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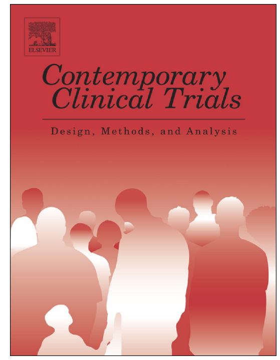

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Preliminary efficacy and feasibility of referral to exercise specialists, psychologists and provision of a technology-based behavior change support package to promote physical activity in school teachers 'at risk' of, or diagnosed with, type 2 diabetes: The 'SMART Health' Pilot Study Protocol.

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ABSTRACT

Introduction: Type 2 diabetes mellitus (T2DM) is a global public health concern. Aerobic physical activity (PA) and resistance training (RT) play significant roles in the prevention and management of T2DM. The aim of this pilot trial is to determine the preliminary efficacy and confirm feasibility of referral to exercise physiologists, psychologists, and provision of a technology-based behavior change support package to promote aerobic PA and RT in school teachers 'at risk' of or diagnosed with T2DM.

Research design and methods: The SMART (**S**upport, **M**otivation and **P**hysical **A**ctivity **R**esearch for **T**eachers') Health pilot study will be evaluated using a three-arm randomized controlled trial. The intervention will be guided by Social Cognitive Theory, Health Action Process Approach Model and Cognitive Behavioral Therapy strategies. The participants will be randomly allocated to one of three study groups: Group 1: wait-list control group; Group 2: 5 face-to-face visits with a psychologist and exercise specialist over 3 months; and Group 3: same as Group 2 plus technology-based behavior change support package for an additional 6 months. Assessments will be conducted at baseline, 3-, 9- (primary time-point) and 18-months post-baseline. The primary outcome will be PA measured with pedometers.

Discussion: SMART Health is an innovative, multi-component intervention, that integrates referral to exercise specialists, psychologists and provision of a technology-based behavior support package to promote PA and RT in adults diagnosed with T2DM or ‘at risk' of T2DM. The findings will be used to guide future PA interventions and to develop effective community-based diabetes prevention and treatment programs.

Trial Registration: Australian New Zealand Clinical Trials Registry No: ACTRN12616001309471

Keywords: resistance training, aerobic activity, behavior change support package, adult, exercise specialist, psychologist.

1. Introduction

1.1. Background

Type 2 diabetes mellitus (T2DM) is an increasing public health concern [1-3]. T2DM is significantly associated with morbidity and mortality and contributes to the economic burden placed on health services. The most recent Australian health survey in 2011-12, showed the prevalence of T2DM in adults to be 5.4%, representing approximately 917,000 Australian adults [4]. However, this is likely to under-represent the true prevalence of T2DM in this country as these figures are based on self-report and many people are unaware they have the disease [4, 5].

Aerobic physical activity (PA) and resistance training (RT), both play significant roles in the prevention and management of T2DM [6-9]. Indeed, there is convincing evidence that participation in physical activity can improve insulin sensitivity [10], glycaemic control, cardiovascular risk factors (e.g. lowering blood lipids and blood pressure), quality of life, reduce weight [2] and medication needs as well as reduce cardiovascular events and mortality [8, 11].

The PA recommendations for Australian adults are to be active on most, preferably all days of the week, accumulating 150 to 300 minutes of moderate intensity PA or 75 to 150 minutes of vigorous intensity PA, or an equivalent combination of both moderate and vigorous intensity PA, each week. Additionally, RT on at least 2 days each week is recommended [12]. These recommendations are consistent with the guidelines given by Diabetes Australia [13].

Despite the known health and economic benefits associated with regular participation in PA, most Australian adults remain insufficiently active [14]. The most recent Australian National Nutrition and Physical Activity Survey reported that only 15% of Australian adults were meeting both the moderate-vigorous PA and RT guidelines. It has been reported that people with T2DM have lower levels of PA compared to the general population [15]. The low levels of PA in adults with T2DM, together with the many known benefits of increasing PA in this population, sets an important challenge for health care teams to assist people with T2DM to increase and maintain their levels of PA to improve physical and mental health.

PA behavior change interventions are more likely to be effective when they are longer in duration and use a larger number of behavior change techniques. Print-based materials [16] and technology-based support such as websites [17, 18], apps [19, 20] and telephone helplines [16, 21] have also been shown to be effective in supporting people with T2DM to increase their level of PA.

There has been little recognition or support for the physical health of Australian school teachers who are a unique and under-examined population group. Currently there are no published data that relate to the prevalence of diabetes in this group or their levels of physical activity. However, the Teachers Health Fund, a major provider of health insurance to the Australian education sector, report that in 2014, >30% of their annual pay-outs were for diabetes related care. Teachers are in the unique position of being able to influence the health behaviours of their students by modelling, teaching and providing opportunities and environments to promote positive physical activity messages. These factors make Australian teachers a novel/unique population to study. The current study will determine whether referral to exercise specialists, psychologists and access to a technology-based behavior support package is effective for increasing PA in school teachers at risk of, or diagnosed with T2DM.

1.2. Objectives

In comparison to a waitlist control group (Group 1), the objectives of this pilot RCT are to determine the efficacy of:

1. A total of a combination of five visits with a psychologist and exercise specialist (Group 2) over 3 months; and
2. Access to a technology-based behavior support package for an additional 6 months in addition to face-to-face visits with a psychologist and an exercise specialist (Group 3),

on PA, among school teachers ‘at risk' of, or diagnosed with T2DM. The second objective is to confirm the feasibility of the study by assessing *recruitment*, *retention*, *adherence* and *satisfaction.*

2. Materials and methods

2.1. Study design

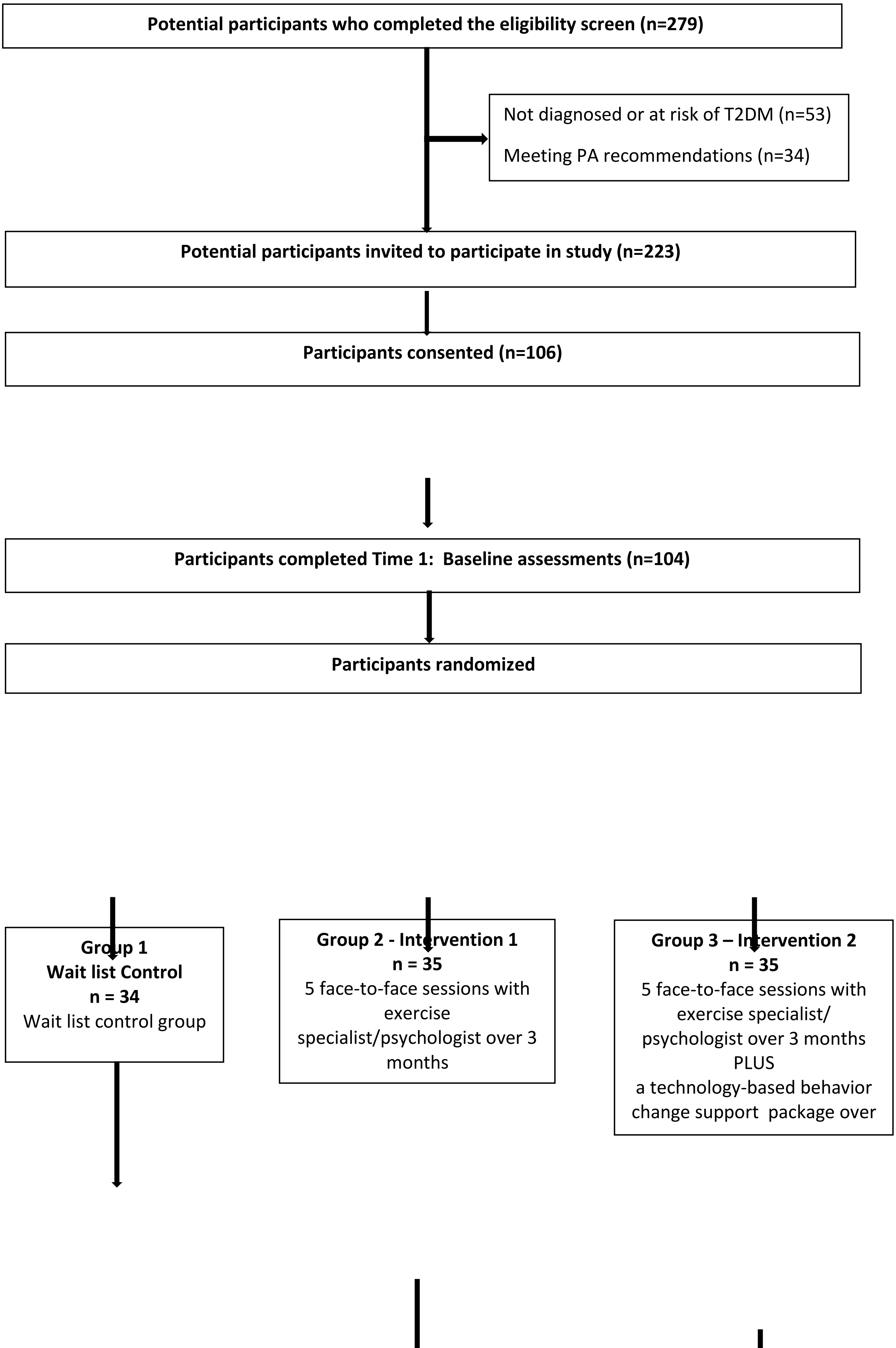
The SMART Health pilot study described here is a feasibility and preliminary efficacy study (not powered for the primary outcome). It will be evaluated using a three-arm, randomized controlled trial. The pilot study will target teachers who are ‘at risk’ of, or diagnosed with, T2DM. Assessments will be conducted at baseline, 3-, 9- and 18-months post-baseline. The primary study time-point will be 9-months post-baseline. The design, conduct and reporting of this RCT adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for group trials [22]. Ethics approval for this study will be obtained from the Human Research Ethics Committee of the University of Newcastle, Australia, the New South Wales Department of Education, the Catholic Schools Office Diocese of Maitland Newcastle and the Association for Independent Schools. Research participants will provide written informed consent. The trial will be registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR).

2.2. Participants: eligibility, recruitment and screening

Members of the research team will recruit teachers from Government, Catholic and Independent schools as well as childcare centres in the Newcastle, Hunter and Central Coast regions of New South Wales. Teachers with known T2DM (as diagnosed by their GP) or those who report they might be ‘at risk’ of T2DM will be invited to participate in the study. Recruitment methods will include flyer distribution to schools and pre-schools, social media posts, and media releases with subsequent promotion on local radio, television, newspapers and the local university-affiliated Medical Research Institute. Following ethics approval, school principals will be approached to forward information and recruitment flyers to their staff. Potential participants who are interested in taking part in the study will be directed to complete a five minute online survey comprising the Australian type 2 diabetes risk assessment tool (AUSDRISK) [23] and the Exercise and Sports Science Australia adult pre-exercise screening tool [24]. Members of the research team will use the results of this AUSDRISK survey to determine the potential participants’ eligibility to participate in the study. Individuals scoring ≥ 6 on the AUSDRISK screening tool [25] will be classified as being ‘at risk’ of developing T2DM. The inclusion and exclusion criteria are listed in Table 1. Those completing the online survey will provide an address, email address and phone number so they can be contacted if eligible to join the study.

Table 1: Eligibility criteria for the study

Inclusion criteria:
Childcare, primary or secondary school teachers in the Hunter Region of NSW who:
• Are 18 years or older
• Are 'at risk' of developing T2DM as assessed by the 10-item Australian T2DM Risk Assessment Tool (score ≥ 6) [23] or currently diagnosed with T2DM (HbA_1C >7.0 or as diagnosed by the participant's general practitioner);
• Are not meeting the national PA guidelines for adults (at least 150 minutes of moderate PA each week and 2 muscle strength training activities each week)
• Pass the Exercise and Sports Science Australia Adult Pre-exercise Screening Tool [24]
• Are prepared to complete the study protocol
• Read the Participant Information Statement, sign and return the Participant Consent Form and obtain written medical clearance if necessary.
Exclusion criteria:
• Presence of a medical condition that might be adversely affected by increasing PA as determined by the Adult Pre-exercise Screening Tool [24]. Note: If participants Body Mass Index (BMI) is >40 or they are identified as exhibiting other risk factors, they will be required to gain a written GP clearance prior to participating in the study
• Pregnancy
• Currently participating in an alternative PA research project
• Currently seeing an exercise specialist
• Not available for assessment sessions


Potential participants who completed the eligibility screen (n=279)
Not diagnosed or at risk of T2DM (n=53)
Meeting PA recommendations (n=34)
Potential participants invited to participate in study (n=223)
Participants consented (n=106)
Participants completed Time 1: Baseline assessments (n=104)
Participants randomized
Group 1
Wait list Control
n = 34
Wait list control group
Group 2 - Intervention 1
n = 35
5 face-to-face sessions with exercise specialist/psychologist over 3 months
Group 3 – Intervention 2
n = 35
5 face-to-face sessions with exercise specialist/ psychologist over 3 months
PLUS
a technology-based behavior change support package over

Time 2, 3 & 4: Follow-up assessments
(3-, 9- and 18-month follow-up from baseline)

Time 2, 3 & 4: Follow-up assessments
(3-, 9- and 18-month follow-up from baseline)

Figure 1: Flow Diagram of the SMART Health study

2.3. Blinding and randomization

Recruitment and baseline assessments will be conducted prior to randomization. Participants will be stratified for T2DM diagnosis (at risk of T2DM; diagnosed with T2DM) and sex (male; female). Random allocation to the wait-list control group or to one of the two intervention groups will be performed using a computer-based random number producing algorithm by a researcher unrelated to the SMART Health study. This method of randomization ensures that participants have an equal chance of being allocated to each of the three groups.

2.4. Intervention

SMART Health is a 9-month community-based, multi-component PA intervention. The intervention will integrate five face-to-face visits with a psychologist and exercise specialist over 3 months (Group 2 and Group 3) with a technology-based behavior support package (website,

Time 2, 3 & 4: Follow-up assessments
(3-, 9- and 18-month follow-up from baseline)

smartphone app and telephone helpline) for an additional 6 months (Group 3 only). The wait list control group will receive the full intervention at 9-months (the primary time point) to allow a three group comparison and promote study retention at the 18-month time point.

2.5. Intervention components and delivery

Group 2 will receive five individual visits with a psychologist and exercise specialist over three months. The first session will be facilitated by the psychologist and will be 60 minutes in duration. Subsequent sessions will alternate between the exercise specialist and psychologist up to and including the fourth session and will be 30 minutes in duration. Participants will choose whether they see the psychologist or the exercise specialist for their fifth session, depending on their perceived needs. The psychology sessions will consist of cognitive mentoring delivered by a clinical psychologist (See Table 2). The exercise specialist sessions will involve the assessment of PA tolerance, promotion of regular PA and patient-centred PA counselling to develop a PA plan (See Table 2), in accordance with the recommendations for Australian adults [12].

Table 2: Content of the sessions held with the Psychologist and Exercise Specialist in the SMART Health program

Session	psychology session	exercise specialist session
1	Automatic thoughts and goal setting: • The influence of thoughts and emotions on PA behavior. • The effect of sabotaging thoughts on behavior change. • Setting realistic and achievable goals • Implementing motivational strategies • Building self-confidence regarding PA behavior	• Introduce participants to PA and exercise – importance of and health benefits. • Assess participants' knowledge and ability to participate in PA. • Discuss participants' intention to makes changes in current behavior. • Assist with goal setting using motivational interviewing techniques. • Discuss time management strategies/create weekly planner. • Discuss and demonstrate exercises to be included in participants' program (Note: participants were emailed an electronic version of their program, which included images of the exercises and a description the day following their session).
2	Unhelpful thinking styles • The role and influence of unhelpful self-statements and thoughts (e.g., mental filter, catastrophizing, blaming yourself, all or nothing perception) on PA behavior. • Changing negative thoughts for more positive and supportive statements.	• Discuss if participants' intention to makes changes has shifted since the previous session • Action and coping strategies (barrier awareness) • Discuss if goals are being worked towards (set new goals if necessary) • Time management strategies • Attitudes/improvements • Progression strategies, future goal setting and maintenance
3	Problem solving • Finding solutions for PA problems and barriers using "Seven-Step" problem solving strategy.	• Future goal setting and progression strategies • Implementing progression strategies and maintaining improvements • Time management strategies • Positive behavior change – the ability to self-plan and increase knowledge.

Group 3 will receive the above intervention plus a technology-based behavior support package after their final face-to-face session and 3-month assessment. The support package will included access to the SMART Health website, eCoFit smartphone application and telephone helpline for an additional 6 months. The eCoFit smartphone application is explained in more detail following Table 3. Participants will be provided with verbal and written instructions to access and operate each component of the support package after attending their fifth face-to-face session. They will be asked to notify the research team if they experience any difficulties. The non-interactive SMART Health website will contain materials to support participants to achieve and maintain their PA goals. It will include case studies, PA research, evidence-based responses to common PA myths, weekly fitness tips, examples and photos of RT exercises, and links to other evidence-based websites that promote adoption and maintenance of a healthy lifestyle (See Table 3).

Table 3: Summary of contents for the SMART Health website

	Module	PA Myth	Case Study or Education topic	Fitness Tip
Week 1	Self-efficacy	If I didn't exercise when I was younger, it's too late.	- 45 year old mother with cardiovascular risk factors. - 45 year old female manager with T2DM. - 64 year old man with T2DM, post-heart attack.	Foot care for walking and other PA.
Week 2	Outcome Expectations	If I can't exercise regularly then I shouldn't bother at all.	Benefits of PA.	Energy expenditure for various activities.

Week 3	Self-control	Weight gain is inevitable as we age.	PA terminology explained e.g. aerobic fitness, muscular strength, muscular endurance, body composition.	Exercising at the right level of exertion.
Week 4	Situation	No pain means no gain when it comes to exercise.	Role of PA in preventing chronic diseases.	Being prepared for PA by taking appropriate footwear in the car.
Week 5	Reinforcement	If I do resistance exercises with heavy weights my muscles will get too bulky.	Benefits of resistance training on health.	Fitting small, regular amounts of physical activity into your routine.
Week 6	Social support	You can lose fat from specific parts of your body by exercising those spots.	Importance of stretching.	Getting enough sleep.
Week 7	Emotional coping response	When you stop exercising, your muscles turn to fat.	Why should I warm-up and cool-down?	Keeping PA fun and interesting.
Week 8	Behavioral capability	The best time to exercise is early in the morning.	Varying your PA routine – changing the intensity, duration and type.	Keeping well hydrated.
Week 9	Environment	The only way to burn calories is by doing cardiovascular exercises like walking and jogging.	Explaining body composition.	Measuring the intensity of your workout.
Week 10	Observational Learning	Home workouts are fine but going to a gym is the best way to get fit.	Explaining different body shapes.	Remembering to exercise and keeping yourself motivated.
Week 11	Relapse prevention	If you exercise, you can eat anything you want.	Making fitness centres less scary.	Planning when to be physically active and preparing ahead.
Week 12	Summary	Doing housework is just as good as doing aerobic exercise like brisk walking, swimming, or biking.	Mental health benefits of PA	Scheduling PA

The interactive eCoFit smartphone application was developed primarily to increase outdoor PA [26]. It included a description of where and how to use the outdoor environment to be more physically active, a standardized location based “eCoFit challenge”, a standardized “indoor challenge” which could be undertaken at home, a standardized “outdoor challenge” which could be undertaken at any local oval**,** a function to set weekly PA goals and self-monitor progress, “FitMind Challenges” and links to social media. The app guides participants through a range of aerobic and strength training activities and allows participants to time these activities if they desire. Each eCoFit challenge has a standardised distance of 3km as well as 6 standardised resistance training activities. The development and features of the “eCoFit” smartphone application are detailed elsewhere [26]. The telephone helpline may be accessed for up to 15 minutes once a week to gain additional support, advice and encouragement from the exercise specialist and/or the psychologist to help participants achieve and maintain PA goals.

eCoFit Challenge – Dixon Park, Newcastle, Australia Example Level 3*		6 resistance training activities in the eCoFit “challenge”
1.	Walk or run 30m	Seated Recline Hold for 15 seconds 
2.	Seated Recline Hold for 15 seconds	
3.	Walk or Run 200m	
4.	10 Push-ups	
5.	Walk or Run 300m	
6.	20 Alternate Knee Lifts (free standing)	
7.	Walk or Run 200m	10 Push-ups 
8.	15 Tree-hugs, 1x15 second Tree-hug Hold	
9.	Walk or Run 200m	
10.	10 squats	
11.	Walk or Run 400m turn right onto the Anzac memorial walk	20 Alternate Knee Lifts (free standing) 
12.	Walk or run 40m	
13.	15 Bus-stops (45 degrees)	
14.	Walk or Run 130m	
15.	Turn	15 Tree-hugs, 1x15 second Tree-hug Hold
16.	Walk or Run 130m back to the start	
17.	15 Bus-stops (45 degrees)	

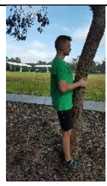
18.	Walk or Run 440m	
19.	10 squats	
20.	Walk or Run 200m	
21.	15 Tree-hugs, 1x15 second Tree-hug Hold	
22.	Walk or Run 200m	10 Squats
23.	20 Alternate Knee Lifts (free standing)	
24.	Walk or Run 300m	
25.	10 push-ups	
26.	Walk or run 200m	
27.	Seated Recline Hold for 15 seconds	
28.	Walk or Run 30m	15 Bus-stops (45 degree)
29.	15 Bus-stops (45 degrees)	
	Finish	

Figure 2. A standardized eCoFit "Challenge" from the *eCoFit* smartphone App. (incorporated aerobic and resistance training activities)

2.6. Theoretical basis of SMART Health

"The SMART Health intervention will be guided by Social Cognitive Theory [27], the Health Action Process Approach Model [28] and Cognitive Behavioral Therapy techniques [29]. Bandura's Social Cognitive Theory describes the ongoing dynamic interaction between personal, cognitive and environmental factors and their impact on human behavior and motivation [30]. Self-efficacy, goal setting, outcome expectations and social support are key Social Cognitive Theory constructs [30] that will be operationalized in the SMART Health Study. Self-efficacy refers to an individual's belief that he/she can complete a task or challenge [32]. An individual's sense of self-efficacy will determine whether he/she chooses to engage in an activity or accomplish a task or challenge. Receiving information about PA and its benefits, observing RT demonstrations and receiving feedback on individual technique within the SMART Health exercise specialist sessions may increase an individual's confidence in their ability to perform these tasks. With increased self-efficacy, individuals who have previously not been exposed to RT, may be more inclined to continue performing RT exercises.

During consultations with the exercise specialist participants will be educated about the benefits of PA, instructed on how and where they could perform RT exercises and will be encouraged to set PA goals. The exercise specialist will also provide feedback on their progress. They will be encouraged to complete eCoFit challenges, home-, gym- and/or outdoor-based RT, as well as aerobic activities, taking into consideration individuals' co-morbidities, exercise tolerance, and facilities available to them. Finally, participants will be encouraged to develop, strengthen and maintain social networks, which are known to provide support for behavior change [26].

Action planning and coping planning are significant components described by Schwarzer in the Health Action Process Approach Model [34] to support individuals to implement desired behaviors. Action planning can help people to overcome obstacles and cope with difficulties by anticipating situations that might undermine the performance of their intended behavior [34]. Action planning and coping planning will be applied by the SMART Health psychologist as an integrated component of the cognitive mentoring sessions and also in the eCoFit app (where participants plan their PA “challenge”). To operationalize these strategies, the psychologist and exercise specialist will ask participants to think about a future situation and a behavior or action that would enable them to achieve their PA goal. Action and coping planning will be used to support participants to make a detailed plan regarding their PA and to prepare participants for unexpected circumstances so that their PA plans can still be implemented.

Cognitive-Behavioral Therapy is an effective, evidence-based therapeutic approach used in clinical trials to treat a range of psychological symptoms [31]. The psychologist in the SMART Health study will use cognitive behavioral techniques to support research participants to explore and reflect on their cognitive and behavioral functioning regarding PA. To help participants overcome barriers to participating in PA, the psychologist will assist them to address automatic thoughts and unhelpful thinking styles, set goals and apply motivational and problem-solving strategies to effect behavior change.

These theories, constructs and techniques were used to inform the intervention delivery modes chosen for the SMART Health Study (face-to- face consults with allied health professionals and a technology-based behavior support package). The intervention components have also been efficaciously used to promote PA in a similar study of adults with (or at risk of) type 2 diabetes [32].

2.7. Outcomes

A protocol manual will be used by the study's trained research assistants to ensure consistency in conducting all assessments at baseline, 3-, 9- and 18-months. Assessments for all four time-points will be conducted at the University of Newcastle, Australia, except for blood collection. Blood collection will take place at a "Pathology North" laboratory, the preferred pathology laboratory for standardization of measurements used by the local public health service in the Hunter Region of New South Wales. During assessments at the university, a range of primary and secondary outcomes will be measured by trained research assistants at all four time-points. Online questionnaires will be completed in a quiet room, prior to the physical assessments, to obtain demographic information including age, gender, marital status, ethnic origin, level of education, gross annual family income and employment status. Additional self-report information will be collected including health and medical background, past behavior related to aerobic activity and resistance training, smoking and diet. Physical assessments will be undertaken sensitively in a private room.

2.7.1. Primary outcome

PA will be measured using a YAMAX SW-200 pedometer (YAMAX Corp, Tokyo, Japan), which has acceptable convergent validity with other objective measures of PA [33]. The pedometer will be worn by participants for seven consecutive days. Participants will be instructed to wear the pedometer during waking hours and will be given a pedometer log sheet. They will receive verbal and written instructions on wearing the pedometer and completing the pedometer log sheet. Participants will be asked to record their step count for 7 consecutive days as well as non-ambulatory activity e.g. swimming, cycling. An average daily step count will be calculated using a minimum of four days of recorded steps, regardless of whether the steps were recorded on weekdays or weekends. Non-ambulatory activity will be converted to an equivalent step count using validated methods described elsewhere [34]. Adjusted (i.e. with log values) and unadjusted step counts (without log imputations) will be examined for the primary analysis.

2.7.2. Secondary outcomes

2.7.2.1 Behavioral Outcomes

Self-reported aerobic PA levels will be measured using a modified version of the Godin Leisure-Time Exercise Questionnaire [35-37] to determine the average number of times per week they engage in strenuous, moderate and mild PA (in the preceding four weeks). Participants will also be asked to specify the average duration of each session (minimum of 10 min per session) for each of the three intensity levels.

Self-reported RT training levels will be assessed using a modified version of the GLTEQ [35] to determine the number of times per week they engage in resistance training (in the preceding four weeks). Participants will also be asked to specify the average duration of each session (minimum of 10 min per session).

Sedentary behavior will be calculated using the 1-item scale from the 45 and UP Study Questionnaire: "About how many hours in each 24 hour day do you usually spend……sleeping (including at night and naps), watching television or using a computer, standing, sitting? [38].

Perceived insufficient sleep will be measured using the 1-item scale from the Behavioral Risk Factor Surveillance System (BRFSS) Survey: "During the past 30 days, for about how many days have you felt you did not get enough rest or sleep?" [39].

Diet will be evaluated using 12 items from the original 120-item Australian Eating Survey for Adults. e.g. How many serves of fruit do you usually eat each day? [40].

2.7.2.2. Clinical Outcomes

Blood sugar, glycaemic control (HbA_1C) and plasma lipids (high density lipoproteins, low density lipoproteins, triglycerides) will be assessed using a fasting blood test. Participants will be asked to fast for a minimum of 10 hours.

Body mass index (BMI) will be calculated using a digital scale and BSM370 stadiometer (Biospace, Korea) with an inbuilt BMI calculator.

Blood pressure will be measured using a digital sphygmomanometer with a self-closing brachial cuff. *Waist circumference* will be measured using a non-extensible steel tape.

2.7.2.3. Mental Health and Quality of Life Outcomes

Quality of life will be assessed using the short form-12 Health Survey (SF-12) [41]. *Health-related quality of life* will be determined using four items from the original five-item version of the EuroQol-5D [42].

Depression severity will be measured using a nine-item Patient Health Questionnaire (PHQ-9) [43]. *Anxiety severity* will be measured using the seven-item Generalised Anxiety Disorder Questionnaire (GAD-7) [44].

2.8. Measures for potential mediators of physical activity change

Stage of behavior change will be determined using a 1-item scale assessing stages of change from the Transtheoretical Model of Health Behavior Change [45].

'Regular physical activity' will be defined as engaging in at least 150 minutes of moderate physical activity each week by participating in brisk walking for 30 minutes, 5 days per week (This includes activities that last for at least 10 minutes e.g. three 10 minute walks in the same day is the same as one 30 minute walk). Only activities that are carried out at a moderate intensity should be counted. (These include activities such as brisk walking, recreation and sporting activities (e.g., jogging, swimming, bicycling), and yard work such as raking leaves, and mowing the lawn at a moderate intensity. These activities should make participants feel warm and increase their breathing rate.

Response options range from “no regular PA and no plan to get regular PA in the next 6 months” (1) to “regular PA and have been getting regular PA for longer than 6 months (5). *Intention* will be assessed using a 3-item scale from The Theory of Planned Behavior [46] e.g. “I intend to get regular physical activity as part of my leisure time”. Response options range from “totally disagree” (1) to “totally agree” (4). *Implementation intention* will be measured using a 7-item scale adapted from the Gollwitzer’s principle of implementation intentions [36] e.g. “To what extent do you have concrete plans for how often you will do regular physical activity?” Response options range from “not at all” (1) to “completely” (5). *Self-efficacy* will be determined using a 10-item scale (from a 13-item scale) adapted for PA [47] e.g. “I am confident that I can participate in regular physical activity when I have many other demands on my time.” Response options range from “not at all confident” (1) to “extremely confident” (5). *Maintenance self-efficacy* will be assessed using a 4-item scale adapted for PA [48] e.g. “I can be physically active at least 3 times a week for 30 minutes/day.” Response options range from “not at all true” (1) to “exactly true” (4). *Recovery self-efficacy* will be assessed using a 3-item scale adapted for PA [48]. e.g. “I am sure I can be physically active again regularly, even if I postpone my plans several times." Response options range from "not at all true" (1) to "exactly true" (4). *Outcome expectancies* will be evaluated using a 12-item scale adapted for PA [48, 49] e.g. "Over the next 5 months regular physical activity is something I will enjoy doing." Response options range from "strongly disagree" (1) to "strongly agree" (5). *Risk perception related to type 2 diabetes* will be assessed using a 3-item scale [50] e.g. "Getting further diabetes complications would be a very bad thing to happen to me." Response options range from "definitely not" (1) and "definitely yes" (5). *Risk perception (general health risk)* will be measured using a 6-item scale [51] e.g. "How likely is it you will have, at some stage in your life a heart attack?" Responses range from "very unlikely" (1) and 5 is "very likely (5). *Risk perception (general health severity)* will be determined using a 6-item scale with 5-point response options [51] e.g. "How severe (serious) is high cholesterol if it is not medicated or remains undetected?"; "not severe at all" (1) to "very severe" (5). *Social support* will be evaluated using a 2-item scale with 7-point response options [52] e.g. "People in my social network are likely to help me participate in regular physical activity." ("strongly agree" = 1; "strongly disagree" = 7). *Perceived environment* will be assessed using a 7-item scale [53]. "There are many interesting things to look at while walking in my local area."; "strongly disagree" = 1; "strongly agree" = 4.

Nature relatedness will be measured using the short form, 6-item version of the Nature Relatedness Scale with 5-point response options ranging from “strongly disagree” (1) to “strongly agree” (5) [54]”.

2.9. Teaching self-efficacy measures

General *teaching self-efficacy and self-efficacy related to teaching physical education* will be measured using a 13-item scale adapted from two other scales [55, 56]. “I am determined to teach PE and/or sport lessons that provide large amounts of physical activity. Responses range from “definitely false” (1) to “definitely true” (7).

2.10. Process outcomes

A range of process measures will be collected at the 3-, 9- and 18-month time points to determine the feasibility of the study. These will include: the number of participants recruited and invited to baseline assessments (*recruitment*); attendance at the face-to-face psychology and exercise specialist sessions and follow-up sessions (*adherence*); the number of participants returning for follow-up at 3-, 9- and 18-month follow-up appointments (*retention*); and participants’ satisfaction with the SMART Health intervention (*satisfaction)*. Measures of satisfaction will include: i) overall enjoyment and perceived usefulness of the study; ii) assessment of the delivery of the SMART Health program; iii) feedback regarding the perceived knowledge and skills of the psychologist and exercise specialist in relation to helping participants change PA behaviors; iv) satisfaction and engagement with the SMART Health behavior support package; v) barriers to using and engaging with the SMART Health behavior support package; vi) feedback regarding the intervention's strengths and barriers; and vii) ideas for improvement. Additional process measures will include: new types of PA or other exercise undertaken as a result of participating in the SMART Health study; perceived reduction in absenteeism from work due to improved health/wellbeing; changes in participants' health or personal circumstances that may have impacted on their ability to engage with the SMART Health study (e.g. T2DM, cancer, heart disease, broken bones, pregnancy and adverse personal/family circumstances).

2.11. Statistical Methods

Linear-mixed model analyses adjusted for baseline scores will be conducted to examine the differences on primary and secondary study outcomes between the groups. IBM SPSS Statistics for Mac, Version 22.0 will be used for the analysis.

Cohen's d will be used to provide a measure of effect:

$$d = \frac{M_1 - M_2}{SD_{pooled}}$$

where M_1 and M_2 are the mean changes for the intervention and control samples, and SD_{pooled} is the pooled standard deviation for the samples. The effects will be based on the comparison of residualized change scores between the groups.

The mixed models will follow intention-to-treat principles. Differences between completers and those who drop out or withdraw from the study will be examined using Chi-square and independent samples t-tests. Possible cognitive mediators of behavior change will be assessed using the Preacher and Hayes INDIRECT macro [57]. Descriptive statistics will be employed to examine the feasibility components of the study, specifically *recruitment*, *retention*, *adherence* and *satisfaction*. Additional moderators of intervention effect (e.g. sex, age, diabetes type) will be explored using linear mixed models with interaction terms.

3. Discussion

The aim of the SMART Health study is to determine the preliminary efficacy and feasibility of referral to exercise physiologists, psychologists and provision of a technology-based behavior support package to promote PA and RT in school teachers ‘at risk' of, or diagnosed with, T2DM. The intervention has been designed to provide teachers with the knowledge, motivation and skills to increase and maintain changes in PA behavior. Consequently, it will address the low levels of PA and RT currently observed among the adult population [14].

Aerobic PA and RT are recommended by the Australian College of General Practitioners and Diabetes Australia for the prevention and effective management of T2DM [9, 58]. Participation in both forms of PA requires individuals to have knowledge and skills about the frequency, intensity, type, technique and duration of activity as well as availability of equipment and its use [26]. RT sometimes requires additional instruction to ensure exercises are performed safely and effectively, creating challenges for some individuals [26].

A systematic review and meta-analysis has reported that effective PA interventions have the potential to reduce the personal and economic costs associated with T2DM [59]. However, it has been suggested that those who potentially have the most to gain from PA are often the ones who find it most difficult to engage in this health behavior [59, 60]. The effectiveness of PA as a therapeutic intervention is also seriously hampered by uncertainty about how clinical care teams should support people with T2DM to meet and maintain PA guidelines. This is an example of the “evidence-practice gap” [2]. The low levels of PA in adults with T2DM, together with the many known benefits of increasing

PA in this population, sets an important challenge for health care teams to assist people with T2DM to increase and maintain their levels of PA to improve physical and mental health.

Appropriately qualified health professionals, such as psychologists and exercise specialists, can help individuals address barriers to PA, while taking into account their comorbidities and complications [58].

In Australia, the Federal Government offers patients living with a chronic medical condition (such as T2DM), access to a Chronic Disease Management (CDM) Plan [61]. With a general practitioner referral, patients can claim a maximum of five visits annually, to a variety of allied healthcare professionals, including dietitians, psychologists, exercise physiologists and podiatrists. The efficacy of these five individual sessions for adults with T2DM has not yet been determined [21]. The CDM scheme is not currently funded to provide allied health services to patients without a diagnosed chronic disease [61]. Consequently, patients at-risk of developing T2DM or with pre-diabetes are not eligible to access allied health intervention under the CDM scheme.

Accredited Exercise Physiologists have been added to the list of allied health professionals available to patients through the CDM plan [62].

Accredited Exercise Physiologists are university qualified health professionals with expertise in designing, delivering and evaluating safe and effective exercise interventions for people with acute, sub-acute or chronic health conditions [63]. However, a recent systematic review and meta-analysis of eight randomized controlled trials (5190 participants) questioned the efficacy and cost effectiveness of PA referral schemes for increasing PA and recommended further trials, especially those that are theory-driven [64]. It should be noted that many of the referral schemes used leisure centres for group-based programs which did not provide expert supervision in the Australian context, James and colleagues [21] recently took up this and demonstrated a significant increase in PA among insufficiently active primary care patients who were provided a referral to receive five sessions from an exercise specialist.

Psychologists also play an important role in assisting in behavior change to positively impact health and quality of life [65]. Psychological assistance has previously been found to be successful in increasing PA among people with diabetes [66]. Psychological strategies increase motivation to change, decrease barriers to change and encourage behaviors that lead to maintenance of change [66].

Smartphone apps [67], web-based support [68] and telehealth [21] are interventions that can be used as an adjunct to allied health interventions, but will have greater efficacy if they are grounded in health behavior change theory [68].

Theory-driven interventions that use specific behavior change techniques to target PA behaviors in adults with T2DM have been shown to be effective in increasing PA levels and improving glycaemic control in both clinical and community settings [2, 59] and reducing weight in community settings [59]. Some of the commonly used behavior change techniques in PA interventions include: prompting generalization of target behaviors; using follow-up prompts; prompt reviewing of behavioral goals; providing information on where and when to perform PA; planning social support/social change; PA goal setting; managing time; focussing on past successes; identifying and problem-solving barriers to PA; and highlighting the consequences specific to the individual [2]. The psychologist and exercise specialist in the SMART Health study will incorporate many of these behavior change techniques in their face-to-face sessions with research participants.

Independently, face-to-face consultation, smartphone technology, web 2.0 technology and telehealth have been shown to be efficacious in promoting PA in adults [21, 69, 70]. A strength and unique feature of the SMART Health study is that it is a multi-component intervention that will use all of these methods simultaneously to promote PA and RT in a community setting. It is also an application to a unique population of school teachers which has been understudied. Other strengths of the SMART Health trial include its randomized controlled trial design with wait-list control group, randomization procedure, objective measure of PA, intention-to-treat plan and 18-month follow-up. In addition to the primary outcome (objectively measured PA), a range of secondary outcome measures will be assessed to determine the broader psychological, behavioral and cognitive effects of the intervention. Additionally, process and impact evaluations will be conducted to ensure that future interventions with this population group could be tailored to their needs.

Despite these strengths, there are a number of limitations that should be noted. One limitation of the study is the inability to isolate the effect of individual components of each of the intervention arms (i.e. the effect of the psychologist versus the exercise specialist and the individual contributions of the smartphone app versus website versus telephone helpline). Another limitation of the study is the lack of a group social support component for participants as this is known to enhance participation in PA [71, 72]. Pedometers will not be sealed in this study. It could be argued that step count isn't an objective measure of PA as participants could potentially tamper with the pedometer or exaggerate their step count when recording these on their log sheet. The use of accelerometers may have overcome the issue of objectivity but they also have their limitations. The participants in this study are all school teachers. This is a very specific population group, therefore the results may not be generalizable. Finally, there will be no fitness measures taken in this study and this may also be considered a limitation.

If the pilot is found to be efficacious, this would support an application for a fully powered trial. If found effective, the SMART Health study would have implications for the way in which PA is prescribed and promoted to people with or at risk of T2DM. Additionally, it may provide evidence for the inclusion of five allied health sessions in the CDM Plan for people 'at risk' of T2DM, not just if currently diagnosed with T2DM. A positive outcome from the SMART Health study would reduce the financial and travel burden experienced by some individuals by providing them with a home-based program that incorporates both PA and RT. This would be beneficial for people from low socio-economic areas or those who are geographically isolated. SMART Health is scalable for larger population groups in community settings and can be applied to different target groups.

4. Conclusion

This paper has outlined the rationale and pilot study protocol for the SMART Health intervention for school teachers ‘at risk' of, or diagnosed with, T2DM. SMART Health is an innovative, community-based study that integrates face-to-face consultations with exercise specialists and psychologists and a technology-based behavior support package (smartphone app, website and telephone helpline) to increase PA. The intervention is theory-driven and includes a number of novel strategies to increase both PA and RT PA. The findings will be used to guide the development of future PA interventions for teachers and other population groups. If the SMART Health intervention is found to be efficacious in increasing MVPA and RT, a cost-benefit analysis will be undertaken.

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