) and at follow-up weeks 24 (β=2586.31± SE660.33 steps/day, p<0.001) and week 36 (β=2084.94±SE685.25 steps/day, p=0.003) when compared to the control group. Further, the PS group showed significantly greater daily pedometer readings from baseline at post-intervention week 12 (β=1416.12±SE621.62 steps/day, p=0.024) and at follow-up weeks 36 (β=1416.67±SE661.68 steps/day, p=0.034) when compared with the PF group. Therefore, the results support that PF in combination with peer support intervention (PS) led to significant changes in the pedometer determined level of physical activity compared with PF and control groups across the study period.

Table 6.1: Comparisons of daily pedometer readings among the three groups across study period

	Pedometer readings (steps/day)					
	PF		**PS**		**CG**	
	N	**Mean±SE**	**N**	**Mean±SE**	**N**	**Mean±SE**
• Baseline	23	3771.78±486.64	23	3681.91±486.34	23	3341.78±486.64
• Week 12	21	5337.95±509.28	22	6776.55±497.57	18	4134.33±555.09
• Week 24	19	6166.74±535.42	20	6682.85±521.86	17	3661.94±566.04
• Week 36	19	5564.89±535.42	17	7234.06±566.04	16	4583.81±583.46
	Time specific comparisons of standardised estimates between groups					
	β±SE		**95% CI**		**P value**	
PF vs. CG						
• Week 12	849.73±648.61		-430.25, 2129.72		0.192	
• Week 24	2093.18±666.89		777.19, 3409.17		0.002*	
• Week 36	668.27±674.24		-662.23, 1998.76		0.323	
PS vs. CG						
• Week 12	2265.85±642.93		997.05, 3534.66		0.001*	
• Week 24	2586.31±660.33		1283.21, 3889.41		<0.001*	
• Week 36	2084.94±685.25		732.69, 3437.18		0.003*	
PS vs. PF						
• Week 12	1416.12±621.62		189.19, 2643.05		0.024*	
• Week 24	493.13±643.55		-777.01, 1763.27		0.445	
• Week 36	1416.67±661.68		110.78, 2722.57		0.034*	

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

Each PF and PS groups did show increased mean pedometer steps/day over time while the control group remain unchanged as shown in Figure 6.1.

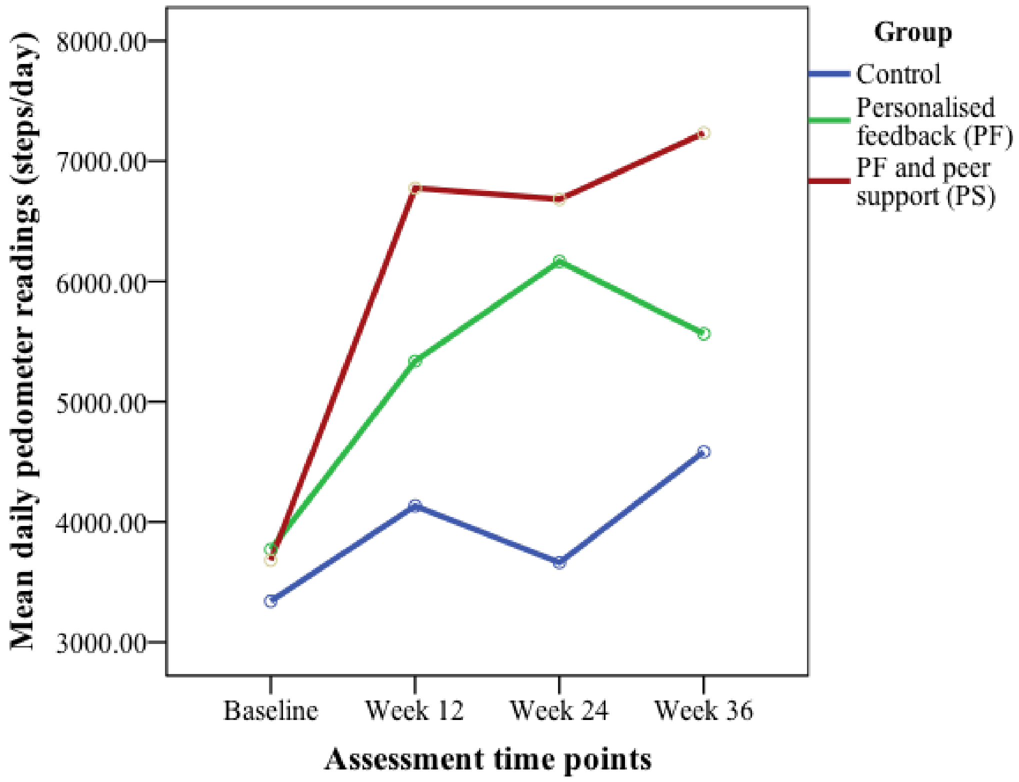

Figure 6.1: Comparisons of adjusted means of daily pedometer readings among the three groups across study period

6.2 Secondary outcomes

6.2.1 Self-reported physical activity levels

The physical activity diary and the Physical Activity Scale for the Elderly questionnaire measured the self-reported physical activity in this RCT.

Physical activity diary

From the physical activity diary, the weekly duration and frequency of physical activity were calculated.

1. Weekly duration of physical activity

The weekly duration of physical activity was presented as minutes/week of moderate intensity structured physical activity. There was a significant difference in the weekly duration of structured physical activity between the three groups across the study period (F (6, 178.57)=6.29, p<0.001; final model χ^2 (11)=145.43, p<0.001; adjusted R^2=0.386) with a medium to large effect size. The hypothesis 2.6 (b) that there would be significant difference in the weekly duration of structured physical activity between the three groups across the study period was supported. All the assumptions were checked and fulfilled. Table 6.2 compared the weekly duration of structured physical activity between the three groups across the study period.

Table 6.2: Comparisons of weekly duration of structured physical activity among the three groups across study period

	Duration of structured physical activity (minutes/week)					
	PF		**PS**		**CG**	
	N	**Mean±SE**	**N**	**Mean±SE**	**N**	**Mean±SE**
• Baseline	23	21.48±16.05	23	18.48±16.05	23	14.78±16.05
• Week 12	21	120.88±16.64	22	172.12±16.33	18	42.18±17.72
• Week 24	19	117.84±17.26	20	167.82±16.91	17	39.20±18.11
• Week 36	19	130.47±17.26	17	180.99±17.92	16	50.22±18.51

	Time specific comparisons of standardised estimates between groups		
	β±SE	**95% CI**	**P value**
PF vs. CG			
• Week 12	71.99±25.22	21.89, 125.21	0.005*
• Week 24	71.94±25.90	20.84, 123.04	0.006*
• Week 36	73.56±26.18	9.63, 152.90	0.006*
PS vs. CG			
• Week 12	126.24±25.02	76.88, 175.59	<0.001*
• Week 24	124.93±25.67	74.28, 175.57	<0.001*
• Week 36	127.09±26.62	74.56, 179.60	<0.001*
PS vs. PF			
• Week 12	54.24±24.26	6.36, 102.12	0.027*
• Week 24	52.98±25.08	3.49, 102.47	0.036*
• Week 36	53.53±25.77	2.68, 104.38	0.039*

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

Compared with controls, both the PS (at week 12 β=126.24±SE25.02 minutes/week, p<0.001; at week 24 β=124.93±SE25.67 minutes/week, p<0.001; at week 36 β=127.09±SE26.62 steps/day, p<0.001) and PF (at week 12 β=54.24±SE24.26 minutes/week, p<0.001; at week 24 β=124.93±25.67 minutes/week, p<0.001; at week 36 β=127.09±SE26.62 minutes/week, p<0.001) groups showed significantly greater weekly duration of physical activity across the different time points when compared to baseline. The PS group also had greater duration of physical activity over time (at week 12 β=71.99±SE25.08 minutes/week, p=0.036; at week 36 β=53.53±SE25.77 minutes/week, p=0.039) compared to the PF group. Figure 6.2 showed that both PF and PS groups showed increased mean minutes/week of structured physical activity across the study period, while the control group remained unchanged.

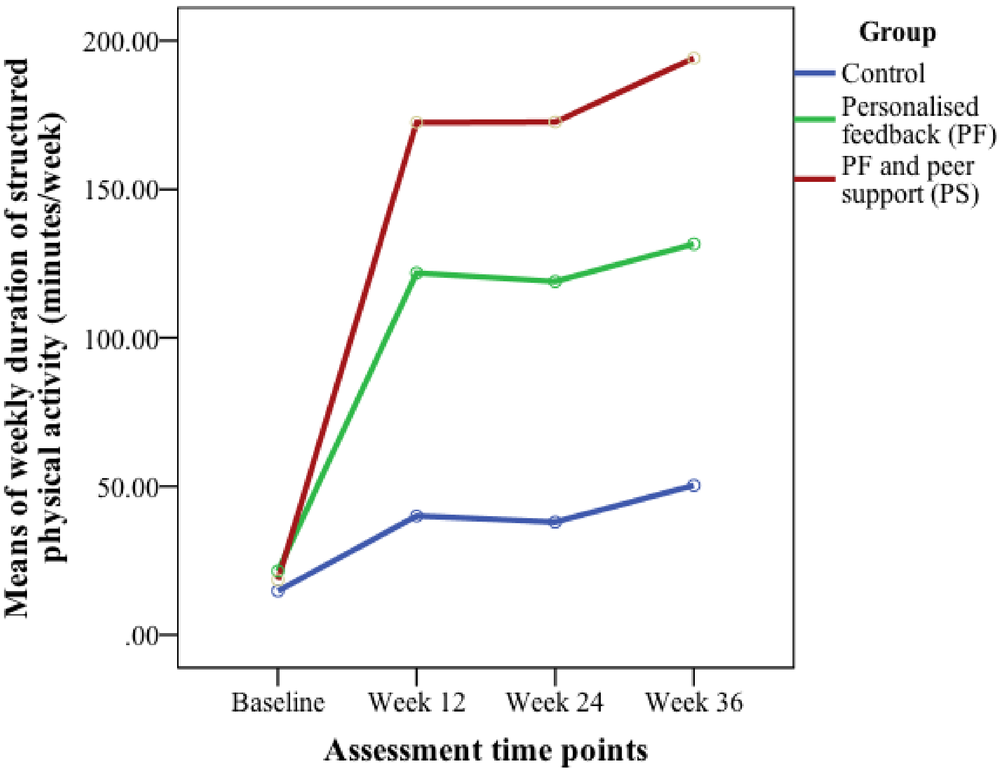

Figure 6.2: Comparisons of adjusted means of weekly duration of structured physical activity among the three groups across study period

2. Weekly frequency of structured physical activity

The weekly frequency of structured physical activity is presented as mean days/week of moderate intensity physical activity. A significant difference between the three groups across the study period on the weekly frequency of structured physical activity (F (6, 180.38)=7.20, p<0.001; final model χ^2 (11)=183.38, p<0.001; adjusted R^2=0.465) with a medium to large effect size was observed as summarised in Table 6.3. Therefore, hypothesis 2.6 (c) that there would be a significant difference in the weekly frequency of structured physical activity between the three groups across the study period was supported. All the assumptions were checked and fulfilled.

Table 6.3: Comparisons of weekly frequency of structured physical activity among the three groups across study period

	Frequency of structured physical activity (days/week)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	0.57±0.39	23	0.48±0.39	23	0.48±0.39
• Week 12	21	0.60±0.41	22	0.49±0.40	18	0.34±0.44
• Week 24	19	3.50±0.43	20	5.17±0.42	17	1.64±0.45
• Week 36	19	4.19±0.43	17	5.32±0.45	16	1.97±0.47
	Time specific comparisons of standardised estimates between groups					
	β±SE		**95% CI**		**P value**	
PF vs. CG						
• Week 12	0.18±0.69		-1.19, 1.55		0.912	
• Week 24	1.77±0.72		0.36, 3.18		0.014*	
• Week 36	2.13±0.72		0.71, 3.56		0.004*	
PS vs. CG						
• Week 12	0.15±0.69		-1.21, 1.52		0.825	
• Week 24	3.53±0.71		2.13, 4.93		<0.001*	
• Week 36	3.35±0.73		1.89, 4.79		<0.001*	
PS vs. PF						
• Week 12	-0.02±0.67		-1.35, 1.31		0.974	
• Week 24	1.76±0.69		0.39, 3.13		0.012*	
• Week 36	1.22±0.71		-0.19, 2.62		0.090	

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

Both PS (at week 24 β=3.53±SE0.71 days/week, p<0.001; at week 36 β=3.53±SE0.73 days/week, p<0.001) and PF (at week 24 β=1.77±SE0.72 days/week, p=0.014; at week 36 β=2.13±SE0.72 days/week, p=0.004) groups had greater frequency of structured physical activity than the control group over the different time points when compared to baseline. The PS group also showed a greater frequency of structured physical activity (β=1.76±SE0.69 days/week, p=0.012) at week 24 than the PF group when compared to the baseline.

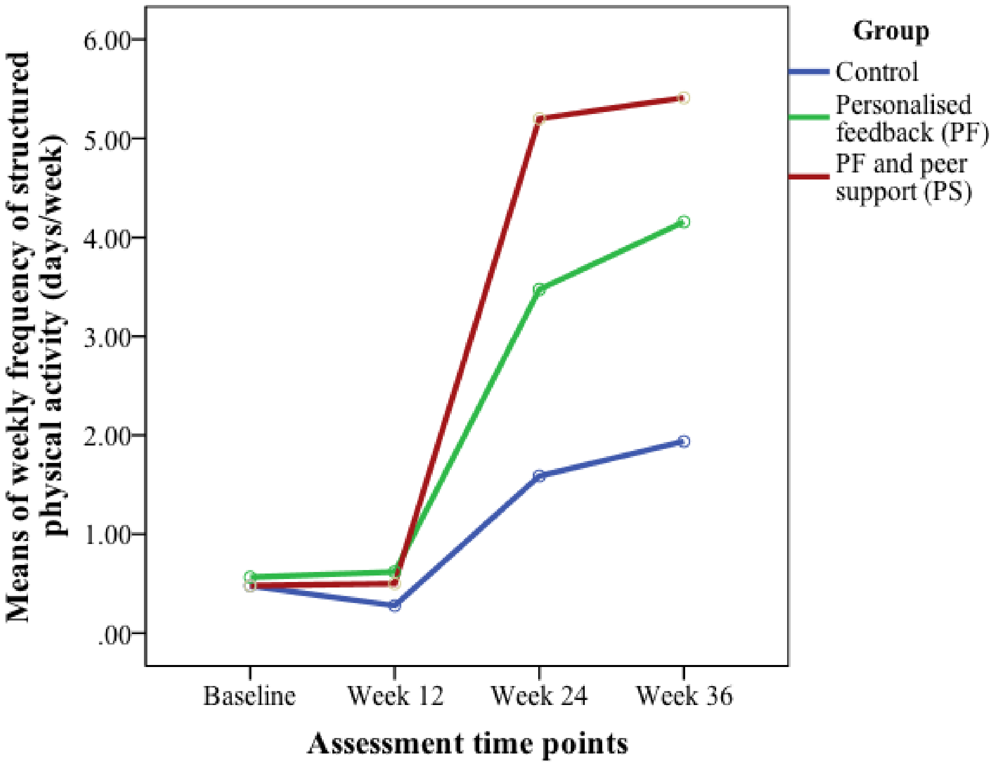

Figure 6.3: Comparisons of adjusted means of weekly frequency of structured physical activity among the three groups across study period

From Figure 6.3, none of the groups showed any increase in the mean days/week of physical activity at post-intervention (week 12), however, all groups showed increased mean days/week of physical activity at the follow-up weeks 24 and 36.

Physical Activity Scale for Elderly

The Physical Activity Scale for Elderly (PASE) measured the self-reported physical activity levels and the sedentary behaviour.

1. Physical Activity Scale for Elderly (PASE) scores

There was a significant difference between the PASE scores of the three groups over time (F (6, 174.60)= 3.43, p=0.003; final model χ^2 (11)=28.83, p<0.005; adjusted R^2=0.078) with a small effect size as summarised in Table 6.4. The hypothesis 2.6 (d) that there would be a significant difference between the groups on the PASE scores over time was therefore supported. All the assumptions were checked and fulfilled.

Table 6.4: Comparisons of PASE scores among the three groups across study period

	PASE scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	142.00±10.83	23	118.87±10.83	23	121.87±10.83
• Week 12	21	120.90±11.33	22	144.41±11.08	18	89.06±12.25
• Week 24	19	131.26±11.92	20	137.80±11.61	17	98.00±12.60
• Week 36	19	117.05±11.92	17	162.06±12.60	16	103.50±12.99

	Time specific comparisons of standardised estimates between groups		
	β±SE	**95% CI**	**P value**
PF vs. CG			
• Week 12	14.45± 17.86	-20.79, 49.69	0.419
• Week 24	13.89± 18.34	-22.28, 50.08	0.449
• Week 36	-5.96±18.53	-42.53, 30.61	0.748
PS vs. CG			
• Week 12	61.66± 17.72	26.69, 96.62	0.001*
• Week 24	42.77± 18.17	6.91, 78.63	0.020*
• Week 36	57.44± 18.84	20.26, 94.62	0.003*
PS vs. PF			
• Week 12	47.21± 17.19	13.26, 81.16	0.007*
• Week 24	28.88± 17.77	-6.19, 63.95	0.106
• Week 36	63.40± 18.26	27.37, 99.43	0.001*

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; $P<0.05$=statistical significant.

When compared to baseline, the PS group had significantly greater PASE scores (at week 12 β=47.21± 17.19, p=0.007; at week 36 β=63.40± 18.26, p=0.001) than the PF group across the different assessment time points. The PS groups also had greater PASE scores than the control group (at week 12 β=61.66± 17.72, p=0.001; at week 24 β=42.77± 18.17, p=0.020; at week 36 β=57.44± 18.84, p=0.003) across the study period. There was no difference between the PF and control groups over time.

From Figure 6.4, both PF and PS groups demonstrated fluctuations in the mean PASE scores across the study period. The control group had reduced PASE scores at week 12 but increased PASE scores at follow-up weeks 24 and 36.

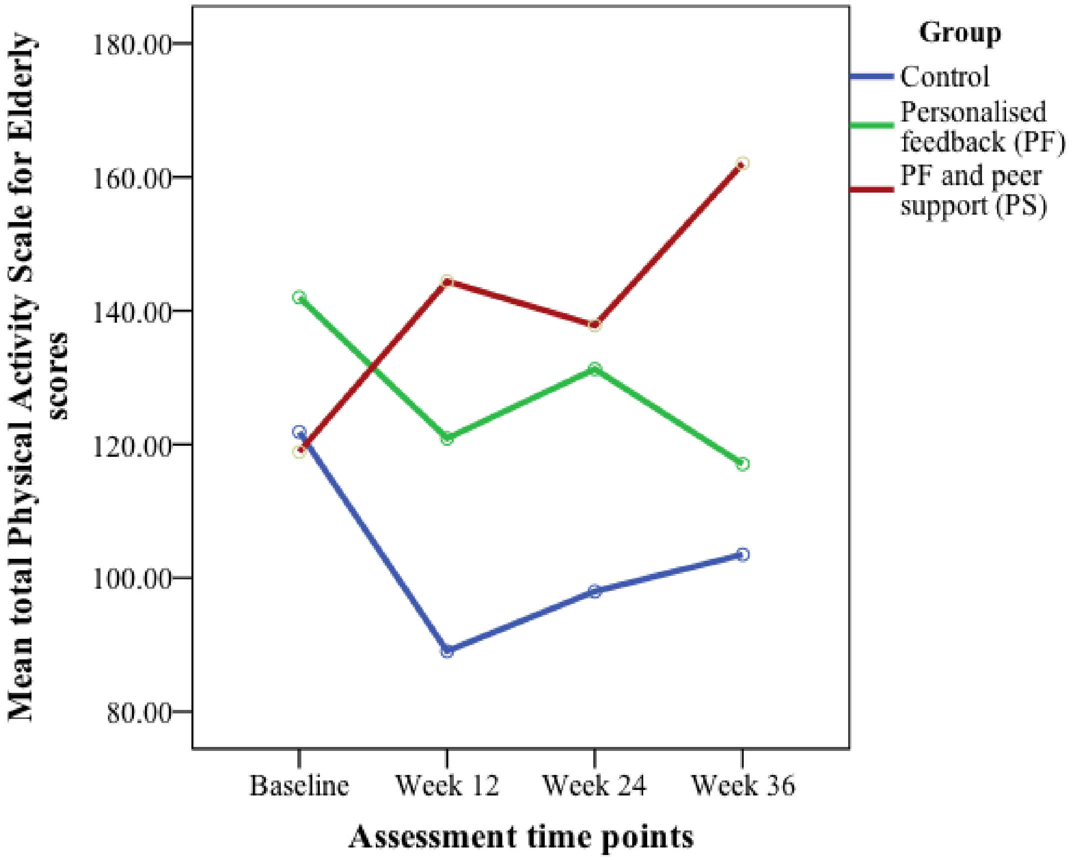

Figure 6.4: Comparisons of adjusted means of PASE scores among the three groups across study period

A subanalysis on the subscale scores of PASE for leisure-time, household and work related activities were conducted to quantify the types of physical activity that contributed to the PASE scores. Both subscale scores on the PASE leisure-time physical activity (*F* (6, 180.63)=2.31, p=0.036, adjusted R^2=0.093) and the subscale scores on PASE household activity (*F* (6, 168.59)=2.27, p=0.036, adjusted R^2=0.034) were significantly different among the three groups across the study period (see Table 6.5). The subscale scores on PASE work related activity was not significantly different (*F* (6, 238.00)=0.93, p=0.476) between the three groups over time.

The PS group had significantly greater subscale scores on PASE leisure time physical activity (LTPA) and subscale scores on PASE household activity from baseline across the study period when compared with the PF and control groups. There was no difference in these scores between the PF group and the control group across the study period. The PS group had a gradual increase in the adjusted mean subscale scores on PASE LTPA from baseline to the follow-up week 36. Both PF and the control groups showed a decline in the mean scores at post-intervention week 12. The PF group then showed increased mean scores at the two follow-up time points, but the control group remained unchanged. The PS and PF groups showed fluctuations in the adjusted mean subscale scores on PASE household activity from baseline to the follow-up week 36. The control group showed initial reduction in the scores at week 12, but continued to increase at weeks 24 and 36. Therefore, the increased subscale scores on PASE LTPA contributed the greater PASE scores observed in the PS group across the study period. The increased subscale scores on PASE household activity contributed to the increased PASE scores in the control groups observed at weeks 24 and 36.

Table 6.5: Comparisons of subscale scores of PASE among the three groups across the study period

	Personalised feedback (PF)		PF and peer support (PS)		Control (CG)		PF vs. controls	PS vs. controls	PS vs. PF
	No	**Mean±SE[a]**	**No**	**Mean±SE[a]**	**No**	**Mean±SE[a]**	**β±SE[b] (95% CI)**	**β±SE[b] (95% CI)**	**β±SE[b] (95% CI)**
Subscale scores on PASE leisure time physical activity									
Baseline	23	34.43±5.95	23	28.00±5.95	23	27.91±5.95			
Week 12	21	25.19±6.21	22	40.20±6.07	18	15.49±6.67	3.19±10.60 (-17.73, 24.11)	24.63±10.53 (3.86, 45.39)*	21.44±10.24 (1.23, 41.65)*
Week 24	19	32.39±6.49	20	45.50±6.33	17	18.56±6.84	7.31±10.88 (-14.15, 28.77)	26.86±10.79 (5.58, 48.14)*	19.55±10.57 (-1.30, 40.39)
Week 36	19	40.70±6.49	17	54.38±6.79	16	17.62±7.02	16.56±10.99 (-5.12, 38.24)	36.68±11.18 (14.63, 58.72)**	20.12±10.85 (-1.29, 41.52)
Subscale scores on PASE household activity									
Baseline	23	107.57±7.32	23	91.61±7.32	23	91.30±7.32			
Week 12	21	93.05±8.05	22	107.35±7.85	18	74.35±8.51	2.16± 12.86 (-23.23, 27.55)	32.79± 12.76 (7.61, 57.97)*	30.63±12.49 (5.96, 55.29)*
Week 24	19	97.37±8.05	20	88.65±8.51	17	78.94±8.77	3.16± 13.00 (-22.49, 28.82)	8.29±13.23 (-17.82, 34.42)	5.14±12.84 (-20.21, 30.48)
Week 36	19	83.45±7.85	17	104.11±8.27	16	82.56±8.27	-14.33± 12.63 (-39.25, 10.60)	18.51±12.85 (-6.85, 43.88)	32.84±12.61 (7.95, 57.73)*
Subscale scores on PASE work related activity									
Baseline	23	0.35±0.20	23	0.04±0.20	23	0.13±0.20			
Week 12	21	0.52±0.21	22	0.41±0.21	18	0.00±0.23	0.31±0.43 (-0.53, 1.15)	0.50±0.42 (-0.34, 1.33)	0.19±0.42 (-0.63, 1.01)
Week 24	19	0.11±0.23	20	0.55±0.22	17	0.00±0.24	-0.11±0.44 (-0.97, 0.75)	0.64±0.43 (-0.22, 1.49)	0.75±0.43 (-0.09, 1.59)
Week 36	19	0.00±0.23	17	0.35±0.24	16	0.00±0.25	-0.22±0.44 (-1.08, 0.65)	0.44±0.45 (-0.44, 1.32)	0.66±0.44 (-0.20, 1.51)

Note: SE=standard error; 95% CI=95% confidence interval; a=adjusted means; b=standardised estimates compared to baseline; *p<0.05, **p<0.01= statistical significant

2. Daily PASE activities while seated

From Table 6.6, the daily PASE activities while seated showed no significant difference between the three groups over time (F (6, 180.15) = 0.726, p=0.629). Therefore, hypothesis 2.6 (e) that there would be a significant difference in the daily PASE activities performed while seated between the three groups across the study period was rejected.

Table 6.6: Comparisons of daily PASE activities while seated among the three groups across the study period

	Daily PASE activities while seated (hours/day)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	2.37±0.30	23	2.76±0.30	23	2.11±0.30
• Week 12	21	2.49±0.32	22	2.52±0.31	18	2.57±0.34
• Week 24	19	1.94±0.33	20	2.19±0.32	17	2.24±0.35
• Week 36	19	2.47±0.33	17	2.70±0.35	16	3.19±0.36

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.98±0.62	-2.20, 0.24	0.558
• Week 24	-0.56±0.61	-1.77, 0.64	0.358
• Week 36	-0.33±0.59	-1.51, 0.85	0.580
PS vs. CG			
• Week 12	-0.70±0.59	-1.88, 0.47	0.239
• Week 24	-0.71±0.61	-1.91, 0.49	0.245
• Week 36	-1.13±0.63	-2.38, 0.11	0.073
PS vs. PF			
• Week 12	-0.37±0.58	-1.52, 0.78	0.525
• Week 24	-0.15±0.59	-1.32, 1.03	0.808
• Week 36	-0.15±0.65	-1.36, 1.05	0.802

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

Figure 6.5 showed that the PS group showed a trend in decline of the mean hours/day of daily PASE activities while seated from baseline to follow-up week 24 but increased in the duration at follow-up week 36 but this trend was not statistically significant. Both the PF and control groups showed fluctuations in the duration of daily activities while seated across the study period.

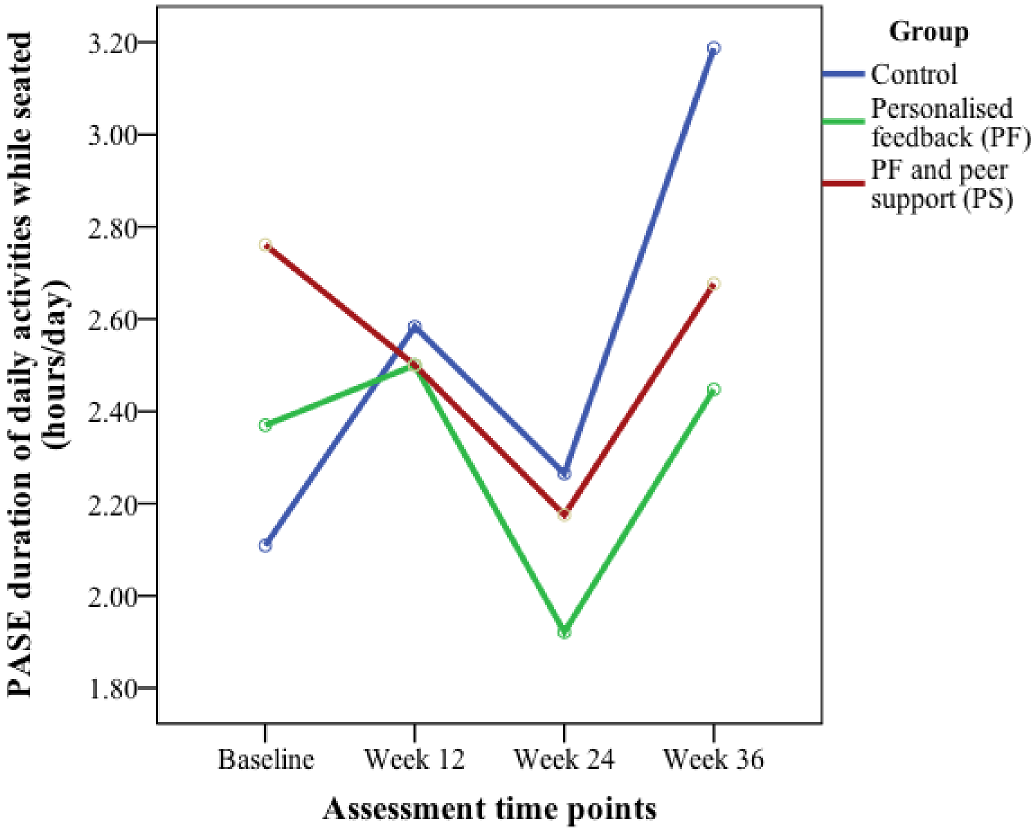

Figure 6.5: Comparisons of adjusted mean hours/day of daily PASE activities while seated among the three groups across the study period

Summary

At post-intervention week 12 and follow-up week 36, the PS group showed greater increased in the weekly duration of structured physical activity and PASE scores when compared with the PF and control groups. The greater subscale scores for PASE leisure-time physical activity when compared with PF and control groups contributed to the total PASE scores. There was no difference between the PF and control groups on the PASE scores over time. Also, the PS group had increased weekly frequency of structured physical activity more than the PF and control groups at week 24. The daily PASE activities while seated did not contribute to the change in the level of physical activity across the study period between the three groups.

6.2.2 Cardiovascular disease risk factors

The cardiovascular disease (CVD) risk factors measured in this study included glycosylated haemoglobin (HbA1c), blood pressure (systolic and diastolic), weight, body mass index, waist circumference, body fat percentage, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol and triglycerides. There was a significant difference in the mean body fat percentage among the groups across the study period (F (6, 169.09) = 3.36, p=0.004, adjusted R^2=0.258). There was no significant difference between the other CVD risk factors of the three groups across the study period.

Glycosylated haemoglobin

There was no significant difference in the glycosylated haemoglobin (HbA1c) level between the three groups across the study period (F (6, 171.38)=0.38, p=0.894). Therefore, the hypothesis 2.7 (a) that there would be a significant difference in the HbA1c level among the three groups over time was rejected. The levels of HbA1c fluctuated in all the three groups across the different assessment time points with similar mean levels at each time points. Table 6.7 summarises these findings.

Table 6.7: Comparisons of glycosylated haemoglobin level among the three groups across the study period

	HbA1c (%)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	8.39±0.36	23	8.33±0.36	23	8.73±0.36
• Week 12	21	8.15±0.38	22	7.84±0.37	18	8.44±0.41
• Week 24	19	8.22±0.39	20	8.02±0.38	17	8.44±0.42
• Week 36	19	8.08±0.39	17	8.12±0.42	16	8.19±0.43

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	0.15±0.30	-0.44, 0.74	0.617
• Week 24	-0.10±0.31	-0.71, 0.51	0.741
• Week 36	-0.05±0.31	-0.67, 0.56	0.868
PS vs. CG			
• Week 12	-0.16±0.29	-0.74, 0.43	0.599
• Week 24	-0.28±0.31	-0.89, 0.32	0.353
• Week 36	-0.05±0.32	-0.67, 0.58	0.880
PS vs. PF			
• Week 12	-0.31±0.29	-0.87, 0.26	0.285
• Week 24	-0.18±0.29	-0.77, 0.40	0.539
• Week 36	0.00±0.30	-0.59, 0.61	0.990

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *$P<0.05$=statistical significant.

From Figure 6.6, all the groups showed a downward trend in the level of HbA1c at week 12 post-intervention. However, the PS group showed an upward trend from then onwards to the end of the study period, while the PF and control groups had fluctuations in their HbA1c levels.

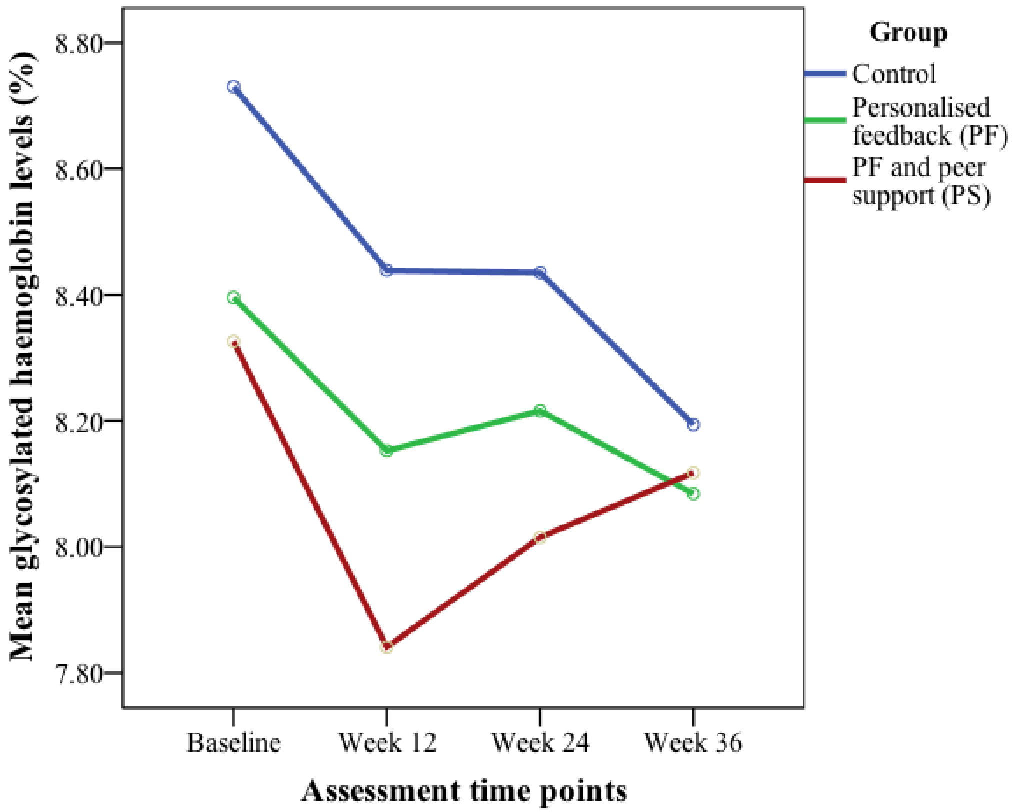

Figure 6.6: Comparisons of adjusted mean glycosylated haemoglobin among the three groups across study period

Blood pressure

The blood pressure (BP) measures were analysed separately: systolic BP and diastolic BP.

1. Systolic blood pressure

The systolic BP (*F* (6, 172.84)=0.49, p=0.810) was not significantly different among the three groups over time as shown in Table 6.8. Therefore, hypothesis 2.7 (b) that there would be a significant difference between the groups over time on systolic blood pressure was rejected.

Table 6.8: Comparisons of systolic blood pressure among the three groups across study period

	Systolic BP (mmHg)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	137.35±2.58	23	138.52±2.58	23	139.04±2.58
• Week 12	21	135.90±2.70	22	133.14±2.64	18	139.56±2.92
• Week 24	19	136.00±2.84	20	134.05±2.77	17	137.41±3.00
• Week 36	19	136.16±2.84	17	132.00±3.00	16	137.13±3.09
	Time specific comparisons of standardised estimates between groups		
	β±SE	**95% CI**	**P value**
PF vs. CG			
• Week 12	-1.07±4.26	-9.48, 7.34	0.802
• Week 24	2.19±4.38	-6.44, 10.83	0.616
• Week 36	2.50±4.42	-6.23, 11.23	0.572
PS vs. CG			
• Week 12	-5.39±4.23	-13.74, 2.95	0.204
• Week 24	-2.36±4.34	-10.92, 6.19	0.587
• Week 36	-2.73±4.49	-11.61, 6.14	0.544
PS vs. PF			
• Week 12	-4.32±4.10	-12.42, 3.78	0.294
• Week 24	-4.56±4.24	-12.93, 3.81	0.284
• Week 36	-5.23±4.36	-13.83, 3.36	0.231

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

Figure 6.7 showed that both PF and PS groups had a trend towards reduction in the systolic BP at week 12-post-intervention, but the PS group showed a fluctuation in the levels while the PF group remained unchanged from after the intervention to the end of the study period. The control group also showed some fluctuating trend in the systolic BP levels across the study period.

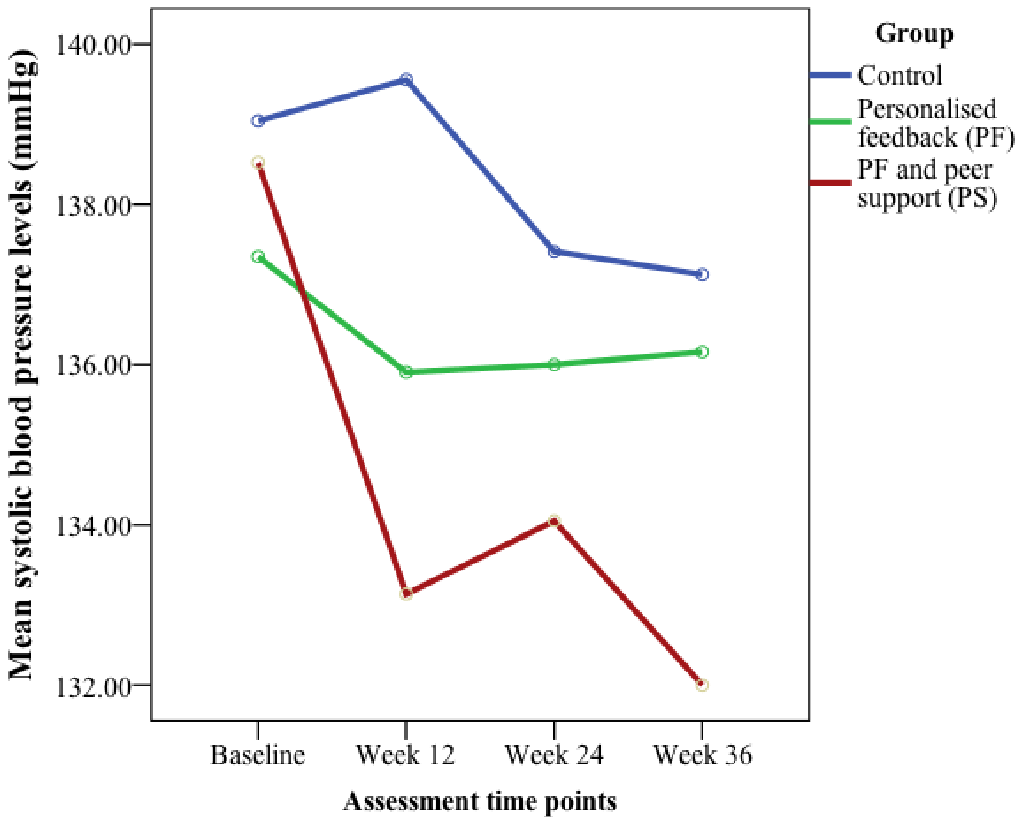

Figure 6.7: Comparisons of adjusted mean systolic blood pressure among the three groups across study period

2. Diastolic blood pressure

The diastolic blood pressure (*F* (6, 171.38)=1.26, p=0.279) level was not significantly different among the three groups over time as shown in Table 6.9. Therefore, hypothesis 2.7 (c) that there would be a significant difference between the groups over time on diastolic blood pressure was rejected.

Table 6.9: Comparisons of diastolic blood pressure among the three groups across study period

	Diastolic BP (mmHg)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	77.69±1.66	23	77.22±1.66	23	76.17±1.66
• Week 12	21	75.76±1.74	22	74.77±1.70	18	78.50±1.88
• Week 24	19	77.37±1.83	20	74.10±1.79	17	74.82±1.94
• Week 36	19	77.68±1.83	17	76.53±1.94	16	80.19±1.99

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-3.54±2.50	-8.48, 1.41	0.160
• Week 24	1.62±2.57	-3.46, 6.69	0.530
• Week 36	-3.41±2.60	-8.54, 1.73	0.192
PS vs. CG			
• Week 12	-4.46±2.48	-9.36, 0.45	0.075
• Week 24	-1.31±2.55	-6.34, 3.72	0.609
• Week 36	-4.01±2.65	-9.23, 1.21	0.131
PS vs. PF			
• Week 12	-0.92±2.41	-5.67, 3.83	0.703
• Week 24	-2.93±2.49	-7.84, 1.99	0.241
• Week 36	-0.61±2.56	-5.66, 4.44	0.812

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

The mean diastolic BP levels showed a trend towards reduction in the PS group from baseline to follow-up week 24 but the mean diastolic BP increased at follow-up week 36 (Figure 6.8). Both the PF and control groups showed fluctuations in the mean diastolic BP levels during the course of the study.

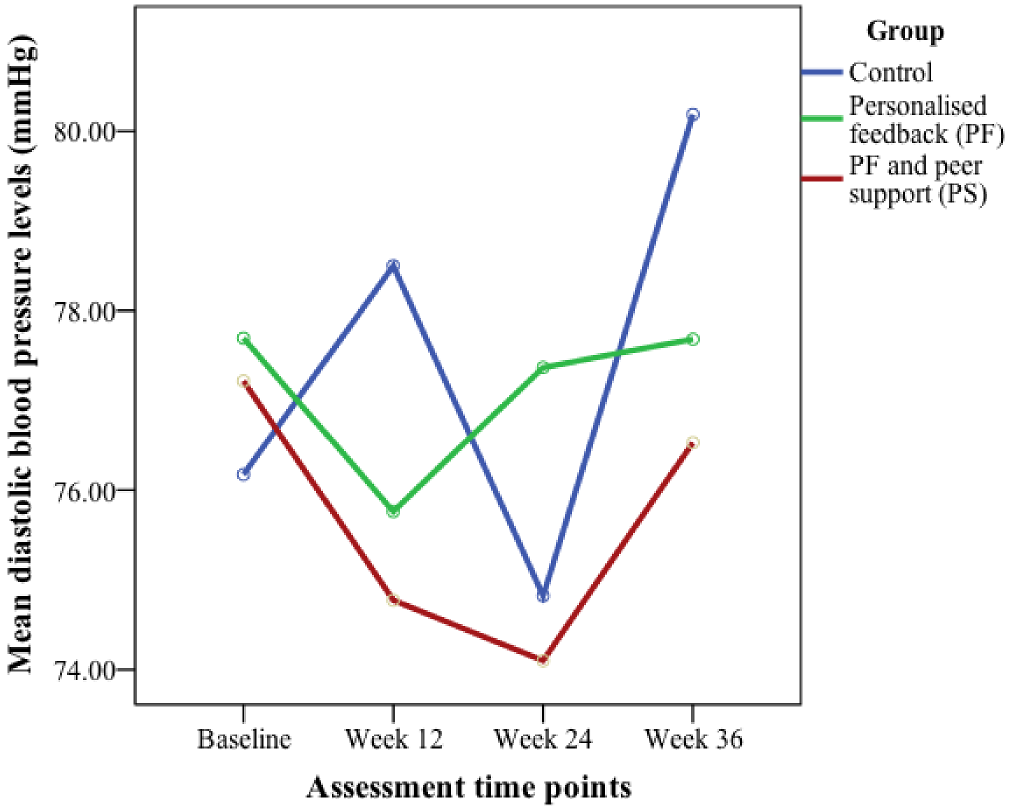

Figure 6.8: Comparisons of adjusted mean diastolic blood pressure among the three groups across study period

Weight

The weight among the three groups did not significantly differ across the study period (F (6, 168.93)=1.98, p=0.071) as in Table 6.10. The hypothesis 2.7 (d) that there would be a significant difference between the groups over time on the weight was rejected.

Table 6.10: Comparisons of weight among the three groups across study period

	Weight (kg)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	70.02±2.44	23	69.92±2.44	23	70.62±2.44
• Week 12	21	68.13±2.56	22	68.06±2.50	18	67.50±2.76
• Week 24	19	68.03±2.69	20	66.51±2.62	17	67.64±2.84
• Week 36	19	69.45±2.69	17	66.65±2.84	16	68.01±2.93

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.10±0.50	-1.08, 0.88	0.837
• Week 24	-0.86±0.51	-1.86, 0.15	0.096
• Week 36	-0.53±0.52	-1.55, 0.49	0.309
PS vs. CG			
• Week 12	-0.49±0.49	-1.47, 0.47	0.310
• Week 24	-0.75±0.50	-1.75, 0.24	0.138
• Week 36	-1.53±0.52	-2.56, 0.49	0.400
PS vs. PF			
• Week 12	-0.39±0.47	-1.33, 0.53	0.400
• Week 24	0.10±0.49	-0.86, 1.07	0.832
• Week 36	-1.00±0.50	-1.99, 0.01	0.480

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

Figure 6.9 showed that the weight of participants in all groups showed a trend towards reduction at week 12 post-intervention and the PS group showed further reduction at the follow-up week 24. Both the PF and control groups showed a trend towards increased mean weight after intervention to the end of the study.

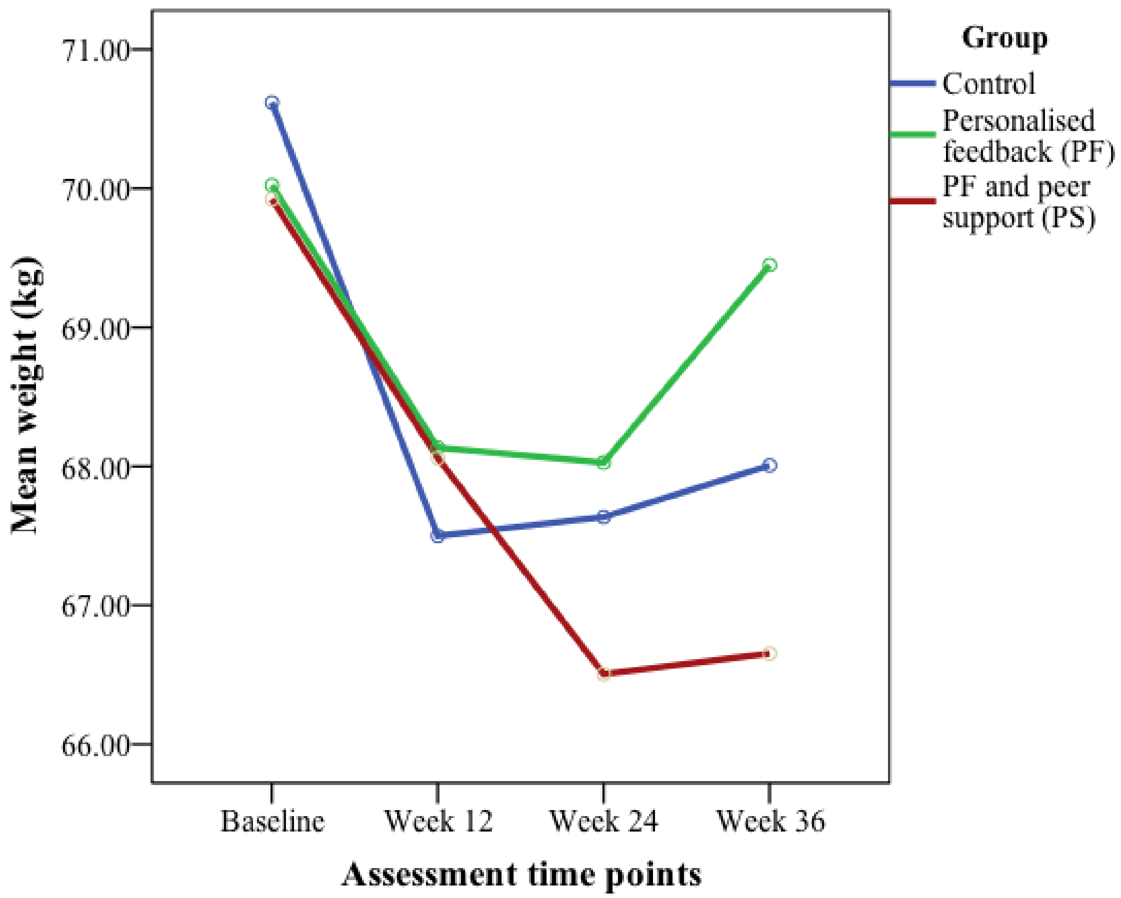

Figure 6.9: Comparisons of adjusted mean weight among the three groups across study period

Body mass index

The body mass index (BMI) was not significantly different between the three groups over time (F (6, 168.77)= 0.67, p=0.677) as summarised in Table 6.11. Hypothesis 2.7 (e) that there would be a significant difference in the BMI between the groups across the study period was rejected.

Table 6.11: Comparisons of body mass index among the three groups across study period

	Body mass index (kg/m^2)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	26.96±0.87	23	28.28±0.87	23	27.72±0.87
• Week 12	21	26.29±0.91	22	27.34±0.89	18	27.03±0.99
• Week 24	19	26.12±0.96	20	26.58±0.94	17	26.84±1.01
• Week 36	19	26.87±0.96	17	27.03±1.04	16	27.59±1.05

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.19±0.42	-1.02, 0.63	0.635
• Week 24	-0.32±0.43	-1.17, 0.53	0.455
• Week 36	-0.38±0.43	-1.23, 0.48	0.387
PS vs. CG			
• Week 12	-0.29±0.41	-1.10, 0.53	0.486
• Week 24	-0.23±0.42	-1.07, 0.60	0.581
• Week 36	-0.81±0.44	-1.68, 0.06	0.067
PS vs. PF			
• Week 12	-1.05±1.25	-4.13, 2.03	1.000
• Week 24	-0.46±1.35	-3.78, 2.87	1.000
• Week 36	-0.16±1.25	-3.25, 2.93	1.000

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

All groups showed a similar trend of reduction in the mean body mass index from baseline to follow-up week 24 but then increased at follow-up week 36 as shown in Figure 6.10.

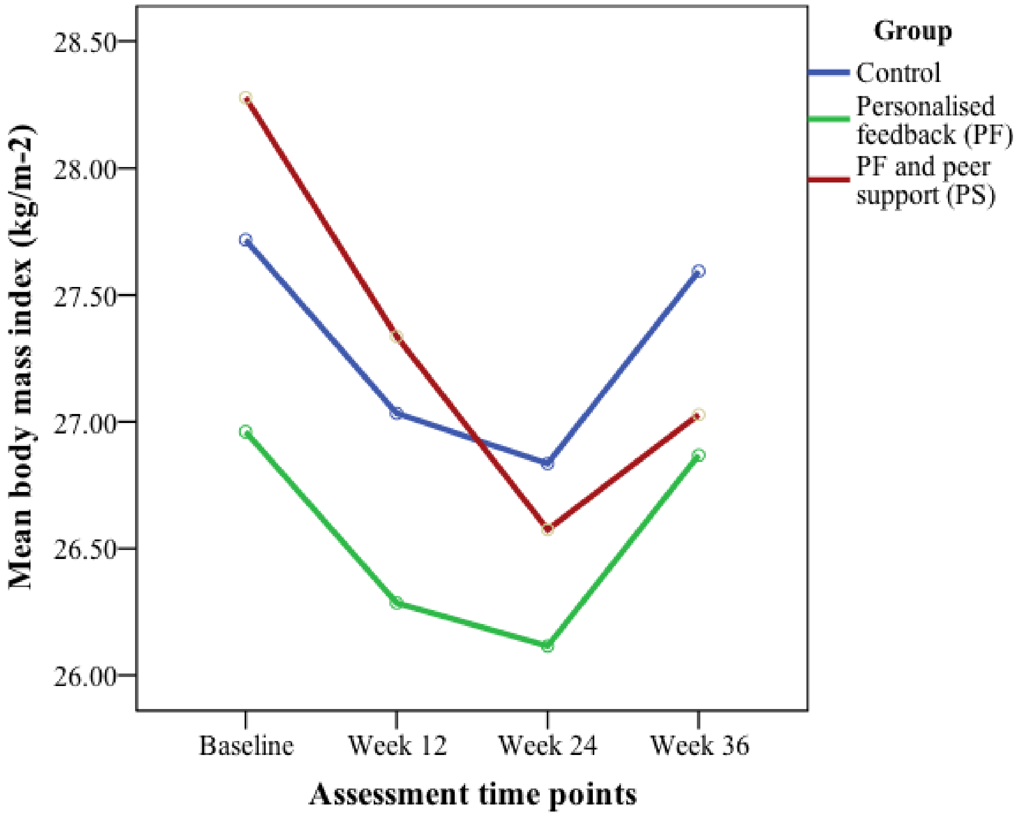

Figure 6.10: Comparisons of adjusted mean body mass index among the three groups across study period

Waist circumference

There was no significant difference in the waist circumference measure among the three groups across the study period (*F* (6, 168.55)= 1.68, p=0.130) as shown in table 6.12. Therefore, hypothesis 2.7 (f) that there would be a significant difference in the waist circumference among the three groups over time was rejected.

Table 6.12: Comparisons of waist circumference among the three groups across study period

	Waist circumference (cm)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	92.93±1.87	23	92.65±1.87	23	95.22±1.87
• Week 12	21	90.43±1.88	22	90.50±1.88	18	93.45±1.90
• Week 24	19	90.17±1.89	20	90.73±1.89	17	94.57±1.91
• Week 36	19	92.67±1.89	17	90.97±1.90	16	94.50±1.91

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.74±0.97	-2.66, 1.18	0.446
• Week 24	-2.12±1.00	-4.09, 0.15	0.350
• Week 36	0.45±1.01	-1.55, 2.44	0.659
PS vs. CG			
• Week 12	-0.38±0.96	-2.28, 1.52	0.690
• Week 24	-1.27±0.99	-3.23, 0.68	0.199
• Week 36	-0.98±1.03	-3.00, 1.05	0.342
PS vs. PF			
• Week 12	0.36±0.92	-1.47, 2.18	0.699
• Week 24	0.85±0.96	-1.04, 2.74	0.377
• Week 36	-1.43±0.99	-3.37, 0.52	0.150

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

All groups showed a trend in reduced mean waist circumference at week 12 post-intervention, with further reductions seen in the PF and PS groups, as shown in Figure 6.11.

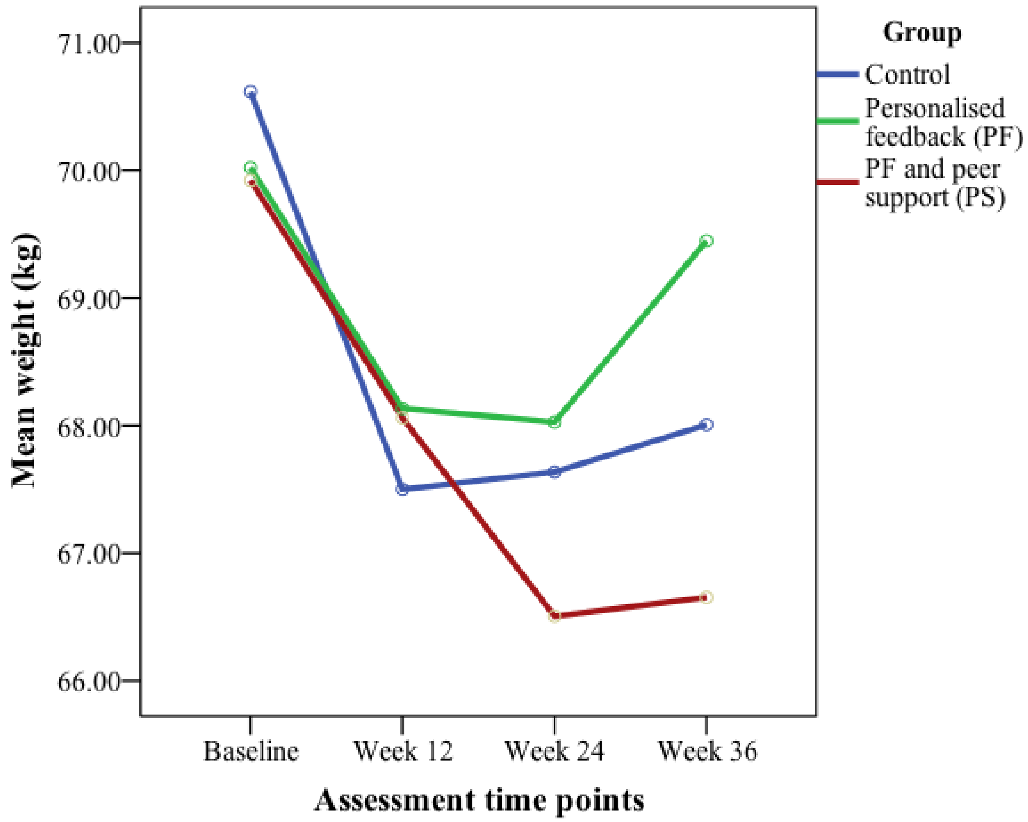

Figure 6.11: Comparisons of adjusted mean waist circumference among the three groups across study period

Body fat percentage

The body fat percentage was significantly different among the three groups over time (*F* (6, 169.09)=3.36, p=0.004; final model χ^2 (11)=23.64, p<0.05; adjusted R^2=0.258) with a small to medium effect size as summarised in Table 6.13. Hypothesis 2.7 (g) that there would be a significant difference in the body fat percentage among the three groups over time was supported. All the assumptions were checked and fulfilled.

Compared to baseline, the PS group had significantly lower body fat percentage over time (at week 12 β=-1.69±SE0.79 %, p=0.034; at week 24 β=-1.75±SE0.82 %, p=0.033; at week 36 β=-3.27±SE0.85 %, p<0.001) than the control group. The PF group also had lower body fat percentage over time at week 12 (β=-1.63±SE0.80 %, p=0.044) and week 36 (β=2.86±SE0.84 %, p=0.001) from baseline when compared with the control group. There was no difference in the body fat percentage between the PS and PF groups across the study period.

Table 6.13: Comparisons of body fat percentage among the three groups across study period

	Body fat (%)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	30.25±1.81	23	33.42±1.81	23	32.97±1.81
• Week 12	21	29.28±1.89	22	32.18±1.85	18	33.33±2.04
• Week 24	19	28.87±1.99	20	30.04±1.94	17	32.40±2.10
• Week 36	19	28.41±1.99	17	30.15±2.10	16	34.39±2.16

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-1.63±0.80	-3.21, -0.04	0.044*
• Week 24	-0.66±0.83	-2.29, 0.97	0.423
• Week 36	-2.86±0.84	-4.51, -1.21	0.001*
PS vs. CG			
• Week 12	-1.69±0.79	-3.27, -0.13	0.034*
• Week 24	-1.75±0.82	-3.37, -0.14	0.033*
• Week 36	-3.27±0.85	-4.95, -1.59	<0.001*
PS vs. PF			
• Week 12	-0.07±0.76	-2.02, 1.19	0.613
• Week 24	-1.09±0.79	-2.65, 0.47	0.171
• Week 36	-0.41±0.82	-2.02, 1.19	0.928

Note: CG=control group PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

Figure 6.12 showed that the both PS and PF groups showed a reduction of the mean body fat percentage over time while the control group did not.

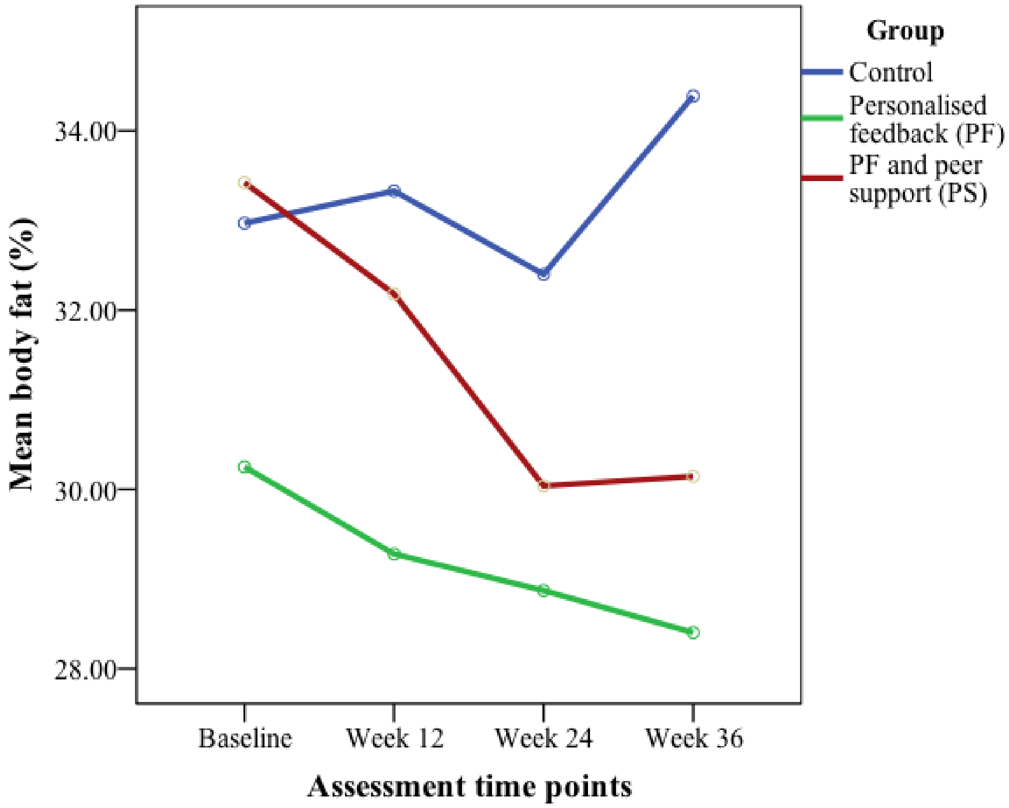

Figure 6.12: Comparisons of adjusted mean body fat percentage among the three groups across study period

Low density lipoprotein cholesterol level

There was no significant difference in the low-density lipoprotein cholesterol (LDL-C) level between the three groups across the study period (F (6, 174.25)= 1.28, p= 0.270) as shown in Table 6.14. The hypothesis 2.7 (h) that there would be a significant difference in the LDL-C level among the three groups over time was rejected.

Table 6.14: Comparisons of low-density lipoprotein cholesterol among the three groups across study period

	Low-density lipoprotein cholesterol level (mmol/L)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	3.11±0.18	23	3.30±0.18	23	3.24±0.18
• Week 12	21	3.12±0.19	22	3.01±0.19	18	3.26±0.20
• Week 24	19	3.37±0.19	20	2.91±0.19	17	2.99±0.21
• Week 36	19	3.03±0.19	17	2.72±0.21	16	2.81±0.22

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	0.07±0.27	-0.46, 0.59	0.795
• Week 24	0.52±0.28	-0.02, 1.07	0.060
• Week 36	0.33±0.28	-0.22, 0.88	0.233
PS vs. CG			
• Week 12	-0.22±0.27	-0.75, 0.30	0.404
• Week 24	-0.13±0.27	-0.67, 0.41	0.625
• Week 36	-0.05±0.28	-0.61, 0.51	0.867
PS vs. PF			
• Week 12	-0.29±0.26	-0.80, 0.22	0.258
• Week 24	-0.66±0.27	-1.18, 0.13	0.150
• Week 36	-0.38±0.27	-0.92, 0.16	0.166

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

From Figure 6.13, the PS group showed a trend towards reduced mean LDL-C across the study period. At week 12 post-intervention, the mean LDL-C remained unchanged for both PF and control groups. But at the follow-up weeks 24 and 36 the control group showed a reducing trend in LDL-C while the PF group showed fluctuations in the mean LDL-C level.

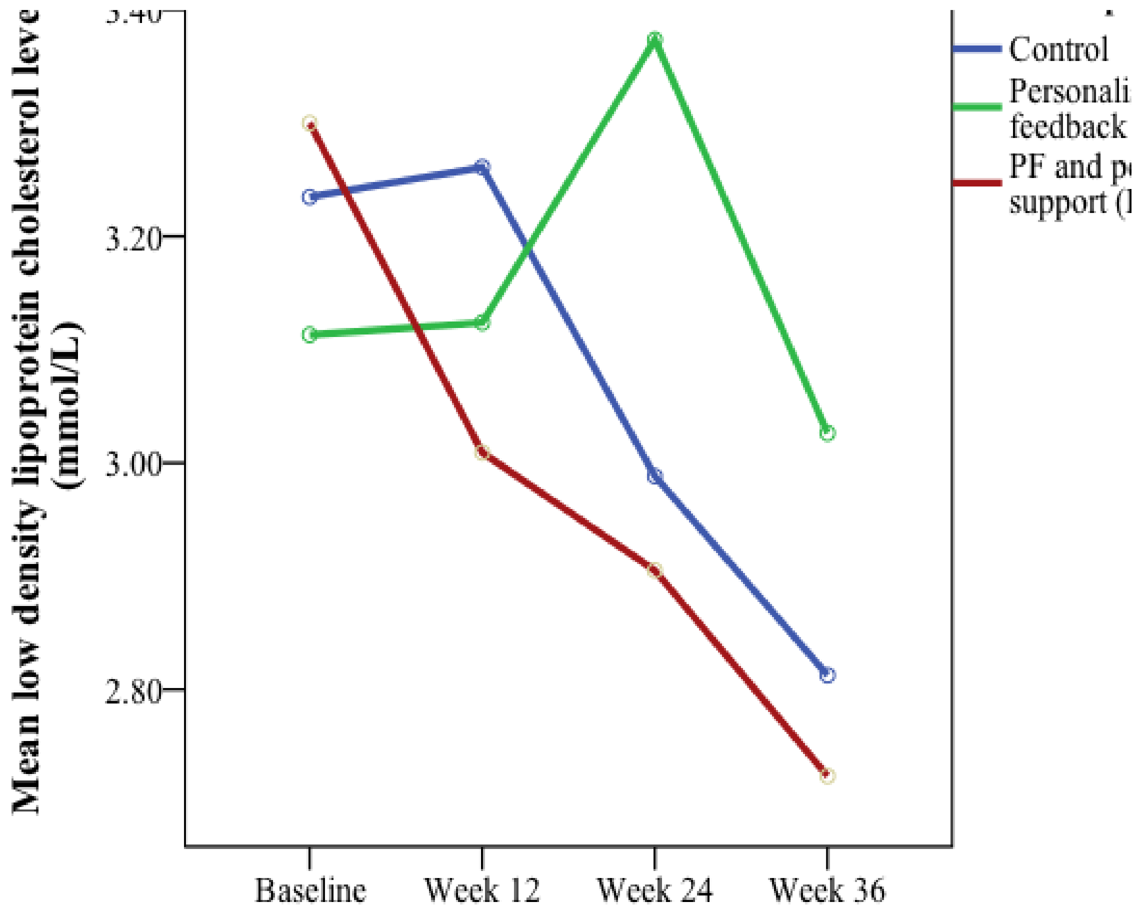

Figure 6.13: Comparisons of adjusted mean low-density lipoprotein cholesterol among the three groups across study period

High density lipoprotein cholesterol level

The high-density lipoprotein cholesterol (HDL-C) level was not significantly different among the three groups over time (F (6, 172.07)=0.32, p=0.925) as shown in table 6.15. The hypothesis 2.7 (i) that there would be a significant difference in the HDL-C level among the three groups over time was therefore rejected.

Table 6.15: Comparisons of high-density lipoprotein among the three groups across study period

	High-density lipoprotein cholesterol level (mmol/L)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	1.13±0.04	23	1.06±0.04	23	1.10±0.04
• Week 12	21	1.12±0.05	22	1.09±0.04	18	1.12±0.05
• Week 24	19	1.14±0.05	20	1.06±0.05	17	1.10±0.05
• Week 36	19	1.17±0.05	17	1.13±0.05	16	1.17±0.05

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.01±0.05	-0.12, 0.09	0.839
• Week 24	0.02±0.06	-0.09, 0.12	0.778
• Week 36	-0.01±0.06	-0.12, 0.09	0.803
PS vs. CG			
• Week 12	0.03±0.05	-0.07, 0.14	0.534
• Week 24	0.04±0.05	-0.07, 0.15	0.496
• Week 36	0.05±0.06	-0.06, 0.16	0.373
PS vs. PF			
• Week 12	0.04±0.05	-0.06, 0.15	0.392
• Week 24	0.02±0.05	-0.08, 0.13	0.683
• Week 36	0.06±0.05	-0.04, 0.17	0.239

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

At week 12 post-intervention, both PS and control groups showed a trend of increased mean HDL-C level followed by fluctuations in the levels at the follow-up weeks (see Figure 6.14). The PF group initially showed a trend of reduction in the mean HDL-C level post-intervention but then an increased trend at the end of the study.

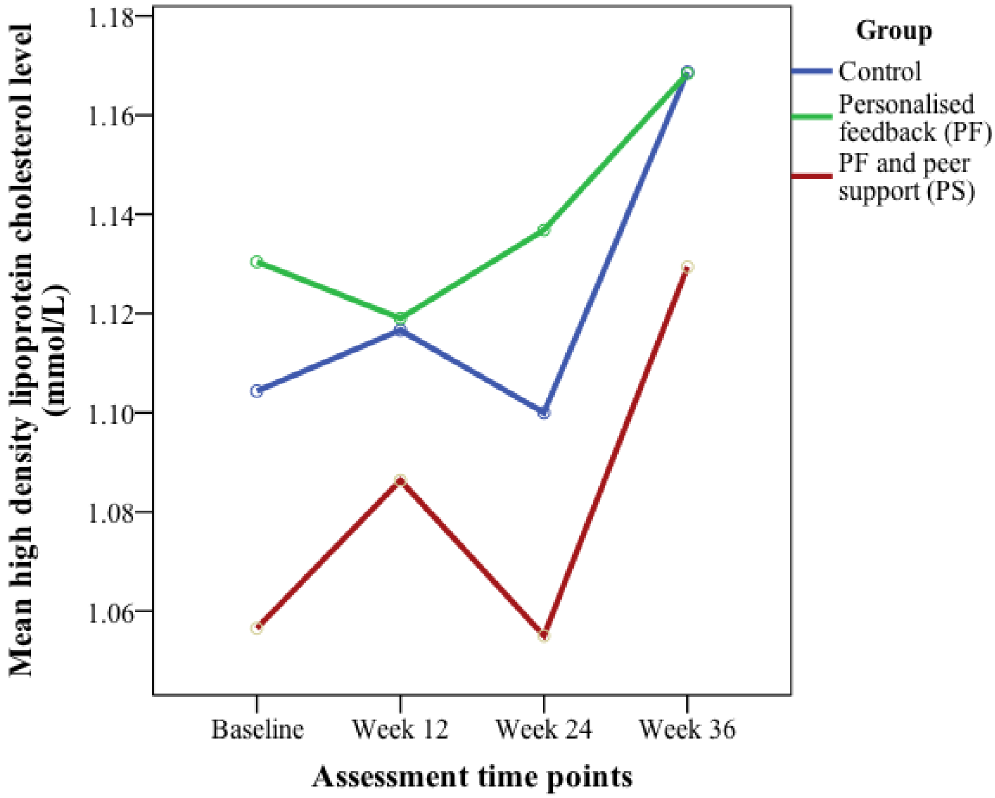

Figure 6.14: Comparisons of adjusted mean high-density lipoprotein cholesterol among the three groups across study period

Triglycerides level

There was no significant difference in the triglycerides level among the three groups over time (F (6, 170.24)=1.46, p=0.194) as summarised in Table 6.16. The hypothesis 2.7 (j) that there would be a significant difference in the triglycerides level among the three groups over time was rejected.

Table 6.16: Comparisons of triglycerides level among the three groups across study period

	Triglycerides level (mmol/L)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	1.41±0.17	23	1.81±0.17	23	1.93±0.17
• Week 12	21	1.63±0.17	22	1.75±0.17	18	2.11±0.18
• Week 24	19	1.48±0.18	20	1.65±0.17	17	1.66±0.18
• Week 36	19	1.50±0.18	17	1.42±0.18	16	1.78±0.19

	Time specific comparisons of standardised estimates between groups		
	β±SE	**95% CI**	**P value**
PF vs. CG			
• Week 12	0.03±0.20	-0.36, 0.42	0.875
• Week 24	0.24±0.20	-0.17, 0.64	0.245
• Week 36	0.24±0.21	-0.17, 0.64	0.254
PS vs. CG			
• Week 12	-0.24±0.09	-0.63, 0.15	0.223
• Week 24	0.11±0.20	-0.28, 0.51	0.570
• Week 36	-0.24±0.21	-0.66, 0.17	0.247
PS vs. PF			
• Week 12	-0.27±0.19	-0.88, 0.08	0.190
• Week 24	-0.12±0.19	-0.51, 0.27	0.532
• Week 36	-0.05±0.20	-0.65, 0.10	0.154

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

The PS group showed a reducing trend in the mean triglycerides level across the study period, while both the PF and control groups showed fluctuating trend in the mean level during the course of this study as shown in Figure 6.15.

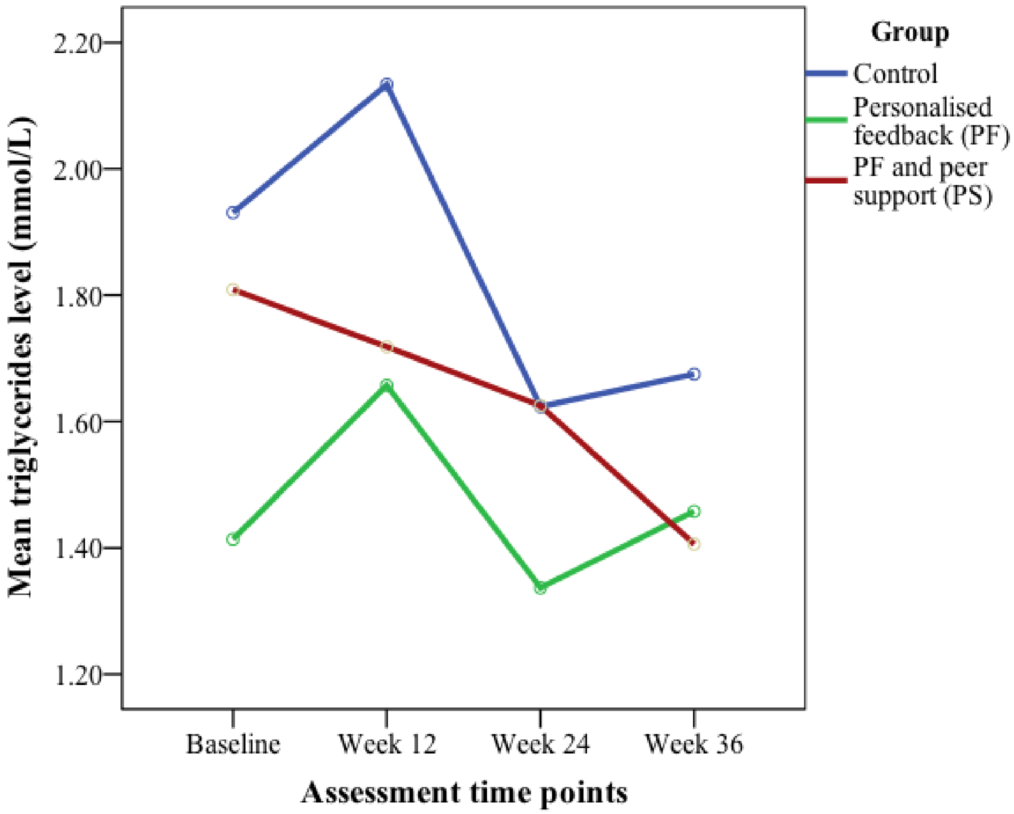

Figure 6.15: Comparisons of adjusted mean triglycerides level among the three groups across study period

Summary

The results show that body fat percentage was significantly different among the three groups across the study period but there was no difference among the groups across time on the other cardiovascular disease risk factors. Both PS and PF groups had significantly lower body fat percentage than the controls, but there was no significant difference between the PF and PS groups on the body fat percentage.

6.2.3 Functional status

In this study, functional status was measured by the six-minute walk test (cardiorespiratory fitness), and the timed up and go test (balance).

Six minutes walk test

The six minutes walk test was presented as the metres walked in six minutes. A significant difference was observed in the six- minute walk test with a small effect size between the three groups over time (F (6, 171.12)=5.43, p<0.001; final model χ^2 (11)=24.55, p<0.025; adjusted R^2=0.256) as summarised in Table 6.17. The hypothesis 2.8 (a) that there would be a significant difference in the metres walked in six minutes among the three groups across the study period was supported. All the assumptions were checked and fulfilled.

Table 6.17: Comparisons of six-minute walk test among the three groups across study period

	Six minute walk test (metres)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	236.00±10.42	23	216.52±10.42	23	196.52±10.42
• Week 12	21	206.57±10.90	22	203.27±10.65	18	176.11±11.78
• Week 24	19	205.32±11.46	20	250.50±11.17	17	166.53±12.12
• Week 36	19	261.53±11.46	17	286.76±12.12	16	215.69±12.49

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-10.34±14.53	-39.01, 18.33	0.478
• Week 24	-2.22±14.93	-31.69, 27.25	0.882
• Week 36	5.31±15.09	-24.49, 35.11	0.725
PS vs. CG			
• Week 12	5.69±14.40	-22.73, 34.12	0.693
• Week 24	62.79±14.79	33.61, 91.98	<0.001*
• Week 36	45.06±15.35	14.78, 75.35	0.004*
PS vs. PF			
• Week 12	16.03±13.93	-11.46, 43.53	0.251
• Week 24	65.02±14.42	36.56, 93.48	<0.001*
• Week 36	39.75±14.82	10.49, 69.01	0.008*

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

The PS group walked a greater distance in the six-minute walk test across the study period from baseline compared with the PF group (at week 24 β=65.02±SE14.42, $p<0.001$; at week 36 β=39.75±SE14.82, $p=0.008$) and the control group (at week 24 β=62.79±SE14.79 metres, $p<0.001$); at week 36 β=45.06±SE15.35 metres, $p=0.004$).

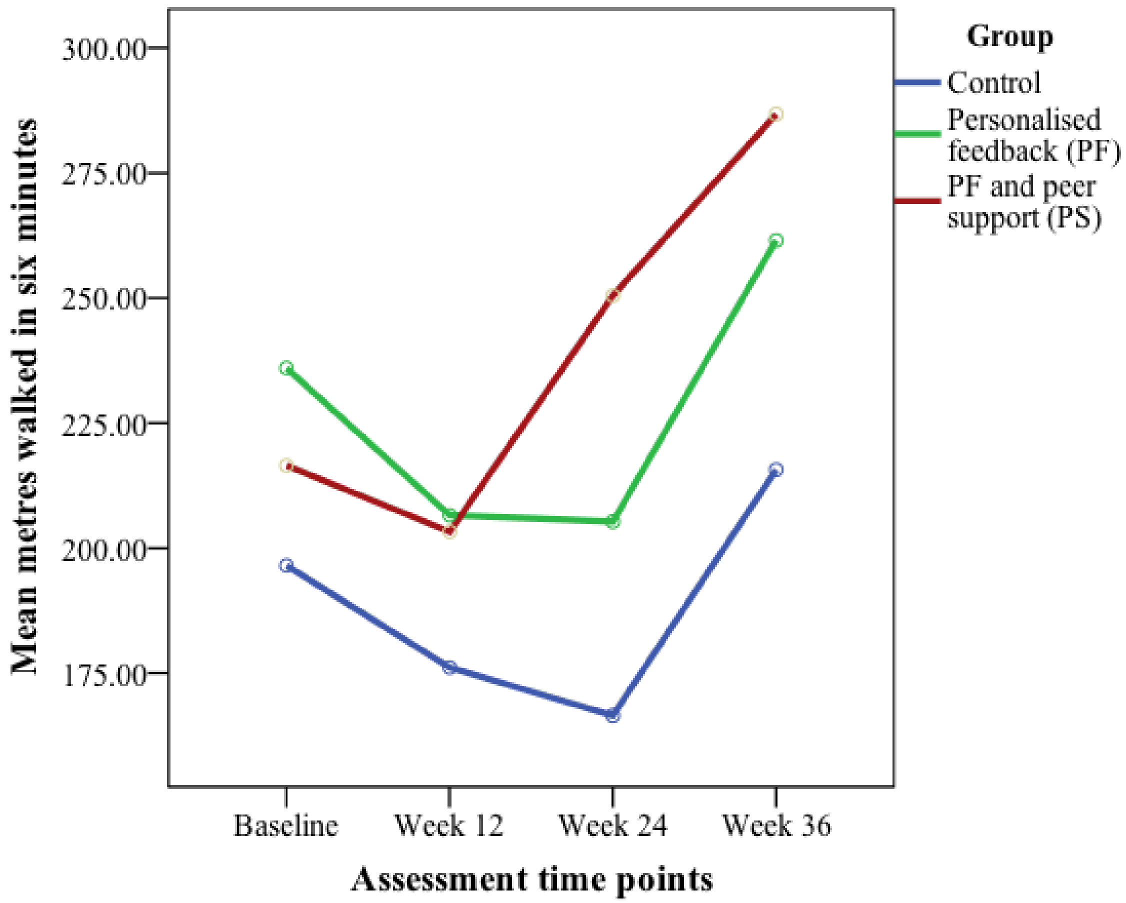

Figure 6.16: Comparisons of adjusted mean metres walked in six minutes among the three groups across study period

Figure 6.16 compared the mean metres walked in six minutes among the three groups over time. All groups had reduced adjusted mean metres walked in six minutes at weeks 12 but PS group showed increased mean metres walked in six minutes at weeks 24 and 36 while the other two groups increased at follow-up week 36.

Timed up and go test

The seconds taken to timed up and go represented the timed up and go test. There was no significant difference in the time taken for the timed up and go test between the three groups across the study period (*F* (6, 172.09)=1.84, p=0.093) as shown in Table 6.18. Therefore, the hypothesis 2.8 (b) that there would be a significant difference between the timed up and go test results of the groups over time was rejected.

Table 6.18: Comparisons of timed up and go test among the three groups across study period

	Timed up and go test (seconds)					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	9.30±0.32	23	9.26±0.32	23	9.69±0.32
• Week 12	21	8.50±0.33	22	8.23±0.33	18	9.86±0.36
• Week 24	19	8.46±0.35	20	8.55±0.34	17	9.35±0.37
• Week 36	19	8.43±0.35	17	7.88±0.37	16	9.37±0.38
	Time specific comparisons of standardised estimates between groups					
	β±SE		**95% CI**		**P value**	
PF vs. CG						
• Week 12	-1.01±0.41		-1.82, 0.19		0.150	
• Week 24	-0.49±0.42		-1.32, 0.34		0.248	
• Week 36	-0.52±0.43		-1.36, 0.32		0.226	
PS vs. CG						
• Week 12	-1.17±0.41		-1.97, 0.37		0.050	
• Week 24	-0.25±0.42		-1.07, 0.57		0.547	
• Week 36	-0.72±0.43		-1.57, 0.14		0.100	
PS vs. PF						
• Week 12	-0.16±0.39		-0.93, 0.61		0.685	
• Week 24	0.24±0.41		-0.56, 1.04		0.561	
• Week 36	-0.19±0.42		-1.02, 0.62		0.634	

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE= standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

At week 12 post-intervention, both the PF and PS groups had a reduced trend in the mean seconds taken to get up and go while the control group showed an upward trend in the mean seconds taken as shown in Figure 6.17.

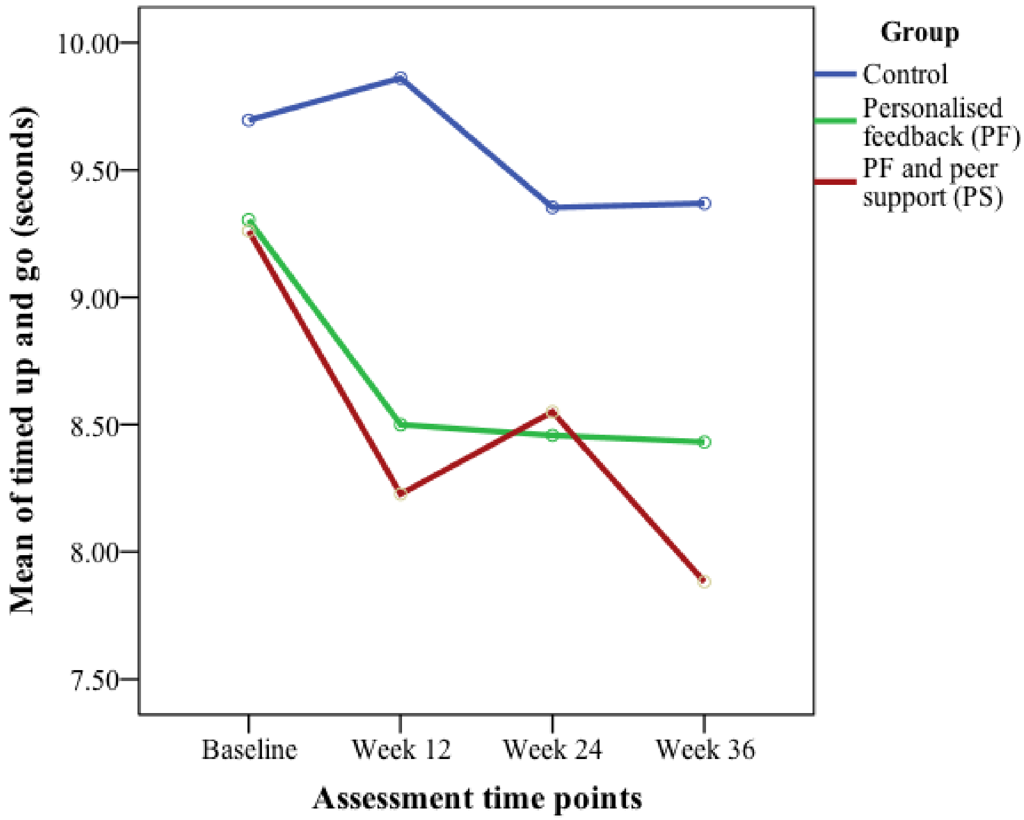

Figure 6.17: Comparisons of adjusted mean seconds for timed up and go test among the three groups across study period

Summary

The PS group contributed to the change in the functional status with greater metres walked in six minutes over time compared to the PF and control groups. There was no significant group difference over time on the timed up and go test.

6.2.4 Quality of life

The quality of life was measured based on the SF-12 Health Survey and presented as two component summary scores: the SF-12 physical component summary (PCS) and SF-12 mental component summary (MCS) scores.

SF-12 Physical Component Summary scores

The SF-12 PCS scores (F (6, 171.33)= 1.09, p=0.369) were not significantly different among the three groups over time (see Table 6.19). Therefore, the hypothesis 2.9 (a) that there would be a significant difference in the SF-12 PCS scores among the groups over time was rejected.

Table 6.19: Comparisons of SF-12 physical component summary scores among the three groups across study period

	SF-12 Physical Component Summary scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	48.32±1.64	23	41.81±1.64	23	41.97±1.64
• Week 12	21	50.65±1.71	22	47.17±1.67	18	44.79±1.84
• Week 24	19	48.18±1.79	20	46.33±1.75	17	43.81±1.90
• Week 36	19	48.86±1.79	17	49.32±1.90	16	44.89±1.96

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	0.08±2.83	-5.51, 5.67	0.978
• Week 24	-1.43±2.91	-7.17, 4.31	0.624
• Week 36	-1.75±2.94	-7.55, 4.05	0.552
PS vs. CG			
• Week 12	3.07±2.81	-2.48, 8.62	0.276
• Week 24	3.23±2.88	-2.46, 8.93	0.263
• Week 36	5.08±2.99	-0.82, 10.98	0.091
PS vs. PF			
• Week 12	2.99±2.73	-2.40, 8.39	0.275
• Week 24	4.66±2.82	-0.91, 10.23	0.100
• Week 36	6.83±2.89	-1.11, 12.55	0.200

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

Figure 6.18 shows a trend of reduction in the mean SF-12 PCS scores at week 12 post-intervention, followed by a trend of increased and reduction again in the follow-up weeks for all groups.

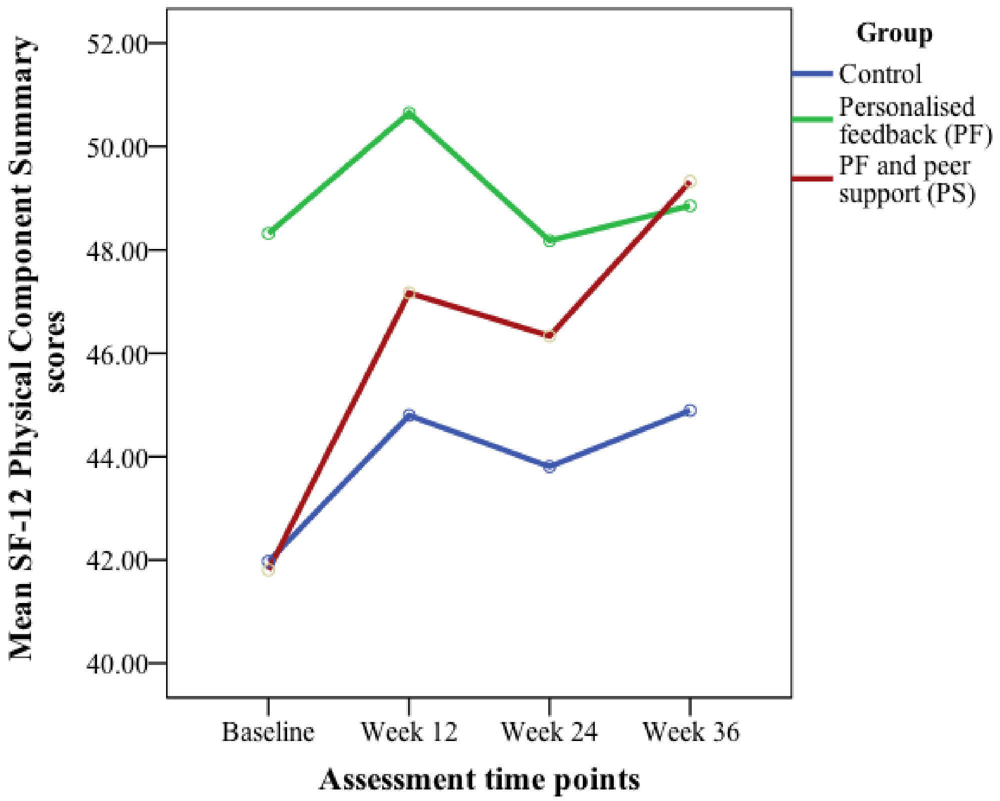

Figure 6.18: Comparisons of adjusted mean SF-12 physical component summary scores among the three groups across study period

SF-12 Mental Component Summary scores

The SF-12 MCS scores (*F* (6, 175.25)=1.41, p=0.214) were not significantly different among the three groups over time as shown in Table 6.20. Therefore, hypothesis 2.9 (b) that there would be a significant difference between the MCS scores of the groups over time was rejected.

Table 6.20: Comparisons of SF-12 mental health component summary scores among the three groups across study period

	SF-12 Mental Component Summary scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	56.09±1.24	23	59.81±1.24	23	55.36±1.24
• Week 12	21	57.75±1.29	22	58.76±1.26	18	59.69±1.38
• Week 24	19	56.86±1.35	20	59.36±1.32	17	59.74±1.42
• Week 36	19	58.04±1.35	17	59.23±1.51	16	58.66±1.46

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-2.68±2.18	-6.98, 1.62	0.221
• Week 24	-3.62± 2.24	-8.03, 0.79	0.107
• Week 36	-1.35±2.26	-5.81, 3.11	0.552
PS vs. CG			
• Week 12	-5.38±2.16	-9.65, -1.11	0.140
• Week 24	-4.83±2.12	-9.20, 0.45	0.310
• Week 36	-3.87±2.30	-8.41, 0.66	0.094
PS vs. PF			
• Week 12	-2.70±2.10	-6.86, 1.45	0.201
• Week 24	-1.21±2.17	-5.49, 3.08	0.579
• Week 36	-2.53±2.23	-6.93, 1.88	0.259

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

From figure 6.19, the PF and control groups showed an increased trend in the mean SF-12 MCS scores at week 12-post-intervention while the PS group showed a trend of reduction. The group SF-12 MCS scores remained unchanged after intervention to the end of the study.

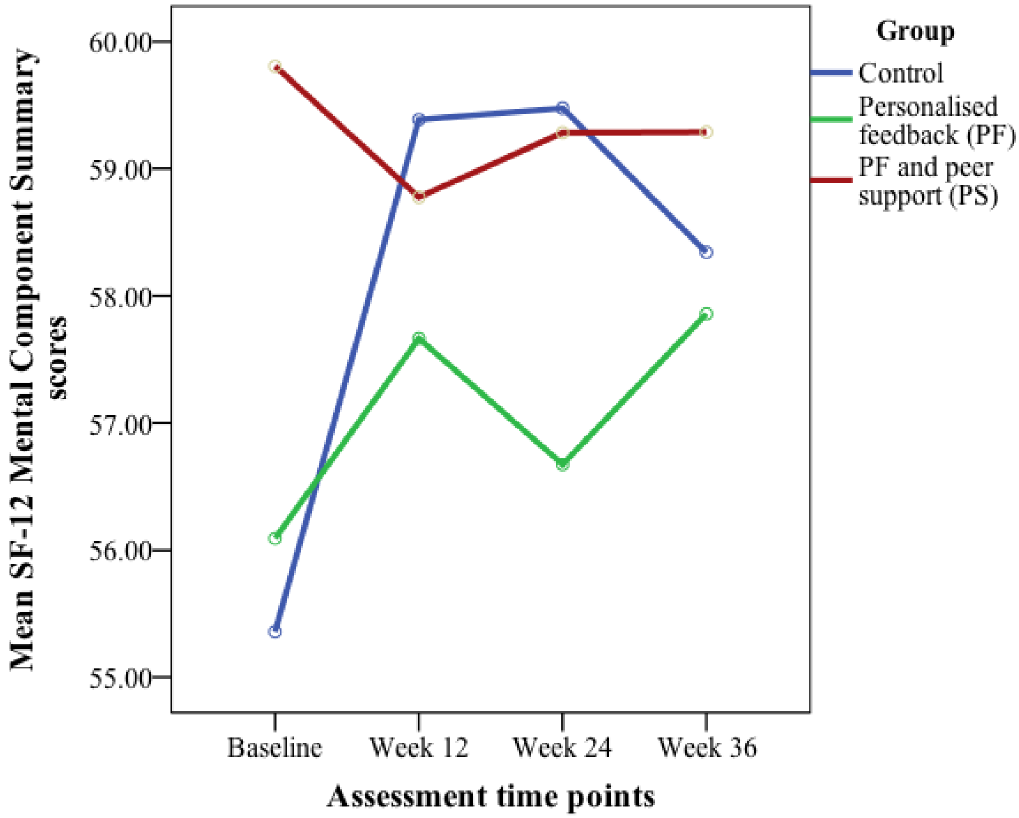

Figure 6.19: Comparisons of adjusted mean SF-12 mental component summary scores among the three groups across study period

Summary

There was no significant group difference over time on SF-12 PCS and MCS scores.

6.2.5 Psychosocial wellbeing

The General Health Questionnaire-12 (psychological wellbeing), the Multidimensional Scale for Perceived Social Support (MSPSS) and the Self-Efficacy for Exercise Scale represented the psychosocial wellbeing. There was a significant improvement in the scores of the MSPSS (friends) (F (6, 170.72)=1.69, p=0.032, adjusted R^2=0.084) between the three groups over time while other measures of psychosocial wellbeing did not differ between groups over time.

General Health Questionnaire-12

The mean General Health Questionnaire-12 (GHQ-12) scores among the three groups did not significantly differ across the study period (F (6, 183.59)=0.94, p=0.469) as summarised in Table 6.21. The hypothesis 2.10 (a) that there would be a significant difference in the GHQ-12 scores among the groups over time was rejected.

Table 6.21: Comparisons of General Health Questionnaire-12 scores among the three groups across study period

	General Health Questionnaire-12 scores					
	PF		PS		CG	
	N	**Mean±SE**	**N**	**Mean±SE**	**N**	**Mean±SE**
• Baseline	23	0.61±0.15	23	0.17±0.14	23	0.48±0.15
• Week 12	21	0.33±0.16	22	0.09±0.16	18	0.39±0.17
• Week 24	19	0.66±0.17	20	0.00±0.16	17	0.19±0.18
• Week 36	19	0.56±0.17	17	0.00±0.18	16	0.01±0.18
	Time specific comparisons of standardised estimates between groups					
	β±SE		**95% CI**		**P value**	
PF vs. CG						
• Week 12	-0.19±0.29		-0.78, 0.39		0.504	
• Week 24	0.34±0.30		-0.26, 0.94		0.259	
• Week 36	0.41±0.31		-0.19, 1.02		0.178	
PS vs. CG						
• Week 12	0.00±0.29		-0.58, 0.58		0.998	
• Week 24	0.11±0.30		-0.48, 0.70		0.714	
• Week 36	0.29±0.31		-0.32, 0.91		0.347	
PS vs. PF						
• Week 12	0.19±0.29		-0.37, 0.77		0.489	
• Week 24	-0.23±0.29		-0.82, 0.35		0.432	
• Week 36	-0.12±0.30		-0.72, 0.48		0.691	

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *P<0.05=statistical significant.

As shown in Figure 6.20 there were trends towards a reduction in the mean GHQ-12 scores for all groups at the week 12 post-intervention, which the PS and control groups subsequently continued to show a trend of reduction in the mean scores at the follow-up weeks.

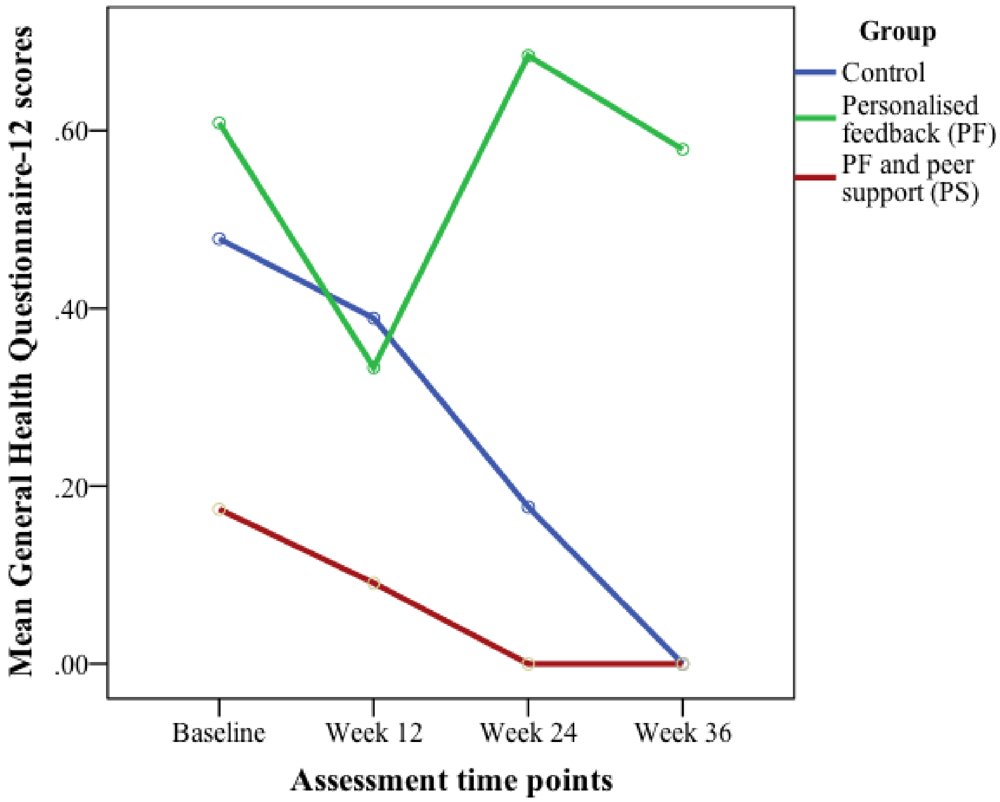

Figure 6.20: Comparisons of adjusted mean General Health Questionnaire-12 scores among the three groups across study period

Multidimensional Scale of Perceived Social Support

The Multidimensional Scale of Perceived Social Support (MSPSS) has three subscales representing the source of social support. The results were presented based on scores of the individual subscales that were perceived social support from significant others, family and friends.

1. Multidimensional Scale for Perceived Social Support (significant others)

There was no significant difference in the scores of MSPSS from significant others (F (6, 178.91)=0.855, p=0.529), as presented in Table 6.22. Therefore, the hypothesis 2.10 (b) that there would be significant difference in the scores among the groups over time was rejected.

Table 6.22: Comparisons of MSPSS (significant others) scores among the three groups across study period

	MSPSS (significant others) scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	5.72±0.15	23	6.12±0.15	23	6.03±0.15
• Week 12	21	5.84±0.15	22	5.89±0.15	18	6.12±0.16
• Week 24	19	5.76±0.16	20	5.70±0.16	17	5.83±0.17
• Week 36	19	5.57±0.16	17	5.87±0.17	16	6.01±0.17

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.24±0.20	-0.73, 0.24	0.653
• Week 24	-0.05±0.19	-0.52, 0.42	1.000
• Week 36	-0.43±0.28	-1.12, 0.26	0.395
PS vs. CG			
• Week 12	0.04±0.26	-0.47, 0.54	0.886
• Week 24	0.24±0.26	-0.28, 0.76	0.364
• Week 36	-0.13±0.26	-0.65, 0.39	0.627
PS vs. PF			
• Week 12	-0.35±0.25	-0.83, 0.14	0.162
• Week 24	-0.45±0.25	-0.96, 0.05	0.076
• Week 36	-0.10±0.26	-0.62, 0.41	0.690

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *$P<0.05$=statistical significant.

Both the PF and control groups showed a trend of increased mean scores of MSPSS (significant others) at week 12 post-intervention, while the PS group showed a trend towards reduction in the mean scores (see Figure 6.25). All the groups had a trend towards reduced mean scores at follow-up week 24, which the PF group continued to have a reduced trend in the mean scores at week 36 too.

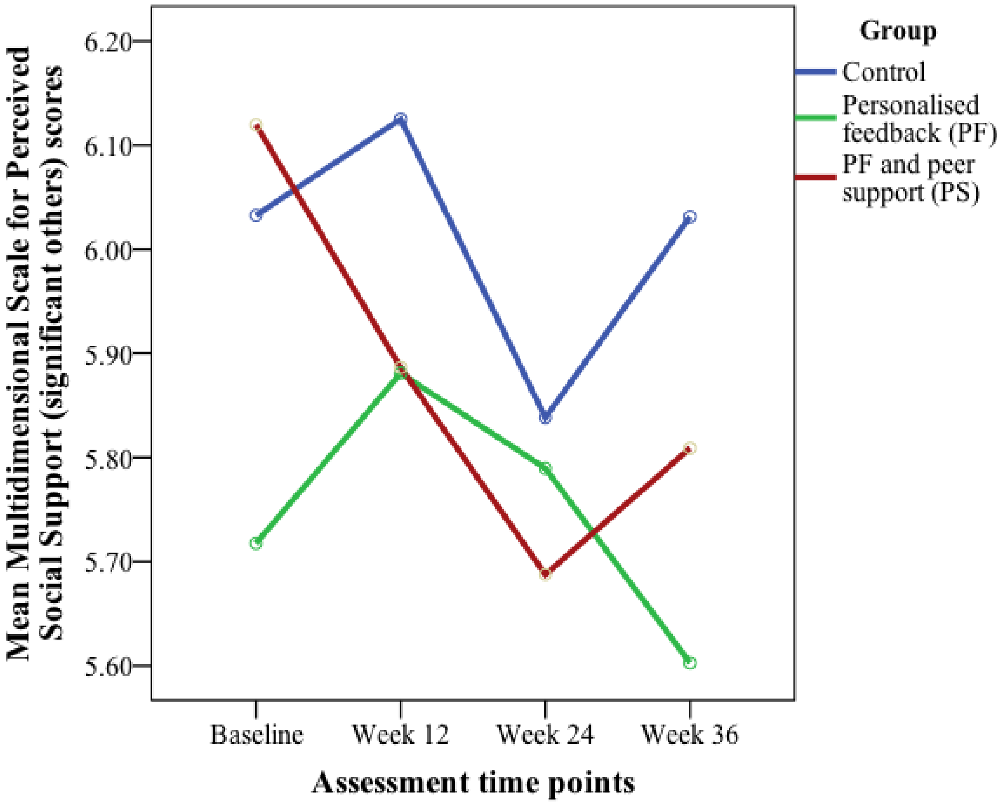

Figure 6.21: Comparisons of adjusted mean MSPSS (Significant others) scores among the three groups across study period

2. Multidimensional Scale for Perceived Social Support (family)

The scores of MSPSS from family (F (6, 181.72)=0.71, p=0.639) did not show any significant difference between the groups as presented in Table 6.23. Therefore, the hypothesis 2.10 (c) that there would be significant difference in the scores among the groups over time was rejected.

Table 6.23: Comparisons of MSPSS (family) scores among the three groups across study period

	MSPSS (family) scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	5.84±0.15	23	6.22±0.15	23	6.00±0.15
• Week 12	21	5.71±0.16	22	6.02±0.15	18	5.63±0.17
• Week 24	19	5.46±0.16	20	5.77±0.16	17	5.56±0.17
• Week 36	19	5.78±0.16	17	5.78±0.17	16	5.91±0.18
	Time specific comparisons of standardised estimates between groups					
	β±SE		**95% CI**		**P value**	
PF vs. CG						
• Week 12	0.24±0.26		-0.28, 0.76		0.363	
• Week 24	0.08±0.27		-0.46, 0.61		0.779	
• Week 36	0.04±0.27		-0.49, 0.58		0.881	
PS vs. CG						
• Week 12	0.17±0.26		-0.34, 0.69		0.506	
• Week 24	0.00±0.27		-0.53, 0.53		0.998	
• Week 36	-0.34±0.28		-0.89, 0.21		0.225	
PS vs. PF						
• Week 12	-0.07±0.25		-0.57, 0.43		0.794	
• Week 24	-0.08±0.26		-0.59, 0.44		0.771	
• Week 36	-0.38±0.27		-0.91, 0.15		0.161	

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; *$P<0.05$=statistical significant.

All groups had reduced trend in the mean scores of MSPSS (family) at week 12 and week 24 from baseline, which the PS group continued to have reduced trend in the mean scores at week 36 as shown in Figure 6.22. Both the PF and control groups showed an increased trend of the mean scores at end of the study.

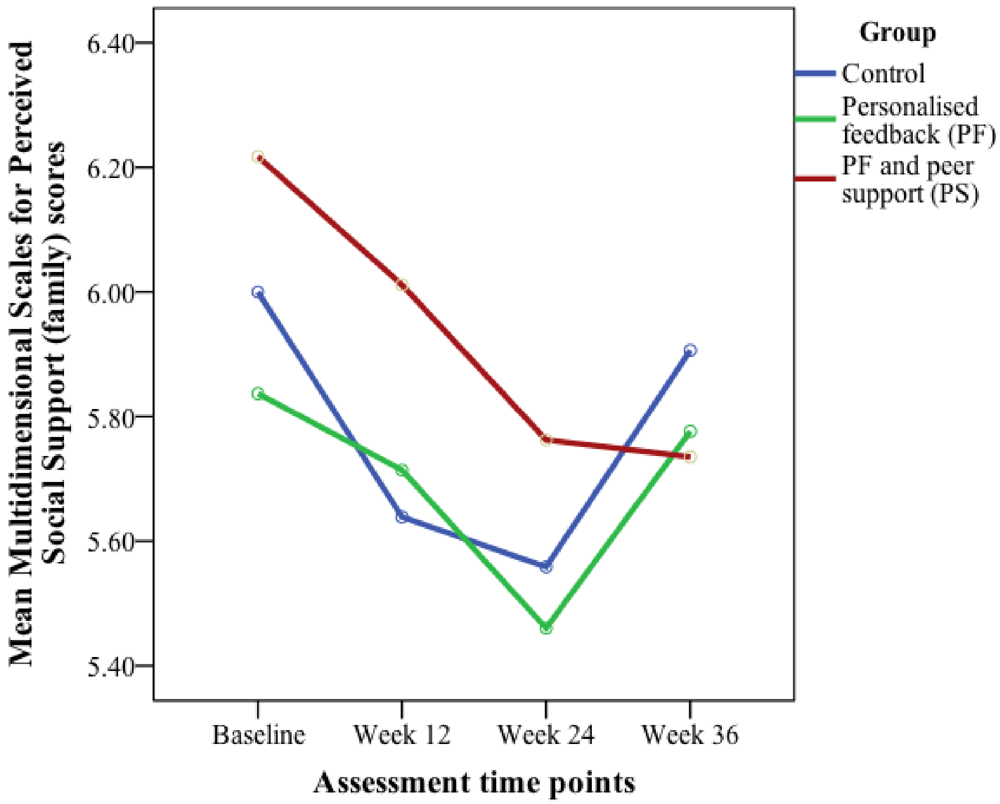

Figure 6.22: Comparisons of adjusted mean MSPSS (family) scores among the three groups across study period

3. Multidimensional Scale for Perceived Social Support (friend)

The scores of MSPSS (friends) (*F* (6, 170.72)=1.69, p=0.032; final model χ^2 (11)=24.55, p<0.025; adjusted R^2=0.084) with a small effect size among the three groups over time was significantly different as shown in Table 6.24. Hypothesis 2.10 (d) was therefore supported. All the assumptions were checked and fulfilled.

The PS group had greater scores of MSPSS (friend) at week 24 (β=1.42±SE0.52, p=0.007) and week 36 (β=1.10±SE0.54, p=0.043) from baseline compared to the control group, as well as at week 24 (β=1.25±SE0.51, p=0.015) when compared to the PF group as summarised in Table 6.24. There was no difference in the MSPSS (friend) scores between the PF group and the control group over time.

Table 6.24: Comparisons of MSPSS (friends) scores among the three groups across study period

	MSPSS from friend scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	4.73±0.30	23	4.62±0.30	23	4.57±0.30
• Week 12	21	4.23±0.32	22	4.89±0.32	18	4.15±0.34
• Week 24	19	4.19±0.33	20	5.34±0.31	17	3.86±0.35
• Week 36	19	4.70±0.33	17	5.40±0.34	16	4.23±0.36

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	-0.07±0.51	-1.09, 0.94	0.884
• Week 24	0.17±0.53	-0.87, 1.21	0.749
• Week 36	0.29±0.53	-0.76, 1.35	0.581
PS vs. CG			
• Week 12	0.69±0.51	-0.31, 1.69	0.177
• Week 24	1.42±0.52	0.39, 2.45	0.007*
• Week 36	1.10±0.54	0.03, 2.17	0.043*
PS vs. PF			
• Week 12	0.77±0.50	-0.21, 1.75	0.124
• Week 24	1.25±0.51	0.24, 2.26	0.015*
• Week 36	0.81±0.53	-0.23, 1.85	0.125

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE= standard error; 95% CI=95% confidence interval; *$P<0.05$=statistical significant.

Figure 6.23 shows that the PS group had a gradual increased in the MSPSS (friends) scores across the different assessment time points. Both the PF and control groups showed a trend towards reduction in the mean scores post-intervention and only increased at follow-up week 36.

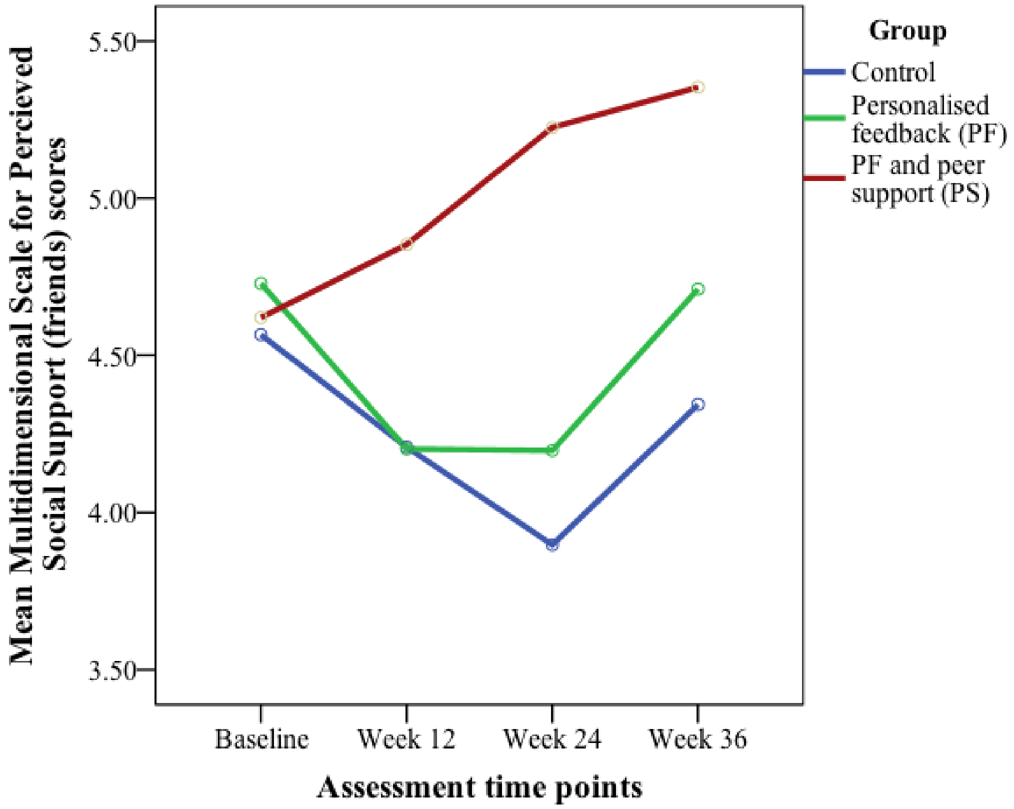

Figure 6.23: Comparisons of adjusted mean MSPSS (friends) among the three groups across study period

Self Efficacy for Exercise Scale

The Self-Efficacy for Exercise Scale (SEES) score was not significantly different among the three groups over time (F (6, 168.39)=1.33, p=0.248) as summarised in Table 6.28. Therefore, the hypothesis 2.10 (e) that there would be a significant difference in the SEES scores among the groups across the study period was rejected.

Table 6.25: Comparisons of Self-Efficacy for Exercise Scale scores among the three groups across study period

	Self-Efficacy for Exercise Scale scores					
	PF		PS		CG	
	N	Mean±SE	N	Mean±SE	N	Mean±SE
• Baseline	23	6.73±0.30	23	6.75±0.30	23	6.44±0.30
• Week 12	21	6.42±0.31	22	6.78±0.30	18	5.74±0.33
• Week 24	19	5.60±0.32	20	6.25±0.31	17	5.67±0.34
• Week 36	19	5.82±0.32	17	7.14±0.34	16	5.69±0.35

	Time specific comparisons of standardised estimates between groups		
	β±SE	95% CI	P value
PF vs. CG			
• Week 12	0.42± 0.50	-0.57, 1.42	0.402
• Week 24	-0.37± 0.52	-1.39, 0.65	0.478
• Week 36	-0.15± 0.52	-1.19, 0.88	0.772
PS vs. CG			
• Week 12	0.74±0.51	-0.25, 1.73	0.141
• Week 24	0.24±0.52	-0.77, 1.25	0.642
• Week 36	0.97±0.54	-0.06, 2.04	0.066
PS vs. PF			
• Week 12	0.32±0.49	-0.64, 1.28	0.516
• Week 24	0.61±0.50	-0.39, 1.60	0.229
• Week 36	1.14±0.52	-0.12, 2.16	0.290

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; SE=standard error; 95% CI=95% confidence interval; **P*<0.05=statistical significant.

The PF and control groups showed a trend towards reduction in the mean SEES scores at baseline and week 12 post-intervention, while the PS group remained unchanged as shown in Figure 6.24. The PF group had a further trend towards a reduction to end of the study while the PS group had an increased trend in the mean SEES scores at week 36 and the control group remained unchanged.

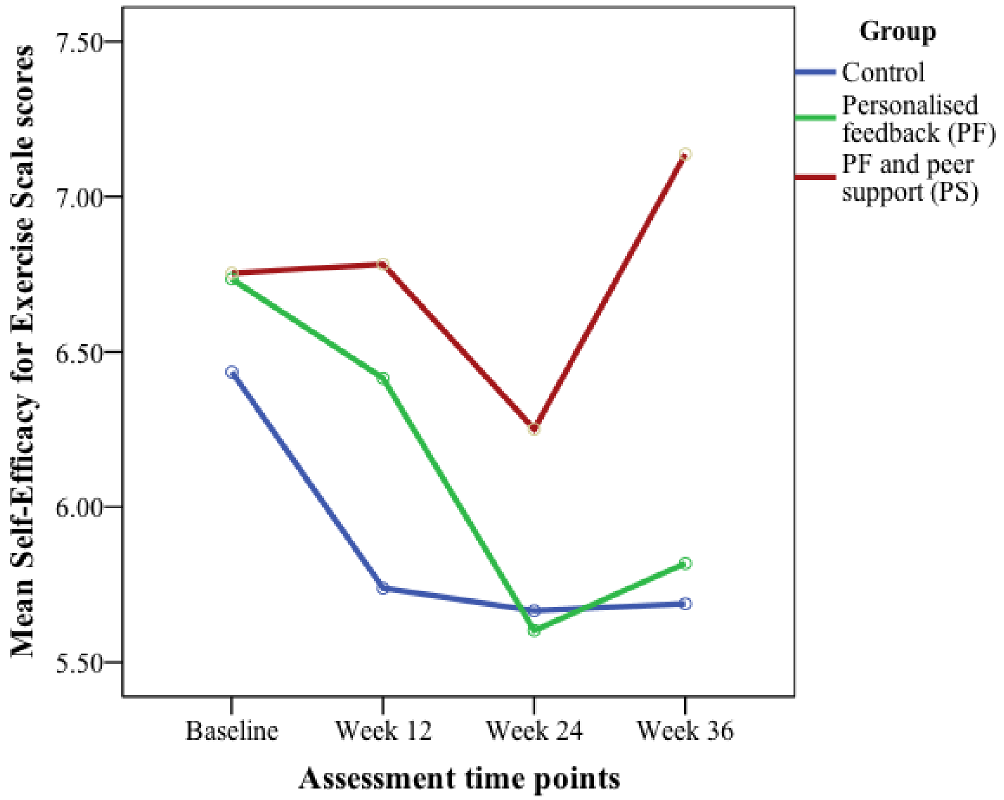

Figure 6.24: Comparisons of adjusted mean Self-Efficacy for Exercise Scale scores among the three groups across study period

Summary

The PS group contributed to the change in the psychosocial wellbeing with greater scores of perceived social support from friends over time compared with the PF and control groups. There was no significant group difference over time on GHQ-12 scores, and MSPSS from significant others and from family scores.

6.3 Summary of the overall findings

In this RCT, the personalised feedback about physical activity patterns combined with peer support (PS) group showed significant improvements in the pedometer-determined level of physical activity with greater daily pedometer readings compared with personalised feedback about physical activity patterns (PF) and control groups. The PF also had greater daily pedometer readings across the study period compared to the control group.

As for the secondary outcomes, the PF and PS groups also had greater weekly duration and frequency of structured physical activity, and lower body fat percentage, compared with the controls. The PS group had a greater PASE score, distance walked in the six-minute walk test and MSPSS (friend) scores than the PF and control groups. Table 6.27 summarises the significant study outcomes among the three groups over time. The MSPSS and SEES were potential mediators on pedometer-determined physical activity; but it was beyond the scope of this study to perform a mediation analysis.

Table 6.26: Summary of significant outcomes among the three groups across study period

Outcomes	Group	[a] Estimates ± SE at Week 12	[a] Estimates ± SE at Week 24	[a] Estimates ± SE at Week 36	*F (df)*	P value (R^2)
Daily pedometer readings (steps/day)					4.10 (6, 173.85)	0.001* (0.212)
	PF vs. CG		2093.18±666.89**			
	PS vs. CG	2265.85±642.93**	2586.31±660.33***	2084.94±685.25**		
	PS vs. PF	1416.12±621.62*		1416.67±661.68*		
Weekly duration of physical activity (minutes/week)					6.29 (6, 178.57)	<0.001* (0.386)
	PF vs. CG	71.99±25.22**	71.94±25.90**	73.56±26.18**		
	PS vs. CG	126.24±25.02***	124.93±25.67***	127.09±26.62***		
	PS vs. PF	54.24±24.26*	52.98±25.08*	53.53±25.77*		
Weekly frequency of physical activity (days/week)					7.20 (6, 180.38)	<0.001* (0.465)
	PF vs. CG		1.77±0.72*	2.13±0.72**		
	PS vs. CG		3.53±0.71***	3.35±0.73***		
	PS vs. PF		1.76±0.69*			
Physical Activity Scale for Elderly scores					3.43 (6, 174.60)	0.003* (0.078)
	PS vs. CG	61.66± 17.72*	42.77± 18.17**	58.59±17.15*		
	PS vs. PF	47.21± 17.19**		63.40± 18.26**		
Body fat (%)					3.36 (6, 169.09)	0.004 (0.258)
	PF vs. CG	-1.63±0.80*		-2.86±0.84**		
	PS vs. CG	-1.69±0.79*	-1.75±0.82*	-3.27±0.85***		
Distance of the six minute walk test (metre)					5.43 (6, 171.12)	<0.001* (0.256)
	PS vs. CG		62.79±14.79***	45.06±15.35**		
	PS vs. PF		-45.18± 12.11**			
Scores of MSPSS from friend					1.69 (6, 170.72)	0.032 (0.084)
	PS vs. CG		1.42±0.52**	1.10±0.54*		
	PS vs. PF		1.25±0.51*			

Note: CG=control group; PF=personalised feedback about patterns of physical activity group; PS=PF and peer support group; a=standardised estimate; SE=standard error; **P*<0.05, ***P*<0.01 and ****P*<0.001=statistical significant.

CHAPTER 7 DISCUSSION AND CONCLUSION FOR THE FINDINGS FROM THE RANDOMISED CONTROLLED TRIAL

This chapter discusses the findings and conclusions from the randomised controlled trial (RCT). First, the RCT's participants' characteristics and retention in the study ar discussed. Second, the findings from the effectiveness of the interventions are summarised and discussed according to the primary and secondary outcomes. Third, the process evaluation of this RCT, with its strength and limitations, is discussed. Finally, conclusions on the major findings are made.

The Phase 3 of this thesis, a three-arm randomised controlled trial (RCT), was conducted over a course of 36 weeks with 12 weeks of intervention and a 24-weeks of follow-up. The purpose of this RCT was to determine the effectiveness of personalised feedback about physical activity pattern alone (PF) and in combination with peer support (PS), in addition to the usual diabetes care. It was hypothesised that both intervention groups, the personalised feedback about physical activity pattern alone (PF) and in combination with peer support (PS), would have more favourable outcomes than the controls.

In this RCT, the primary outcome was the pedometer-determined level of physical activity, which was measured by daily pedometer readings. The secondary outcomes included self-reported physical activity levels, cardiovascular disease (CVD) risk factors, functional status, quality of life and psychosocial wellbeing. The self-reported physical activity levels were represented by weekly duration and frequency of structured physical activity, Physical Activity Scale for Elderly (PASE) scores and duration of daily PASE activities while seated. The CVD risk factors were measured by glycosylated haemoglobin (HbA1c), blood pressure, body composition (weight, BMI, waist circumference and body fat percentage) and lipid profile (LDL-C, HDL-C and triglycerides). The functional status measures included the six minutes walk test (for cardiorespiratory fitness) and timed up and go test (for balance). The quality of life was measured by the SF-12 Health Survey (for generic quality of life measures), while the psychosocial wellbeing was measured by General Health Questionnaire-12 (for psychological wellbeing), Multidimensional Scale for Perceived Social Support (for social support) and Self-Efficacy for Exercise Scale (self-efficacy).

7.1 Participants' characteristics and retention

Sixty-nine participants enrolled in this RCT and 23 were randomised into each of the three groups. Some of the participants' socio-demographic profiles were similar to the general population of older people in Malaysia. In this RCT most of the participants aged less than 75 years old (95.7%). A qualitative study among older Korean American reported that advancing age was perceived as a negative factor that influenced exercise non-participation (204). It is possible that older Malays from the current study sample had similar perceptions resulting in fewer older Malays aged 75 years and above joining the current study. Most of the participants in this RCT co-resided with their adult children (75.5%). A similar trend has been reported by Chan and Davanzo (205), where 60.0% of Malays aged 50 years and above lived with an adult child. For the Malays and Muslims, it is the obligation of their adult children, irrespective of gender, to care for their aged parents financially, emotionally and physically (157). Further, older parents with poorer health would require physical assistance and care from their children; so, they would be more likely to co-reside with the adult children.

In this RCT, the proportion of participants attaining secondary education or higher was 73.6%. Over the last few decades, a trend showed that older people in Malaysia are becoming more educated. The proportion of older people aged 60 years and above who had never been to school has declined from 73.2% in year 1980 to 51.3% in year 2000 (206). Over the same period, the proportion receiving secondary education or higher have increased from 3.7% to 11.3%. The average monthly gross household income among this RCT's participants was RM 3,354.64 ± SD3067.93, which was above the poverty line income of RM 830.00 but was below the average monthly household income among the Malays and indigenous *Bumiputera* of RM 4,457.00 in Malaysia (207). Some of the participants in this RCT were still working (29.0%). In Malaysia, until the year 2012, the compulsory retirement age for the public and private formal sectors was 55 years (208). Many of the participants in this RCT were retired as they were engaged in the civil service (or public sector) previously and therefore, were subject to the compulsory retirement at age 55 and were receiving pensions.

There were significantly more men (53.6%) than women participated in this study. The aim of this RCT was to promote and maintain physical activity through walking activity. A previous study reported that men were more likely to engage in outdoor physical activity such as walking compared to women while women preferred indoor activity (209). Further, some women were reported to be embarrassed about engaging in outdoor activities (67,126). The prospect of having to engage in walking exercise may therefore be the reason why fewer women joined the current study. Another possibility is that women may believe that their household chores are an adequate form of physical activity; this was suggested by comments made in the qualitative focus-group study. The need to engage in a physical activity programme may be of less interest to women.

At the end of the 36 weeks, 52 (75.4%) participants had completed the RCT. Sixteen (69.6%) participants from the control group, 19 (82.6%) participants from the PF group and 17 (73.9%) participants from the PS group completed the study. Three participants (two from the control group and one from the PF groups) withdrew from the study because they could not comply with the study protocol because of the time constraint. Other participants withdrew from the study for other personal reasons. The participants who completed the RCT were comparable to those who discontinued in terms of their baseline characteristics. But, more women than men discontinued from this study. In Malaysia, the Malay women hold traditional roles in the family as required by Islam. Obligations to their spouse and family take priority, which was also reported in another study in Australia that included Muslim women's views (126). It was perceived that cultural norms among the older generation required most domestic duties such as cooking and cleaning, and family affairs to be undertaken by women regardless of the external employment. This factor could explain why fewer proportion of women completed this study.

7.2 Effectiveness of interventions on the level of physical activity

The primary outcome in this RCT was the pedometer-determined physical activity level. Both the personalised feedback about physical activity patterns alone (PF) and in combination with peer support (PS) groups significantly improved the daily pedometer readings when compared with the controls. The use of a simple feedback chart did significantly increase the daily pedometer readings, but combination with peer support was found to be even more effective in improving the pedometer steps/day in the present RCT.

The PF group had greater daily pedometer readings at week 24 follow-up than the control group, but not at weeks 12 and 36. At week 12-post-intervention, both the PF and control groups did show some improvement in the daily pedometer readings from baseline but the change was too small to be significant statistically. In contrast, Allen (59) in a RCT among adults aged 18 years and above with T2DM in the United States of America showed that feedback from a glucose chart led to significant improvement in the accelerometer-based moderate intensity physical activity . Also, they showed reduced sedentary activity post-intervention compared with the control group. However, they did not evaluate the long-term effect of the intervention because their intervention was eight weeks with no follow-up period. During the present RCT, from an informal observation during the week-12 visit by the researcher, some participants in the PF group compared each other's charts while waiting for consultation. Perhaps this interaction could have triggered the behaviour change observed at the follow-up period. The strength of the RCT reported in this thesis is the long-term post-intervention follow-up period that allowed observation on the evolution of behaviour change following an intervention.

The participants in the PS group showed greater daily pedometer readings compared with both the PF and control groups post-intervention and this was maintained at the follow-up period. Consistent with a previous study in Canada, peer support led to improvement in the physical activity level among adults with T2DM. The participants showed significant changes in the daily pedometer step counts over time (58). In this quasi-experimental study conducted over 16 weeks with no follow-up, the participants received a physical activity programme using the pedometer as a motivational tool delivered either by the peer mentors or health care professionals. Both groups showed improvement in the daily pedometer step counts during the study. However, the daily pedometer step counts did not differ between the two groups. The present RCT not only improved physical activity levels in the short-term but also was able to show a sustained impact on the behaviour of the older Malays. Additionally, peers has been shown to influence one another through sharing of information and experiences, which resulting in adoption of similar behaviours (210,211). Furthermore, the participants in the PS group also met some of their group and peer mentors outside the scheduled time. Some men in the PS group developed their own walking groups while some women joined each other's religious classes. These interactions could have contributed to the adherence to regular physical activity. This "flow-on" effect is an important finding from the study. The participants were able to take the experience of the intervention and translate it into sustainable activities.

7.3 Effectiveness of interventions on self-reported physical activity levels

A secondary outcome of this study was the self-reported physical activity levels represented by the weekly duration and frequency of structured physical activity and the Physical Activity Scale for Elderly (PASE). In this RCT, both the PF and PS groups significantly improved the weekly duration and frequency of structured physical activity when compared with controls across the study period. The PS group also had significantly greater weekly duration and frequency of structured physical activity, and PASE scores than the PF and control groups.

In the present RCT, the use of a chart with goal setting and problem solving did bring about a change in physical activity behaviour based on the weekly duration and frequency of structured physical activity. However, the PF group did not reach the recommended level of 150 minutes/week of structured physical activity throughout the 36 weeks of the study period, despite a trend towards gradual increase. Further, the frequency of structured physical activity only showed a significant increased at the follow-up weeks 24 and 36, and did not reach the recommended frequency of at least five days a week of structured physical activity. From extensive literature search, there is no study that evaluated the use of a chart as a feedback on the duration and frequency of structured physical activity among older people with T2DM. An Australian study motivated people with T2DM to engage in walking activity for 24 weeks using health coaching and a pedometer as a feedback (60). The group receiving feedback did show improvements in the minutes a day of walking activity over time similar to the findings in the PF group found in the present study. But, no significant difference in the minutes a day of walking activity was observed when compared with group receiving health coaching alone.

The PS group showed significantly greater weekly duration and frequency of structured physical activity over time when compared with the PF and control groups. The participants in the PS group also achieved the recommended level of 150 minutes a week and at least five days a week of structured physical activity based on the activity diary. This was consistent with previous studies that incorporated peer support and measured the duration and frequency of structured physical activity (109,212). These studies reported significant improvement in the minutes a week (212) and days a week (109) of structured physical activity following a 12-month intervention. However, in these studies, the intervention was group-based diabetes self-management education and the peer group leaders and other health care providers delivered the intervention. Also, the primary outcome was self-management behaviour that included diet and exercise and not focused on physical activity alone.

The Physical Activity Scale for Elderly (PASE) scores was significantly greater in the PS group when compared with the PF and control groups in the present RCT. Feedback alone did not contribute to the changes in the PASE scores. The sub analysis on the three subscales of PASE (leisure time physical activity (LTPA), household activity and work-related activity) showed the PS group had significantly greater subscale scores on PASE LTPA and on PASE household activity from baseline during the study when compared with the PF and control groups. Similar to previous studies, peer support programmes reported greater physical activity levels based on self-reported physical activity scale scores compared with controls (109,114,212). But, the scales used to measure self-reported physical activity in these studies varied, making comparison difficult. Furthermore, the focus of these studies was on diabetes self-management, which included diet, exercise and stress management and not on physical activity alone.

This RCT showed no difference in the sedentary behaviour between the groups across the study period. In contrast, previous studies showed social support from group sessions led by health care professionals decreased sedentary time when compared with controls (87,108). Most participants in all the groups of the current RCT reported spending less than four hours a day on activities while seated that remained unchanged during the course of the study. Through informal communication with some participants in this RCT, some took naps in mornings and afternoons. They did not report this as the question from PASE was about the hours spent in a day on activities done while seated and not lying down. Further, they were asked to name the types of sitting activities. Thus, the true extent of the sedentary behaviour change in this RCT may have been underestimated.

A review of the measurement of adult sedentary time suggested that it is more difficult for participants to recall the time spent during an entire day of seated activities with self-reported measures than on a specific behaviour (213). So, a self-reported measure should include assessments of various sedentary behaviours and not overall sitting time. The use of a device such as an accelerometer would provide a reliable, valid and stable measurement of overall sedentary time compared to the self-reported measures such as PASE (214). But, long periods of low counts from the accelerometer may be indistinguishable from sleeping time or can be misclassified as non-wear (215). Therefore, a combination of both self-reported and device-based measures is recommended in monitoring sedentary behaviour (213).

7.4 Effectiveness of interventions on the cardiovascular disease risk factors

In the current study, the interventions did not have an impact on the cardiovascular disease (CVD) risk factors except for the change in body fat percentage. Both the PF and PS groups showed significant improvements in the mean body fat percentage over the study period compared with the controls. The effect of the PF intervention improved body fat percentage at week-12 post-intervention and at the week-36 follow-up. The PS group showed more improvement in the body fat percentage than the control group across each assessment time point, but reduction in body fat percentage did not differ when the PS group was compared with the PF group. A greater reduction in the body fat percentage was observed in the PS group at the week-36 follow-up.

Comparison with previous studies that incorporated a chart as feedback or peer support among adults with T2DM could not be made as these studies did not measure body fat percentage as an outcome (58,59,109,114). A quasi-experimental study in Canada used a pedometer as feedback to improve physical activity levels in adults with T2DM (118). The study showed improvement in the body fat percentage, but no group differences were detected. Both the PF and PS groups of the current RCT showed a reduction in the body fat percentage as well as increased weekly duration and frequency of structured physical activity. Previous study reported that fat is the source of energy when one engages in physical activity at low and moderate intensities, whereas vigorous intensity of physical activity relies on carbohydrate as the source of energy (216). Further, an increase in physical activity could lead to a reduction in both visceral and subcutaneous fat regardless of the physical activity intensity (217). Mechanisms in the fat metabolism could explain the reduction of body fat percentage observed in the intervention groups of the current RCT.

In the present RCT, the interventions were not effective in improving other CVD risk factors such as the level of HbA1c, blood pressure, other anthropometric measurements (BMI, weight, waist circumference) and lipid profile. After reviewing previous studies that used a chart as feedback or peer support to promote physical activity in adults with T2DM, three studies measured HbA1c and/or other CVD risk factors as their outcomes (58,59,109). Interventions in previous studies that used a self-blood glucose monitoring chart as feedback (59) and peer support (109), respectively showed significant reduction in the HbA1c level as opposed to the findings of this RCT. However, the improvements in HbA1c in these studies were short-term. In this RCT, all groups showed a similar trend of reduction in the means of HbA1c level, weight, BMI and waist circumference at week 12 post-intervention, which explains why the difference between groups was not detected. The reduction in these variables in the intervention groups could be due to the walking activity. But in the control group it is unclear why such a reduction was observed, as they had not engaged in regular physical activity. A ‘trial effect’ could explains this observation; a phenomenon where a trial may bring about positive effects on the participants’ results. The participants may alter their behaviour to improve themselves as a result of being in a study (also known as the Hawthorne effect) (218). Another possibility could be that the control group may have improved their dietary control during the intervention, as their duration and frequency of structured physical activity did not change during the study. But, this RCT was not able to confirm this, as dietary intake of the study participants was not measured.

In the present study, there was no improvement in blood pressure (BP) levels between groups. A previous study that used a chart or pedometer as feedback did not show improvement in the BP levels when compared to controls (59,60,92,118). But studies that incorporated peer support to promote physical activity (58) and diabetes self-management study showed improvement in the BP levels over time (212). All participants in the three groups in the present study began with adequate BP control with an average of about 130/80 mmHg, and BP was maintained in all groups during this study. The ‘normal’ BP in the participants of this RCT at enrolment could explain the observed no change in BP between the three groups.

The lipid profile (LDL-C, HDL-C and triglycerides levels) in the present study did not show significant difference between the groups. Similarly, previous studies that used a pedometer as feedback (60,92) and peer support in diabetes self-management study (109) showed no improvement in lipid profile when compared to controls. At baseline, all groups in the present study had LDL-C levels that were not targeted. The PS group had triglycerides levels below the target. During this RCT, all groups reduced their LDL-C and triglycerides levels, which could explain the non-significant difference observed between the groups. The increased level of physical activity could explain the improvements observed in the intervention groups. As for the control group, they could possibly have improved because of their dietary control of fat intake, but it was not measured in the current study. The HDL-C levels did not improve over time across the study period for all the groups in this study. A previous study that involved 24 weeks of endurance exercise showed increased HDL-C levels and reductions in other lipid profile that was independent of diet or change in body fat in older adults (219). However, in a study with a nine-month endurance training intervention involving sedentary older men, HDL-C increased in lean and overweight older men but not in obese older men (220). In the current RCT on average the participants at baseline were obese, which could explain why the HDL-C did not change over time.

7.5 Effectiveness of interventions on the functional status, quality of life and psychosocial wellbeing

The PS group significantly increased the metres walked in six minutes and scores of the Multidimensional Scale for Perceived Social Support (friend) at weeks 24 and 36 of follow-up when compared with both the PF and control groups. There was no group difference in the timed up and go test (to evaluate balance), health related quality of life, psychological wellbeing, perceived social support from significant other and family, and self-efficacy to exercise.

The PS group initially did not improve in cardiorespiratory fitness as measured by the distance walked in six minutes at post-intervention when compared with both the PF and control groups. The improvement was observed at the follow-up weeks 24 and 36. Comparison with previous studies could not be done as there were no studies on feedback or peer support that measured cardiorespiratory fitness of older people with T2DM following physical activity interventions. But, a meta analysis found regular structured physical activity did improve cardiorespiratory fitness in people with T2DM (221). Also, higher intensity physical activity could lead to greater improvement in the cardiorespiratory fitness. In this RCT, the PS group was the only group that achieved the recommended duration and frequency of structured physical activity. This could explain the observed difference between the groups in the cardiorespiratory fitness.

In this RCT, the PS group showed greater scores of the MSPSS (friends) compared with both the PF and CG groups. The mean scores of MSPSS (significant others) and MSPSS (family) remained unchanged in all groups during this RCT. There was no difference between the three groups. Traditionally most Asian older people rely on their family members for support (222,223). A quasi-experimental study on Chinese women that evaluated group based Tai Chi exercise on social support reported significant increased scores of MSPSS (family) and MSPSS (significant others) but not the scores of MSPSS (friends) (224). In the present study, social interaction that took place between the peer mentors and the PS group participants as well as among the participants themselves could have influenced the greater perceived social support from friends. They may have considered their newly acquainted peers as their new friends. Further, friends have been shown to correlate positively to older people's participation in leisure activities (225), which could also explain the greater level of physical activity seen in the PS group. Through informal communications with the participants and peer mentors during this study, the PS group did have social interactions among themselves and with the peer mentors outside the scheduled visits. This could have led to the greater mean MSPSS (friends) scores as compared to the other groups.

Neither the PF nor the PS interventions showed any improvements in the participants' balance, health related quality of life, psychological wellbeing, perceived social support form significant other and family, and self-efficacy for exercise. On average, time taken for the Timed Up and Go test and the psychological wellbeing (GHQ-12) scores were within normal limits at baseline for all participants in this study. Further, there were no significant changes over time. Hence, there may not have been a clinical need for improvement in these measures, and the interventions in this RCT were not specifically targeted to enhancing wellbeing but rather physical activity levels.

The scores for health related quality of life using the SF-12 Health Survey remained unchanged during this RCT with no group differences. None of previous studies that evaluated feedback or peer support in promoting physical activity in people with T2DM measured health related quality of life. Neither did previous studies that promoted physical activity in people with T2DM using community-based or clinic-based intervention show improvements in the quality of life of their participants (57,117). One possible reason for the non-significant findings from the previous studies and the current study may be that the questionnaire used was a generic scale and not specific for diabetes.

The present RCT found no significant difference between the three groups on the self-efficacy to exercise across the study period. On the contrary, previous studies that used a chart as feedback and incorporated peer support programmes did show a significant increase in self-efficacy to exercise among the intervention group participants compared with their controls (59,109,114). The mean SEES scores remained unchanged in all groups during the course of this RCT and the changes between groups were perhaps too small to show significant difference. It is worth noting that both self-efficacy and perceived social support are potential mediators of physical activity behaviour. Previous RCT using cognitive behavioural approaches and constructs of social cognitive theory in people with T2DM found changes in self-efficacy toward barriers to physical activity (87). Also, social support from family was found to mediate the change in daily pedometer readings at six months post-intervention (226). The present RCT was underpowered for a mediation analysis; hence, the mediators of physical activity in this study could not be ascertained.

7.6 Process evaluation of the randomised controlled trial

This randomised controlled trial (RCT) was conducted with two intervention arms; the personalised feedback about physical activity patterns alone (PF), and in combination with peer support (PS), in addition to the usual diabetes care. The controls received the usual diabetes care only. This RCT was conducted according to the published study protocol. Throughout this study, field notes were documented on the delivery of the interventions, competency of the peer mentors during training and during the group meetings, and feedback from the peer mentors during their debriefing sessions. On completion of the RCT, the participants in both intervention arms, and the peer mentors, were interviewed to obtain their opinions and reactions toward the delivery of the interventions.

Overall, the older Malays with T2DM in both the PF and PS groups and the peer mentors were supportive and valued the opportunity to be part of this study. They provided encouraging positive feedback about it. The feedback from the physical activity pattern chart did motivate the participants to increase their level of physical activity throughout the study period. Interestingly, charting the information about walking activities (pedometer step counts and duration spent on walking activity) also facilitated them in keeping track of their progress, which was later consolidated through the feedback from the chart. In the present RCT, observed changes in physical activity level could be due to the record keeping and the feedback. This was consistent with the findings of a quasi experimental study in the United States of America on weight loss maintenance among obese adults aged 25 years and more, who were provided group counselling on moderate calorie reduction and increased physical activity (227). They found that recording of daily food intake and physical activity were significant predictors of weight loss during their five-month intervention.

The participants receiving feedback and peer support valued the interactions and group activities with their peer mentors and with other participants in their groups. They expressed that peer mentors' experience and support in addressing the participants' barriers and problems were beneficial. The other participants in their group also provided support and motivation to improve their level of physical activity through sharing of experiences. Achievements of other group members were used as an additional motivation to improve their physical activity levels. The peer mentors were also encouraging and happy to participate in this study. They expressed hope for continuation of such a study. They found the experience self-fulfilling and rewarding. Their diabetes self-management knowledge, skills and confidence had improved through the training workshop, group sessions and peer mentors' debriefing sessions. They also shared a sense of satisfaction as their peers improved their physical activity levels. Consistent with the literature, in general, peer support interventions not only provided positive experiences for the participants but also for the peer mentors (75,80). This was achieved through training and mutual sharing of common experiences.

Some participants shared that their earlier motivation to improve their physical activity levels was initially to impress the researcher, as they did not want to be seen as a failure. But as they became more active and saw the improvements in their glycaemic and other CVD risk factor control, they realised the importance of regular physical activity. They expressed that walking activity provided pleasant outcomes such as feeling happier, less moody and more energetic. They expressed that they now cannot live without exercise. These experiences reflected the theoretical framework behind this RCT that incorporated self-efficacy as a strategy for behaviour change (98). Self-efficacy was influenced by personal mastery experiences when the participants accomplished behaviour change through perseverance based on their personal experiences. In addition, the pleasant physiological state experienced as a result further strengthened their resolve to continue with the walking activity. In addition, participants felt that they had learned the “how to do”, and not just the “what to do” to improve their physical activity levels from the exercise prescription, which improved their confidence. Some participants in the PS group also liked the idea of becoming peer mentors themselves, as they believed they could share with others their rewarding experiences from this study.

Family members were reported as an important source of support. Some participants commented that their family kept motivating them to get active now that they were involved in this study. Also, in some instances the spouse and/or grandchildren joined them in the walking activity. Studies have shown that greater family influence and support improved diabetes self-management behaviours (80) and participation in physical activity among older people (228). Further, family was not only a source of support but also as an important motivator to stay healthy in order to provide care for family members (70,228).

Support from friends was also perceived as an important motivator for behaviour change among the participants in the present RCT. The interaction with other peer mentors and participants has led to an expansion of their social network. This was achieved through the new friends made and meeting outside the scheduled sessions. They were able to share common issues with their peers. They valued the social and emotional support that facilitated the behaviour change. This is consistent with Ingram (80) who reported that people with T2DM were more comfortable talking with friends about the effects of diabetes on their emotions. In addition, their study found that both tangible and emotional supports were correlated with improved glycaemic control.

7.7 Strength and limitations of the randomised controlled trial

There are several strengths of this study. First, the RCT allows causal-effect relationship and effectiveness of an intervention to be determined (229). Such design also provides both external and internal validation of the study findings through the rigorous methods involved. In addition, the random allocation concealment ensures that no systematic bias occurred in this RCT (230). Second, the present study would be the first RCT to evaluate the effectiveness of simple visual feedback using a chart alone and in combination with peer support in the older people with T2DM. The use of a feedback elicits change in physical activity behaviour both in the short and long term. The combination of feedback and peer support not only changes physical activity behaviour but also improved cardiorespiratory fitness of older Malays with T2DM. There is no existing evidence on the effects of physical activity on the Malay community and among those with chronic non-communicable diseases such as diabetes. This is the first RCT that involves a sample of older Malays with the T2DM population.

An important strength of this study is its evaluation of the sustainability of the behaviour change that is walking activity as a result of the intervention. This study provided data on the adherence to walking activity six months after the intervention. The use of a pedometer allowed physical activity levels to be measured objectively. Previous studies have shown that motion-sensor devices such as a pedometer are more reliable and valid measure of physical activity level than self-reported instruments (119,120). Using the motion-sensor devices could address recall bias and allow physical activity levels to be classified more accurately.

There are several limitations in addressing the major findings of the RCT. First, the response rate to participate in this RCT was low. About half of those who were eligible to participate in this study declined participation and of those who agreed to participate almost half of them did not enrol. The process of recruitment involved several stages that require potential participants to undergo extensive screening process before randomisation. Further, the study required the potential participants to comply with the study protocol for duration of nine months. Perhaps, these factors could have discouraged some of the participants from participating because of the perceived long period of study. In addition, the participants who finally enrolled into this RCT would be those who were most likely to be highly motivated to change their behaviour (231). This may be a source of recruitment bias.

Second, significantly more men who completed the RCT. Further those who completed this RCT had lower weight and body mass index (BMI), and better cardiorespiratory fitness and balance compared with those who withdrew. Thus, the outcomes from this RCT may not necessarily apply to women, those with higher weight and BMI, and those with lower cardiorespiratory fitness and balance. Future studies on behaviour modification among older Malays or older people need to explore better strategies to encourage more women and those who are overweight to participate.

In this RCT, it should be emphasised that sedentary behaviour was assessed as a part of physical activity level. However the sedentary behaviour was assessed using activities while seated, whereas true sedentary behaviour should include activities while lying down. Ideally self-reported measures of sedentary behaviour should evaluate the time spent on each sedentary activity rather than the time spent on these activities in total (213). Future trials should include both self-reported and objective measures to permit researchers to validate and classify sedentary behaviour accurately.

The current RCT used a generic scale to evaluate the health related quality of life. The effectiveness of an intervention on the burden of diabetes from the perspective of health related quality of life might be evaluated more sensitively by using disease-specific health related quality of life measures. In future studies, use of both generic and disease specific measures would provide a more comprehensive assessment of the effects of an intervention on health related quality of life.

The sample size of this RCT was also relatively small that prevented quantitative evaluation of the effect of the interventions on the HbA1c and other cardiovascular diseases risk factors. A future trial with larger sample size may provide more definitive evidence of the interventions effectiveness on these outcomes. Besides, this RCT used physical activity levels rather than clinical indicators such as HbA1c levels as the motivating factor to promote physical activity. The use of a clinical indicator that closely reflects the participants' disease control could plausibly further enhance behaviour changes. Finally, this RCT's participants were recruited from a sample of older Malays with T2DM in the district of Shah Alam. The findings of the current RCT are only generalisable to older Malays, and could not be applied to the Chinese, Indian and other Bumiputera communities in Shah Alam or even the rest of Malaysia.

7.8 Conclusions

This RCT aimed to evaluate the effectiveness of personalised feedback about patterns of physical activity alone or combined with peer support in sedentary older Malays with type 2 diabetes mellitus (T2DM). With the reference to initial study hypotheses, the following conclusions can be made:

- Both personalised feedback about patterns of physical activity alone or combined with peer support interventions significantly improved the level of physical activity, cardiorespiratory fitness and body fat percentage of older Malays with T2DM compared with the usual diabetes care.

- The overall findings suggests that older Malays with T2DM can make significant improvements in the level of physical activity, body fat percentage and cardiorespiratory fitness when a socio-culturally appropriate peer support programme is implemented.

- However, no significant group differences in the glycaemic and other cardiovascular disease risk factor control and other functional status measures of the older Malays with T2DM were observed.

The RCT was implemented according to the initial study protocol and findings of this thesis have significant implications in improving the health of older Malays with T2DM. This will be discussed in Chapter 8.

CHAPTER 8 THESIS CONCLUSIONS

The study reported in this thesis was conducted in three phases, which comprised: Phase 1, a systematic review; Phase 2, a qualitative focus group study; and Phase 3, a randomised controlled trial. This chapter provides the thesis conclusion and includes an overview of the major findings from the three phases of the study, the strength and limitations of this thesis, implications for future practice and recommendations for future research.

8.1 Overview of key findings of this thesis

The objective of this thesis's Phase 1 was to systematically review the scientific evidence on interventions to promote physical activity in older people with T2DM. The systematic review found 21 studies (18 RCT and three quasi-experimental) that promoted physical activity in people with T2DM, from eight countries. Only one study focused specifically on people aged 65 years and above. Strategies that increased the level of physical activity in people with T2DM were evident but most studies focused on middle-aged rather than on older people and none were conducted in Asia, which was the focus of this thesis. Strategies to promote physical activity varied markedly between studies but most incorporated health behaviour theories and multiple approaches to facilitate and maintain behaviour change. There was a lack of well-designed trials, so more studies of satisfactory methodological quality with interventions promoting physical activity in older people are justified, which formed in part the rationale for Phases 2 and 3 of this thesis.

The purpose of the qualitative focus group study that formed Phase 2 of this thesis was to explore the socio-cultural perceptions of physical activity, and its motivators for and barriers to physical activity in the older Malay community with T2DM, as well as the sources of motivation and receptiveness towards diary keeping and the use of a pedometer. The focus group discussion (FGD) found that older Malays with T2DM viewed physical activity as an important aspect of the self-care management of diabetes. The conventional perceptions regarding the definition of physical activity, and the motivators for and barriers to physical activities, were intertwined with social rules, as well as the cultural and spiritual expectations of the Malay community. They defined recreational activities, household chores and body motions that included prayers as physical activities. Walking activity was perceived as the most suitable form of physical activity in older people.

Awareness about diabetes and the pleasant outcomes as the result of engagement in regular physical activity were perceived motivators for physical activity shared between the participants in the FGDs. Among the perceived barriers included the health problems related to diabetes, obligations to kin, and the priority of spiritual or religious activities. Health care professionals, family and peers were other sources of motivation for these older people. Spiritual-related activities emerged as a core theme in defining physical activity and its barriers. Therefore, in diabetes self-care management, emphasis on regular physical activity that not only improves glycaemic control but also allows continuation with religious obligations is important for older Malays with T2DM. The findings from the FGD have provided many relevant and salient suggestions in facilitating the design of the intervention to promote physical activity for older Malays with T2DM, and were incorporated in the design of the Phase 3 of this thesis.

The randomised controlled trial (RCT) that formed Phase 3 was aimed at determining the effectiveness of personalised feedback about physical activity patterns alone (PF) and in combination with peer support (PS), in addition to the usual diabetes care. The outcome measures for this RCT were the level of physical activity, cardiovascular disease risk factors, functional status, quality of life and psychosocial wellbeing. Both PF and PS groups had more pedometer steps a day, greater weekly duration and frequency of moderate intensity structured physical activity, and lower body fat percentage than the controls. Also, the PS group showed significantly greater PASE scores, distance walked in the six-minute walk test and MSPSS (friend) scores compared to PF group and the controls. Most of these changes had both short- and long-term effects. This information suggests that older Malays with T2DM could make significant improvements in the level of physical activity and functional status when a personalised feedback combined with peer support was implemented.

8.2 Strengths and limitations of the thesis

8.2.1 Phase 1 – Systematic review

A strength of the systematic review is that the search was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, which include a search through multiple major databases and assessments of methodological quality. A limitation of this review is the possibility of selection bias when retrieving the literatures for the systematic review despite conducting a thorough search through multiple major databases. In addition, a plausible risk of assessment bias is present as the researcher was the only reviewer involved in the assessment of studies' eligibility for the review.

8.2.2 Phase 2 – Qualitative focus group study

Because of the lack of literature on older Malays related to physical activity behaviour, a needs assessment by means of qualitative focus group methods was conducted before the RCT. The aim of the focus group discussion was to identify perceived barriers to and motivators for physical activity among older people with T2DM. The receptiveness towards the use of the pedometer and charting the physical activity diary, and the role of peer mentors as a source of motivation were explored. The qualitative focus group study has provided in-depth knowledge on the perceptions of physical activity and the motivators for and barriers to physical activity among older Malays with T2DM. This knowledge has facilitated the design of an intervention promoting physical activity that was appropriate for a targeted population. However, this study is not without limitation. The qualitative focus groups were unable to explore the influence of gender on the perceptions of physical activity on account of the low response rate from women.

8.2.3 Phase 3 – Randomised controlled trial

There are several strengths of this study. First, a randomised controlled trial (RCT) was conducted to promote physical activity allowing the causal-effect relationship and effectiveness of an intervention to be evaluated. Such a design also provides both external and internal validation of the study findings through the rigorous methods involved. Second, the random allocation concealment in this RCT ensures that no systematic bias occurred. In addition, to the best of the researcher's knowledge, this RCT would be the first that evaluated the effects of personalised feedback alone and in combination with peer support among older people with T2DM, as well as the first among the Malay community and in Asia. An important strength of the RCT is the evaluation of the sustainability of the behaviour change, walking activity, as a result of the intervention. Finally, the use of a pedometer has provided an objective measure for the physical activity levels for this study.

There are several limitations in addressing the major findings of the RCT. The response rate for the RCT was also low with a possibility of recruitment bias as the participants who enrolled were more likely to be highly motivated to change their behaviour. Further, the findings of this RCT may not apply to women as significantly more women withdrew from this study. Next, sedentary behaviour may have been underestimated as this study only assessed seating activities and did not include lying down activities in evaluating sedentary behaviour. Finally, the findings of this RCT were limited to a sample of older Malays with T2DM in Shah Alam, which could not be generalised to older Malays in rural areas, other ethnic groups in Shah Alam, or the general population.

8.3 Implications for practice

The findings of the qualitative focus group and the randomised controlled trial in this thesis have several implications for future practice. From the qualitative focus group, the opinions of older people with T2DM were an important basis for the development of a socio-culturally appropriate and feasible intervention to promote physical activity. Knowledge of the perceptions about motivations for and barriers to physical activity among older people with T2DM is an essential initial stage in developing a physical activity promotion educational programme tailored to the values of a cultural group. Health care providers should address cultural barriers to physical activity when providing counselling to older people to initiate physical activity.

One of the stereotypes of ageing is that older people are inflexible and resistant to change (232). Older people are usually considered a hard-to-change population. Such attitudes have created a prejudice based on age, known as ageism (233). Ageism refers to the negative beliefs about the older people and the process of ageing. This may lead to discrimination and social inequalities. Unfortunately, ageism is not only prevalent in society but also in medicine. Studies have shown that health inequalities exist and that age is often used as a criterion for the decision to offer health care (234–237). There is evidence that ageism exists among the health care providers (234,235), but the reasons for such attitudes are unclear. The findings of this current study showed older people with T2DM are able to make substantial changes from a sedentary lifestyle to adopting regular physical activity. This shows that people can be motivated to change their behaviour even at a later age. Health care providers dealing with older people with NCDs should therefore encourage their patients to engagement in regular physical activity. Also, adequate education and counselling should be provided to improve their physical activity levels, especially if they are sedentary. Older people with T2DM are at increased risk of CVDs and coronary events (43). A sedentary lifestyle has been shown to increase the risk of these events (146). Health care professionals therefore have a responsibility to address sedentary behaviour in older people with T2DM.

Clinically, participants in the intervention groups of the RCT showed improved body fat percentage and cardiorespiratory fitness. This further supports the effects of regular physical activity on the health of older people and of those with T2DM (111,112,118,221,238,239). Aerobic physical activity such as walking exercise has been shown to reduce older people's body fat (239) including those with T2DM (118), even without a decrease in body weight. Reduced body fat percentage in older people is associated with increased lung function (240). Also, regular physical activity improves adiposity that helps to restore a higher metabolic rate in older people (241). Further, adiposity has been shown to increase the risk of CVD and coronary heart disease in people with T2DM (242).

Similarly, aerobic physical activity improves cardiorespiratory fitness in both older people (238) and people with T2DM (111,112,221). The improved cardiorespiratory fitness reduces their mortality risk (243). Also, it significantly predicts all-cause mortality risk in older people independent of body mass index, waist circumference and body fat percentage (244). It is therefore important for health care providers to preserve the functional capacity of older people, especially in the presence of NCDs such as T2DM, by recommending regular physical activity such as the walking activity implemented in the current RCT. Regular physical activity positively influences a broad range of physiological systems among older people, which could be an indicator for successful ageing (13).

The findings of this RCT add to the growing evidence on peer support programmes in chronic disease management. The peer mentors provided on going support to improve physical activity behaviour. Peer support not only changed the physical activity behaviour but also improved the cardiovascular risk and functional capacity of older Malays with T2DM. This peer led programme could sustain the behavioural change even without formal contact with the research team or the peer mentors after the initial period of the intervention. Peer support led to more than 90% adherence to the exercise prescription during this RCT. A smaller number of the participants who received peer support had their medications modified compared to the other groups as described in Chapter 5 of this thesis. Such peer support programmes may be more appealing and acceptable to the targeted population since the peer mentors were similar to the participants, being themselves individuals with diabetes. Others may view the peer mentors as reliable role models since they live in the same community and may therefore have a stronger influence on their fellows. In addition, the peer mentors provided the context and supportive environment needed by these individuals with diabetes and acted as the link to clinical care. A peer support programme might be a cost-effective approach to change and maintain behaviour as well as to improve the health and functional status of older people with T2DM in primary care. This peer support programme can be translated on to larger scale in more diverse community health settings and other NCDs that require behaviour change in Malaysia.

Translation of research into clinical practice is defined as the uptake, implementation and sustainability of results from clinical studies into daily clinical practice and health care decision-making (245,246). Such translation aims to reduce the gaps between evidence-practice and policy so that patients would benefit from improvements in health care. Translating research into practice would assist in two ways: first, to accelerate the impact of health research on direct patient care; and second, to "improve the outcomes, quality, effectiveness, efficiency, and/or cost effectiveness of care through partnerships between health care organizations and researchers" (247). It would also ensure that stakeholders – policy makers, health care professionals, consumers (patients, family members, and informal carers), researchers, and industry – are aware of research evidence and use it to inform health and the health care decision-making (248). Clinical studies that assist patients to change behaviour in a real-world health care setting with theory-driven approaches are a part of translational research (249). The current RCT helped older patients with T2DM in a community primary health care clinic to change from being sedentary to becoming physically active. Further, the design of this RCT intervention was theory driven incorporating constructs of social cognitive theory to facilitate behaviour change. It was designed on the basis of evidence synthesis and qualitative methods to address the evidence practice gap as evaluated in this thesis's Phases 1 and 2.

Unfortunately, often implementing evidence and clinical guidelines into routine daily clinical primary care practices is a challenge. While billions of dollars are spent globally each year on health care research, it has been reported that it takes an average of 17 years to integrate 14% of original research findings into clinical care (250). Human behaviour, organisational inertia and infrastructure, and both human and financial constrains result in further delays in adopting evidence into clinical practice, especially in busy primary care clinics (249,250). Promoting physical activity can be initiated and/or supported effectively in the primary care settings. The primary care physicians could share the load of intervention with health educators, community personnel and other clinical staff, especially when they perceive time constraints as a major barrier to implementing such strategies (251–253). In the current RCT, peer support significantly improved the participants’ physical activity levels and health status through the peer mentors and support group. The peer mentors, who were volunteers and patients with T2DM, assisted the health care providers in delivering continuing support to improve the patients’ physical activity. The use of peer support could not only ease the burden of the clinical staff, but also may prove cost effective. This is consistent with recommendations that suggest that physical activity promotion delivered at the primary care settings should move beyond the exclusive domain of physician-patient interactions to include social support and community resources that support behavioural change (254,255).

Increasing evidence also suggests interventions that include social support and individually tailored health behaviour change programmes increased participation in physical activities (109,114,212,256). Interventions that are individually tailored and include input from patients on a plan of action through goal-setting, strategies to overcome barriers, and monitoring progress are more effective than generic prescription of physical activities (251,252). This study prescribed walking activity that incorporated a plan of action and goal setting with patients in the intervention groups. The potential barriers to participants to physical activity were identified and addressed. The progress of the participants on the physical activity levels were monitored and feedback given to them during the intervention. This resulted in significant improvements in the physical activity and health parameters seen in the participants in the intervention groups as compared with the controls. Further, peer mentors in this RCT were from the same community as the participants. This led to a social support network to be implemented outside this RCT. The social support network was shared as beneficial to both participants and peer mentors in providing them with physical and emotional support. Also, the peer mentors were supported with the initial training, regular peer mentors’ debriefing meetings, and nominal financial incentives.

Among older patients with T2DM in Malaysia, hypertension and dyslipidaemia are common co-morbid NCDs (36). As with T2DM, regular physical activity is a major part of management in hypertension (257–260) and dyslipidaemia (261–264). Secondary prevention recommendations for regular physical activity have also been disseminated broadly in order to prevent or delay complications related to chronic NCDs (9). Similar interventions as delivered in the current RCT using feedback and peer support with theory-driven approaches to promote physical activity could be implemented in the management of patients with hypertension and dyslipidaemia. Strategies used by the peer mentors to support behaviour change could be adapted to other components of self-management of T2DM such as diet and weight management in clinical practice, in addition to promoting physical activity. These would address most issues involved in self-management of chronic NCDs. However it has been argued that individual studies by themselves rarely provide adequate evidence to warrant practice or policy change as these studies may vary in their target population, clinical outcomes and target audience (248,265). Therefore, evidence synthesis such as an up-to-date systematic review is needed prior to translating the results of individual studies into practice.

8.4 Recommendations for future research

Based on the qualitative focus group, the response rate from women was too low to allow analysis of the influence of gender on the perceptions of barriers to and motivators for physical activity in the Malay community. Future studies could explore the extent of gender differences on the perceived barriers to and motivators for physical activity since the men and women play different societal and cultural roles in this community (159). Furthermore, Malaysia is a multi-ethnic society; exploration of the perceived motivators for and barriers to physical activity of the other ethnic groups is warranted as previous studies found that these do vary among those of different ethnicity and cultural background, even when they are living in the same environment (63,67,68).

Based on the encouraging findings of this RCT, a peer support programme is feasible among older people with T2DM, bridging primary health care and the community settings in Malaysia. It has positive effects on physical activity behaviour, and the health and functional status of older people with T2DM. This current RCT only evaluated the effectiveness of such a programme among older Malays with T2DM. Future trials should investigate the effects of this intervention among the other ethnic groups in Malaysia and should be conducted in other settings perhaps in collaboration with community organizations, which would allow better generalisability of such a programme. Since physical activity is a component of self-management in diabetes care, future trials on the role of peer support to improve the broader self-management of diabetes may be warranted.

Finally, with the Malaysian population ageing and the increasing proportion of older people with T2DM, a cost-effective approach to improve the health of older people in the face of significant resource constraints is imperative. A peer support programme does require resources but the investment may be relatively lower when older people can be empowered and become more self-reliant in self-managing their diabetes. While it is beyond the scope of the present thesis, an economic evaluation of the peer support approach needs to be included in future trials promoting physical activity in older people and in people with T2DM. Definite recommendations could not be made without a comprehensive cost analysis. Hence, a longer follow-up period of at least one year and rigorous cost analysis should be integrated into future trials.

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APPENDIX A: PUBLISHED ARTICLES FROM THIS STUDY

A.1. Systematic review article

frontiers in PUBLIC HEALTH

REVIEW ARTICLE
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Interventions to promote physical activity in older people with type 2 diabetes mellitus: a systematic review

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Introduction: Type 2 diabetes mellitus (T2DM) among people aged 60 years and above is a growing public health problem. Regular physical activity is one of the key elements in the management of T2DM. Recommendations suggest that older people with T2DM will benefit from regular physical activity for better disease control and delaying complications. Despite the known benefits, many remain sedentary. Hence, this review assessed interventions for promoting physical activity in persons aged 65 years and older with T2DM.

Methods: A literature search was conducted using Ovid MEDLINE, PubMed, EMBASE, SPORTDiscus, and CINAHL databases to retrieve articles published between January 2000 and December 2012. Randomized controlled trials and quasi-experimental designs comparing different strategies to increase physical activity level in persons aged 65 years and older with T2DM were included. The methodological quality of studies was assessed.

Results: Twenty-one eligible studies were reviewed, only six studies were rated as good quality and only one study specifically targeted persons aged 65 years and older. Personalized coaching, goal setting, peer support groups, use of technology, and physical activity monitors were proven to increase the level of physical activity. Incorporation of health behavior theories and follow-up supports also were successful strategies. However, the methodological quality and type of interventions promoting physical activity of the included studies in this review varied widely across the eligible studies.

Conclusion: Strategies that increased level of physical activity in persons with T2DM are evident but most studies focused on middle-aged persons and there was a lack of well-designed trials. Hence, more studies of satisfactory methodological quality with interventions promoting physical activity in older people are required.

Keywords: physical activity, older people, type 2 diabetes mellitus, geriatric medicine, health promotion

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most common chronic non-communicable diseases (NCDs) in many countries especially in the developing countries (1). The prevalence continues to increase with changing lifestyles and increasing obesity affecting all ages including older people. Current estimates indicate a growing burden of T2DM worldwide, which is greatest among persons aged 60 years and older (2, 3). Therefore, an emphasis on the lifestyle interventions such as regular physical activity to offset the trends of the increasing prevalence of T2DM is imperative. Regular physical activity is one of the key elements in the management of T2DM, and evidence has shown that engaging in regular physical activity leads to better control of T2DM and delayed complications (4, 5). Increasingly, recommendations suggest older people will benefit from regular physical activity especially in the presence of chronic NCDs such as T2DM (4, 6–8). Despite the evident health benefits, many people with T2DM, especially older people, remain sedentary or inactive (9–13).

Previous systematic reviews have been conducted to evaluate interventions promoting physical activity (14–18) but none have focused specifically on increasing levels of physical activity in people with T2DM. Only one review focused on T2DM but the review evaluated the effects of exercise on T2DM parameters and not on strategies to increase levels of physical activity (8). Only one review focused on persons aged 65 years and older, which compared the effects of home based with centre based physical activity programs on participants' health (15). This review, however, did not include persons with T2DM. Furthermore, these reviews found that most interventions promoting physical activity had short-term effectiveness with several methodological weaknesses. To the best of our knowledge, no systematic review has been conducted evaluating interventions promoting physical activity in older people with T2DM. This review provides a qualitative evaluation of interventions promoting physical activity in older people with T2DM.

METHODS

A systematic review using a qualitative synthesis method was conducted to retrieve and review the findings of previous literature on interventions promoting physical activity in older people (aged

65 years and over) with T2DM. In this review, changes in physical activity level was selected as the outcome variable instead of changes in exercise level, as exercise is a subset of physical activity. Physical activity is defined as "body movement that is produced by the contraction of skeletal muscles and that increases energy expenditure," while exercise is "a planned, structured, and repetitive movement to improve or maintain one or more components of physical activity" (p.1511) (6).

DATA SOURCES AND SEARCH STRATEGY

The search was conducted electronically according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (19) using the following databases: Ovid MEDLINE, PubMed, EMBASE, SPORTDiscus, and CINAHL. The Medical Subject Heading terms used in Ovid MEDLINE were adapted from Foster et al. (18) as presented in **Table 1**. Comparable searches were made for the other databases.

Only peer-reviewed published articles between years 2000 and end of December 2012 were used. No published reviews articles on physical activity were included but were used as a source of randomized controlled trials (RCTs). The reference lists of review articles and included studies were hand searched for other potentially eligible studies. Only articles published in English language were considered due to limited resources for translation. No attempts were made to contact authors for additional information, but cross-referencing on related previously published studies was performed to obtain additional information. All the titles, abstracts, and full-text of every study retrieved from the search were initially screened by one reviewer (Shariff-Ghazali Sazlina) using a standardized form with the eligibility criteria. A second reviewer (Shajahan Yasin) assessed the retrieved study if the first reviewer was in doubt on the paper's eligibility.

STUDY SELECTION

All RCTs and quasi-experimental designs comparing different strategies to increase physical activity level in older people with T2DM were considered in this review. Studies that included self-management of diabetes and combined lifestyle (diet and physical activity) were also included. Studies with those aged 65 years and older with T2DM and living in the community were considered for this review. Studies performed on people with type 1 diabetes mellitus and impaired glucose tolerance were excluded. However, studies reporting combined results for T2DM and impaired glucose tolerance were included if the analysis of these results are conducted separately. The interventions may include one or combination of: (1) one-to-one or group counseling or advice, (2) self-directed or prescribed physical activity, (3) supervised or unsupervised physical activity, (4) on-going face to face support, (5) telephone support, (6) written motivation support material, and (7) self-monitoring devices (pedometer/accelerometer).

Interventions conducted by one or combinations of providers (health care providers, exercise specialist, peer coaches/mentors, and/or community health worker) were considered. No restrictions were included on the type and contents of the control group. The interventions could be compared with no intervention control, attention control (receiving attention such as usual diabetes care matched to length of intervention) or minimal intervention control group. The primary outcome measures in the included studies were changes in physical activity level. Studies with changes in cardiovascular disease risk factors (blood pressure, anthropometric measurements) and biochemical markers (glycosylated hemoglobin, lipid profiles) related to T2DM also were included.

Table 1 | Search strategy used in Ovid MEDLINE.

Dates 2000–December 2012	
1	Physical activity.mp
2	Exp exercise/
3	Exp walking/
4	Exp physical exertion/
5	Exp sports/
6	Exp lifestyle/
7	Exp physical fitness/
8	Strength training.mp
9	Exp resistance training/
10	Aerobics.mp
11	Physical$.mp
12	Exercis$.mp
13	Sport$.mp
14	Aerobic$.mp
15	Walk$.mp
16	Lifestyle$.mp
17 (or/1–16)	
18	Exp diabetes mellitus, type 2/
19	Exp diabetes mellitus/
20 (or/18–19)	
21	Exp health education/
22	Exp patient education/
23	Exp health promotion/
24	Promot$.mp
25	Educat$.mp
26	Program$.mp
27 (or/21–26)	
28 (17 and 20 and 27)	
29 [limit 28 to (English language and all aged 65 and over and RCT or quasi-experimental)]	

DATA EXTRACTION

The data and outcomes extracted from the included studies were not combined and re-analyzed due to the qualitative nature of this systematic review and the variability in the interventions used. Each full-text article retrieved was evaluated systematically and summarized according to previously suggested method (20). These included the study's: (1) objective (on effectiveness of physical activity interventions), (2) targeted health behavior (physical activity, self-management, or combined physical activity and nutrition), (3) characteristics of the study (study design, participants' age, behavioral theoretical model, and sample size), (4) contents of the intervention (intervention strategies, intervention provider, length of intervention, and follow-up contacts), (5) targeted outcome(s), and (6) major results.

METHODOLOGICAL QUALITY ASSESSMENT

Each of the included studies was further evaluated for its methodological quality using a list of 13 criteria adopted from an internet-based physical activity interventions systematic review (16) (see **Table 2**), which was based on the Cochrane Collaboration Back Review Group guidelines (21). The score to indicate good methodological quality was adopted from van den Berg et al. as there is no existing guideline on the cut-offs to rate methodological quality (16). All criteria were scored as "yes," "no," or "unclear" and resulting in a summary score between 0 and 13. A good methodological quality of study is considered if two thirds or more of the criteria are fulfilled, which is a summary score of 9 or higher (16).

Table 2 | Criteria of methodological quality.

1	Were the eligibility criteria specified?
2	Was the method of randomization described?
3	Was the random allocation concealed? (i.e., Was the assignment generated by an independent person not responsible for determining the eligibility of the patients?)
4	Were the groups similar at baseline regarding important prognostic indicators?
5	Were both the index and the control interventions explicitly described?
6	Was the compliance or adherence with the interventions described?
7	Was the outcome assessor blinded to the interventions?
8	Was the dropout rate described and were the characteristics of the dropouts compared with the completers of the study?
9	Was a long-term follow-up measurement performed (outcomes measured $\geq$6 months after randomization)?
10	Was the timing of the outcome measurements in both groups comparable?
11	Was the sample size for each group described by means of a power calculation?
12	Did the analysis include an intention-to-treat analysis?
13	Were point estimates and measures of variability presented for the primary outcome measures?

Adapted from: van den Berg et al. (16).

RESULTS

The initial search identified 696 potential articles from the database searches and another 26 were found through cross-referencing. A total of 520 studies were excluded because they did not examine physical activity, did not employ an RCT or quasi-experimental design, or did not examine T2DM or measure outcomes related to level of physical activity. A total of 36 full-text articles were selected and 21 were included in the final qualitative synthesis. **Figure 1** describes the flow diagram for the study selection. We initially filtered for articles with persons aged 65 years and older, but the articles obtained from the database searches captured persons in younger age groups with some included persons aged 65 years and older. Hence, the selected studies in this review included studies that recruited both younger participants and participants aged 65 years and older.

Table 3 describes the characteristics of included studies. Eighteen studies were RCTs (22–39) and three were quasi-experimental designs (40–42). Ten studies were conducted in North America (23, 25, 27, 32, 33, 35, 37, 39–41), nine studies conducted in Europe (22, 24, 26, 28–31, 34, 38), and two studies in Australia (36, 42). About half of the included studies' interventions focused on physical activity (22, 24, 26, 28–34, 36, 38, 41) while others on self-management of T2DM. All studies included participants aged $\geq$65 years with T2DM and only one study specifically studied people aged 65–80 years (23).

The type of interventions used in each study varies markedly as shown in **Table 3**. Most interventions were delivered either as a group (22, 24, 25, 27, 28, 30, 35, 39, 41, 42) or using one-to-one counseling/advice (23, 24, 26, 29, 31–34, 36–38, 40). The majority of the studies' interventions were delivered by one or more health-care providers (22–30, 35, 37, 39–42) and some included peers as the interventionists (25, 35, 39, 41). In order to provide support and motivation, seven studies contacted the participants on $\geq$2 occasions in the first 4 weeks of the intervention (24–26, 29, 30, 35, 37).

Most studies incorporated one or a combination of health behavior theories in their interventions and social cognitive theory was the most commonly adopted theory (22, 24, 25, 32, 37, 40–42). Half of the included studies' interventions were compared with control groups receiving usual diabetes care alone (22–27, 35). The outcome measures and results of interventions promoting physical activity are presented in **Table 2**. In most studies the primary outcome was either level of physical activity alone, or physical activity level in combination with other health outcomes. The level of physical activity were measured objectively using pedometer and/or accelerometer (22, 24, 28, 31, 33, 38, 39, 41) in combination with a questionnaire (22, 24, 31, 38). Eleven studies assessed level of physical activity subjectively using only a questionnaire (23, 25–27, 29, 32, 35–37, 40, 42), the content of which varied widely. The unit of measurement to represent the level of physical activity also varied.

Ten of the 12 studies which compared the physical activity intervention to a control group reported a significant increase in the level of physical activity in the intervention group (22–25, 28–30, 35, 37, 39). Some studies also reported improvements in HbA1c level (22, 25, 29, 30), other CVD risk factors (blood pressure, waist circumference, and lipid profiles) (22, 29) and in cardiorespiratory fitness (30). Nine studies which did not differ in number of contacts, but only on treatment procedure between the intervention and comparison groups, showed no difference between groups on physical activity level and CVD risk factors (31, 32, 34, 36, 41). Six of the 21 studies fulfilled nine or more criteria of methodological quality implying good quality studies (see **Table 3**) (25, 28, 29, 31, 35, 39). Only three studies applied intention-to-treat analysis principles (25, 30, 31). Studies with lower scores demonstrated methodological weaknesses related to randomization processes, sample size estimation, and outcomes assessment processes.

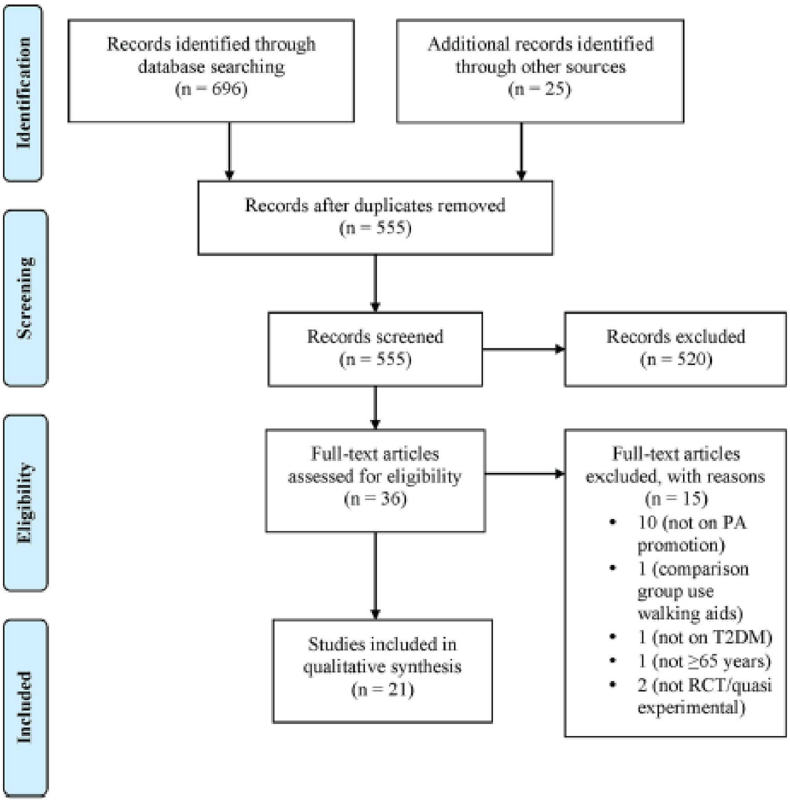

FIGURE 1 | Flow diagram for study selection according to PRISMA (19).

DISCUSSION

This review identified 21 studies (18 RCTs and 3 quasi-experimental designs) that promoted physical activity in persons with T2DM, which involved older people. These studies were conducted in eight countries with none from the Asian region. The majority of the studies had participants in the middle age groups and only one study specifically recruited participants aged ≥65 years. Half of the studies focused on physical activity, while others focused on the self-management of diabetes. From this review, it is evident that significant heterogeneity in the interventions existed making comparisons difficult and any general conclusions must be made with caution.

The levels of physical activity of the participants often differed at randomization; hence, it was difficult to make valid conclusions about the effectiveness of these interventions. From this review, only three studies controlled for baseline physical activity. Other studies either controlled for variables that differed at baseline or there was no difference between groups at baseline and therefore the authors did not report controlling for baseline physical activity (27, 29, 32). Only a third of the studies targeted sedentary or inactive participants at recruitment, but the definition of sedentary or inactivity varied greatly (26, 29–31, 33, 36, 41). In some studies, the participants were asked to build on their present physical activity; hence, these participants may be physically active at recruitment. Participants who are already physically active are more likely to comply with physical activity interventions and maintain a healthy lifestyle than those who are sedentary or inactive (43).

Both one-to-one and group sessions improved the level of physical activity. However, most of these studies incorporated multiple constructs from health behavior theories including strategies such as goal setting, problem solving, self-monitoring, and social support in their interventions. It is assumed that these approaches incorporate multiple constructs and strategies to facilitate behavior change and maintenance (44). The constructs of social cognitive theory such as self-efficacy and social support were the most frequently used, with positive results in changing physical activity level (22, 24, 25, 33, 35, 37, 42) and improving glycemic control (22, 25, 33). However, this review is not able to provide the evidence to recommend the most suitable health behavior theories for future interventions. Some studies incorporated more than one health behavior theory in their interventions making comparison between studies difficult.

Interventions promoting physical activity with follow-up contacts during the study period did increase the level of physical

Table 3 | Characteristics of selected studies.

Study	Methods	Quality of methods	Participants	Intervention/control or comparison group	Intervention/ follow-up period and intervention provider(s)	PA/other outcomes	Summary of key findings	Notes
De Greef et al. (22)	3 Arm RCT Focus on PA Social cognitive theory	6	Primary care clinic, Belgium $N = 67$ (IG1: 22, IG2: 21, CG: 24) Aged ≤80 years, overweight (25–35 kg/m^2) with T2DM, HbA1c ≤12%	IG1: 3 Individual counseling with goal setting by GP IG2: 3 cognitive behavioral group sessions with goal setting by psychologist CG: usual diabetes care	12 weeks/- and GP vs. psychologist	Pedometer (steps/day) IPAQ (min/day)/Weight, BMI, WC, cholesterol, FBG, HbA1c	Retention rate: 95.5% IG 2 increased steps/day (+837 ±688) than IG 1 and (+313 ±493) CG ($P < 0.05$) and total PA and MVPA min/day ($p < 0.05$) than IG1 and CG; IG1 improved WC (−1.4 cm), HbA1c (−0.32%) and total cholesterol (+7.2 mg/dl) than IG2 and CG ($p < 0.05$)	Significant findings for level of PA, HbA1c, WC, and total cholesterol
Weinstock et al. (23)	RCT Focus on self-management	8	Primary care clinic, USA $N = 1650$ (IG: 837, CG: 813) Aged 65–80 years with T2DM	IG: individual home video-conference every 4–6 weeks CG: usual diabetes care	5 years/- and diabetes educator, primary care providers	Diabetes Self-Care Activities for assessment of PA/BMI, BP, HbA1c, ADL, self-care activities, social support	Retention rate: IG had lower rate of decline in PA ($p = 0.013$) and higher self-care activity level ($p = 0.003$) than CG	Significant findings for level of PA but not for other outcomes
De Greef et al. (24)	RCT Focus on PA Social cognitive theory, motivational interviewing	8	Tertiary care clinic, Belgium $N = 92$ (IG: 60, CG: 32) Aged 35–75 years, overweight (25–35 kg/m^2), with T2DM ≥6 months, HbA1c ≤12%	IG: 7 individual cognitive behavioral sessions (goal setting, self-efficacy, social support) and telephone support CG: usual diabetes care	24 weeks/1 year and psychologist	Pedometer (steps/day), accelerometer (min/day), IPAQ (min/day)/-	Retention rate: 95.7% at week 24: IG improved (+2744 steps/day, $p < 0.001$), total PA (+23 min/day, $p < 0.001$) and sedentary behavior (−23 min/day, $p < 0.05$) at 1 year: (+1872 steps/day, $p < 0.001$), total PA (+11 min/day, $p < 0.001$) and sedentary behavior (−12 min/day, $p < 0.001$)	Significant group difference for level of PA post intervention and at 1 year
Toobert et al. (25)	RCT Focus on self-management Social cognitive theory, goal systems	10	Primary care clinic, USA $N = 280$ (IG: 142, CG: 138) Aged 30–75 years, Latina ethnicity, T2DM ≥6 months	IG: 6× group counseling, then every 2 weeks with lay group leaders CG: usual diabetes care	1 year/- and dietitian, exercise physiologist, stress management instructor and lay group leaders	IPAQ (days/week)/BMI, BP, HbA1c, lipids, stress management, self-care, nutrition	Retention rate: 78% at 6 months IG improved in days/week exercised ($p < 0.05$), calories from fat ($p < 0.01$), and HbA1c ($p < 0.01$) than CG	Significant group difference for level of PA, fat intake and HbA1c

(Continued)

Table 3 | Continued

Study	Methods	Quality of methods	Participants	Intervention/control or comparison group	Intervention/follow-up period and intervention provider(s)	PA /other outcomes	Summary of key findings	Notes
Wisse et al. (26)	RCT Focus on PA	7	Tertiary care clinic, Netherlands $N = 74$ (IG: 38, CG: 36) Adults (age not stated) with T2DM, on insulin and inactive (exercise ≤160 min/week)	IG: 2 personalized sessions and 2 telephone calls, and individual consultation alternate with telephone calls every 6 weeks CG: usual diabetes care	2 years/- and physio-therapist and physicians	Tecumseh/Minnesota scale: leisure time activities (MET/week)/Quality of life, BP, weight, HbA1c, FBG, lipids	Retention rate: 82.4% leisure time activities increased for IG (33 ± 4 MET/week from 15 ± 3 MET/week) and CG (39 ± 6 MET/week from 23 ± 5 MET/week) ($p = 0.171$)	No significant findings for level of PA or other outcomes
Osborn et al. (27)	RCT Focus on self-management Information-motivation-behavioral skills model	6	Primary care clinic, USA $N = 118$ (IG: 59, CG: 59) Aged ≥18 years, Puerto Ricans, with T2DM >1 year	IG: group diabetes self-care counseling CG: usual diabetes care	12 weeks/- and medical assistants, dietitian, diabetes educator, psychologist	PA subscale of summary of diabetes self-care activities (SDSCA) (frequency of PA/7 days)/diet subscale of SDSCA, HbA1c, BMI	Retention rate: 77.1%. No group difference on PA scores ($p = 0.230$) and HbA1c ($p = 0.760$)? BMI results	No significant findings for level of PA or other outcomes
De Greef et al. (28)	RCT Focus on PA Motivational interviewing, cognitive behavioral	11	Tertiary care clinic, Belgium $N = 41$ (IG: 20, CG: 21) Aged 35–75 years, with T2DM ≥6 months	IG: 5 cognitive behavioral group sessions (social support, self-monitoring) and a booster session CG: usual diabetes care and one single group PA education	12 weeks/1 year and exercise coaches, clinical psychologist	Pedometer (steps/day), accelerometer (min/day)/weight, BMI, HbA1c, BP	Retention rate: 90.3% at 12 weeks, 87.8% at 1 year IG improved steps/day ($p < 0.05$) and sedentary behavior ($p < 0.05$) post intervention than CG, not at 1 year	Significant group difference on PA level only at post intervention
Balducci et al. (29)	RCT Focus on PA	10	Tertiary care clinic, Italy $N = 606$ (IG: 303, CG: 303) Aged 40–75 years, with T2DM and sedentary (? definition)	IG: 2 supervised exercise sessions/week, 4 individual exercise counseling CG: usual diabetes care and exercise counseling	1 year/- and exercise specialist and diabetologist	Minnesota Leisure time PA questionnaire (MET h/week)/HbA1c, lipids, BP, indirect VO_{2max}, flexibility	Retention rate: 92.9% IG improved in MET h/week (mean diff. +10.00, $p < 0.001$), VO_{2max} (2.8, $p < 0.001$), HbA1c (−0.30%, $p < 0.001$), systolic BP (−4.2 mmHg, $p = 0.002$), diastolic BP (−1.7 mmHg, $p = 0.030$) HDL-C (+3.7 mg/dl, $p < 0.001$), and LDL-C (−9.6 mg/dl, $p = 0.003$); WC (−3.6 cm, $p < 0.001$) than CG	Significant group difference on PA level, VO_{2max}, HbA1c, BP, HDL-C, LDL-C, and WC

(Continued)

Table 3 | Continued

Study	Methods	Quality of methods	Participants	Intervention/control or comparison group	Intervention/follow-up period and intervention provider(s)	PA /other outcomes	Summary of key findings	Notes
Negri et al. (30)	RCT Focus on PA	7	Tertiary care clinic, Italy $N = 59$ (IG: 39, CG: 21) Aged 50–75 years, inactive (? definition), T2DM ≥2 years, HbA1c 6.5–9.9%	IG: 3 supervised walking group/week, one individual and one group counseling CG: standard lifestyle advice	16 weeks/- and personal exercise trainer	Activity log (MET h/week)/HbA1c, FBG, lipids, 6 min walk test	Retention rate: 86.4% IG improved MET h/week ($p = 0.008$), HbA1c ($p = 0.01$), and distance walked in 6 min ($p = 0.001$) than CG	Significant group difference on PA level, HbA1c and 6 min walk test
Kirk et al. (31)	3 arm RCT Focus on PA Trans theoretical model	11	Multifaceted care, UK $N = 134$ (IG1: 47, IG2: 52, CG: 35) Inactive (? definition) adults (age not stated) with T2DM	IG1: written self instructional walking plan (with goal setting) IG2: written self instructional walking plan (with goal setting) with 2 individual consultation CG: usual diabetes care and a leaflet on PA	1 year/- and research team	Accelerometer (h/day), 7-day recall questionnaire/HbA1c, BMI, WC, BP, lipids	Retention rate: 86.6% No group difference on accelerometer ($p = 0.863$), step counts ($p = 0.739$), minutes of moderate PA/week ($p = 0.212$). Time effects on HbA1c ($p = 0.026$), total cholesterol ($p = 0.001$), HDL-C ($p = 0.029$), WC ($p = 0.020$), systolic BP ($p = 0.037$), and diastolic BP ($p = 0.001$)	No group difference PA level or other outcomes, significant time effects on HbA1c, lipid profiles, BP, and WC
Dutton et al. (32)	RCT Focus on PA Trans theoretical model, social cognitive theory	7	Primary care clinic, USA $N = 85$ (CG: 39; IG: 46) Aged ≥18 years with T2DM	IG: one-to-one tailored print-based PA counseling motivation (included self-efficacy, goal setting, social support) CG: diabetes specific dietary tip sheet advice, no advice on PA	4 weeks/- and research team	7-day PA recall for MVPA (min/week)/-	Retention rate: 94.0%. No group difference on min/week of PA ($p = 0.220$)	No group difference on level of PA

(Continued)

Table 3 | Continued

Study	Methods	Quality of methods	Participants	Intervention/control or comparison group	Intervention/follow-up period and intervention provider(s)	PA /other outcomes	Summary of key findings	Notes
Allen et al. (33)	Pilot RCT Focus on PA Self-efficacy theory	7	Primary care clinic, USA $N = 52$ (CG: 25; IG: 27) Aged >18 years with T2DM, not on insulin, inactive (<3 days/week of physical activity), HbA1c >7.5%	IG: individual glucose monitoring counseling, feedback from glucose chart and one telephone call (goal setting, problem solving) CG: individual diabetes education and one telephone call	8 weeks/- and research team	Accelerometer (min/day)/BP, BMI HbA1c, Self-efficacy for exercise behavior	Retention rate: 88.5% IG improved light/sedentary activity (-2.7 ± 4.8 min/day, $p < 0.05$), moderate activity (5.5 ± 2.9 min/day, $p < 0.05$), HbA1c ($-1.2 \pm 1.0\%$, $p < 0.05$), and BMI (0.5 ± 0.7 kg/m^2, $p < 0.05$) than CG	Significant group difference on PA level, HbA1c, and BMI
Bjørgaas et al. (34)	RCT Focus on PA	7	Tertiary care clinic, Norway $N = 69$ (IG: 31, CG: 37) Aged <80 years with T2DM	IG: 2 individual PA sessions + pedometer use (self-monitoring) CG: 2 individual PA sessions	24 weeks/- and Research team	Questionnaire on physical fitness and activity, exercise testing using VO_{2peak} (l/min)/HbA1c, FBG, lipids	No group difference on the physical fitness and activity scores ($p > 0.800$), health outcomes ($p > 0.640$), VO_{2peak} ($p > 0.170$). CG increased VO_{2peak} over time ($p = 0.036$)	No group difference on PA levelor other outcomes; CG had increased VO_{2peak} over time
Toobert et al. (35)	RCT Focus on self-management Social cognitive theory, goal systems, social ecological theory	11	Primary care clinic, USA $N = 279$ (IG: 163, CG: 116) Aged <75 years, post menopausal women, T2DM ≥6 months	IG: 6× group counseling and support CG: usual diabetes care	1 year/1 year and dietitian, exercise physiologist, stress management instructor, lay group leaders	CHAMPS (kcal/kg/h of moderate intensity PA)/diet, flexibility, stress management, social support, problem solving, self-efficacy, depression, quality of life	Retention rate: 85.0% IG improved kcal/kg/h of moderate intensity PA ($p < 0.01$), min/day of stress management practice ($p < 0.001$), calories of saturated fat ($p < 0.001$) and sit-reach % score ($p < 0.05$) than CG	Significant group difference on PA level, saturated fat intake, stress management and flexibility

(Continued)

Table 3 | Continued

Study	Methods	Quality of methods	Participants	Intervention/control or comparison group	Intervention/ follow-up period and intervention provider(s)	PA/other outcomes	Summary of key findings	Notes
Engel and Lindner (36)	RCT Focus on PA	6	Community, Australia $N=57$ (CG: 30; IG: 24) Aged 50–70 years with T2DM, sedentary ($\leq$30 min/week of physical activity)	IG: 6 individual health related coaching + pedometer use (feedback, self-efficacy, goal setting) CG: 6 individual health related coaching	24 weeks/- and research team	Activity log (min/day of walking activity)/HbA1c, weight, BMI, BP, shuttle test (cardio respiratory fitness)	Retention rate: 88.0% no group difference on time spent walking ($p=0.207$) and other outcomes. Significant time effects on PA ($p<0.001$), weight ($p<0.05$), WC ($p<0.001$), and shuttle test ($p<0.001$)	No group difference on PA level or other outcomes; Significant time effects over time for PA, weight, WC, and cardio respiratory fitness
King et al. (37)	RCT Focus on self-management Goal system theory, social cognitive theory, social ecological theories	6	Primary care clinic, USA $N=335$ (IG: 174, CG: 161) Aged $\geq$25 years, T2DM $\geq$6 months	IG: individual self-management counseling (interactive CD-ROM) with goal setting, 2 follow-up telephone calls and a tailored health newsletter CG: one visit at enrolment for an interactive computerized health risk appraisal and brief health counseling	8 weeks/- and Health coaches	CHAMPS questionnaire (kcal/kg/h and total caloric expenditure/week)/dietary pattern	Retention rate: 92.2% IG improved all PA ($p<0.01$), moderate PA (=0.001), and strength training ($p<0.001$) than CG	Significant group difference on level of PA
Kirk et al. (38)	RCT Focus on PA Trans theoretical model, motivational theory, cognitive behavioral strategies	8	? Setting, UK $N=70$ (IG: 35, CG: 35) Adults (age not stated) with T2DM	IG: one individual exercise consultation with exercise leaflet and 2 follow-up telephone calls (goal setting, social support) CG: exercise leaflet (part of usual diabetes care) and 2 follow-up telephone calls	24 weeks/- and research team	7-day PA recall (min/week), accelerometer (activity counts/week)/indirect VO_{2max}, stage, and processes of change, BP, BMI, HbA1c, lipids, fibrinogen	Retention rate: 90.0% IG improved moderate activity PA ($p<0.001$), activity count/week ($p<0.001$), total exercise duration, and peak gradient ($p<0.005$), HbA1c ($p=0.02$) and systolic BP ($p=0.02$) compared with CG	Significant group difference on PA level, HbA1c, and systolic BP

(Continued)

Table 3 | Continued

Study	Methods	Quality of methods	Participants	Intervention/control or comparison group	Intervention/ follow-up period and intervention provider(s)	PA/other outcomes	Summary of key findings	Notes
Keyserling et al. (39)	3 arm RCT Focus on self-management Behavior change theory	10	Primary care clinic, USA $N = 200$ (IG1: 67, IG2: 66, CG: 67) Aged ≥40 years African American women with T2DM	4 Individual clinic based counseling alone (IG1) or combined with 3 group sessions and 12 telephone calls (IG2) CG: received mailed pamphlet on PA, nutrition, and diabetes	1 year/- and primary care physicians, community diabetes advisor, peer counselors	Accelerometer (kcal/day)/dietary intake, HbA1c, lipids	Retention rate: 85.5% IG2 (44.1 kcal/day, $p = 0.006$) and IG1 (33.1 kcal/day, $p = 0.029$) had higher mean kcal/day than CG. No group difference on the other outcomes	Significant group difference on PA level, not for other outcomes and dietary intake
Diedrich et al. (40)	Quasi-experimental Focus on self-management Social cognitive theory	6	Tertiary care clinic, USA $N = 53$ (IG: 27, CG: 26) Aged 23–89 years with T2DM	IG: diabetes self-management education (DSME) programs + pedometer use (goal setting, self-monitoring) CG: DSME	12 weeks/- and diabetes nurse and dietitian	Paffenbarger PA questionnaire (total scores)/HbA1c, BP, BMI, body fat	Retention rate: 62.0% IG improved diastolic BP ($p = 0.024$) than CG; Effect of time: IG improved in HbA1c ($p = 0.020$) and body fat ($p = 0.037$); CG improved in HbA1c ($p = 0.005$) and weight ($p < 0.001$)	Significant group difference on diastolic BP but not for PA. Significant time effect on HbA1c, body fat, and weight
Tudor-Locke et al. (41)	Quasi-experimental Focus on PA Social cognitive theory	7	Tertiary care clinic, Canada $N = 220$ (CG: 157; IG: 63) Aged 40–70 years with T2DM, inactive (walks <8800 steps/day)	4 Group sessions followed and 12 self-directed behavior change (goal setting, self-monitoring and feedback) by healthcare professionals (IG) or by peers (CG)	16 weeks/- and Health care professionals vs. peers	Pedometer (steps/day)/Weight, WC, resting HR, BP	Retention rate: 75.0%. No group difference on all outcomes; Effect of time: both IG and CG improved steps/day ($p < 0.001$), weight ($p < 0.001$), WC ($p < 0.001$), and BP ($p < 0.001$)	No group difference on PA level or other outcomes; Significant time effects on PA, weight, WC, and BP
Furber et al. (42)	Quasi-experimental Focus on self-management Social cognitive theory	6	Community, Australia $N = 226$ (IG: 121, CG: 105) Adults (age not stated) with T2DM or impaired glucose tolerance	IG: one group education session + pedometer use (goal setting, self-monitoring) Length: 2 weeks, follow-up at 20 weeks	2 weeks/20 weeks and diabetes nurse educator, dietitian CG: one group education session	Active Australia survey on PA (min/week)/-	Retention rate: 92.9% at week 2; 81.4% at week 20 IG improved time spent walking (mean diff. 59.4 min/week, $p < 0.05$) and moderate intensity PA ($p < 0.05$) post intervention than CG; No group difference at week 20	Significant group difference on PA level

PA, physical activity; IG, intervention group; CG, control or comparison group; GP, general practitioner; IPAQ, international physical activity questionnaire; MET, metabolic equivalent time; CHAMPS, community healthy activities program for seniors; BMI, body mass index; WC, waist circumference; FBG, fasting blood glucose; HbA1c, glycosylated hemoglobin; BP, blood pressure; LDL-C, low density lipoprotein cholesterol; HDL-C, high density lipoprotein cholesterol; ADL, activities of daily livings; MVPA, moderate-to-vigorous physical activity.
A summary score of 9 or higher indicate good methodological quality.

activity and improved control of glycemia and other CVD risk factors. Five studies had a long period of intervention of at least 1-year duration (23, 25, 29, 35, 39) with reported long-term effects of the interventions for the level of physical activity. The effects of follow-up contacts with the intervention provider and long intervention duration could influence the observed positive outcomes in these studies.

The majority of the studies measured the level of physical activity as the primary outcome and most studies used a single physical activity outcome measure, predominantly validated self-reported scales or an activity log (23, 25–27, 29, 30, 32, 35, 36, 40, 42). Most of these studies did *not use objective measures to assess* the change in the level of physical activity but use self-report measures to obtain energy expenditure, total scale scores, oxygen uptake or the relative change in duration, frequency, and/or intensity of physical activity. Some studies did use objective measures such as motion sensor devices (accelerometer and/or pedometer) (22, 24, 28, 31, 33, 38, 41). However, self-reported physical activity scales do lack validity in measuring physical activity and were found to be inferior to the motion sensor devices (45, 46). This would lead to less precise measurement and misclassification of the level of physical activity. Hence, an objective measure of physical activity is necessary to establish the effect of intervention in a trial, as it allows a uniform measurement of the physical activity level.

In this current review, healthcare providers delivered the majority of the studies' interventions and they may be more motivated to deliver the interventions than they might in a non-trial setting. In addition, the participants in most of these studies had to undergo extensive screening prior to randomization, and hence, participants who finally participated in these studies were more likely to be highly motivated (16). The evidence of effectiveness is also limited by the control or comparison groups, which varied widely. In some studies participants in the control group received only usual diabetes care or more general information about lifestyle changes while others received additional counseling about physical activity and some had multiple counseling sessions on diabetes self-care management. A number of studies included feedback from pedometer use, goal setting, and social support in the control/comparison groups as received by the intervention group as these studies were assessing a specific component of their intervention such as who delivers the interventions.

The methodological quality of the included studies in this review varies. Only six studies (all RCTs) were rated as good quality. The quality of the included studies in this review was limited by a lack of intention-to-treat analysis as only three studies perform such analysis. The studies with low scores have weaknesses in terms of inadequate description of the randomization methods; no information on random assignment performed by an independent person, insufficient description of sample size estimation and lack of information on whether an independent assessor assesses the main outcome measures. Inadequate methodological approaches in trials are associated with bias (47).

This review included multiple major databases with vigorous and systematic search strategy. However, there are limitations from this review. Only peer-reviewed papers published in recent years (i.e., from year 2000) and published in English are included in the data extraction, hence a possibility of selection bias exists. In addition, even though the searches are done thoroughly through multiple major databases with cross-referencing; there is a possibility that some papers are not included due to the inclusion criteria used for this current review. In this review, only one reviewer assessed the studies for eligibility, which could contribute to an increased risk of evaluation bias.

CONCLUSION

The number of well-designed trials on interventions promoting physical activity in older people with T2DM is limited as evident in this present review. The methodological quality, type of interventions promoting physical activity and outcome measure for level of physical activity in the included studies included in this review differed widely. Studies with interventions promoting physical activity that compared with usual diabetes care do have significant findings in changing the level of physical activity in persons with T2DM. Moreover, on-going follow-up support seems to contribute in increasing level of physical activity. However, these studies are restricted to middle-aged persons with T2DM in western countries. In addition, very few studies had follow-up assessment post intervention to allow evaluation on sustainability of interventions promoting physical activity. Peer support for adults with T2DM may have potential in promoting physical activity but the evidence is scarce. Furthermore, standardization on the measure for physical activity with the use of objective tool such as the pedometer or the accelerometer is needed to allow a uniform classification of level of physical activity. Therefore, further exploration in these areas is warranted when developing interventions to promote physical activity in older people with T2DM.

AUTHORS CONTRIBUTION

Colette Browning conceived the primary research question for the study. Shariff-Ghazali Sazlina, Colette Browning, and Shajahan Yasin were involved in the study conception and design. Shariff-Ghazali Sazlina was responsible for data extraction and Shajahan Yasin assessed any doubtful papers. Shariff-Ghazali Sazlina interpreted the results and drafted the initial manuscript. Colette Browning and Shajahan Yasin provided input on interpretation of results and provided critical revision to the manuscript for important intellectual content. All authors read and approved the final manuscript.

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A.2. Randomised controlled trial protocol article

Open Access Protocol

BMJ open accessible medical research

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

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ABSTRACT

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

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

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

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

ARTICLE SUMMARY

Article focus

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

Key messages

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

Strength and limitations of this study

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

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most prevalent non-communicable diseases (NCDs) in developed as well as developing countries.[1] It is associated with significant morbidity, mortality and increased healthcare cost.[2 3] In 2010, about one-third of people with diabetes were over 60 years of age.[4] The greatest increase in the prevalence is expected to occur in Asia and Africa due to the joint trends of urbanisation and lifestyle changes.[1]

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

Feedback to promote behavioural change is one of the frequently used interventions. Motion sensor devices (accelerometer or pedometer) and exercise log were used as feedbacks to increase physical activity.[17–22] They served as motivational tools and allow self-monitoring of the intended behaviour change, hence empowering patients to self-care. These studies reported improvements in daily step counts, metabolic controls,[19] cardiorespiratory 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 term.[23 24] The lack of ongoing educational support and attention to behaviour change principles are often contributing factors to the short-term positive changes in health status. The increasing number of attendees to primary care clinics and shortage of healthcare professionals trained in self-management approaches also contribute to these suboptimal approaches to T2DM management.

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

In 2010, Malaysia was ranked among the top 10 countries in the world for diabetes prevalence, with 11.6% of the 17 million people aged 20–79 years with diabetes.[1] The prevalence of diabetes in Malaysia increased from 8.2% in 1996 to 14.9% in 2006.[29] The highest prevalence is among people aged 60–64 years at 26.1%. Furthermore, elderly with T2DM have low levels of physical activity than younger patients (41.5% vs 25.3%).[30] Those who are less active have poorer glycaemic control.

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

The rapid increased in the incidence of T2DM and a shift towards an ageing population over the last decade[33] warrants the need for an intervention program to promote physical activity and improve the health status of elderly with T2DM in Malaysia. With the limited healthcare resources, peer support and feedback about physical activity behaviour in the management of T2DM may prove to be a cost-effective approach. Furthermore, targeting elderly Malays is appropriate in view of the low prevalence of adequate exercise and poorer glycaemic control in this group in Malaysia. Hence, the objective of this trial is to evaluate the relative effectiveness of personalised feedback about physical activity patterns alone and in combination with peer support to promote and maintain physical activity compared to usual care.

METHODS AND ANALYSIS

Study design

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

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

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

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

Study setting and participants

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

Determination of sample size

A sample size was estimated for this study taking into account the desired statistical significance level set at

5%, and the power of the study set at 80%, which allows an overall type I error rate of less than 0.05 and a 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 4099±2152 (preintervention) to 7976±4118 (postintervention). The sample size was calculated using the G*Power V.3.1.3 software.[36] Hence, to detect a difference in the step counts a day, a minimum of 17 participants in each group is required to detect 80% power and maintaining a two-sided significance level at 5%.

Recruitment and randomisation process

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

Box 1 List of participant's selection criteria

Inclusion criteria

1. Aged 60 years and above
2. Diagnosed with T2DM at least for 1 year
3. Participating in regular follow-up; at least 2 visits in the last 12 months
4. Sedentary lifestyle
5. No acute medical illness in the last 6 months

Exclusion criteria

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

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

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

The intervention

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

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

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

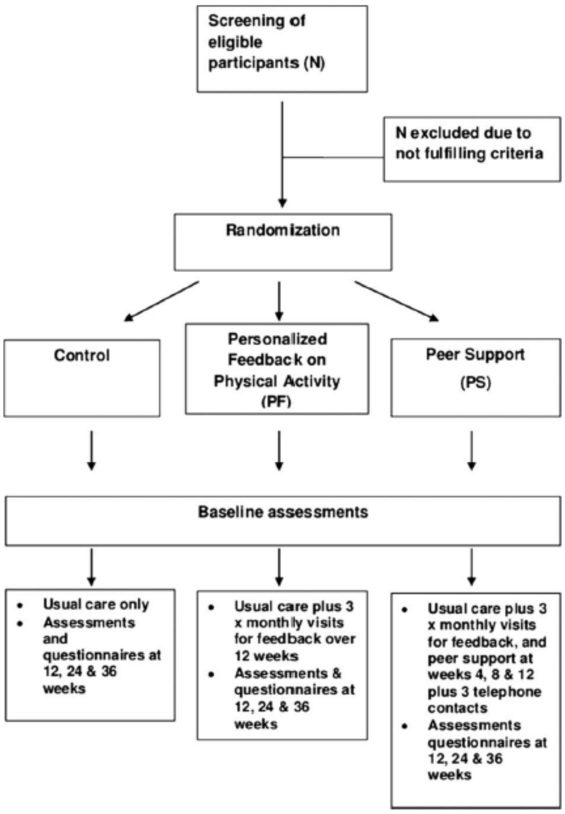

Figure 1 Flow of participants during this study.

PF on physical activity

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

Peer support

Participants in this group also will receive a structured written feedback on their physical activity patterns from the research team and support from their peer mentors. A peer mentor will be involved with a group of 3–5 participants from the point of enrolment in the trial. The aim of the peer mentors is to motivate the participants to participate in physical activity and adhere to the activity. The peer mentors will motivate their peers based on the structured written feedback on the physical activity patterns through three face-to-face contacts over the 12 weeks. In addition, peer mentors will provide support on physical activity through three telephone contacts during the intervention period. During these sessions, the peer mentors will discuss the participant's identified perceived barriers and motivations to physical activity and encourage participants to be empowered to 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 potential peer mentors. A peer mentor is a volunteer with ≥5 years of T2DM, engaged in regular physical activity, has glycosylated haemoglobin level (HbA1c) <8% and living in the community of the study location. Other criteria for a peer mentor include owning a mobile telephone, being willing to attend a 2-day training and complying with the study protocol. The peer mentors agree to a 9-month commitment to the study project, adhere to the scheduled meeting and provide support on physical activity and *undergo outcome assessments as their peers.*

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

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

Study outcome measures

The primary outcome of this study is level of physical activity. The physical activity will be measured objectively using a pedometer and subjectively using the Physical Activity Scale for the Elderly (PASE) and an activity diary.[42 43] A validated Yamax Digi-Walker CW 700/701 pedometer that measures step count will be used during their waking hours over 7 days measured at four intervals: at baseline, at 12 weeks and a follow-up at 24 and 36 weeks for all the three groups.[44 45] The participants are instructed to record the total daily step counts in an activity diary. The pedometer also has a memory recall for 2 weeks to allow the researchers to recover the step counts in cases where the participants do not record their step counts in the activity diary.

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

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

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

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

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

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

A 12-item General Health Questionnaire (GHQ-12), a validated tool to screen psychological disorders in a non-psychiatric clinical setting, will be used.[55] It has 12 questions about general level of happiness, depression, anxiety and sleep disturbances over the past 4 weeks. Each item is scored by four responses using the binary scoring method (0 to 1). The two least symptomatic answers score 0 and the two most symptomatic answers score 1. Scores of four or more indicate a high level of psychological distress.

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

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

Data analysis

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

ETHICS AND DISSEMINATION

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

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

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

DISCUSSION

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

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

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

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

Competing interests None.

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

Provenance and peer review Not commissioned; internally peer reviewed

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APPENDIX B: COMPARABLE SYSTEMATIC REVIEW SEARCHES FOR OTHER DATABASES

B.1. PubMed search

Dates 2000 – Dec 2012	
1	("Exercise"[Mesh] OR "Resistance Training"[Mesh] OR "Walking"[Mesh] OR "Sports"[Mesh] OR "Life Style"[Mesh] OR "Physical Activity"[tiab] OR "Exertion"[tiab] OR "Strength Training"[tiab] OR "Aerobics"[tiab] OR "physical*"[tiab] OR "Exercis*"[tiab] OR "Sport*"[tiab] OR "Aerobic*"[tiab] OR "Walk*"[tiab] OR "lifestyle*"[tiab])
2	("DiabetesMellitus, type 2"[MeSH] or "Diabetes Mellitus"[tiab])
3	("Health Education"[Mesh] OR "Patient Education as Topic"[Mesh] OR "Health Promotion"[Mesh] OR "promot*"[tiab] OR "educat*"[tiab])
4	1 AND 2 AND 3
5	Filter RCT/Quasi experimental
6	Limit to ‘English, human, Aged: 65+ years

Note: RCT=Randomised controlled trial

B.2. EMBASE search

Dates 2000 – Dec 2012	
1	Physical activity
2	Exercise
3	Walking
4	Physical Exertion
5	Sports
6	Lifestyle
7	Physical fitness
8	Strength training
9	Resistance training
10	Aerobics
11	Physical$
12	Exercis$
13	Sport$
14	Aerobic$
15	Walk$
16	Lifestyle$
17 (or/1-16)	
18	Diabetes mellitus, type 2
19	Diabetes mellitus
20 (or/18-19)	
21	Health Education
22	Patient Education
23	Health Promotion
24	Promot$
25	Educat$
26	Program$
27 (or/21-26)	
28 (17 and 20 and 27)	
29 (limit 28 to (English language and All aged 65 and over and RCT or quasi-experimental)	

Note: RCT=Randomised controlled trial

B.3. SPORTDiscus search

Dates 2000 – Dec 2012	
1	Physical activity
2	Exercise
3	Walking
4	Physical Exertion
5	Sports
6	Lifestyle
7	Physical fitness
8	Strength training
9	Resistance training
10	Aerobics
11	Physical*
12	Exercis*
13	Sport*
14	Aerobic*
15	Walk*
16	Lifestyle*
17 (or/1-16)	
18	Diabetes mellitus, type 2
19	Diabetes mellitus
20 (or/18-19)	
21	Health Education
22	Patient Education
23	Health Promotion
24	Promot*
25	Educat*
26	Program*
27 (or/21-26)	
28	Elderly
29	Older people
30	Older Adults
31	Older People
32	Elder*
33	Older*
34 (or/28-33)	
35	Randomised controlled trial
36	Randomized controlled trial

37	Quasi experimental
38 (or/35-37)	
39 (17 and 20 and 27 and 34 and 37)	
40 (limit 39 to English language)	

Note: RCT=Randomised controlled trial

B.4. CINAHL search

Dates 2000 – Dec 2012	
1	Physical activity
2	Exercise
3	Walking
4	Physical Exertion
5	Sports
6	Lifestyle
7	Physical fitness
8	Strength training
9	Resistance training
10	Aerobics
11	Physical*
12	Exercis*
13	Sport*
14	Aerobic*
15	Walk*
16	Lifestyle*
17 (or/1-16)	
18	Diabetes mellitus, type 2
19	Diabetes mellitus
20 (or/18-19)	
21	Health Education
22	Patient Education
23	Health Promotion
24	Promot*
25	Educat*
26	Program*
27 (or/21-26)	
28 (17 and 20 and 27)	
29 (limit 28 to (English language and All aged 65 and over and RCT or quasi-experimental))	

Note: RCT=Randomised controlled trial

APPENDIX C: ETHICS COMMITTEE APPROVAL LETTERS

C.1. Medical Research Ethics Committee, Ministry of Health Malaysia approval letter

PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
(PENYELIDIKAN & SOKONGAN TEKNIKAL)
(RESEARCH & TECHNICAL SUPPORT)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Aras 12, Blok E7, Parsel E, Presint 1
Level 12, Block E7, Parcel E, Precinct 1
Pusat Pentadbiran Kerajaan Persekutuan
Federal Government Administrative Centre
62590 PUTRAJAYA

Tel. : 03 88832543
Faks : 03 88895184

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Ruj. Kami : (2) dlm.KKM/NIHSEC/08/0804/P10-730
Tarikh : 28 Februari 2011

Dr Mohamed Shajahan Yasin
Fakulti Perubatan & Sains Kesihatan
Universiti Monash Sunway

Tuan,

<u>NMRR-10-1107-7328</u>
Promoting Physical Activity In Sedentary Older Adults With Type 2 Diabetes

Lokasi Projek : Klinik Kesihatan Shah Alam

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) mengambil maklum bahawa projek tersebut adalah untuk memenuhi keperluan akademik Dr Sazlina Bt Shariff Ghazali pelajar PhD Perubatan dan Sains Kesihatan, Universiti Monash Sunway.

3. Sehubungan dengan itu, pihak JEPP KKM tiada halangan, dari segi etika ke atas pelaksanaan projek tersebut. JEPP mengambil maklum bahawa kajian ini tidak melibatkan sebarang intervensi dan hanya menggunakan borang soal-selidik untuk mengumpul data kajian. Segala rekod dan data pesakit adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai data *confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah Hospital di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Tuan perlu akur dan mematuhi keputusan tersebut.

4. Laporan tamat kajian dan sebarang penerbitan dari kajian ini hendaklah dikemukakan kepada Jawatankuasa Etika & Penyelidikan Perubatan selepas tamatnya projek ini.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menurut perintah,

[redacted]

(DATO' DR CHANG KIAN MENG)
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia

C.2. Monash University Human Research Ethics Committee's approval letter – Qualitative focus group study

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**28 March 2011**
Project Number:	**CF10/3191 – 2010001702**
Title:	**Promoting physical activity in sedentary older adults with Type 2 Diabetes**
Chief Investigator:	**Prof Colette Browning**
Approved:	**From: 28 March 2011 To: 28 March 2016**

Terms of approval

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Assoc Prof Mohamed Shajahan Yasin, Dr Sazlina Shariff Ghazali

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone [redacted] **Facsimile +61 3 9905 3831**
Email [redacted] **www.monash.edu/research/ethics/human/index/html**
ABN 12 377 614 012 CRICOS Provider #00008C

C.3. Monash University Human Research Ethics Committee's approval letter – Randomised controlled trial

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**15 August 2011**
Project Number:	**CF11/1018 - 2011000524**
Project Title:	**Promoting physical activity in sedentary older adults with type 2 diabetes**
Chief Investigator:	**Prof Colette Browning**
Approved:	**From: 15 August 2011 to 15 August 2016**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Assoc Prof Shajahan Yasin; Dr Sazina Shariff Ghazali

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone [redacted] Facsimile +61 3 9905 3831
Emai[redacted] www.monash.edu/research/ethics/human/index/html
ABN 12 377 614 012 CRICOS Provider #00008C

APPENDIX D: NOTICE FOR FOCUS GROUP PARTICIPANTS RECRUITMENT

D.1. Notice for focus group participants recruitment – English

MONASH University

ELDERLY WITH DIABETES WANTED

A study on physical activity will be conducted among older Malays with diabetes. We are inviting Malay patients aged 60 years and above with diabetes to participate. The study involves a focus group discussion for approximately one to two hour. The study will be conducted in this clinic and the cost for transportation will be compensated.

If you are interested, please stop by room 10 for more details and to sign up.

If you have any questions please contact Dr Sazlina Shariff Ghazali at 012 232 5659.

Thank you for your kind attention**.**

D.2. Notice for focus group participants recruitment – Bahasa Malaysia

MONASH University

WARGA TUA MENGIDAP DIABETES

DIPERLUKAN

Satu kajian berkenaan kegiatan jasmani akan dilaksanakan di kalangan warga tua Melayu yang mengidap diabetes. Kami menjemput pesakit diabetes Melayu berumur 60 tahun ke atas untuk menyertai kajian ini. Kajian ini melibatkan satu kumpulan perbincangan selama satu ke dua jam. Kajian ini akan dilaksanakan di klinik ini dan kos pengangkutan akan dibiayai.

Jika anda berminat, sila datang ke bilik no. 10 untuk maklumat lanjut dan menyertai kajian ini.

Jika anda mempunyai sebarang soalan, sila hubungi Dr Sazlina Shariff Ghazali di talian 012 232 5659.

Terima kasih di atas perhatian anda.

APPENDIX E: FOCUS GROUP RECRUITMENT SCREENING QUESTIONNAIRE

GALAKAN KEGIATAN JASMANI DI KALANGAN WARGA TUA YANG TIDAK AKTIF DAN MENGIDAP DIABETES JENIS KE-2

(PROMOTING PHYSICAL ACTIVITY IN SEDENTARY OLDER MALAYS WITH TYPE 2 DIABETES MELLITUS)

SOALAN SARINGAN UNTUK PERBINCANGAN KUMPULAN BERFOKUS

(SCREENING QUESTIONNAIRE FOR FOCUS GROUP DISCUSSION)

No. Peserta (*Participant No.*) : | | - | | |

Tarikh (*Date*) : [   ]

Semua maklumat dalam kajian ini akan dirahsiakan dan hanya digunakan untuk tujuan kajian sahaja. Kerjasama anda dalam kajian ini amat dihargai. Terima kasih.

(All information given in this study will be kept confidential and will be used for the purpose of research only. Your cooperation to participate in this study is highly appreciated. Thank you.)

Jeffrey Cheah School of Medicine and Health Sciences

Monash University Sunway Campus

Malaysia

SEKSYEN 1 *(SECTION 1)*: **MAKLUMAT PESERTA** *(PARTICIPANT'S PROFILE)*

1. Umur anda adalah *(Your age is)* : __________ tahun *(years)*

2. Anda adalah seorang *(You are a)* : Lelaki *(Male)* ☐ 1

			Perempuan *(Female)*	☐	2
3.	Tahap perkahwinan anda adalah *(Your marital status is)*	:	Bujang *(Single)*	☐	1
			Berkahwin *(Married)*	☐	2
			Duda(Janda)/Bercerai *(Widow(er)/Divorce)*	☐	3
4.	Tahap pendidikan tertinggi anda *(Your highest level of education is)*	:	Universiti/Kolej *(University/college)*	☐	1
			Menengah *(Secondary)*	☐	2
			Rendah *(Primary)*	☐	3
			Tiada pendidikan formal *(No formal education)*	☐	4
5.	Pekerjaan anda adalah *(Your occupation is)*	:	Pesara *(Retiree)*	☐	1
			Pencen *(Pensioner)*	☐	2
			Masih bekerja *(Still working)*	☐	3
			Tidak bekerja/Surirumah *(Unemployed/Housewife)*	☐	4
6.	Pendapatan bulanan seisi rumah anda adalah *(Your monthly household income is)*	:	RM ___________/ month		

SEKSYEN 2 *(SECTION 2)*: TAHAP AKTIVITI JASMANI *(PHYSICAL ACTIVITY LEVEL)*

Adakah anda berjalan laju, bertai chi, berenang, bermain badminton atau kegiatan yang setara selama 30 minit sehari untuk sekurang-kurangnya 5 hari seminggu? *(Do you do any brisk walking, tai chi, swimming, badminton or other similar activities at least 30 minutes a day for at least 5 days in a week?)*	☐ Ya *(Yes)* 1	☐ Tidak *(No)* 2
Adakah anda berjalan laju, bertai chi, berenang, bermain badminton atau kegiatan yang setara kurang dari 150 minit seminggu? *(Do you do any brisk walking, tai chi, swimming, badminton or other similar activities less than 150 minutes in a week?)*	☐ Ya *(Yes)* 1	☐ Tidak *(No)* 2

SEKSYEN 3 *(SECTION 3)*: Soal selidik Penilaian Kognitif Warga Emas *(Elderly Cognitive Assessment Questionnaire)*

1 markah untuk setiap jawapan betul *(Score 1 for each correct answer)*

INGATAN *(MEMORY)*	**Markah *(Score)***
Saya mahu anda ingatkan nombor ini (Contoh: 4517). Boleh anda ulangi? *(I want you to remember this number (e.g. 4517). Can you repeat after me?)*	___________
Saya akan uji anda selepas 10 minit. *(I shall be testing you again in 10 minutes)*	
Berapakah umur anda? *(How old are you?)*	___________
Bilakah hari lahir anda? *(When is your birthday?)*	___________
Atau *(Or)*	
Pada tahun apakah anda dilahirkan? *(In what year were you born?)*	
ORIENTASI DAN MAKLUMAT (*ORIENTATION AND INFORMATION)*	
Apakah hari ini? *(What day of the week is today?)*	___________
Apakah tarikh hari ini *(What is the date tody?)*	
Hari *(Day)*	___________
Bulan *(Month)*	___________
Tahun *(Year)*	___________
Apakah nama tempat ini? *(What is this place called?)*	___________
Apakah pekerjaan dia (cth: jururawat atau doctor dll.)? *(What is her/his job (e.g. nurse or doctor etc)?)*	___________
INGAT SEMULA *(MEMORY RECALL)*	
Bolehkah anda ingatkan number tadi? (*Can you recall the number again?*)	___________
JUMLAH *(TOTAL)*	___________

PEMARKAHAN *(SCORE)*:

0-4 Kemungkinan kes *(Probable case)*
5-6 Kes sempadan *(Borderline case)*
> 7 Normal

Untuk dilengkapkan oleh penyelidik *(To be completed by researcher)*

SUBJECT ELIGIBILITY : ☐ Yes ☐ No

Participant ID: ________________

Reason for not eligible:

____

____

Completed by:

Researcher's initial	**:**		**Researcher's signature**	**:**	
Date	**:**				

APPENDIX F: EXPLANATORY STATEMENT FOR FOCUS GROUP PARTICIPANTS

F.1. Explanatory statement for focus group participants – English

MONASH University

September 2011

Explanatory Statement for Focus Group

Title: Promoting Physical Activity in Sedentary Older Malays with Type 2 diabetes mellitus

This information sheet is for you to keep.

My name is Dr Sazlina Shariff Ghazali and I am conducting a research project with Professor Dr Colette Browning from School of Primary Health Care and Associate Professor Dr Shajahan Yasin, from the School of Medicine and Health Sciences towards a PhD-Med at Monash University. This means that I will be writing a thesis, which is the equivalent of a short book.

After reading our notice you contacted us to participate in the project. You have been chosen to participate because you are Malay, 60 years old and above and have diabetes. We are interested in understanding the barriers and motivations of physical activity from people of different background.

The aim/purpose of the research

The aim of this study is to identify the barriers and motivators to physical activity among Malay adults aged 60 years and above with diabetes.

Possible benefits

The results of this study will provide better understanding on the factors that would influence the participation of physical activity among older adults with diabetes especially those who are sedentary.

What does the research involve?

The study involves focus group discussions in groups of 8 to 10 people. Questions on physical activity will be asked and the discussion will be audio taped and later transcribed.

How much time will the research take?

The focus group discussion will be approximately one to two hours.

Inconvenience/discomfort

There should not be any discomfort or harmful effect from this discussion. All information obtained from the discussion will be kept anonymous and confidential.

Payment

Cost for transportation will be provided for participating.

Can I withdraw from the research?

Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may only withdraw prior to the beginning of the focus group.

Confidentiality

Everything will be done to protect your right to privacy. There will be no mention of names or the identity of participants will not be made available during the analysis of the results as well as in the thesis writing and published articles.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Results

If you would like to be informed of the aggregate research finding, please contact Dr Sazlina Shariff Ghazali on her mobile: [redacted] The findings are accessible from 1 February 2012 until 31 July 2012.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research <insert your project number here> is being conducted, please contact:
Professor Dr Colette Browning Healthy Ageing Research Unit Faculty of Medicine, Nursing and Health Sciences Postal address: School of Primary Health Care, Building 1, 270 Ferntree Gully Rd, Notting Hill, VIC 3168. [redacted] Or Dr Sazlina Shariff Ghazali PhD-Med Candidate School of Medicine and Health Sciences Monash University Sunway Campus Malaysia. Tel: 012 232 5659 Email: ssha145@student.monash.edu	Tang Hooi Ru, Joyce Head of Planning and Research Management Monash University Jalan Lagoon Selatan Bandar Sunway Selangor Darul Ehsan [redacted]

Thank you.

[redacted]

Dr Sazlina Shariff Ghazali

F.2. Explanatory statement for focus group participants – Bahasa Malaysia

MONASH University

September 2011

Kenyataan Penjelasan Untuk Kumpulan Fokus

Tajuk: Galakan Kegiatan Jasmani Di Kalangan Warga Tua Melayu Yang Tidak Aktif dan Menghidap Diabetes Jenis Ke-2

Kertas penjelasan ini adalah untuk simpanan anda.

Nama saya adalah Dr Sazlina Shariff Ghazali, dan sedang menjalankan projek penyelidikan bersama Profesor Dr Colette Browning dari Sekolah Penjagaan Kesihatan Primer and Prof Madya Dr Shajahan Yasin, dari Sekolah Perubatan dan Sains Kesihatan, untuk memperoleh ijazah Doktor Falsafah Perubatan di Monash University. Ini bermakna saya akan melakukan penulisan tesis, sama seperti penulisan sebuah buku yang ringkas.

Anda telah menghubungi kami untuk menyertai kajian ini setelah membaca iklan kami. Anda telah dipilih untuk menyertai kajian ini kerana anda Melayu, berumur 60 tahun ke atas dan mengidap diabetes. Kami berminat untuk memahami halangan dan dorongan terhadap kegiatan jasmani di kalangan warga tua yang mempunyai latarbelakang yang berbeza.

Tujuan kajian

Tujuan kajian ini adalah untuk mengenal pasti dorongan dan halangan terhadap kegiatan jasmani di kalangan warga Melayu yang berumur 60 tahun ke atas dan mengidap diabetes.

Faedah yang dapat diperoleh

Hasil dari kajian ini dapat memberi pemahaman yang lebih mendalam terhadap faktor yang boleh mempengaruhi penglibatan dalam kegiatan jasmani di kalangan warga tua yang mengidap diabetes terutamanya di kalangan mereka yang tidak aktif.

Apakah yang terlibat dalam kajian ini?

Kajian ini melibatkan perbincangan kumpulan secara berfokus dalam kumpulan 6 orang. Soalan berkenaan kegiatan jasmani akan diajukan dan perbincangan itu akan di rakam secara audio dan kemudiannya akan dituliskan.

Berapa lamakah kajian ini dijalankan?

Perbincangan kumpulan secara berfokus ini adalah selama lebih kurang satu jam.

Kesulitan/ Ketidakselesaan

Perbincangan ini tidak akan menimbulkan sebarang kesulitan atau ketidakselesaan. Semua maklumat yang diperolehi dari perbincangan ini akan disimpan tanpa menulis nama anda dan dirahsiakan.

Pembayaran

Kos pengangkutan akan dibiayai oleh pihak penyelidik untuk semua peserta kajian ini.

Bolehkan saya menarik diri dari kajian ini?

Penyertaan dalam kajian ini adalah secara sukarela dan tidak dipaksa untuk memberi keizinan untuk penyertaan. Walau bagaimanapun, jika anda bersetuju untuk menyertai kajian ini, anda hanya boleh menarik diri sebelum bermulanya kumpulan fokus.

Kerahsiaan

Semasa kajian ini, setiap perkara yang dilakukan adalah untuk melindungi hak asasi anda. Nama atau identiti peserta dalam kajian ini tidak akan dinyatakan dalam analisa keputusan, penulisan tesis atau artikel yang diterbitkan.

Penyimpanan data

Penyimpanan data kajian akan disimpan dengan mematuhi undang-undang Universiti di premis Universiti dalam almari/kabinet fail berkunci selama 5 tahun. Satu laporan dari kajian ini mungkin akan dihantar untuk penerbitan, tetapi peserta tidak akan dikenalpasti dalam laporan itu.

Keputusan

Jika anda ingin mengetahui keputusan kajian ini, sila hubungi Dr Sazlina Shariff Ghazali melalui no. telefon bimbit: [redacted] Keputusan kajian boleh diperolehi dari 1 Februari 2012 until 31 Julai 2012.

Jika anda ingin menghubungi penyelidik-penyelidik mengenai sebarang perkara berkaitan kajian, sila hubungi ketua penyelidik:	Jika anda mempunyai sebarang aduan berkaitan cara kajian ini <insert your project number here> dijalankan, sila hubungi:
Professor Dr Colette Browning School of Primary Health Care, Building 1, 270 Ferntree Gully Rd, Notting Hill, VIC 3168. [redacted] ATAU Dr Sazlina Shariff Ghazali PhD-Med Candidate School of Medicine and Health Sciences Monash University Sunway Campus Malaysia. [redacted]	Tang Hooi Ru, Joyce Head of Planning and Research Management Monash University Jalan Lagoon Selatan Bandar Sunway Selangor Darul Ehsan [redacted] .

Terima kasih.

[redacted]

Dr Sazlina Shariff Ghazali

APPENDIX G: CONSENT FORM FOR FOCUS GROUP PARTICIPANTS

G.1. Consent form for focus group participants – English

MONASH University

Consent Form for Focus Group

Title: Promoting Physical Activity in Sedentary Older Malays with Type 2 diabetes mellitus

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to be involved in the focus group ☐ Yes ☐ No
I agree to allow the focus group to be audio-taped ☐ Yes ☐ No

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw prior to the beginning of the focus group without being penalised or disadvantaged in any way.

I understand that any data that the researcher extracts from the focus group for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

I understand that data from the focus group will be kept in a secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name : My Kad No.:
Signature :

Date :

Witness's name : My Kad No.:
Signature :

Date :

G.2. Consent form for focus group participants – Bahasa Malaysia

MONASH University

Borang Persetujuan Untuk Kumpulan Fokus

Tajuk: Galakan Kegiatan Jasmani Di Kalangan Warga Tua Yang Tidak Aktif dan Mengidap Diabetes Jenis Ke-2

NOTA: Borang persetujuan ini akan bersama penyelidik Monash University untuk simpanan rekod mereka

Saya bersetuju untuk mengambil bahagian dalam projek penyelidikan Monash University seperti di atas. Saya telah diberi penjelasan dan telah membaca kenyataan penjelasan mengenai projek ini. Saya memahami persetujuan untuk menyertai kajian ini bermakna:

Saya bersetuju untuk terlibat dalam kumpulan fokus ☐ Ya ☐ Tidak

Saya bersetuju untuk membenarkan kumpulan fokus tersebut dirakam secara audio ☐ Ya ☐ Tidak

Saya memahami penyertaan ini adalah secara sukarela, di mana saya boleh memilih untuk tidak menyertai projek ini dan saya hanya boleh menarik diri sebelum bermulanya kumpulan fokus tanpa didenda atau mengalami kerugian.

Saya memahami bahawa maklumat diperoleh semasa kumpulan fokus untuk kegunaan dalam laporan atau penerbitan, tidak mempunyai nama atau ciri yang boleh dikenalpasti.

Saya memahami bahawa maklumat yang diperolehi semasa kumpulan fokus akan disimpan dalam tempat yang terjamin selamat dan hanya berhak digunakan oleh kumpulan penyelidikan. Saya juga memahami bahawa maklumat ini akan dimusnahkan selepas 5 tahun kecuali saya membenarkan untuk kegunaan penyelidikan di masa hadapan.

Nama peserta : No. My Kad:
Tandatangan :

Tarikh :

Nama saksi : No. My Kad:
Tandatangan :

Tarikh :

APPENDIX H: FOCUS GROUP INTERVIEW SCHEDULE

H.1. Focus group interview schedule – English

MONASH University

FOCUS GROUP INTERVIEW SCHEDULE

TITLE : PROMOTING PHYSICAL ACTIVITY IN SEDENTARY OLDER MALAYS WITH TYPE 2 DIABETES MELLITUS

VENUE : SECTION 7 HEALTH CENTRE, SHAH ALAM

1. Introduction (20 minutes)

"Good morning/afternoon. Thank you all for coming today and volunteering your time. My name is Sazlina Shariff Ghazali, and I am conducting a research project with Professor Dr Colette Browning from School of Primary Health Care and Associate Professor Dr Shajahan Yasin, from the School of Medicine and Health Sciences towards a PhD-Med at Monash University. Assisting me today is Mr. Shashi Kumar.
We are attempting to gain information about factors that influence initiation and maintenance of physical activity.
This session is audio-recorded so that we do not miss anything you say. You have all signed an informed consent form but please be assured that you will not be identified other than in general terms in the final report. So that we can understand this session is audio-recorded, it is important that only one person speaks at a time. We will make sure that everyone get a chance to have their say.
Does anyone have any questions at this point of time? (Pause for a while). If none, let us go around the table and introduce ourselves."

	2. About diabetes	**(10 minutes)**
	In your opinion, what does someone with diabetes has to do to achieve good diabetes care?	*PROMPT* Does it include: • Diet control • Exercise/ Physical activity • Medications • Insulin

	3. Meaning of physical activity	**(20 minutes)**
	Could you describe the kind of activities that you understand as physical activities?	*PROMPT* Physical activity = any form of muscular movement And what about *? Do you see this as physical activity? **series of prompts regarding definition of physical activity (select as appropriate)* • Activities of daily living • Recreational activities • Work related activities • Household chores

4.	**Factors that influence physical activity**	**(40 minutes)**
	In your opinion, what are the factors that influence engagement in physical activity?	
	How can older people be encouraged to participate in physical activity/exercise?	*PROMPT* You mentioned about some of the motivators to physical activity, do you prefer * or **? * & ***series of prompts regarding motivators to physical activity (select as appropriate)* • *Home versus **centre based activity • *Individual versus **group activity • *Indoor versus **outdoor activity *PROMPT* And what about *? **series of prompts regarding encouragers as appropriate)* • Feedback • Pedometer • Use of a diary • Telephone support • Peer support
	Who would be a good source of encouragement and support for older people to participate in physical activity/exercise?	*PROMPT* Some of you mentioned peer as a source of encouragement, what type of peer support would work?
	Some people are not as active as they could be. Can you tell me some of the reasons why you or other older people might not participate in physical activity/exercise?	
	How do you feel about participating in each of the following activities*? How do you think most older people would feel about doing them*?	*PROMPT* *Provide the list of activities to participants: • Brisk walking • Jogging • Dancing/Po Cho Po Cho • Swimming • Tai Chi What makes *(use above list)

	Which of the reasons for not taking part in physical activity/exercise that we discussed earlier are the most important in preventing you or other older people from participating in physical activity/exercise?	difficult to do? And what about *? **series of prompts regarding barriers to physical activity (select as appropriate)* • Health reason • Fear of injury • Fear of hypoglycaemia • Safety of environment • Weather • Family commitment • Lack of energy • Lack of time • Laziness
5.	**Use of pedometer and charting activity diary**	**(20 minutes)**
	A pedometer is a device that helps to count steps while someone is walking. In your opinion, how would older people react to wearing a device like this? What would help to improve the use of wearing such device? If older people need to chart an activity diary such as this (show the activity diary), in your opinion, how would they react to this? What would help to improve in charting the diary?	Show and explain to the participants about pedometer • Its function and how to use the pedometer
6.	**Is there anything else about physical activity/exercise that we have not discussed and you think is important?**	

H.2. Focus group interview schedule – Bahasa Malaysia

MONASH University

PERBINCANGAN KUMPULAN BERFOKUS

TAJUK : **GALAKKAN KEGIATAN JASMANI DI KALANGAN PENGHIDAP DIABETES WARGA EMAS MELAYU YANG TIDAK AKTIF**

TEMPAT : **POLIKLINIK KOMUNITI SHAH ALAM, SEKSYEN 7, SHAH ALAM**

1.	**Pengenalan**	**(20 minit)**
	"Assalamualaikum. Terim kasih kerana hadir pada hari ini dan meluangkan masa. Nama saya ialah Dr Sazlina Shariff Ghazali, dan saya akan melaksanakan projek penyelidikan bersama Professor Dr Colette Browning dari Sekolah Penjagaan Kesihatan Primer dan Prof Madya Dr Shajahan Yasin, dari Sekolah Perubatan dan Sains Kesihatan, untuk Kedoktoran Falsafah saya di Monash University. Pembantu saya pada hari ini adalah En. Shashi Kumar. Kami ingin mendapatkan maklumat mengenai faktor yang mempengaruhi sesseorang melakukan kegiatan jasmani. Sesi perbincangan ini akan dirakam audio agar kami tidak ketinggalan akan apa yang anda kongsi bersama. Anda telah menandatangani borang keizinan tetapi semua ini akan dirahsiakan. Memandangkan sesi ini dirakam, saya mohon agar setiap peserta bercakap pada satu masa. Kami akan pastikan yang semua orang berpeluang untuk bercakap. Sebelum kita bermula, ada sebarang pertanyaan? Jika tidak, kita mulakan dengan mengenalkan diri masing-masing."	
2.	**Mengenai diabetes**	**(20 minit)**
	Pada pendapat anda, apakah yang perlu dilakukan untuk mencapai tahap penjagaan diabetes yang baik?	***PROMPT*** Adakah termasuk: • Penjagaan pemakanan • Senaman/kegiatan jasmani • Ubatan • Insulin
3.	**Maksud kegiatan jasmani**	**(20 minit)**
	Bolehkah anda terangkan jenis kegiatan yang dianggap kegiatan fizikal?	***PROMPT*** **Kegiatan fizikal** = sebarang pergerakkan otot Bagaimana pula dengan*? Adakah pada pendapat anda ini kegiatan fizikal? * • Kegiatan seharian • Kegiatan rekreasi • Kegiatan berhubung kerja • Kegiatan kerja rumah

4. Faktor-faktor yang mempengaruhi kegiatan jasmani (40 minit)

Pada pendapat anda, apakah factor-faktor yang mempengaruh penglibatan dalam kegiatan jasmani?

Bagaimana warga emas boleh didorong untuk terlibat dalam kegiatan fizikal / senaman?

Anda ada sebutkan pendorong kegiatan fizikal/senaman, adakah anda lebih suka * atau **?

PROMPT
* & **
- *Aktiviti di rumah atau **di klinik
- *Secara berseorangan atau ** berkumpulan
- *aktiviti di dalam atau **di luar

Bagaimana pula dengan *?

PROMPT*
- Mendapat dorongan
- Mencatat dalam diari
- Dihubung melalui telefon
- Sokongan dari rakan

Ada di antara kamu mengatakan sokongan rakan adalah sumber dorongan, sokongan rakan yang bagaimana adalah sesuai?
Siapakah yang sesuai sebagai pendorong atau sokongan untuk warga emas terlibat dalam kegiatan fizikal/senaman?

Sesetangah orang tidak seaktif sepertimana yang mereka mahu.
Bolehkan anda berkongsi bersama apakah sebabnya anda atau warga emas lain tidak melibatkan diri dengan kegiatan fizikal/senaman?
Bagaimana anda rasa mengenai melibatkan diri untuk setiap kegiatan ini*?

PROMPT*
- Berjalan laju
- Berjoging
- Menari
- Tai Chi
- Berenang

Bagaimana anada rasa warga emas lain rasa mengenai melakukan kegiatan ini*?
Apakah yang mereka sukar untuk lakukan (senarai kegiatan fizikal)?

Bagaimana pula jika *?
- Kesihatan terjejas
- Takut cedera
- Takut paras gula rendah
- Persekitaran tidak selamat
- Cuaca
- Tanggungjawab keluarga
- Tiada masa
- Tiada tenaga
- Malas

Yang manakah antara sebab utama yang menghalang anda atau warga emas lain melibatkan diri dalam kegiatan fizikal atau senaman?

5. Menggunakan pedometer dan mencatat diari aktiviti (20 minit)

Pedometer adalah sejenis alat yang membantu untuk menggira langkah seseorang semasa berjalan. Pada pendapat anda, bagaimanakah reaksi warga emas jika mereka perlu menggunakannya?

Tunjuk dan terangkan kepada peserta pedometer.
- Fungsi dan cara penggunaannya

	Apakah cara yang dapat membantu meningkatkan penggunaan alat ini? Jika warga emas perlu untuk mencatat kegiatan jasmani mereka ke dalam diari, pada pendapat anda, bagaimanakah reaksi mereka untuk mencatat maklumat tersebut? Apakah cara yang dapat membantu seseorang untuk memcatat maklumat ke dalam diari?
6.	**Adakah apa-apa yang lain anda rasakan penting mengenai kegiatan fizikal /senaman tetapi kita tidak bincangkan?**

APPENDIX I: WALKING ACTIVITY SCHEDULE

Phase *(Peringkat)*	**Week** *(Minggu)*	**Frequency** *(Kekerapan)*	**Intensity** *(Ketekunan)*	**Duration** *(Masa)* **(min)**
Initiation *(Permulaan)*	1	3x/week *(seminggu)*	Low *(Rendah)*	5 - 10
	2	3x/week *(seminggu)*	Low *(Rendah)*	10 – 15
	3	3x/week *(seminggu)*	Low *(Rendah)*	15 – 20
	4	4-5x/week *(seminggu)*	Low *(Rendah)*	20 – 30
	5	4-5x/week *(seminggu)*	Moderate *(Sederhana)*	30
	6	5x/week *(seminggu)*	Moderate *(Sederhana)*	30
	7	5x/week *(seminggu)*	Moderate *(Sederhana)*	30
	8	5x/week *(seminggu)*	Moderate *(Sederhana)*	30
Maintenance *(Pengekalan)*	9	5-7x/week *(seminggu)*	Moderate *(Sederhana)*	30
	10	5-7x/week *(seminggu)*	Moderate *(Sederhana)*	30
	11	5-7x/week *(seminggu)*	Moderate *(Sederhana)*	30
	12	5-7x/week *(seminggu)*	Moderate *(Sederhana)*	30

APPENDIX J: GRAPH FOR FEEDBACK ABOUT PHYSICAL ACTIVITY PATTERNS

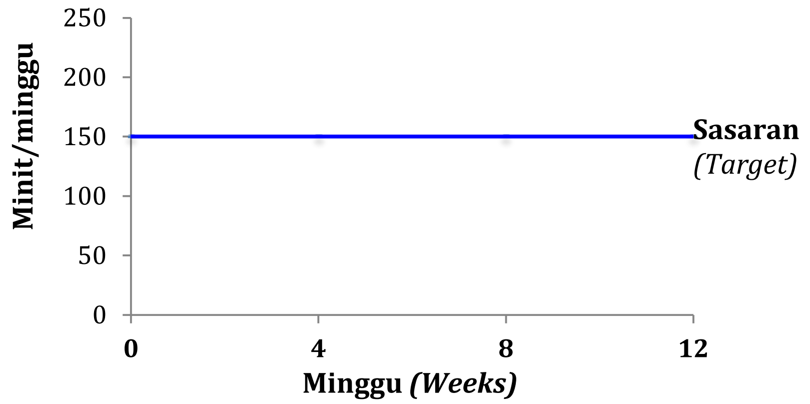
CARTA KEMAJUAN *(PROGRESS PLOTS)*:

LAWATAN (VISITS): **Minggu 4/ 8/ 12** *(Week 4/ 8/ 12)*

Adakah anda melakukan aktiviti berjalan kaki? YA *(YES)* / **TIDAK** *(NO)*

(Did you do walking activity?)

Minggu *(Week)*	**Tempoh (min/minggu)** *(Duration (min/week))*	**Kekerapan (hari/minggu)** *(Frequency (days/week))*	**Ketekunan senaman** *(Intensity of exercise)*



Pelan tindakan : ______________________________

***(**Plan of actions)* ______________________________

APPENDIX K: NOTICE FOR PEER MENTORS RECRUITMENT

K.1. Notice for peer mentors recruitment – English

What are the benefits being a peer mentor?

You will:

- Receive a certification in leadership
- Receive recognition from the clinic, community & the Ministry of Health
- Become self-sufficient in managing own diabetes
- Help individuals & their families in managing their diabetes
- Create a support network in your community for people with diabetes
- Have satisfaction of doing good deeds

If you are interested, please stop by room 10 for more details and to sign up.
Please contact Dr Sazlina Shariff Ghazali at 012 232 5659, if you have further questions.

Thank you for volunteering.

The Research Team

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MONASH University

Promoting Physical Activity in Sedentary Older Diabetes Persons

Jeffrey Cheah School of Medicine and Health Sciences
Monash University Sunway Campus
Malaysia

Introduction

A program to promote physical activity will be conducted among older adults with diabetes in Poliklinik Komuniti Shah Alam. We are looking for patients aged 60 years and above with diabetes to volunteer to be peer mentors. Upon completion of the program, we will get answers to important questions like "Can peer mentors help older people with diabetes to be physically active and improve their diabetes?"

This program is a research study by Monash University with the collaboration with the Ministry of Health. The people involved in this program included researchers from Monash University and Ministry of Health Malaysia, staff of Poliklinik Komuniti Shah Alam, you as the potential peer mentor and the patients with type 2 diabetes from the clinic. The program will be conducted in this clinic and the cost of transportations and related to the program will be compensated.

What is a peer mentor?

Peer mentors are volunteers who have type 2 diabetes and live in Shah Alam and want to help their communities.
As peer mentor, you:

- Care about your community.
- Want to help.
- Are familiar with what it is like to live with diabetes.

Who can become the peer mentors?

Peer leaders:

- Have the desire to help others
- Have type 2 diabetes
- Do regular physical exercise
- Has good glycaemic control
- Willing to attend a 2-day training workshop
- Willing to comply to the program protocols for 9 months

What is the role of a peer mentor?

Attend training on diabetes and communication skills
Attend enrolment day in Poliklinik Komuniti Shah Alam and meet with 3-5 peers
Work together for 3 months:

- As agroup: Once every 4 weeks for 12 weeks (30-60 minutes, total of 4 hours)
- Telephone:
  - 3 calls over 12 weeks (15-30 minutes, total of 1.5 hours) to ask about their physical exercise

Meet once a month with the other volunteers to support each other
Attend data collection days at weeks 12, 24 and 36.

K.2. Notice for peer mentors recruitment – Bahasa Malaysia

Apakah faedah sebagai pemimpin rakan sebaya?

Anda akan:
- Menerima sijil kepimpinan
- Menerima pengiktirafan dari klinik dan komuniti
- Berkeupayaan dalam penjagaan kendiri diabetes anda
- Membantu individu dan keluarga mereka dalam penjagaan kendiri kencing manis mereka
- Menwujudkan satu rangkaian sokongan dalam komuniti anda untuk pesakit kencing manis
- Berpuashati dengan sumbangan amal jariah anda

Jika anda berminat, sila ke bilik 10 untuk maklumat lanjut dan berdaftar sebagai pemimpin rakan sebaya. Untuk sebarang pertanyaan, sila hubungi Dr Sazlina Shariff Ghazali di 012 232 5659.

Terima kasih kerana mengambil bahagian.

Kumpulan Penyelidik

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MONASH University

Menggalak Kegiatan Jasmani di Kalangan Warga Emas Menghidap Diabetes

Jeffrey Cheah School of Medicine and Health Sciences
Monash University Sunway Campus Malaysia

Pengenalan

Satu program untuk menggalakkan kegiatan jasmani akan dilaksanakan di kalangan warga emas Melayu yang menghidap diabetes. Kami sedang mencari sukarelawan berumur 60 tahun ke atas dan mengidap diabetes sebagai pemimpin rakan sebaya. Kami berharap untuk mendapat jawapan terhadap persoalan penting seperti "Bolehkah pemimpin rakan sebaya membantu warga emas menghidap diabetes untuk aktif berjasmani dan meningkatkan tahap kesihatan mereka?"

Program ini merupakan satu kajian oleh Monash University dengan kerjasama Kementerian Kesihatan Malaysia. Penyelidik-penyelidik dari Monash University dan Kementerian Kesihatan Malaysia, warga kerja Poliklinik Komuniti Shah Alam, anda sebagai bakal pemimpin rakan sebaya dan pesakit diabetes di klinik akan telibat dalam program ini. Program ini akan dilaksanakan di klinik ini dan kos pengangkutan dan yang berkaitan dengan program ini akan dibiaya.

Siapakah pemimpin rakan sebaya?
Pemimpin rakan sebaya adalah sukarelawan yang mengidap diabetes dan tinggal di Shah Alam serta mahu membantu komuniti mereka.
Sebagai pemimpin rakan sebaya, anda:
- Ambil berat mengenai komuniti anda.
- Anda mahu membantu.
- Telah mengalami kehidupan sebagai pengidap diabetes.

Siapa boleh menjadi pemimpin rakan sebaya?
Pemimpin rakan sebaya:
- Mempunyai keinginan untuk membantu orang lain
- Menghidap diabetes jenis ke-2
- Kerap bersenam
- Mempunyai tahap kawalan gula yang baik
- Boleh menghadiri bengkel latihan selama 2 hari
- Akan mematuhi protokol program selama 9 bulan

Apakah peranan pemimpin rakan sebaya?

Menghadiri latihan berkaitan diabetes dan kemahiran komunikasi
Menghadiri hari pendaftaran program di Poliklinik Komuniti Shah Alam dan berjumpa bersama 3-5 rakan sebaya
Bekerja bersama:
- Secara berkumpulan : setiap 4 minggu selama 12 minggu (30-60 minit, sejumlah of 4 jam)
- Melalui telefon:
  - 3 panggilan selama 12 minggu (15-30 minits, sejumlah 1.5 jam) untuk bertanya mengenai senaman fizikal

Sebulan sekali berjumpa bersama pemimpin rakan sebaya yang lain untuk sokongan.
Menghadiri hari pengumpulan data pada minggu 12, 24 dan 36..

APPENDIX L: SCREENING CHECKLIST FOR PEER MENTORS' RECRUITMENT

MONASH University

Screening Checklist for Peer Mentors' Recruitment

Name : ______________________________________

ID No. : ______________________________________

☐ Wants to volunteer

☐ Aged 60+ years

☐ Lives in Shah Alam

☐ Diagnosed with T2DM for more than 5 years

☐ Does regular physical activity (at least 150 minutes/week, 5 times a week)

☐ Has HbA1c < 8% (HbA1c% = _______)

☐ Has a mobile telephone

☐ Willing to attend 2 days training workshop

Eligibility as peer mentors: ☐Yes ☐No

Completed by:

Name : ______________________________________

Signature : ______________________________________

Date : ______________________________________

APPENDIX M: PEER MENTOR'S COMPETENCY CHECKLIST

MONASH University

Peer Mentors Training: Competency checklist from role play

Name of peer mentor : ____________________________

Date : ____________________________

			Comments
1.	Did the peer mentor ask his/her peer to identify barriers and motivations to physical activity?	☐ Yes ☐ No	____________________ ____________________
2.	Did the peer mentor explore his/her peer's further actions on the identified barriers or motivations?	☐ Yes ☐ No	____________________ ____________________
3.	Did the peer mentor help guide his/her peer to identify potential solutions for the anticipated barriers or motivations?	☐ Yes ☐ No	____________________ ____________________
4.	Did the peer mentor encourage his/her peer to explore the risks and benefits of each potential solution?	☐ Yes ☐ No	____________________ ____________________
5.	The peer mentor developed good rapport with his/her peer	☐ Yes ☐ No	____________________ ____________________
6.	The peer mentor used open-ended questions	☐ Yes ☐ No	____________________ ____________________
7.	The peer mentor listened attentively to his/her peer	☐ Yes ☐ No	____________________ ____________________
8.	The peer mentor was somewhat confrontational with his/her peer	☐ Yes ☐ No	____________________ ____________________

Completed by:

Name of observer : ____________________________

APPENDIX N: PEER MENTORS TRAINING

The peer mentors training was conducted over 2 days on 7 and 8 March 2011 at Shah Alam Community Polyclinic in Section 7. Below is the content and schedule of peer mentors training conducted over 2 days.

Day 1	**CONTENT**
8.00 – 8.15 am	Registration
8.15 – 8.45 am	Introduction to the programme • Overview of the intervention • Training goals and objectives • Training schedule • Contact information • Roles and responsibilities of peer leaders
8.45– 10.15 am	Diabetes and its management • Types of diabetes • Diabetes risk factors • Manifestations of diabetes • Complications of diabetes • Management of diabetes: • Self-care management (diet, physical activity, foot care, SBGM, target control, weight monitoring) • Diabetes medicines • Hyperglycaemia and hypoglycaemia • The sick day • Common diabetes myths Implementation: • Interactive lecture and small group discussions
10.15 – 10.30 am	Tea break
10.30 am – 12.00 pm	Physical activity • Definitions of physical activity and physical exercise • Benefits of physical exercise in diabetes • Barriers and motivations to physical exercise • Recommendations on physical exercise in older people • Walking activity • The DO's and DON'Ts • Pedometer and activity diary Implementation • Interactive lecture and small group discussions
12.00 – 1.00 pm	Stress management • Recognition of signs and symptoms of stress • Coping techniques for stress management • Signs and symptoms of depression • Brief relaxation exercise Implementation • Interactive lecture, small group discussions and simulations
1.00 – 2.00 pm	Lunch
2.00 – 3.30 pm	Communication and goal setting • Effective communication skills

	• Active listening • Goal setting Implementation • Interactive lecture, simulations, role plays and small group discussions • Use of case vignettes
3.30 – 5.00 pm	Problem solving and overcoming barriers • Steps in problem solving • Overcoming barriers Implementation • Interactive lecture, simulations, role plays and small group discussions • Use of case vignettes

Day 2	**CONTENT**
8.00 – 8.15 am	Registration
8.15 – 10.15 am	Knowing your limitations • Limitations as peer mentors • Identify barriers and problems as peer mentor • Knowing the resources Implementation • Simulations, role plays and group discussions
10.15 -10.30 am	Tea break
10.30 am – 1.00 pm	Tasks and protocols I • First meetings • Phone calls guidelines and scripts Implementation • Simulations, role plays and group discussions
1.00 – 2.00 pm	Lunch
2.00 – 3.30 pm	Tasks and protocols II • Clinic visits • Peer mentors meetings • Data collection forms Implementation • Simulations, role plays and group discussions
3.30 – 4.30 pm	Research and ethics • Principles of ethics • Handling client information • Privacy and confidentiality Implementation

	• Interactive lecture and small group discussions
4.30 – 5.00 pm	Certificates presentation and closing

APPENDIX O: NOTICE FOR RCT PARTICIPANTS RECRUITMENT

O.1. Notice for RCT participants recruitment – English

MONASH University

DO YOU WANT TO GET ACTIVE?

A study to promote physical activity will be conducted among older Malays with diabetes. We are inviting patients aged 60 years and above with diabetes to participate. The study involves participation in walking activity. The study will be conducted in this clinic and the cost of transportation will be compensated.

If you are interested, please stop by room 10 for more details and to sign up.

If you have any questions please contact Dr Sazlina Shariff Ghazali at [redacted].

Thank you for your kind attention.

O.2. Notice for RCT participants recruitment – Bahasa Malaysia

MONASH University

MAHUKAH ANDA AKTIF?

Satu kajian berkenaan menggalakkan kegiatan jasmani akan dijalankan di kalangan warga tua yang mengidap diabetes. Kami ingin menjemput pesakit diabetes berumur 60 tahun ke atas untuk menyertai kajian ini. Kajian ini melibatkan aktiviti berjalan kaki. Kajian ini akan dilaksanakan di klinik ini dan kos pengangkutan akan dibiayai.

Jika anda berminat, sila datang ke bilik no. 10 untuk maklumat lanjut dan menyertai kajian ini.

Jika anda mempunyai sebarang soalan, sila hubungi Dr Sazlina Shariff Ghazali di talian [redacted]

Terima kasih di atas perhatian anda.

APPENDIX P: SCREENING CRF

Promoting physical activity in sedentary older Malays with type 2 diabetes mellitus

Screening for participants

Name : ________________________________

MyKad No. : ________________________________

Tel. No. : ________________________________

☐ Aged 60 years and above (Age: ________ years)
☐ Have type 2 DM ≥ 1 year
☐ Followed up in this clinic ≥ 2 times a year
☐ Do not exercise or exercise less than 150 minutes/week
"Adakah anda melibatkan diri dalam kegiatan fizikal seperti berjalan laju, tai chi, berenang bermain badminton atau kegiatan lain yang setara sekurang-kurangnya 30 minit sehari selama 5 hari seminggu? *(Are you involved in any physical activity such as brisk walking, tai chi, swimming, badminton or other similar activities at least 30 minutes a day on at least 5 days in a week?")*
☐ Able to walk without assistance
☐ FBS > 13 mmol/L
☐ BP < 180/100 mmHg
☐ No known chest pain
☐ No known shortness of breath
☐ No known visual problem
☐ No known hearing problem
☐ No known diabetes complication(s)

ECAQ scores : ______ /10
Eligibility as participants : ☐ Yes ☐ No
Completed by:
Name : ________________________________
Signature : ________________________________
Date : ________________________________

Soal selidik Penilaian Kognitif Warga Emas ***(Elderly Cognitive Assessment Questionnaire)***

1 markah untuk setiap jawapan betul *(Score 1 for each correct answer)*

INGATAN *(MEMORY)*	**Markah *(Score)***
Saya mahu anda ingatkan nombor ini (Contoh: 4517). Boleh anda ulangi? *(I want you to remember this number (e.g. 4517). Can you repeat after me?)*	___________
Saya akan uji anda selepas 10 minit. *(I shall be testing you again in 10 minutes)*	
Berapakah umur anda? *(How old are you?)*	___________
Bilakah hari lahir anda? *(When is your birthday?)*	___________
Atau *(Or)*	
Pada tahun apakah anda dilahirkan? *(In what year were you born?)*	
ORIENTASI DAN MAKLUMAT (*ORIENTATION AND INFORMATION)*	
Apakah hari ini? *(What day of the week is today?)*	___________
Apakah tarikh hari ini *(What is the date tody?)*	
Hari *(Day)*	___________
Bulan *(Month)*	___________
Tahun *(Year)*	___________
Apakah nama tempat ini? *(What is this place called?)*	___________
Apakah pekerjaan dia (cth: jururawat atau doctor dll.)? *(What is her/his job (e.g. nurse or doctor etc)?)*	___________
INGAT SEMULA *(MEMORY RECALL)*	
Bolehkah anda ingatkan number tadi? (*Can you recall the number again?*)	___________
JUMLAH *(TOTAL)*	___________

PEMARKAHAN *(SCORE)*:

0-4 Kemungkinan kes *(Probable case)*
5-6 Kes sempadan *(Borderline case)*
> 7 Normal

APPENDIX Q: EXPLANATORY STATEMENT FOR RCT PARTICIPANTS

Q.1. Explanatory statement for RCT participants – English

MONASH University

April 2012

Explanatory Statement- Randomised Controlled Trial

Title: Promoting Physical Activity in Sedentary Older Malays With Type 2 Diabetes Mellitus

This information sheet is for you to keep.

My name is Dr Sazlina Shariff Ghazali and I am conducting a research project with Professor Dr Colette Browning from School of Primary Health Care and Associate Professor Dr Shajahan Yasin, from the School of Medicine and Health Sciences towards a PhD-Med at Monash University. This means that I will be writing a thesis, which is the equivalent of a short book.
You have been chosen to participate in this study because you have type 2 diabetes mellitus and you do not engage in regular physical activity.

The aim/purpose of the research
I am conducting this research to find out if walking activity will help sedentary older adults with type 2 diabetes mellitus engaged in regular physical activity and improve their health.

Possible benefits
You will participate in regular physical activity and engaging in regular physical activity has health benefits for diabetes in controlling sugar and preventing complications. In addition, you will undergo health assessment, which helps to identify your current health status.

What does the research involve?
This is a 36-week physical activity study, which has three groups. If you agree to participate, you will be randomly allocated to one of these groups: Group 1 is a comparison group who will receive usual diabetes care. Group 2 will participate in regular walking activity and receive physical activity feedback from the research team. Group 3 will participate in the programme and receive feedback on physical activity and peers support from a peer mentor. You are required to engage in walking activities at least 30 minutes a day, 5 days a week or 150 minutes a week. You will undergo health assessments to ensure eligibility to participate in increase level of physical activity.

At the start of the study, you will undergo health assessments comprise measurements of blood pressure, body mass index, body composition, balance test and walk for 6 minutes test and the distance will be recorded. You are required to complete 5 questionnaires and continue with you usual diabetes care. You need to do blood test for sugar and cholesterol on 4 occassions. All groups will have 6 visits during a period of 36 weeks. All participants will be asked to use a pedometer for 7 days at 4 points of assessment. Participants in groups 2 and 3 are required to record their physical acitivities in a diary for 12 weeks. Group 3 participants also will receive 3 telephone calls from their peer mentors. All the same health assessments, balance test, walk for 6 minutes test and completing 5 questionnaires are done for all groups at 12, 24 and 36 weeks.

How much time will the research take?

The study will be conducted over 9 months. Three months for the physical activity programme and two follow-ups at 6 and 9 months after completion of the study. Each visit to the clinic will take approximately an hour.

Inconvenience/discomfort

There should not be any discomfort or harmful effect from this study as you will be assessed for safety to participate in physical activity. A guide and advice to exercise safely will be provided. However, in case of unexpected event, you will need to contact the research team (Dr Sazlina Shariff Ghazali at 012 232 5659) and appropriate referral will be made. If any of the results from the questionnaires is unsatisfactory appropriate referral will be made. All information obtained from this study will be kept anonymous and confidential.

Payment

Cost of transportation will be provided for participating.

Can I withdraw from the research?

Being in this study is voluntary and you are under no obligation to consent to participation. The medical care will not be affected due to your decision on participation and you may withdraw from the study at any point of time.

Confidentiality

There will be no mention of names or identity of participants will not be made available during the analysis of the results as well as in the thesis writing and published articles.

Storage of data

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Results

If you would like to be informed of the aggregate research finding, please contact Sazlina Shariff Ghazali on 012 232 5659 or fax at 603-5514 6307. The findings are accessible from 1 April 2013 until 30 June 2013.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research <insert your project number here> is being conducted, please contact:
Professor Dr Colette Browning Healthy Ageing Research Unit Faculty of Medicine, Nursing and Health Sciences Postal address: School of Primary Health Care, Building 1, 270 Ferntree Gully Rd, Notting Hill, VIC 3168. [redacted] Or Dr Sazlina Shariff Ghazali PhD-Med Candidate School of Medicine and Health Sciences Monash University Sunway Campus Malaysia. [redacted]	Tang Hooi Ru, Joyce Head of Planning and Research Management Monash University Jalan Lagoon Selatan Bandar Sunway Selangor Darul Ehsan [redacted]

Thank you.

[redacted]

Sazlina Shariff Ghazali

Q.2. Explanatory statement for RCT participants – Bahasa Malaysia

MONASH University

April 2012

Penyata Penjelasan Untuk Kajian Terkawal Secara Rawak

Tajuk: Galakan Kegiatan Jasmani Di Kalangan Warga Tua Yang Tidak Aktif dan Mengidap Diabetes Jenis Ke-2

Kertas penjelasan ini adalah untuk simpanan anda.

Nama saya adalah Dr Sazlina Shariff Ghazali, dan sedang menjalankan projek penyelidikan bersama Profesor Dr Colette Browning dari Sekolah Penjagaan Kesihatan Primer and Prof Madya Dr Shajahan Yasin, dari Sekolah Perubatan dan Sains Kesihatan, untuk memperoleh ijazah Doktor Falsafah Perubatan di Monash University. Ini bermakna saya akan melakukan penulisan tesis, sama seperti penulisan sebuah buku yang ringkas.

Anda telah menghubungi kami untuk menyertai kajian ini setelah membaca iklan kami. Anda telah dipilih untuk menyertai kajian ini kerana anda berumur 60 tahun ke atas dan mengidap diabetes. dan tidak melibatkan diri dalam kegiatan jasamani.

Tujuan Kajian

Saya menjalankan kajian ini untuk mengetahui jika kegiatan berjalan kaki berkesan untuk menggalakkkan warga tua yang tidak aktif dan mengidap diabetes menyertai kegiatan jasmani secara tetap dan meningkatkan kesihatan mereka.

Faedah yang dapat diperoleh

Anda akan menyertai kegiatan jasmani secara tetap yang mempunyai faedah kesihatan untuk rawatan diabetes dalam pengawalan gula dan mencegah komplikasi. Di samping itu, anda akan menjalani penilaian kesihatan di mana ia membantu dalam mengenalpasti tahap kesihatan terkini anda.

Apakah yang terlibat dalam kajian ini?

Kajian adalah selama 36 minggu dan terdiri daripada 3 kumpulan. Jika anda bersetuju untuk menyertai, anda akan dimasukkan dalam salah satu kumpulan secara rawak. Kumpulan 1 adalah kumpulan perbandingan dan akan menyertai program berjalan kaki setelah kumpulan yang lain selesai penyertaan. Kumpulan 2 akan menyertai kegiatan berjalan kaki secara tetap dan menerima maklumbalas mengenai kegiatan jasmani mereka daripada kumpulan penyelidikan. Kumpulan 3 akan menyertai program ini dan menerima maklumbalas serta sokongan dari pemimpin rakan sebaya. Anda dikehendaki melakukan kegiatan berjalan kaki sekurang-kurangnya 30 minit sehari, 5 hari seminggu atau 150 minit seminggu. Anda akan menjalani penilaian kesihatan untuk memastikan kelayakan penyertaan dalam meningkatkan tahap kegiatan jasmani anda.

Pada permulaan kajian ini, anda perlu menjalani penilaian kesihatan yang merangkumi ukuran tekanan darah, indeks jisim badan, komposisi badan, ujian keseimbangan, dan berjalan selama 6 minit dan jaraknya diukur. Anda perlu melengkapkan 5 borang soalselidik dan meneruskan rawatan diabetes seperti biasa. Anda perlu menjalani ujian darah sebanyak 4 kali untuk kawalan gula dan kolesterol. Semua kumpulan akan mempunyai 6 lawatan ke klinik sepanjang 24 minggu ini. Semua peserta akan memakai *pedometer* selama 7 hari pada 4 masa yang berbeza. Peserta dalam kumpulan 2 dan 3 akan mencatatkan kegiatan jasmani harian mereka dalam diari selam 12 minggu. Di samping itu, peserta dalam kumpulan 3 akan menerima 3 panggilan telefon dari pemimpin rakan sebaya mereka. Semua penilaian kesihatan, ujian keseimbangan dan berjalan kaki selama 6 minit dan mengisi 5 borang soalselidik akan juga dilakukan untuk semua peserta pada minggu ke-12, ke-24 dan ke-36.

Berapa lamakah masa untuk kajian ini?

Kajian ini dilaksanakan selama 9 bulan. Tiga bulan untuk kegiatan jasmani dan susulan pada minggu ke-24 dan ke-36. Setiap lawatan di klinik akan mengambil masa lebih kurang sejam.

Kesulitan/ketidakselesaan

Kajian ini tidak akan menimbulkan sebarang ketidakselesaan atau kesan bahaya sebab anda akan dinilai terlebih dahulu sebelum menyertai kegiatan jasmani. Panduan dan nasihat untuk beriadah secara selamat akan diberikan. Jika berlaku sebarang perkara di luar jangkaan anda perlu menghubungi kumpulan penyelidikan (Dr Sazlina Shariff Ghazali di talian 012 232 5659) dan rujukan yang wajar akan dilakukan. Rujukan akan dilakukan juga jika keputusan soalselidik kurang memuaskan. Semua maklumat yang diperoleh dari kajian ini akan disimpan tanpa nama dan dirahsiakan.

Pembayaran

Kos pengangkutan akan dibiaya untuk penyertaan.

Bolehkah saya menarik diri dari kajian ini?

Penyertaan dalam kajian ini adalah secara sukarela dan tidak dipaksa untuk memberi keizinan. Penjagaan perubatan anda tidak akan terjejas sebab keputusan penyertaan anda dan anda dibenarkan untuk menarik diri pada bila-bila masa semasa kajian ini.

Kerahsiaan

Nama atau identiti anda akan dirahsiakan semasa analisa keputusan, dalam penulisan tesis dan artikel penerbitan.

Penyimpanan data

Penyimpanan data kajian akan disimpan dengan mematuhi undang-undang Universiti di premis Universiti dalam almari/kabinet fail berkunci selama 5 tahun. Satu laporan dari kajian ini mungkin akan dihantar untuk penerbitan, tetapi peserta tidak akan dikenalpasti dalam laporan itu.

Keputusan

Jika anda ingin mengetahui keputusan kajian ini, sila hubungi Dr Sazlina Shariff Ghazali melalui no. telefon bimbit: 012 232 5659 atau email di: ssha145@student.monash.edu. Keputusan kajian boleh diperoleh dari 1 Ogos 2012 hingga 28 Februari 2013.

Jika anda ingin menghubungi penyelidik-penyelidik menegnai sebarang perkara berkaitan kajian, sila hubungi ketua penyelidik:	Jika anda mempunyai sebarang aduan berkaitan cara kajian ini <insert your project number here> dijalankan, sila hubungi:
Professor Dr Colette Browning Healthy Ageing Research Unit Faculty of Medicine, Nursing and Health Sciences Postal address: School of Primary Health Care, Building 1, 270 Ferntree Gully Rd, Notting Hill, VIC 3168. [redacted] Atau Dr Sazlina Shariff Ghazali PhD-Med Candidate School of Medicine and Health Sciences Monash University Sunway Campus Malaysia. [redacted]	Tang Hooi Ru, Joyce Head of Planning and Research Management Monash University Jalan Lagoon Selatan Bandar Sunway Selangor Darul Ehsan [redacted]

Terima kasih.

[redacted]

Dr Sazlina Shariff Ghazali

APPENDIX R: CONSENT FORM FOR RCT PARTICIPANTS

R.1. Consent form for RCT participants – English

MONASH University

Consent Form – *Randomised Controlled Trial*

Title: Promoting Physical Activity in Sedentary Older Malays with Type 2 Diabetes Mellitus

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to be interviewed by the researcher	☐ Yes	☐ No
I agree to have clinical assessments by the researcher including measurements of weight, height, waist circumference, body fat, blood pressure, blood sugar level, cholesterol level, balance test and to walk for 6 minutes	☐ Yes	☐ No
I agree to complete questionnaires asking me about physical activity, social support, general wellbeing, quality of life and confidence to exercise	☐ Yes	☐ No

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project. My medical care will not be affected by the decision to participate and I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

I understand that any data that the researcher extracts from interview and questionnaire for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

I understand that data from the study and questionnaire will be kept in a secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name : My Kad No.:
Signature :
Date :

Witness's name : My Kad No.:
Signature :
Date :

R.2. Consent form for RCT participants – Bahasa Malaysia

MONASH University

Borang Persetujuan – Kajian Terkawal Secara Rawak

Tajuk: Galakan Kegiatan Jasmani Di Kalangan Warga Tua Yang Tidak Aktif dan Mengidap Diabetes Jenis Ke-2

NOTA: Borang persetujuan ini akan bersama penyelidik Monash University untuk simpanan rekod mereka

Saya bersetuju untuk mengambil bahagian dalam projek penyelidikan Monash University seperti di atas. Saya telah diberi penjelasan dan telah membaca kenyataan penerangan mengenai projek ini. Saya memahami dengan bersetuju untuk mengambil bahagian bermakna:

Saya bersetuju untuk di temubual oleh penyelidik	☐ Ya	☐ Tidak
Saya besetuju untuk menjalani penilaian kesihatan oleh penyelidik termasuk ukuran berat badan, ketinggian, ukur lilit pinggang, peratusan lemak badan, tekanan darah, tahap gula dalam darah, kolesterol, ujian keseimbangan dan berjalan selama 6 minit	☐ Ya	☐ Tidak
Saya bersetuju untuk melengkapkan borang soalselidik menegenai aktiviti fizikal, sokongan sosial, kesejahteraan hidup dan keyakinan bersenam	☐ Ya	☐ Tidak

Saya memahami penyertaan ini adalah secara sukarela, di mana saya boleh memilih untuk tidak menyertai projek ini. Penjagaan perubatan saya tidak akan terjejas di atas keputusan penyertaan saya dan saya boleh menarik diri pada bila-bila masa tanpa didenda atau mengalami kerugian.
Saya memahami bahawa maklumat diperoleh semasa kajian untuk kegunaan dalam laporan atau penerbitan, tidak mempunyai nama atau ciri yang boleh dikenalpasti.
Saya memahami bahawa maklumat diperoleh semasa semasa kajian akan disimpan dalam tempat terjamin selamat dan hanya berhak digunakan oleh kumpulan penyelidikan. Saya juga memahami bahawa maklumat ini akan dimusnahkan selepas 5 tahun kecuali saya membenarkan untuk kegunaan penyelidikan di masa hadapan.

Nama peserta : No. My Kad:
Tandatangan :
Tarikh :

Nama saksi : No. My Kad:
Tandatangan :
Tarikh :

APPENDIX S: PHYSICAL ACTIVITY SCALE FOR ELDERLY

S.1. Physical Activity Scale For Elderly – English

We would like to know the time spend doing daily activities such as leisure time, household-related and work-related activities, *over the past seven days*. Please answer the questions, which you think most nearly applies to you. It is important that you try to answer ALL the questions.

Thank you very much for your co-operation.

LEISURE TIME ACTIVITIES

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handicrafts?

[0] never	[1] seldom (1-2 days)	[2] sometimes (3-4 days)	[3] often (5-7 days)
↓	↓	↓	↓

Go to Q.2

1a. What were these activities?

____

1b. On average, how many hours per day did you get engage in these sitting activities <u>on these days</u>?

[1] less than 1 hour [2] 1 but less than 2 hours
[3] 2-4 hours [4] more than 4 hours

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example for fun or exercise, walking to work, walk to the shop etc?

[0] never	[1] seldom (1-2 days)	[2] sometimes (3-4 days)	[3] often (5-7 days)
↓	↓	↓	↓

Go to Q.3

2a. On average, how many hours per day did you spend walking <u>on these days</u>?

[1] less than 1 hour [2] 1 but less than 2 hours
[3] 2-4 hours [4] more than 4 hours

3. Over the past 7 days, how often did you engage in <u>light</u> sport or recreational activities such as 'light' cycling on exercise bike, golf with cart, fishing or other similar activities?

[0] never — Go to Q.4

[1] seldom (1-2 days)

[2] sometimes (3-4 days)

[3] often (5-7 days)

3a. What were these activities?

____

3b. On average, how many hours per day did you engage in these light sport or recreational activities <u>on these days</u>?

[1] less than 1 hour [2] 1 but less than 2 hours
[3] 2-4 hours [4] more than 4 hour

4. Over the past 7 days, how often did you engage in <u>moderate</u> sport or recreational activities such as brisk walking, badminton, ping pong, line dancing/po cho- po cho, golf without a cart, or other similar activities?

[0] never — Go to Q.5

[1] seldom (1-2 days)

[2] sometimes (3-4 days)

[3] often (5-7 days)

4a. What were these activities?

____

4b. On average, how many hours per day did you engage in these moderate sport or recreational activities <u>on these days</u>?

[1] less than 1 hour [2] 1 but less than 2 hours
[3] 2-4 hours [4] more than 4 hours

5. Over the past 7 days, how often did you engage in <u>strenuous</u> sport or recreational activities such as jogging, swimming, cycling, aerobic dancing or other similar activities?

[0] never

[1] seldom (1-2 days)

[2] sometimes (3-4 days)

[3] often (5-7 days)

Go to Q.6

5a. What were these activities?

____

5b. On average, how many hours per day did you engage in these strenuous sport or recreational activities on these days?

[1] less than 1 hour [2] 1 but less than 2 hours
[3] 2-4 hours [4] more than 4 hours

6. Over the past 7 days, how often did you exercise specifically to increase muscle strength and endurance such as lifting weights or heavy objects or push ups etc?

[0] never
[1] seldom (1-2 days)
[2] sometimes (3-4 days)
[3] often (5-7 days)

Go to Q.7

6a. What were these activities?

____

6b. On average, how many hours per day did you engage in exercise the past increase muscle strength or endurance on these days?

[1] less than 1 hour [2] 1 but less than 2 hours
[3] 2-4 hours [4] more than 4 hours

HOUSEHOLD ACTIVITIES

7. During the past 7 days, have you done any light housework such as dusting or washing dishes?

[1] No [2] Yes

8. During the past 7 days, have you done any heavy housework or chores such as vacuuming, mopping the floor or washing windows?

[1] No [2] Yes

9. During the past 7 days, did you engage in any of the following activities?

		No	Yes
a.	Home repairs like painting, wallpapering, electrical etc	0	1
b.	Lawn work or yard care including leave removal	0	1
c.	Outdoor gardening	0	1
d.	Caring for another person such as dependent grand children/ spouse or another adult	0	1

WORK-RELATED ACTIVITIES

10. During the past 7 days, did you work for pay or as a volunteer?

[1] No [2] Yes

10a. How many hours per week did you work for pay or as a volunteer? _______ hours

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

(1) Mainly sitting with light arm movements (e.g. office work, bus driver, taxi driver etc)
(2) Sitting or standing with some walking (e.g. cashier, general office worker etc.)
(3) Walking with some handling of materials generally weighing less than 25 kg (e.g. mailman, waitress, construction worker, heavy tool and machinery worker)
(4) Walking and heavy manual work often requiring handling of materials weighing over 25 kg (e.g. lumbarjack, farming or general labourer)

S.2. Physical Activity Scale For Elderly – Bahasa Malaysia

Pihak kami ingin mengetahui masa anda luangkan untuk aktiviti harian seperti aktiviti di masa lapang, berkaitan dengan kerja rumah dan berkaitan pekerjaan, *dalam tempoh tujuh hari yang lalu*.

AKTIVITI MASA LAPANG

1. Dalam tempoh tujuh hari yang lalu, berapa kerap anda melakukan aktiviti sambil duduk seperti membaca, menonton TV atau kraftangan?

[0] Tidak pernah ↓ Terus ke S.2

[1] Jarang (1-2 hari) ↓

[2] Kadang-kadang (3-4 hari) ↓

[3] Selalu (5-7 hari) ↓

1a. Apakah aktiviti-aktiviti itu?

____

1b. Secara purata, berapa jam sehari anda melakukan aktiviti sambil duduk ini, pada hari-hari di atas?

[1] kurang dari sejam

[2] Sejam tetapi kurang dari 2 jam

[3] 2-4 jam

[4] lebih dari jam

2. Dalam tempoh 7 hari yang lalu, berapa kerap anda berjalan di luar rumah atau di perkarangan rumah untuk apa-apa tujuan? Contohnya, untuk bersiar-siar atau senaman, jalan ke tempat kerja, berjalan ke kedai dll?

[0] Tidak pernah ↓ Terus ke S.3

[1] Jarang (1-2 hari) ↓

[2] Kadang-kadang (3-4 hari) ↓

[3] Selalu (5-7 hari) ↓

2a. Secara purata, berapa jam sehari anda berjalan pada hari-hari di atas?

[1] kurang dari sejam

[2] Sejam tetapi kurang dari 2 jam

[3] 2-4 jam

[4] lebih dari jam

3. Dalam tempoh 7 hari yang lalu, berapa kerap anda melibatkan diri dalam sukan atau aktiviti riadah ringan seperti berkayuh ringan atas basikal senaman, golf menaiki "buggy", yoga, tai chi, memancing atau aktiviti seumpamanya?

[0] Tidak pernah	[1] Jarang (1-2 hari)	[2] Kadang-kadang (3-4 hari)	[3] Selalu (5-7 hari)
↓	↓	↓	↓

Terus ke S.4

3a. Apakah aktiviti-aktiviti itu?

____

3b. Secara purata, berapa jam sehari anda melibatkan diri dalam sukan atau aktiviti riadah ringan pada hari-hari di atas?

[1] kurang dari sejam   [2] Sejam tetapi kurang dari 2 jam

[3] 2-4 jam   [4] lebih dari jam

4. Dalam tempoh 7 hari yang alu, berapa kerapkah anda melibatkan diri dalam sukan atau aktiviti riadah sederhana seperti berjalan pantas, badminton, ping pong, menari po cho-po cho, golf sambil berjalan atau aktivit seumpamanya?

[0] Tidak pernah	[1] Jarang (1-2 hari)	[2] Kadang-kadang (3-4 hari)	[3] Selalu (5-7 hari)
↓	↓	↓	↓

Terus ke S.5

4a. Apakah aktiviti-aktiviti itu?

____

4b. Secara purata, berapa jam sehari anda melibatkan diri dalam sukan atau aktiviti riadah sederhana pada hari-hari di atas?

[1] kurang dari sejam   [2] Sejam tetapi kurang dari 2 jam

[3] 2-4 jam   [4] lebih dari jam

5. Dalam tempoh 7 hari yang lalu, berapa kerapkah anda melibatkan diri dalam sukan atau aktiviti riadah berat seperti berlari anak, berenang, menari aerobic atau aktiviti seumpamanya?

[0] Tidak pernah	[1] Jarang (1-2 hari)	[2] Kadang-kadang	[3] Selalu (5-7 hari)

↓

(3-4 hari)

Terus ke S.6

5a. Apakah aktiviti-aktiviti itu?

____

5b. Secara purata, berapa jam sehari anda melibatkan diri dalam sukan atau aktiviti riadah berat pada hari-hari di atas?

[1] kurang dari sejam [2] Sejam tetapi kurang dari 2 jam

[3] 2-4 jam [4] lebih dari jam

6. Dalam tempoh 7 hari yang lalu, berapa kerapkah anda bersenam bertujuan untuk meningkatkan kekuatan dan ketahan otot seperti mengangkat atau menolak barang berat atau tekan tubi dll?

[0] Tidak pernah [1] Jarang (1-2 hari) [2] Kadang-kadang (3-4 hari) [3] Selalu (5-7 hari)

Terus ke S.7

6a. Apakah aktiviti-aktiviti itu?

____

6b. Secara purata, berapa jam sehari anda melibatkan diri dalam senaman untuk meningkatkan kekuatan dan ketahanan otot pada hari-hari di atas?

[1] kurang dari sejam [2] Sejam tetapi kurang dari 2 jam

[3] 2-4 jam [4] lebih dari jam

AKTIVITI BERKAITAN KERJA RUMAH

7. Dalam tempoh 7 hari yang lalu, adakah anda melakukan sebarang kerja rumah yang ringan seperti mengelap habuk atau membasuh pinggang mangkuk?

[1] Tidak [2] Ya

8. Dalam tempoh 7 hari yang lalu, adakah anda melakukan kerja rumah yang berat

seperti memvakum, mencuci lantai atau mencuci tingkap?

[1] Tidak [2] Ya

9. Dalam tempoh 7 hari yang lalu, adakah anda melibatkan diri dalam aktiviti-aktiviti berikut?

		Tidak	Ya
a.	Kerja pembaikan rumah seperti mengecat, menampal kertas dinding, kerja elektrik dll.	0	1
b.	Kerja laman atau jagaan laman seperti membuang daun-daun dll	0	1
c.	Berkebun	0	1
d.	Menjaga orang lain seperti cucu, pasangan atau orang dewasa lain yang tidak boleh berdikari	0	1

AKTIVITI BERKAITAN PEKERJAAAN

10. Dalam tempoh 7 hari yang lalu, adakah anda melakukan kerja untuk bayaran atau sebagai sukarelawan?

[1] Tidak [2] Ya

10a. Berapa jam seminggu anda berkerja untuk bayaran atau sebagai sukarelawan? _______ jam

10b. Yang mana di antara berikut paling sesuai untuk menerangkan jumlah aktiviti fizikal yang diperlukan semasa kerja atau sebagai sukarelawan?

(1) Kebanyakkannya melibatkan posisi duduk dengan sedikit pergerakan tangan. (Cthnya: kerja di pejabat, pemandu bus, pemandu teksi dll.)
(2) Duduk atau berdiri dan kadang-kadang berjalan. (Cthnya: juruwang, pekerja am dll.)
(3) Berjalan sambil memegang barang di mana beratnya kurang dari 25 kg. (Cthnya: posmen, pelayan, pekerja binaan, pekerja jentera berat)
(4) Berjalan dan melakukan kerja kasar yang berat dan perlu memegang barang di mana beratnya lebih dari 25 kg. (Cthnya: pembalak, petani, atau buruh am)

APPENDIX T: SF-12 HEALTH SURVEY

T.1. SF-12 Health Survey – English

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Moderate activities</u>, such as moving a table, sweeping, playing badminton, or gardening	☐ **1**	☐ **2**	☐ **3**
b Climbing <u>several</u> flights of stairs	☐ **1**	☐ **2**	☐ **3**

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
b Did you have a lot of energy?	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
c Have you felt downhearted and depressed?	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

T.2. SF-12 Health Survey – Bahasa Malaysia

Soal selidik ini meminta pandangan anda mengenai kesihatan anda. Maklumat ini akan memantau keadaan anda dan bagaimana anda dapat melakukan aktiviti biasa anda dengan baik. *Terima kasih kerana melengkapkan tinjauan ini!*

Untuk setiap soalan berikut, sila tandakan ☒ di dalam satu kotak yang paling baik menerangkan jawapan anda.

1. Secara umum, adakah anda akan mengatakan bahawa kesihatan anda adalah:

Paling baik	Sungguh baik	Baik	Sederhana	Tidak baik
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

O.2. Soalan-soalan berikut adalah mengenai aktiviti yang mungkin akan dilakukan oleh anda pada hari biasa. Adakah <u>anda terhad</u> di dalam sebarang aktiviti berikut kerana <u>keadaan kesihatan anda sekarang</u>?
Jika ya, sejauh mana?

	Ya, terbatas dengan banyaknya	Ya, terbatas dengan sedikitnya	Tidak, tidak terbatas sama sekali
a <u>Aktiviti sederhana</u>, seperti mengalihkan meja, menyapu, bermain badminton atau bercucuk tanam…….	☐ **1**………	☐ **2** ………	☐ **3**
b Menaiki <u>beberapa</u> larian tangga…………………………..	☐ **1**………	☐ **2**………	☐ **3**

O.3. Dalam masa <u>4 minggu yang lalu</u>, berapa kerapkah anda mengalami sebarang masalah berikut dengan pekerjaan atau aktiviti harian tetap anda yang lain <u>akibat daripada kesihatan fizikal anda</u>?

	Setiap masa	Kebanyakan masa	Kadang-kala	Sedikit masa	Tidak sama sekali
a <u>Mencapai kurang</u> daripada yang diingini	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
b Terbatas dari segi <u>jenis</u> pekerjaan atau aktiviti lain	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

O.4. Dalam masa <u>4 minggu yang lalu</u>, berapa kerapkah anda mengalami sebarang masalah berikut dengan pekerjaan atau aktiviti harian tetap anda yang lain <u>akibat daripada sebarang masalah emosi</u> (seperti merasa murung atau bimbang)?

	Setiap masa	Kebanyakan masa	Kadang-kala	Sedikit masa	Tidak sama sekali
a <u>Mencapai kurang</u> daripada yang diingini	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
b Melakukan pekerjaan atau aktiviti lain dengan <u>kurang berhati-hati daripada biasa</u>	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

O.5. Dalam masa <u>4 minggu yang lalu</u>, sejauh manakah <u>kesakitan</u> telah mengganggu pekerjaan biasa anda (termasuk pekerjaan di luar rumah dan kerja rumah)?

Tidak sama sekali	Sedikit	Sederhana	Agak banyak	Amat sangat
☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

O.6. Soalan-soalan ini adalah mengenai perasaan dan keadaan anda dalam masa 4 minggu yang lalu. Untuk setiap soalan, sila berikan satu jawapan yang paling hampir dengan keadaan perasaan anda. Dalam masa 4 minggu yang lalu, berapa kerapkah…

	Setiap masa	Kebanyakan masa	Kadang-kala	Sedikit masa	Tiada sama sekali
a Pernahkah anda merasa tenang dan aman?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Adakah anda sungguh bertenaga?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Pernahkah anda merasa sedih dan murung?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

O.7. Dalam masa 4 minggu yang lalu, berapa kerapkah kesihatan fizikal atau masalah emosi telah mengganggu aktiviti sosial anda (seperti melawat sahabat-handai, sanak-saudara, dll.)?

Setiap masa	Kebanyakan masa	Kadang-kala	Sedikit masa	Tiada sama sekali
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

APPENDIX U: GENERAL HEALTH QUESTIONNAIRE-12

U.1. General Health Questionnaire-12 – English

We should like to know if you have had any medical complaints, and how your health has been in general, *over the past few weeks*.

	HAVE YOU RECENTLY:				
1	been able to concentrate on whatever you're doing?	Better than usual	Same as usual	Less than usual	Much less than usual
2	lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
3	felt that you are playing a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
4	felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less capable
5	felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
6	felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
7	been able to enjoy your normal day-to-day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
8	been able to face up to your problems?	More so than usual	Same as usual	Less able than usual	Much less able
9	been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
10	been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
11	been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual
12	been feeling reasonably happy, all things considered?	More so than usual	About same as usual	Less so than usual	Much less than usual

U.2. General Health Questionnaire-12 – Bahasa Malaysia

Pihak kami ingin mengetahui mengenai masalah perubatan anda sekarang atau kebelakangan ini, bukan yang lampau secara am *pada beberapa minggu yang lepas*.

	BARU-BARU INI ADAKAH ANDA:				
1	dapat menumpukan perhatian pada apa yang anda lakukan?	Baik dari biasa	Sama seperti biasa	Kurang dari biasa	Sangat kurang dari biasa
2	kurang tidur kerana kerisauan?	Tidak langsung	Tidak lebih dari biasa	Lebih dari biasa	Sangat lebih dari biasa
3	merasakan anda memainkan peranan yang tidak berguna dalam sesuatu perkara?	Lebih dari biasa	Sama seperti biasa	Tidak berguna dari biasa	Sangat tidak berguna
4	merasai berupaya membuat keputusan dalam sesuatu perkara?	Lebih dari biasa	Sama seperti biasa	Kurang dari biasa	Sangat kurang dari biasa
5	sentiasa merasai dalam ketegangan?	Tidak langsung	Tidak lebih dari biasa	Lebih dari biasa	Sangat lebih dari biasa
6	merasai anda tidak boleh mengatasi masalah anda?	Tidak langsung	Tidak lebih dari biasa	Lebih dari biasa	Sangat lebih dari biasa
7	dapat menikmati aktiviti harian biasa anda?	Lebih dari biasa	Sama seperti biasa	Kurang dari biasa	Sangat kurang dari biasa
8	Berupaya menghadapi masalah anda?	Lebih dari biasa	Sama seperti biasa	Kurang berupaya dari biasa	Sangat kurang berupaya
9	merasai tidak gembira atau sedih?	Tidak langsung	Tidak lebih dari biasa	Lebih dari biasa	Sangat lebih dari biasa
10	hilang keyakinan diri?	Tidak langsung	Tidak lebih dari biasa	Lebih dari biasa	Sangat lebih dari biasa
11	memikirkan diri anda tidak berharga?	Tidak langsung	Tidak lebih dari biasa	Lebih dari biasa	Sangat lebih dari biasa
12	merasai agak gembira?	Lebih dari biasa	Sama seperti biasa	Kurang dari biasa	Sangat kurang dari biasa

APPENDIX V: MULTIDIMENSIONAL SCALE FOR PERCEIVED SOCIAL SUPPORT

V.1. Multidimensional Scale For Perceived Social Support - English

We are interested in how you feel about the following statements. Listen carefully to each statement. Indicate how you feel about each statement.

"1" if Very Strongly Disagree
"2" if Strongly Disagree
"3" if Mildly Disagree
"4" if Neutral
"5" if Mildly Agree
"6" if Strongly Agree
"7" if Very Strongly Agree

1.	There is a special person who is around when I am in need.	1	2	3	4	5	6	7
2.	There is a special person with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
3.	My family really tries to help me.	1	2	3	4	5	6	7
4.	I get the emotional help and support I need from my family.	1	2	3	4	5	6	7
5.	I have a special person who is a real source of comfort to me.	1	2	3	4	5	6	7
6.	My friends really try to help me.	1	2	3	4	5	6	7
7.	I can count on my friends when things go wrong.	1	2	3	4	5	6	7
8.	I can talk about my problems with my family.	1	2	3	4	5	6	7
9.	I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
10.	There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7
11	My family is willing to help me make decisions.	1	2	3	4	5	6	7
12.	I can talk about my problems with my friends.	1	2	3	4	5	6	7

V.2. Multidimensional Scale For Perceived Social Support – Bahasa Malaysia

Kami berminat untuk mengetahui perasaan anda terhadap kenyataan di bawah. Sila dengar setiap kenyataan dengan teliti. Nyatakan perasaaan anda mengenai setiap kenyataan di bawah.

"1" jika Teramat Sangat Tidak Setuju "2" jika Sangat Tidak Setuju
"3" jika Sedikit Tidak Setuju "4" jika Berkecuali
"5" jika Sedikit Setuju "6" jika Sangat Setuju
"7" jika Teramat Sangat Setuju

1.	Terdapat seseorang yang sangat istimewa apabila saya memerlukannya.	1	2	3	4	5	6	7
2.	Terdapat seseorang yang istimewa untuk berkongsi kebahagiaan dan kedukaan saya.	1	2	3	4	5	6	7
3.	Keluarga saya berusaha untuk membantu saya.	1	2	3	4	5	6	7
4.	Saya mendapat bantuan dan sokongan emosi yang saya perlukan dari keluarga saya.	1	2	3	4	5	6	7
5.	Saya mempunyai seseorang yang istimewa yang menjadi tempat saya mengadu.	1	2	3	4	5	6	7
6.	Rakan-rakan saya sangat membantu saya.	1	2	3	4	5	6	7
7.	Saya boleh mengharapkan rakan-rakan saya apabila di dalam keksusahan.	1	2	3	4	5	6	7
8.	Saya boleh bercakap dengan keluarga saya apabila ada masalah.	1	2	3	4	5	6	7
9.	Saya mempunyai rakan-rakan yang boleh berkongsi kebahagiaan dan kedukaan saya.	1	2	3	4	5	6	7
10.	Terdapat seseorang yang istimewa dalam hidup saya yang mengambil berat terhadap perasaan saya.	1	2	3	4	5	6	7
11	Keluarga saya sanggup membantu saya dalam membuat sesuatu keputusan.	1	2	3	4	5	6	7
12.	Saya boleh bercakap dengan rakan-rakan saya mengenai masalah saya.	1	2	3	4	5	6	7

APPENDIX W: SELF-EFFICACY FOR EXERCISE SCALE

W.1. Self-Efficacy For Exercise Scale – English

How confident are you right now that you could exercise five times per week for 30 minutes if:

		Not confident	Very confident
1.	The weather was bothering you	1 2 3 4 5 6 7 8 9 10	
2.	Your were bored by the program or activity	1 2 3 4 5 6 7 8 9 10	
3.	You felt pain when exercising	1 2 3 4 5 6 7 8 9 10	
4.	You had to exercise alone	1 2 3 4 5 6 7 8 9 10	
5.	You did not enjoy it	1 2 3 4 5 6 7 8 9 10	
6.	You were too busy with other activities	1 2 3 4 5 6 7 8 9 10	
7.	You felt tired	1 2 3 4 5 6 7 8 9 10	
8.	You felt stressed	1 2 3 4 5 6 7 8 9 10	
9.	You felt depressed	1 2 3 4 5 6 7 8 9 10	

W.2. Self-Efficacy For Exercise Scale – Bahasa Malaysia

Bagaimanakah keyakinan anda untuk bersenam 3 kali sehari selama 20 minit, jika:

		Tidak yakin	Sangat Yakin
1.	Cuaca mengganggu anda	1 2 3 4 5 6 7 8 9 10	
2.	Anda merasa bosan dengan program atau aktiviti	1 2 3 4 5 6 7 8 9 10	
3.	Anda kesakitan ketika bersenam	1 2 3 4 5 6 7 8 9 10	
4.	Anda terpaksa bersenam bersendirian	1 2 3 4 5 6 7 8 9 10	
5.	Anda tidak menikmatinya	1 2 3 4 5 6 7 8 9 10	
6.	Anda terlalu sibuk untuk aktviti lain	1 2 3 4 5 6 7 8 9 10	
7.	Anda merasa penat	1 2 3 4 5 6 7 8 9 10	
8.	Anda merasa tertekan/stres	1 2 3 4 5 6 7 8 9 10	
9.	Anda merasa sedih	1 2 3 4 5 6 7 8 9 10	

APPENDIX X: CASE REPORT FORMS

X.1. Enrolment CRF

MONASH University

CRF: RCT– Baseline *(Asas)*

Participant's ID *(ID peserta)* : ____ – ___________

Date of visit *(Tarikh kunjungan)* : _________________

A. Socio-demography (*Socio-demografi)*

1. Date of birth *(Tarikh lahir)* : ___/___/___ (dd/mm/yyyy) *(hh/bb/ tttt)* Age : ______ year *(tahun)*

2. Gender (*Jantina)* :
   - ☐Male (*Lelaki)*[1]
   - ☐Female (*Perempuan)*[2]

3. Marital status (*taraf perkahwinan* :
   - ☐Single (*Bujang)*
   - ☐Married *(Berkahwin)*
   - ☐Divorced or Widowed(*Bercerai/duda/janda)*

4. Highest educational level (*Tahap pendidikan tertinggi)* :
   - ☐College/University (*Kolej/Universiti)*[1]
   - ☐Secondary education (*Sekolah menengah)*[2]
   - ☐Primary educatio *(Sekolah rendah)*[3]
   - ☐No formal education (*Tiada pendidikan formal)*[4]

5. Occupation (*Pekerjaan)* :
   - ☐Retiree *(Pesara)*[1]
   - ☐Pensioner *(Pencen)*[2]
   - ☐ Still working (*Masih bekerja)*[3]
   - ☐ Unemployed/housewife *(Tidak bekerja/surirumah)*[4]

6. Living arrangement (*Tinggal bersama)* :
   - ☐Spouse (Pasangan)/ children *(Anak-anak)*[1]
   - ☐Spouse and children (*Pasanagan dan anak-anak)*[2]
   - ☐Relatives or friends *(saudara atau kawan-kawan)*[3]
   - ☐Alone *(Sendirian)*[4]

7. Monthly household income (*Pendapatan seisi rumah dalam sebulan)* : RM ______________________/ month (*bulan)*

8. Smoking *(Merokok)* :
   - ☐ Current smoker *(Masih merokok)*[1] _________cigs/day *(batang rokok/hari)* ________ years *(tahun)*
   - ☐ Never *(Tidak pernah)*[2]
   - ☐Stopped *(berhenti)*[3] _____________ years *(tahun)*

B. Medical history *(Sejarah Perubatan)*

1.	Duration of diabetes *(Jangkamasa menghidap diabetes)*	:	________________ years (*tahun*)	Verification *(Pengesahan)*: Diagnosed in: ___________ (year)
2.	Co-morbid conditions *(penyakit lain)*	:	☐ Hypertension[1] ☐ Dyslipidaemia[2] ☐ Asthma[3] ☐ COPD[4] ☐ Osteoarthritis[4] ☐ Others[5] ______________________	______________________________ ______________________________ ______________________________ ______________________________
3.	Treatment for diabetes *(Rawatan diabetes)*	:	☐ Diet (*Pemakanan)*[1] ☐ Exercise (*Senaman)*[2] ☐ Oral agents (*Ubatan pil)*[3] ☐ Insulin [4]	______________________________ ______________________________ ______________________________ ______________________________
4.	List of medications	:	____________________________ ____________________________ ____________________________	___________________________________ ___________________________________ ___________________________________
5.	Self-blood glucose monitoring	:	☐ Done (*Ada)*[1] ☐ Not done *(Tiada)*[2]	
6.	Complementary and alternative medication *(Ubatan tradisional)*	:	☐ Yes (*Yes)*[1] ☐ No *(Tidak)*[2]	Specify *(Nyatakan)*: ______________________________ ______________________________

C. Clinical information (*Maklumat Klinikal)*

1.	Blood pressure *(Tekanan darah)*	:	______ /_____ mmHg	Heart rate *(Nadi)*: ________beats/min
2.	Weight *(Berat)*	:	________ kg	Height *(Tinggi)* : ___________ metre
3.	BMI	:	________ kg/ m^2	
4.	Waist circumference *(Ukurlilit pinggang)*	:	________ cm	
5.	Body fat % *(% lemak badan)*	:	________ %	

6. 6 MWT : __________ metres

7. Timed up & go : __________ seconds

8. Glycosylated haemoglobin (HbA1c) : __________ % Date done *(Tarikh)*: __________

9. Lipid profile

Total cholesterol	:	___________ mmol/L	Date done *(Tarikh)*: __________
LDL-C	:	___________ mmol/L	
HDL-C	:	___________ mmol/L	
Triglycerides	:	___________ mmol/L	

D. Questionnaires (*Borang soal kaji selidik)*

1.	PASE	☐Done	☐Not done	Sitting activities: _______________ PA: ________________________________ PASE score: _____________________
2.	SF-12	☐Done	☐Not done	
3.	GHQ-12	☐Done	☐Not done	
4.	MDPSS	☐Done	☐Not done	
5.	SEES	☐Done	☐Not done	

E. Physical activity related information *(Maklumat berkaitan kegiatan jasmani)*

Barriers to physical activity? *(Halangan beriadah?)* :

- ☐ None *(Tiada)*[1]
- ☐ Afraid of falling *(Takut jatuh)*[2]
- ☐ No time *(Tiada masa)*[3]
- ☐ Health problems *(Masalah kesihatan)*[4]
- ☐ Busy with religious activities *(Sibuk dengan aktiviti keagamaan)*[5]
- ☐ Tired *(Penat)*[6]
- ☐ No interest *(Tidak berminat)*[7]
- ☐ No facilities *(Tiada kemudahan)*[8]
- ☐ Other reasons *(Sebab-sebab lain)*[9]

Specify *(Nyatakan)*:

____

Motivations to physical activity? *(Dorongan beriadah?)* :

- ☐ None *(Tiada)*[1]
- ☐ To be healthy *(Untuk sihat)*[2]
- ☐ For better health *(Untuk kesihatan yang lebih baik)*[3]
- ☐ Family support *(Sokongan keluarga)*[4]
- ☐ Other reasons *(Sebab-sebab lain)*[5]

Specify*(Nyatakan)*:

____

Baseline pedometer *(Bacaan pedometer asas)* : __________________________

Walking activity prescription *(Preskripsi aktiviti berjalan kaki)* [for intervention groups only] : ____
____
____
____
____

Date of next visit : _________________________

Completed by: ____

( )

X.2. Telephone calls CRF

MONASH University

CRF: Telephone call *(Panggilan telefon)* – Week *(Minggu)*: 2/6/10

Participant's ID *(ID peserta)* : ____ – __________
Date of call *(Tarikh panggilan)* : ________________
Time of call *(Masa membuat panggilan)* : ________________
Time call ends *(Masa panggilan tamat)* : ________________

Did you do walking activity? *(Adakah anda lakukan aktiviti berjalan kaki)* : Yes *(Ya)* / No *(Tidak)*

Do you have side effects from walking activity? *(Adakah mengalami kesan sampingan akibat aktiviti berjalan kaki?)* :

- ☐ None *(Tiada)* [1]
- ☐ Leg pain *(Sakit kaki)* [2]
- ☐ Fall *(Jatuh)*[3]
- ☐ Chest pain *(Sakit dada)* [4]
- ☐ Breathless *(sesak nafas)* [5]
- ☐ Dizzy *(Pening)* [6]
- ☐ Other reasons *(Sebab lain)*[7] Specify *(Nyatakan)*:
- ☐ Not applicable *(tidak berkenaan)*[8]

Actions *(Tindakan)*: __________ __________ __________ __________

Do you have any barriers to physical activity? *(Terdapatkah sebarang halangan untuk anda beriadah?)* :

- ☐ None *(Tiada)*[1]
- ☐ Afraid of falling *(Takut jatuh)* [2]
- ☐ No time *(Tiada masa)* [3]
- ☐ Health problems *(Masalah kesihatan)* [4]
- ☐ Busy with religious activities *(Sibuk dengan aktiviti keagamaan)* [5]
- ☐ Tired *(Penat)* [6]
- ☐ No interest *(Tidak berminat)*[7]
- ☐ No facilities *(Tiada kemudahan)* [8]
- ☐ Other reasons *(Sebab-sebab lain)*[9] Specify *(Nyatakan)*: ____________________________

What are your motivations for physical activity? *(Apakah dorongan beriadah anda?)* :

- ☐ None *(Tiada)*[1]
- ☐ To be healthy *(Untuk sihat)* [2]
- ☐ Family support *(Sokongan keluarga)* [3]
- ☐ Other reasons *(Sebab-sebab lain)* [4] Specify*(Nyatakan)*: ____________________________

Do you have any complaints? *(Anda mempunyai sebarang masalah lain?)* :

- ☐ Yes *(Ya)*[1] Specify *(Sila nyatakan)*: ______________________
- ☐ No *(Tidak)* [2]

Support given *(Sokongan diberi)* : ____
____
____

Date of next visit *(Tarikh susulan)* : ________________

Completed by *(Dilengkapkan oleh)*: ____________________________________

( )

X.3. Clinic visits CRF

MONASH University

CRF: Clinic Visits *(Borang Lawatan)* – Week *(Minggu)*: 4/8

Participant's ID *(ID peserta)* : ____ – __________

Date of visit *(Tarikh kunjungan)* : ________________

Walking activity *(Aktiviti berjalan kaki)* : Yes *(Ya)* / No *(Tidak)*				
Week *(Minggu)*	Duration *(Jumlah masa)* [min./week *(min./minggu)*]	Frequency *(Kekerapan)* [days/week*(hari/ minggu)*]	Pedometer reading *(Bacaan pedometer)*	No. of contacts with peers/week *(Kekerapan berhubung dengan rakan sebaya/seminggu)* [peer support group only]*:*
				0 1 2 3 4 5 6 7

Do you have side effects from walking activity? *(Adakah mengalami kesan sampingan akibat aktiviti berjalan kaki?)* :

☐No *(Tiada)* [1]
☐Leg pain *(Sakit kaki)* [2]
☐Fall *(Jatuh)*[3]
☐Chest pain *(Sakit dada)* [4]
☐Breathless *(sesak nafas)* [5]
☐Dizzy *(Pening)* [6]
☐Other reasons *(Sebab lain)*[7]
Specify *(Nyatakan)*:
☐Not applicable *(tidak berkenaan)*[8]

Actions *(Tindakan)*: ____________ ____________

Do you have any barriers to physical activity? *(Terdapatkah sebarang halangan untuk anda beriadah?)* :

☐None *(Tiada)*[1]
☐Afraid of falling *(Takut jatuh)* [2]
☐No time *(Tiada masa)* [3]
☐Health problems *(Masalah kesihatan)* [4]
☐Busy with religious activities *(Sibuk dengan aktiviti keagamaan)*[5]
☐Tired *(Penat)* [6]
☐No interest *(Tidak berminat)*[7]
☐No facilities *(Tiada kemudahan)* [8]
☐Other reasons *(Sebab-sebab lain)*[9]
Specify *(Nyatakan)*: ______________________________

What are your motivations for physical activity? *(Apakah dorongan beriadah anda?)* :

☐None *(Tiada)*[1]
☐To be healthy *(Untuk sihat)* [2]
☐For better health *(Untuk kesihatan yang lebih baik)* [3]
☐Family support *(Sokongan keluarga)* [4]
☐ Other reasons *(Sebab-sebab lain*
Specify*(Nyatakan)*: ____________________________

Do you have any complaints? *(Anda mempunyai sebarang masalah lain?)* :

☐Yes *(Ya)*[1] Specify *(Sila nyatakan)*: ________________________
☐No *(Tidak)* [2]

Support given *(Sokongan diberi)* : ______________________________
[peer support group only] ______________________________

Date of next visit *(Tarikh susulan)* : ______________

Completed by *(Dilengkapkan oleh)* : ______________________________
( )

X.4. Post-intervention CRF

MONASH University

CRF: RCT– Post-Intervention: Week (*Minggu*) 12 /24/ 36

Participant's ID *(ID peserta)* : ____ – __________

Date of visit *(Tarikh kunjungan)* : _________________

A. Medical history *(Sejarah Perubatan)*

1. For the past 3 months, did your doctor modify your medications? *(Pada 3 bulan yang lalu, adakah doktor anda mengubah ubatan diabetes anda?)* : ☐Yes *(Ya)*[1] ☐No *(Tidak)*[2]

   Verification: _________________

2. For the past 3 months, were you unwell because of your diabetes needing you to go to the clinic? *(Pada 3 bulan yang lalu, adakah anda tidak sihat dan perlu ke klinik kerana diabetes anda?)* : ☐Yes *(Ya)*[1] ☐No *(Tidak)*[2]

3. For the past 3 months, did you receive treatment for low sugar (hypoglycaemia)? *(Pada 3 bulan yang lalu, adakah anda perlu mendapatkan rawatan untuk hipoglisemia?)* : ☐Yes *(Ya)*[1] ☐No *(Tidak)*[2]

4. For the past 3 months, were you admitted to the hospital because of your diabetes? *(Pada 3 bulan yang lalu, adakah anda dimasukkan ke hospital kerana diabetes anda?)* : ☐Yes *(Ya)*[1] ☐No *(Tidak)*[2]

5. Medication list *(Senarai ubatan)* [From medical record] : _______________________

   ____

   ____

   ____

B. Physical activity *(Kegiatan jasmani)*

Walking activity *(Aktiviti berjalan kaki)*: Yes *(Ya)*[1] / No *(Tidak)*[2]

Walk *(Berjalan kaki)* : Alone *(Sendirian*)[1] / In a group *(Berkumpulan)*[2] / Not applicable*(Tidak berkenaan)*[3]

Other walking activity *(Aktiviti berjalan kaki lain)*: Mosque *(Masjid)*[1]/ Shop or market *(Kedai/pasar)*[2] / Others *(Lain-lain)* ____

Week *(Minggu)*	Duration *(Jumlah masa)* [min./week *(min./minggu)*]	Frequency *(Kekerapan)* [days/week *(hari/minggu)*]	Pedometer reading *(Bacaan pedometer)*	No. of contacts with peers/month *(Kekerapan berhubung dengan rakan sebaya/bulan)* [peer support group only]*:*
				0 1 2 3 4 5 6 7

Side effects from walking activity? *(Kesan sampingan akibat aktiviti berjalan kaki?)* :

☐No *(Tiada)* [1]
☐Leg pain *(Sakit kaki)* [2]
☐Fall *(Jatuh)*[3]
☐Chest pain *(Sakit dada)* [4]
☐Breathless *(sesak nafas)* [5]
☐Dizzy *(Pening)* [6]
☐Other reasons *(Sebab lain)*[7]
Specify *(Nyatakan)*:
☐Not applicable *(tidak berkenaan)*[8]

Actions *(Tindakan)*:
____
____
____
____

Barriers to physical activity? *(Halangan beriadah?)* :

☐None *(Tiada)*[1]
☐Afraid of falling *(Takut jatuh)* [2]
☐No time *(Tiada masa)* [3]
☐Health problems *(Masalah kesihatan)* [4]
☐Busy with religious activities *(Sibuk dengan aktiviti keagamaan)* [5]
☐Tired *(Penat)* [6]
☐No interest *(Tidak berminat)*[7]
☐No facilities *(Tiada kemudahan)* [8]
☐Other reasons *(Sebab-sebab lain)*[9]
Specify *(Nyatakan)*:
____

Motivations to physical activity? *(Dorongan beriadah?)* :

☐None *(Tiada)*[1]
☐To be healthy *(Untuk sihat)* [2]
☐For better health *(Untuk kesihatan yang lebih baik)* [3]
☐Family support *(Sokongan keluarga)* [4]
☐Other reasons *(Sebab-sebab lain* Specify*(Nyatakan)*:
____

C. Clinical information (*Maklumat Klinikal)*

1. Blood pressure *(Tekanan darah)* : ______ /_____ mmHg Heart rate *(Nadi)*: ____________beats/min
2. Weight *(Berat)* : ________ kg Height *(Tinggi)* : ___________ metre
3. BMI : ________ kg/ m^2
4. Waist circumference *(Ukurlilit pinggang)* : ________ cm

5. Body fat % *(% lemak badan)* : ________ %

6. 6 MWT : __________ metres

7. Timed up & go : __________ seconds

8. Glycosylated haemoglobin (HbA1c) : __________ % Date done *(Tarikh)*: __________

9. Lipid profile

Total cholesterol	:	___________ mmol/L	Date done *(Tarikh)*: __________
LDL-C	:	___________ mmol/L	
HDL-C	:	___________ mmol/L	
Triglycerides	:	___________ mmol/L	

D. Questionnaires (*Borang soal kaji selidik)*

1.	PASE	☐Done	☐Not done	Sitting activities/hours a day: ______________________ PA: ______________________ PASE score: ______________________
2.	SF-12	☐Done	☐Not done	
3.	GHQ-12	☐Done	☐Not done	
4.	MDPSS	☐Done	☐Not done	SO: _______ / Fam: _______ /Fri: _______
5.	SEES	☐Done	☐Not done	

Any complaints? *(Masalah lain?)* : ☐ Yes *(Ya)*[1] Specify *(Sila nyatakan)*: ______________________

☐ No *(Tidak)* [2]

Date of next visit : ________________

Completed by: ____________________________________

( )