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Physical Activity with Sports Scientist (PASS) programme to promote physical activity among patients with non-communicable diseases: a pragmatic randomised controlled trial protocol

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ABSTRACT

Physical activity (PA) effectively prevents and treats non-communicable diseases in clinical settings. PA promotion needs to be more consistent, especially in busy primary care. Sports scientists have the potential to support PA promotion in primary care. The Physical Activity with Sports Scientist (PASS) programme is created to personalise PA promotion led by a sports scientist in a primary care clinic. A pragmatic randomised controlled trial with two parallel groups will be conducted at a family medicine clinic. Physically inactive participants aged 35–70 years who have type 2 diabetes mellitus, hypertension or dyslipidaemia will be invited. The control group (n=60) will receive usual care. The intervention group (n=60) will receive the PASS programme and usual care. The PASS programme will consist of a tailored PA prescription after the physician's consultation at the first visit and monthly phone follow-ups. The primary outcome is the proportion of participants who have achieved the PA goal defined as aerobic activity (≥150 min/week of moderate to vigorous-intensity PA), muscle-strengthening activity (≥2 days/week of moderate or greater intensity) and multicomponent PA (≥2 days/week of moderate or greater intensity). Secondary outcomes are body composition and physical fitness. The primary and secondary outcomes will be measured and compared between the control and intervention groups at visit 1 (month 0: baseline measurements), visit 2 (months 3–4: follow-up measurements), visit 3 (months 6–8: end-point measurements) and visit 4 (months 9–12: continuing measurements). The study protocol was registered with the Thai Clinical Trials Registry.

Trial registration number: TCTR20240314001.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Clinicians' promotion of physical activity (PA) can potentially improve patients' PA; however, there is a lack of evidence on whether non-clinicians, such as sports scientists, can be trained to effectively support PA promotion in the primary care setting.

WHAT THIS STUDY ADDS

⇒ This study will investigate the effectiveness of integrating a sports scientist into the primary care team to increase the uptake and adherence to PA among patients with non-communicable diseases.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings from this study will add evidence to the emerging care model of 'task shifting' and 'team-based care' in the context of PA promotion for patients with non-communicable diseases in primary care.

INTRODUCTION

Physical activity (PA) prevents and treats non-communicable diseases (NCDs).[1–5] Promoting PA in primary care settings is a potential strategy to increase PA among patients. PA promotion contributes to positive perspectives among both healthcare providers and patients.[6 7] However, several factors are considered barriers to PA promotion in clinical settings for healthcare providers (eg, insufficient knowledge and skills), patients (eg, non-positive perceptions) and systems (eg, time constraints).[8 9] A recent systematic review reveals that less than 40% of primary care patients received PA counselling.[10] In addition, PA was discussed with only 65.5%, 56.8% and 41.6% of patients with diabetes mellitus (DM), overweight or obesity and hypertension (HT), respectively.[10]

A significant gap in PA promotion in primary care is developing team-based care coordination. Previous literature identified

common agents that promote PA in US clinical settings, such as physicians, nurses and nurse practitioners.[11] The literature sheds light on the opportunities to incorporate health educators and coaches to strengthen PA promotion in clinical settings.[11] Sports and exercise specialists, including sports and exercise physicians and allied health teams, can contribute their expertise to promote PA in clinical settings.[12 13] Another approach is PA referral schemes, established in several countries to connect patients with PA professionals or exercise specialists.[14] However, each country has different characteristics and roles of the health system and sports and exercise specialists.[15]

In Thailand, hospital-based outpatient clinics and community health centres (called subdistrict health-promoting hospitals) are the major settings for primary care in the public sector. Physicians and nurses execute hospital-based clinics and have more advanced resources and facilities than community health centres. Patients with NCDs can meet a physician, undergo laboratory tests and receive medications during the same visit to a hospital. Due to the concentration of most hospital resources, several services and initiative activities are commenced in hospitals, including health education and behavioural counselling. This is a common feature of hospital-based primary care in the country. However, PA promotion in primary care has not been well established nor supported by national guidelines.[6] PA referrals to community-based exercise services or specialists outside hospitals are uncommon.

A study conducted in hospital-based clinics in Thailand reflected the need for greater training, tools and teams (team-based care coordination) to support PA promotion in primary care.[6] Several strategies have been applied to identify educational opportunities and develop supporting tools in primary care.[16 17] These efforts have improved knowledge of PA promotion and helped overcome barriers to PA promotion in primary care.[18] Developing team-based care coordination for PA promotion in primary care is still lacking. Hence, physicians and nurses face several barriers to promoting PA. Non-clinicians, such as sports scientists, are well-trained professionals under formal curricula at the higher education level. Regarding knowledge and skills, sports scientists and clinicians can potentially improve PA promotion in primary care.[19]

There are some challenges to using sports scientists for PA promotion in the Thai context. Sports scientists have no professional licence to take care of patients solely. Therefore, setting up a PA referral scheme outside hospitals is less feasible. Integrating sports scientists into primary care teams to care for patients alongside clinicians is more practical. The structure of health services in the public sector of Thailand does not include sports scientists as a well-established position compared with dieticians or nutritionists. More evidence is needed to support the effectiveness of integrating sports scientists into the primary care team. These challenges raise an important research question regarding the effectiveness of PA promotion by sports scientists and physicians in primary care settings.

The Physical Activity with Sports Scientist (PASS) programme is newly designed to integrate sports scientists to support patients with NCDs. Based on physicians' brief counselling and precaution, sports scientists will tailor a PA programme, including aerobic activity, muscle-strengthening activity and multicomponent PA. This study aims to investigate the effectiveness of the PASS programme among physically inactive patients with NCDs in a real-world primary care setting.

METHODS

This study protocol followed the Standard Protocol Items: Recommendations for Interventional Trials to describe the protocol's contents.[20 21]

Study design and setting

The study design is a pragmatic randomised controlled trial (RCT). Two parallel groups with a 1:1 allocation ratio and a superiority framework will be employed. The control group will be usual care. The intervention group will consist of usual care and a PA programme led by a sports scientist (PASS). The study will be conducted at a single hospital-based outpatient clinic (Family Medicine Clinic, Walailak University Hospital) between March 2024 and March 2025.

Participants and sample size

The inclusion criteria will include patients who (1) are aged 35–70 years, (2) have at least one of the following NCDs: type 2 DM, HT and dyslipidaemia and (3) are physically inactive (<150 min/week of moderate-intensity aerobic PA or <75 min/week of vigorous intensity of aerobic PA or <150 min/week of moderate to vigorous-intensity PA (MVPA)). The exclusion criteria were patients who (1) have the presentation or history (since the last medical consultation) of fasting plasma glucose ≥300 mg/dL,[22] hypoglycaemic symptoms, blood pressure ≥180/105 mm Hg[22] or muscle pain from lipid-lowering medication use, (2) have a history of any of the following symptoms in the last 3 months: chest pain, palpitation, syncope, dyspnoea, alteration of consciousness, ankle oedema, (3) are pregnant or are currently breast feeding, (4) have adverse drug reactions due to drug interactions or polypharmacy, (5) have uncontrolled chronic respiratory disease, such as asthma, chronic obstructive pulmonary disease, (6) have movement limitations (eg, using walking aids, muscle weakness) and (7) have another individual residing in the same household as a study participant.

The sample size was calculated using a sample size calculator software, n4Studies, for RCTs using binary data.[23] The proportions of meeting PA recommendations after the PA intervention were obtained from a previous RCT (Crapperton *et al*, 2020) included in a systematic review[24] in which 78% of participants in the intervention

group ($p_{intervention}$=0.78) and 51% in the control group ($p_{control}$=0.51) achieved PA recommendations. Using a type I error of 0.05, type II error of 0.2 and an allocation ratio of 1:1 (intervention to control group) resulted in a sample size of 49 in each group. Accounting for a 20% dropout rate, the final sample size was 60 in each group.

Recruitment and informed consent

Patients attending the Family Medicine Clinic at Walailak University Hospital have their blood drawn and other investigations completed at the laboratory or radiology units before this clinic visit. On registering at a registration station in the Family Medicine Clinic, the patients meet a nurse who interviews them for their medical history at the preconsultation station. During this time, the nurse will check for eligibility criteria for the study. Patients who meet the criteria will be contacted in person at the waiting area by a research assistant, who will provide them with details of the research project by providing them with a patient information sheet and inviting them to participate. Participation in the study is voluntary and will not affect normal care, nor will there be extra requests for blood tests, appointments and service fees. Patients who agree to participate will be asked to provide their written informed consent. This process will continue until 120 participants (60 in each group) have been recruited.

Outcome measurement and instrument

The primary outcomes are the proportion of patients meeting the PA recommendations, including aerobic, muscle-strengthening and multicomponent PA.[25] The aerobic PA recommendations will be assessed using the Exercise Vital Sign (EVS). The Thai translation includes both PA and exercise to make sure everything is clear. Hence, PA is a less common term in the Thai language.[6] Therefore, the Thai translation of the following questions will be used by nursing staff: (1) 'on average, how many days per week do you engage in moderate to strenuous PA or exercise?' or (2) 'on average, how many minutes per day do you engage in moderate to strenuous PA or exercise?'[26 27] Multiplicating the results from the two questions provides the amount of MVPA per week. The EVS is considered a valid questionnaire with excellent reliability (intraclass correlation coefficient 0.98, p<0.01) compared with the accelerometer.[27] The value <150 min/week is considered 'not meeting the recommended PA', while ≥150 min/week is 'meeting the recommended PA'.[25] The result will be translated into a dichotomous variable (meeting PA recommendations; not meeting PA recommendations). For other types of PA, the questions regarding participation in (1) ≥2 days/week of moderate or greater intensity of muscle-strengthening activity and (2) ≥3 days/week of moderate or greater intensity of multicomponent PA will be inquired.

Secondary outcomes include body composition and physical fitness. A sports scientist will measure the body compositions using bioelectrical impedance analysis (Tanita model SC330P; Tanita, Tokyo, Japan). The participant's information, such as age (years), sex (male or female) and body height (cm), will be inputted. The participant will be invited to stand on the footplate of the machine without socks and shoes. The weight of clothing will be discounted by 0.5 kg as per the machine's default setting. Data, including body weight (kg), body mass index (kg/m^2), fat mass (kg), percentage of fat (%), muscle mass (kg) and percentage of muscle mass (%), will be recorded in the participant record form (table 1).

Health-related physical fitness, including (1) flexibility (sit and reach for 35–59 years and back scratch for 60–70 years), (2) muscle strength and endurance (60 s chair stand for 35–59 years and 30 s chair stand) and (3) cardiovascular endurance (3 min step up and down for 35–59 years and 2 min step up and down for 60–70 years), will be assessed by a sport scientist in an available room at the clinic area. The methods and equipment for each test will follow the Thailand Department of Physical Education's manual.[28] The standard criteria for age and sex will be used to indicate 'pass' or 'fail'.[28]

Each participant will be assessed and followed up at the clinic for four in-person visits. Information on each visit will be recorded in a hard copy form. The record form will be transferred through the service flow through nursing stations, physician consultations and sports scientists. A specific form will be used for each visit (table 1).

Randomisation, allocation and blinding

The allocation sequences were generated using an online randomisation generator, Sealed Envelope (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The allocation ratio was 1:1, and a research assistant applied the block size for randomisation. The intervention assignments using codes (two alphabets and one number) will be contained in the concealed envelopes. The physician will be blinded to the allocation and the block size (eg, blocks of 2, 4 or 6). After the PA assessment and physical fitness tests at visit 1, the sports scientist will be unblinded to the allocation. The data analysts (other research team members who are not the physicians at the clinic and the sports scientist) will receive the raw data from group 1 or 2 to blind the intervention assignments.

Intervention

Participants in the control group will receive usual care, including meeting a nurse at the preconsultation and postconsultation stations and routine physician consultations. Brief PA counselling and lifestyle modification advice will be discussed as usual. Follow-up appointments will be made on a normal basis. The participants in this group will meet a sports scientist to measure body composition and physical fitness tests.

Participants in the intervention group will receive usual care and a tailored PA programme per the WHO guidelines using the FITT Pro (frequency, intensity, time, type and progression) by a sports scientist at visit 1.[25 29] The sports scientist will design and discuss the PA programme with the participants based on the physician's brief

Table 1 Participant record forms

Assessment form 1 Visit 1 (month 0) Baseline measurements	Assessment form 2 Visit 2 (months 3–4) Follow-up measurements	Assessment form 3 Visit 3 (months 6–8) End-point measurements	Assessment form 4 Visit 4 (months 9–12) Continuing measurements
Section 1: checklist for inclusion and exclusion criteria screening—8 items (including the two EVS questions) (by a nurse)	Section 1: EVS questions (by a nurse)	Section 1: EVS questions (by a nurse)	Section 1: EVS questions (by a nurse)
Section 2: checklist for participation and informed consent—3 items (by a research assistant)			
Section 3: physician's record (by a physician) ► Participant profile (age, sex, NCDs (type 2 DM, HT, DLP) ► Checklist for brief PA counselling* ► Checklist for precaution†	Section 2: physician's record (by a physician) ► Checklist for brief PA counselling* ► Checklist for precaution†	Section 2: physician's record (by a physician) ► Checklist for brief PA counselling* ► Checklist for precaution†	Section 2: physician's record (by a physician) ► Checklist for brief PA counselling* ► Checklist for precaution†
Section 4: PA assessment and outcome measurements (by a sports scientist)‡ ► Participant's group: intervention or control	Section 3: PA assessment and outcome measurements (by a sports scientist)‡	Section 3: PA assessment and outcome measurements (by a sports scientist)‡	Section 3: PA assessment and outcome measurements (by a sports scientist)‡
Section 5: PA or exercise programme for the intervention group only (by a sports scientist) ► Frequency, intensity, time, type and progression for aerobic, muscle-strengthening and multicomponent PA			
Section 6: checklist monthly follow-ups by phone calls for the intervention group only (by a sports scientist) ► Number, date, challenges of PA, programme review, injuries/abnormal symptoms	Section 4: checklist monthly follow-ups by phone calls for the intervention group only (by a sports scientist) ► Number, date, challenges of PA, programme review, injuries/abnormal symptoms		

*Checklist for brief PA counselling: ICD-10 (Z273, lack of physical exercise); intensity of aerobic activity (low, low to moderate, or moderate to high); intensity of muscle-strengthening activity (low, low to moderate, or moderate to high); intensity of multicomponent PA (low, low to moderate, or moderate to high); and stage of change (precontemplation, contemplation, preparation, action, maintenance or termination).
†Checklist for precaution: no exercise experience or no exercise for a long time; fall risk; body balance precaution; and other (specify).
‡PA assessment and outcome measurements (by a sports scientist): PA assessment: yes or no (single question for each aerobic activity (≥150 min/week of MVPA), muscle-strengthening activity (≥2 times/week) and multicomponent PA (≥3 times/week)); body compositions (body weight (kg), body mass index (kg/m^2), fat mass (kg), percentage of fat (%), muscle mass (kg), percentage of muscle mass (%)); and physical fitness: pass or fail (flexibility, muscle strength and endurance, and cardiovascular endurance).
. DLP, dyslipidaemia; DM, diabetes mellitus; EVS, Exercise Vital Sign; HT, hypertension; ICD-10, International Classification of Diseases, Tenth Revision; MVPA, moderate to vigorous-intensity physical activity; NCD, non-communicable disease; PA, physical activity.

counselling and the precaution. The programme will include aerobic, muscle-strengthening and multicomponent PA. The sports scientist will use videos to illustrate recommended activities. An appropriate resistant elastic band will be provided for each participant. The details of 2–4 sets and 8–15 reps/set of body weight exercises will be suggested for muscle strengthening based on the appropriateness and abilities of the participants.

The sports scientist will provide the phone number to contact the participant and inquire about a convenient time for further communication. A sports scientist will perform monthly phone follow-ups after visits 1 and 2 (figure 1). The phone follow-up will be missed if the sports scientist cannot reach the participant after the initial call and the subsequent day's attempt.

Data collection

Both control and intervention groups will be assessed for the primary (PA participation) and secondary outcomes (body composition and physical fitness) four times (figure 1). The length between each medical appointment is approximately 3–4 months. Data will be recorded using the participant record forms (table 1). The attending physician is a family medicine physician who is this study's principal investigator (AW). The nursing staff at the clinic are part of the clinic team. A sports scientist (SM), a research team member, will be responsible for participant assessment and PA programme delivery. A research assistant will help contact and communicate

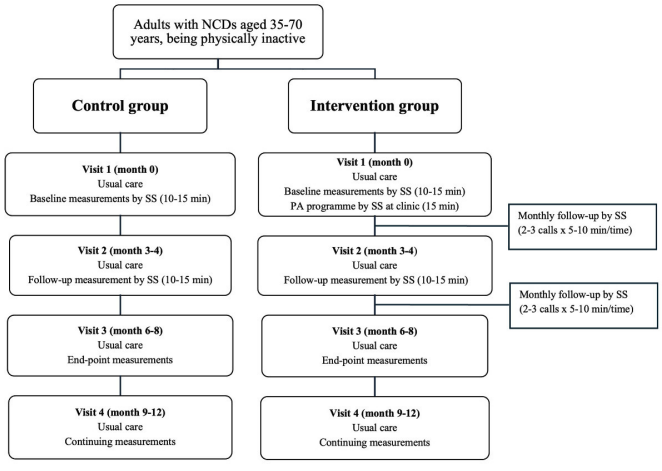

Figure 1 Participant flow diagram. NCD, non-communicable disease; SS, sports scientist.

with participants outside the physician's consultation room.

The primary outcomes, including participation in ≥150 min/week of MVPA, ≥2 times/week of muscle-strengthening activity and ≥3 times/week of multicomponent PA, will be recorded as the categorical variables ('yes' or 'no'). Participation in aerobic PA calculated from the EVS will be collected as a continuous variable (min/week). For secondary outcomes, all body composition components are continuous variables. The physical fitness tests are categorical variables ('pass' or 'fail'). A research assistant will transfer the participant profile, PA participation, body compositions and physical fitness tests to Excel sheets (Microsoft, Redmond, Washington, USA).

Data analysis

Frequencies and percentages will present the categorical variables. The Shapiro-Wilk test will test the continuous variables for normal distribution. Variables with normal distribution will be presented by means and SDs. Otherwise, medians and IQRs will be presented.

The differences in outcomes of each visit between the control and the intervention groups will be tested by analytical statistics. The χ^2 or Fisher's exact tests will be executed for categorical variables. The independent t-test will test the differences among the continuous variables. An alternative test for non-parametric statistics will be the Mann-Whitney U test. The statistical analysis will be performed in R V.4.0.2 (RStudio, Massachusetts, USA). The intention-to-treat analysis will be applied. The level of statistical significance is $p<0.05$.

Safety and monitoring

The research team will reduce and monitor the potential risks across the study period. Hard copy participant record forms are used to avoid unauthorised access to electronic medical records. The research assistants, coresearchers from other institutions and sports scientists will not be allowed to access the electronic medical records to keep data private. All hard copy and electronic documents will contain participant codes instead of identifiable information, except the informed consent form and the separate participant code book.

Safety issues and adverse events (eg, falls, hypoglycaemia, pain, shortness of breath, chest pain) related to the assessment and intervention will be monitored by the physician and the sports scientist at every visit and follow-up call. Participants will be advised to discontinue the intervention or seek medical care if there are concerns about risks, harm and safety issues. Participants will be informed of the research team and the human research ethics committee's contact to report any risks, harms and safety issues.

In addition, if there is a need for first aid or urgent medical care, the principal investigator and nursing staff will evaluate the participant in the clinic area. Consideration for a referral to the emergency department or hospital admission will be based on the severity and urgency of the event. Adverse events outside the clinic will be recommended for management according to standard care protocols (eg, self-care, clinic visits, ambulance calls).

Patient and public involvement

Six individuals living with NCDs were invited to a patient and public involvement (PPI) group, representing diverse sociodemographics (eg, business owners, retired teachers, retired bankers and non-academic university staff). The research team presented the summary of the study protocol to the group at a meeting on 8 January 2024. The PPI group discussed the protocol and research materials (ie, participant record forms). This process was not part of the data collection. This meeting aimed to obtain comments from patients on the feasibility of the study processes and the need for improvement. After the meeting, the research team amended the protocol and materials based on suggestions from the PPI group. The study protocol was revised before the submission to the human research ethics committee. After the completion of the study, a discussion on the findings will be held with the PPI group to gather more insights. The PPI group will be invented to disseminate the findings to key stakeholders, for example, patients and healthcare professionals.

Research ethics and dissemination

The trial registration was submitted to the Thai Clinical Trials Registry (registration number: TCTR20240314001).

The study processes will follow the study protocol, and any protocol amendments will be submitted to the Human Research Ethics Committee of Walailak University. All documents will be kept confidential.

The study protocol will be published in an academic journal. The study results will be disseminated via conference presentations, reports to the grant funder, websites or social media and publications in peer-reviewed journals. The presentation of the study will keep the anonymity of participants.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Human Research Ethics Committee of Walailak University (approval number: WUEC-24-106-01; version 2.0, revised 11 March 2024). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; internally peer reviewed.

Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study. Trial registration is available at https://www.thaiclinicaltrials.org/show/TCTR20240314001.

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