c4-Walking with Diabetes (WW-DIAB) programme a walking programme

by Wara Kushartanti

Submission date: 04-Nov-2019 05:06PM (UTC+0700)
Submission ID: 1206632045
File name: tes_WW-DIAB_programme_a_walking_programme_for_-_sage_journal.pdf (335.15K)
Word count: 7354
Character count: 38836

Original Article

SAGE Open Medicine

Walking with Diabetes (WW-DIAB) programme a walking programme for Indonesian type 2 diabetes mellitus patients: A pilot randomised controlled trial

SAGE Open Medicine
Volume 6: 1–10

DOI: 10.1177/2050312118814391
journals.sagepub.com/home/smo
SAGE

Novita Intan Arovah[1,2,3], Bernadeta Margareta Wara Kushartanti[2], Tracy L Washington[3,4] and Kristiann C Heesch[1,3]

Abstract

Objectives: This pilot study aimed to examine the feasibility and effectiveness of a pedometer-based walking programme in Indonesian type 2 diabetes mellitus patients.

Methods: Feasibility was assessed by monitoring participant recruitment, retention, and adherence to the step-monitoring and recording instructions. Effectiveness was assessed in a pilot randomised controlled trial. Participants were type 2 diabetes mellitus patients randomly assigned to a pedometer-only (PED-only) group (n = 22) and a pedometer with text message support (PED+) group (n = 21). Outcomes were step counts, self-reported physical activity, social cognitive constructs, glycaemic parameters, and health-related quality of life. These were assessed at baseline, 12-week intervention, and 12 weeks later. Longitudinal analyses using generalised estimating equations were carried out to assess treatment and time effects on study outcomes.

Results: All but one participant (98%) attended 12- and 24-week data collection follow-ups. Throughout the study period, 82% of PED+ participants submitted their daily steps log. Daily steps increased in both groups ($p < 0.001$) but more in the PED+ group (2064 more steps at week 24, 95% confidence interval: 200–3925, $p = 0.03$). Self-reported physical activity levels and glycaemic parameters increased similarly in the two groups over time ($p < 0.05$). Improvements in social cognitive processes were seen only in the PED+ group ($p < 0.05$). There were no significant improvements in health-related quality of life.

Conclusion: This study provides preliminary evidence that a pedometer-based walking programme, with or without additional support, is feasible and improves physical activity and glucose levels in Indonesian type 2 diabetes mellitus patients. Greater increases in step counts can result from the provision of text message support and education materials than from the provision of a pedometer only.

Keywords

Diabetes/endocrinology, epidemiology/public health, health promotion, intervention studies, pedometer, physical activity, social cognitive theory, text message

Date received: 20 July 2018; accepted: 30 October 2018

Introduction

The high prevalence of type 2 diabetes mellitus (T2DM) has put a financial burden on healthcare systems in countries around the world, including in Indonesia.[1] In 2014, 40% of the health expenditure for all non-communicable diseases in Indonesia was allocated for managing T2DM and its complications.[2,3] Therefore, the prevention and control of T2DM complications should be an Indonesian public health priority.

Physical activity reduces the risk of T2DM complications by improving glycaemic control and lipid profiles, as well as decreasing blood pressure and body fat.[4–6] It also reduces both total and cardiovascular mortality risks among T2DM

[1]School of Public Health and Social Work, Queensland University of Technology, Brisbane, QLD, Australia
[2]Faculty of Sports Science, Yogyakarta State University, Yogyakarta, Indonesia
[3]Insitute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, QLD, Australia
[4]Faculty of Science and Engineering, Queensland University of Technology, Brisbane, QLD, Australia

Corresponding author:
Novita Intan Arovah, Faculty of Sports Science, Yogyakarta State University, Colombo Street No. 1, Karang Malang Depok Sleman, Yogyakarta 55281, Indonesia.
Email: novita@uny.ac.id

patients.[7] However, physical activity promotion is underutilised in Indonesia. This is likely due in part to the lack of evidence about the most appropriate ways to promote physical activity to T2DM patients in this population.

One of the most recommended, safe, and cost-effective forms of physical activity for T2DM patients is walking.[8] For obtaining optimal health benefits, public health guidelines recommend 30 min of moderately paced walking that generates 3000–4000 steps in addition to daily activity of 6000–7000 steps.[9] Likewise, for clinical improvements in T2DM control, particularly in HbA1c levels, previous research suggests that patients must obtain 4000 steps per day in addition to their usual activity.[10]

To help T2DM patients without physical limitations meet the recommendation, theory-based supports and prompts are suggested.[11] For example, pedometers help patients self-monitor behaviour and set behavioural goals.[12] The use of pedometers with T2DM patients has resulted in increases in daily steps,[13,14] although these increases have been small (below 4000 steps), which could explain why their use has not led to clinical improvements. In practice, use of more than one theory-based technique (e.g. a pedometer) is likely to be required to help T2DM patients attain 4000 additional steps. Indeed, findings of a systematic review suggest that the physical activity programmes most likely to achieve clinically significant improvements in T2DM patients implement at least 10 behaviour change techniques, for a minimum of 6 months.[11]

One of the most widely used theories for increasing physical activity levels is social cognitive theory (SCT).[15] The underlining concept of this theory is reciprocal determinism, which assumes that behaviour (e.g. physical activity), personal factors (e.g. cognitive factors), and environmental factors (e.g. social interactions) are interrelated. Therefore, behaviour changes (i.e. increases in physical activity) are expected when cognitive factors and social interactions improve. Several behaviour change techniques have been used successfully to increase physical activity levels via their influence on four key SCT constructs: self-efficacy, outcome expectations, self-regulation, and social support.[16–18] However, to date, no physical activity interventions with T2DM patients have included techniques to influence all four constructs. Moreover, SCT-based techniques as well as pedometers have not been used in physical activity interventions conducted in Indonesia. In short, the feasibility and effectiveness of implementing physical activity interventions that use SCT-based techniques and pedometers in this population have not been investigated, and given their promise for increasing physical activity levels, their feasibility and effectiveness in this population should be investigated.

The overall aim of this study was to test the feasibility and effectiveness of an SCT- and pedometer-based physical activity programme, which targeted self-efficacy, outcome expectations, self-regulation, and social support, in Indonesian T2DM patients. The first objective was to examine the feasibility of recruiting and retaining members of the target population and of assuring their adherence to the programme protocol. The second objective was to examine the effectiveness of the programme in increasing pedometer-measured daily step counts. The third objective was to examine whether the programme could also improve self-reported physical activity levels, social cognitive processes, clinical outcomes (glycaemic parameters), and health-related quality of life (HRQoL) in these patients. The findings from this study will be used for designing and implementing a larger randomised controlled trial (RCT) study in this population.

Methods

Setting and study population

The recruitment setting was a public hospital in Yogyakarta, the Indonesian city with the highest number of diagnosed T2DM cases in the country.[19] Participants were recruited from the cohort of clinically diagnosed T2DM patients attending the diabetes clinic or weekly exercise sessions at the hospital.

The Walking with Diabetes (WW-DIAB) programme framework and structure

The WW-DIAB programme was developed based on a review of previous theory-based physical activity programmes and a guide for developing theory-based materials.[20] It was also guided by findings from a needs assessment in the target population. The complete theoretical framework of WW-DIAB programme is illustrated in Figure 1.

The WW-DIAB programme was designed to improve patients' self-efficacy through several techniques (i.e. mastery experience, social modelling, psychological feedback, and verbal persuasion), resulting from the use of physical activity prompts (i.e. pedometer and step logs), educational materials (activity-based workbook), and text message support. Patients' outcome expectations were expected to improve through active learning stimulated from reading educational materials and follow-up text messages. Patients' social support was to improve through staff encouragement to enlist social support. Finally, patients' self-regulation was to improve through the use of step goal-setting and self-monitoring with pedometers and step logbooks. Increases in social cognitive processes were expected to result in increases in physical activity, which would then lead to glycaemic control improvements, decreases in complication risks, and improvement in HRQoL.

The programme was delivered in 24 weeks (two 12-week phases). In the first phase, the intensive phase, participants wore a pedometer and completed a workbook consisting of SCT-based activities that included daily step logs. Participants also received text messages (1–3 times/day). These messages summarised in brief theory-based material presented in the workbook to encourage them to walk more, and they included prompts to engage in workbook activities as well as

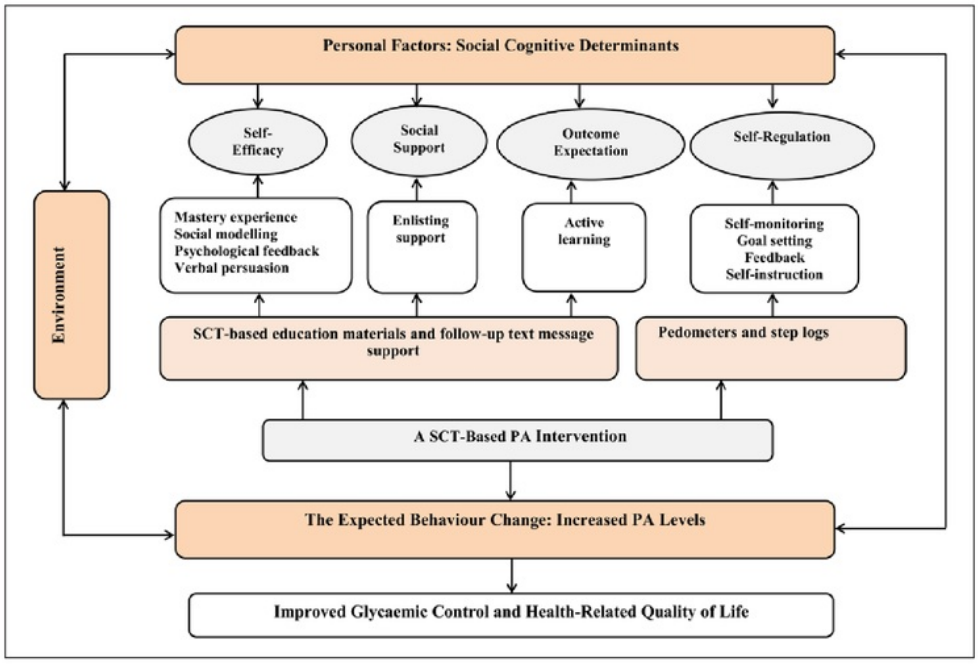

Figure 1. The theoretical framework of the WW-DIAB programme.

to self-monitor and record their steps. Participants were also to submit their daily step counts to the lead author through text messaging once per week. Table 1 illustrates the weekly SCT-based activities that were prompted by workbook and text messages. The workbook and the text message material are available from the author upon request.

In the second phase, the maintenance phase (weeks 13–24), participants no longer received text messages or engaged in structured activities. They were encouraged to apply skills acquired during the first phase and to maintain or increase their walking. During both phases, participants received their usual hospital care. Table 1 describes the weekly workbook activities and text message script themes and links these with the SCT constructs underlying the activities.

Study design

The study was a pilot RCT. Changes in study outcomes over 12 and 24 weeks were compared between an intervention group that received the WW-DIAB intervention (PED+ group) and a control group that received only pedometers and log sheets for recording steps (PED-only group). Because pedometers are a well-known strategy for increasing walking and because the focus of the research was not to examine the effectiveness of providing pedometers, but to assess the effectiveness of an SCT-based physical activity intervention added to the provision of pedometers, no no-treatment control group was included. The provision of pedometers to the control groups has been done previously.[17,21]

Sample size calculation

The primary outcome was daily pedometer step counts. To examine the treatment and time effects, the sample size calculation was based on expected step count differences between groups at the end of the intervention and expected pre–post differences in each group. The calculation used an estimated effect size of 0.87, generated from a recent meta-analysis of previous pedometer-based studies.[14] At a significance level of 0.05, a power level of 80%, with a one-tail hypothesis assumption, the study required 36 participants. Anticipating a dropout rate of 20%, a sample size of 43 participants was required. A one-tail assumption was used because we hypothesised that study outcomes would improve more in the PED+ group compared to the PED-only group based on evidence from previous physical activity studies.[17,18]

Inclusion, exclusion, and discontinuation criteria

The inclusion criteria were as follows: having a clinically confirmed T2DM diagnosis, receiving services from the diabetes clinic at the selected hospital, reporting an ability to walk for at least 15 min at one time, owning a mobile phone, familiarity with text messaging, and an ability to read and write in the local language. Patients with medical conditions that prevented participation in physical activity were excluded. The discontinuation criterion was developing a medical condition that prevents further participation in physical activity during the course of the study.

Table 1. The WW-DIAB intervention structure.

Period	Workbook and text message support	Targeted social cognitive constructs
Phase 1	*The intensive phase*	
Week 1	Creating walking step goals	Self-regulation
Week 2	Reviewing physical activity benefits	Outcome expectations
Week 3	Fitting walking sessions into weekly schedule	Self-efficacy
Week 4	Practising relaxation technique to decrease stress	Self-efficacy
Week 5	Enlisting support from family and friends to become physically active	Social support
Week 6	Providing oneself with a reward when step goal is achieved	Self-regulation
Week 7	Practising positive self-talk to encourage walking	Self-regulation
Week 8	Expanding walking activities in four physical activity domains: transport, household related, occupational, and leisure	Self-regulation
Week 9	Using physical activity prompts (e.g. placing a walking schedule in a visible place at home)	Self-regulation
Week 10	Evaluating and reviewing challenges in following the programme and finding solutions	Self-regulation
Week 11	Improving walking techniques to maximise physical activity benefits	Self-regulation
Phase 2	*The maintenance phase*	
Weeks 13–24	Continue to apply skills learned at the first 12 weeks on one's own. They no longer received text message reminders during these weeks	All

WW-DIAB: Walking with Diabetes.

Participant recruitment

To recruit participants, the lead author placed recruitment brochures in the hospital diabetes clinic and stood at a recruitment table in the diabetes clinic during office hours for five weekdays. She also placed brochures in the hospital exercise class for T2DM patients. Patients who attended the exercise class were in need of further physical activity programming because this weekly 1-h class was insufficient to provide them with the weekly dose of physical activity required to meet physical activity guidelines.

Most patients who asked to participate met the lead author in the diabetes clinic to discuss the study and undergo initial screening against inclusion and exclusion criteria. Those who received the brochure when she was not available were instructed to phone the lead author to arrange to meet her in the diabetes clinic for the initial screening. Patients who met the initial criteria were asked to give permission for the second stage of screening, which included the lead author's review of the patient's medical records to confirm the diagnosis. Those with a confirmed T2DM diagnosis were allowed into the study.

Randomisation and blinding

At baseline, participants were randomised into either PED+ or PED-only group with an allocation ratio of 1:1. A list of participants was created, and then the sequence for the allocation was generated using a random number generator application for mobile application.[22] In view of the inherent difficulties in blinding a behaviour change programme within one community, the allocation was not concealed from participants. The lead author generated the allocation sequence, assigned participants to the study groups, and delivered the programme; she was not, therefore, blinded to group allocation. Other researchers, phlebotomists, laboratory technicians, and research assistants involved in data collection, as well as statisticians, were blinded to group assignment.

Feasibility study outcomes

The outcomes of interest were recruitment, retention, and adherence success. Specifically, the outcomes and criteria of success were (1) of all patients who expressed an interest in participating, the proportion who met all eligibility requirements, including a confirmed T2DM diagnosis (first criterion of success for recruitment: >70%), (2) the proportion of eligible patients who enrolled in the study (second criterion of success for recruitment: >70%), (3) the proportion of patients who enrolled in the study who attended the 12- and 24-week data collection (criterion of success for retention: >80%), and (4) the proportion of PED+ participants who submitted their weekly daily step logs (criterion of success for adherence: >70%).

Except for the retention rate, the criteria of success were arbitrary due to the lack of recommended values from the literature. It was expected that recruitment, retention, and adherence rates would be high because pedometers were still considered novel in this population and thus would encourage participation.

Effectiveness study outcomes, instrument, and assessment schedules

The primary outcome was pedometer-measured daily steps using the Yamax SW200, which has been validated against

the observed step counts.[23] There were four secondary outcomes, which were (1) self-reported walking and moderate-to-vigorous-intensity physical activity (MVPA) minutes per week, using the interviewer-administered 7-day Physical Activity Rating (PAR),[24] (2) glycaemic control parameters (HbA1c, using the chromatography method; fasting plasma glucose, and 2-h plasma glucose, using the hexokinase method), (3) SCT constructs, which were measured using well-established scales that were culturally adapted from English for use in the Indonesian context: a self-efficacy scale developed by Marcus et al.,[25] an outcome expectations scale developed by Rovniak et al.,[26] a self-regulation scale developed by Rovniak et al.,[26] and a social support scale by Sallis et al.,[27] and (4) HRQoL, using the instrument developed by the EuroQol Group,[28] which was available in the Indonesian language. In total, there were 63 SCT and 6 HRQoL items. For the SCT construct scales, negatively worded questions were inversely coded, and then mean scores of scale items were computed to serve as scale scores, with higher mean scores representing higher levels or more of an attribute (e.g. higher self-efficacy). All measures were analysed and interpreted according to their scoring guidelines. The outcomes were assessed at baseline and at weeks 12 and 24.

Data collection

Data collection was conducted by the lead and second authors with the support of nine research assistants, two phlebotomists, and one laboratory technician in a private clinical laboratory in Yogyakarta. The research assistants were students of a university sports science course in Indonesia who were trained prior to data collection.

For each data collection period, participants attended an in-person appointment in the laboratory. During the appointment, the lead author administered the PAR, and participants self-completed the SCT scales and the HRQoL measure. A phlebotomist drew their blood for measuring glycaemic parameters. Research assistants measured blood pressure, height, weight, and waist/hip ratio. At the end of the first appointment, they gave each participant a pedometer and instructions on how to use it. They also instructed participants on completing 7-day step logs. The lead author contacted the participants by telephone 7 days after the first data collection so that they could report their baseline daily steps.

One week before each follow-up appointment, participants received a text message reminder to attend the next data collection and to bring completed step log sheets for the 7-day period immediately before the appointment. At each appointment, participants received a monetary incentive, equal to $US 9.00, as reimbursement for transportation costs.

Statistical analysis

All data were summarised using means and standard deviation (SD) for normally distributed data and frequencies and proportions for categorical data. The longitudinal data were analysed based on an intention-to-treat analysis. Generalised estimating equation (GEE) models were used to predict the primary and secondary outcomes by treatment (PED+ and PED-only), time (baseline, week 12, and week 24), and treatment-by-time interactions. It was confirmed that missing data were completely missing at random and, therefore, met the assumptions for conducting the GEE analysis. All analyses were conducted in SPSS 22 (IBM, Chicago, IL, USA).

The statistical analysis was conducted by the lead author in consultation with senior statisticians. During consultations, the statisticians were blinded. However, the lead author was not blinded because she delivered the intervention and participated in data collection. The research assistants, the laboratory personnel, and other researchers, including the second author, who supervised the data collection, however, were blinded to minimise detection bias by ensuring that the data collection for all participants was performed following the same standardised protocol.

Results

Feasibility study outcomes (recruitment, retention, and adherence)

During the recruitment week early in December 2015, 58 participants expressed an interest in participating in the study. All had a confirmed T2DM diagnosis based on the medical record review. Therefore, 100% of potential participants were confirmed to be eligible. However, 15 participants (53% were male) did not enrol in the study. A total of 4 potential participants could not be contacted and 11 decided not to participate, most because they were not available to attend baseline data collection the week following the recruitment week. The 43 (74%) participants who agreed to join the study were randomised and then participated in baseline data collection. Only one of the 43 did not attend the follow-up data collection appointments at weeks 12 and 24 (retention rate = 97.6%). Figure 2 shows a flowchart of participants' progression through enrolment, allocation, and follow-ups.

During the course of the study, 17 participants in the PED+ group (81.8%) registered their complete daily step record every week.

Baseline data

Participants' baseline characteristics are summarised in Table 2. Participants in both groups were aged 53–76 years. Most were female, married, with no educational certificates beyond a high school diploma. Over half were retired. Most had been diagnosed with T2DM at least 5 years prior to enrolling in the study, and almost all were taking oral antidiabetic medications. On average, participants had normal

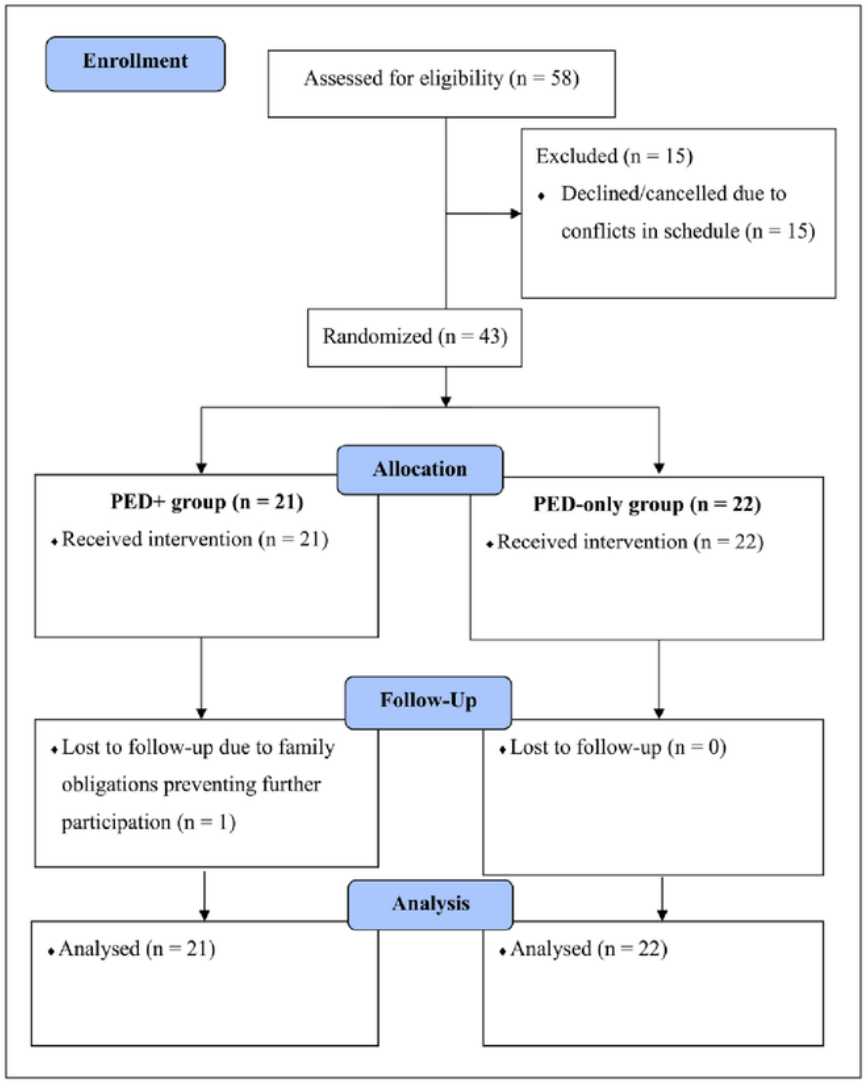

Figure 2. The flowchart of participants' progression through enrolment, allocation, and follow-ups.

blood pressure readings and were categorised as overweight according to Barba et al.,[29] based on the body mass index (BMI) criteria for Asian populations (>23 kg/m²). None of the participants walked more than 10,000 steps per day; however, four participants in each group reported that they were doing at least 150 min of moderate-intensity physical activity per week and thus were meeting international recommendations for physical activity.

Descriptive statistics of the study outcomes and the results of the GEE analysis are presented in Table 3.

Effectiveness study outcomes

Physical activity level. A significant treatment-by-time effect was found for the primary effectiveness outcome, daily step counts. Daily step counts changed over time in the two groups between baseline, week 12, and week 24 ($p < 0.001$) with increases in step counts from baseline to week 12 and from week 12 to week 24 in the PED+ group and from baseline to week 12 in the PED-only group. Average daily steps were significantly higher in the PED+ group than in the PED-only group ($p = 0.03$).

There was no treatment-by-time effect for any self-reported physical activity outcome. However, there was a time effect that indicated increases in self-reported walking and MVPA in both groups between baseline and week 12, and in the PED+ group between weeks 12 and 24. Although there was no treatment effect, the mean walking minutes/week increased by 126 min (SD = 174) in the PED+ group and by 61 min (SD = 129) in the PED-only group, while

Table 2. Baseline characteristics of participants.

Variables	PED-only (n = 22)	PED+ (n = 21)
Age (years), mean ± SD	65.9 ± 6.5	65.1 ± 5.2
Sex, n (%)		
Women	14 (63.6)	13 (61.9)
Men	8 (36.4)	8 (68.1)
Marital status, n (%)		
Married	15 (68.2)	16 (76.2)
Not married	7 (31.8)	5 (23.8)
Education level, n (%)		
Up to high school diploma	15 (68.2)	10 (47.6)
Diploma or higher	7 (31.8)	11 (52.4)
Employment status, n (%)		
Paid work	4 (18.2)	3 (14.3)
No paid work	7 (31.8)	6 (28.6)
Retired	11 (50.0)	12 (57.1)
Smoking status, n (%)		
Smoker	1 (4.5)	0 (0)
Non-smoker	18 (81.8)	20 (95.2)
Ex-smoker	3 (13.6)	1 (4.8)
T2DM duration (years), n (%)		
<5	6 (27.3)	6 (28.6)
5–10	11 (61.1)	7 (33.3)
>10	5 (51.25)	8 (38.1)
Treatment status, n (%)		
Oral	20 (90.9)	19 (90.5)
Insulin	2 (9.1)	2 (9.5)
Anthropometry status		
Body mass index	24.6 ± 3.5	25.5 ± 3.5
Waist/hip ratio	0.90 ± 0.05	0.88 ± 0.05
Blood pressure parameters		
Systole	129 ± 12	123 ± 11
Diastole	78 ± 6	76 ± 7
Baseline physical activity level, n (%)		
Meeting the recommended 10,000 steps/day	0 (0)	0 (0)
Meeting the recommended 150-min moderate physical activity/day	4 (18)	4 (19)

SD: standard deviation; T2DM: type 2 diabetes mellitus.

mean MVPA minutes/week increased by 115 min (SD = 182) in the PED+ group and by 50 min (SD = 106) in the PED-only group.

Glycaemic control. No treatment or treatment-by-time effect was found for glycaemic control parameters. However, there was a time effect: the three glycaemic control parameters improved in the two groups between baseline and week 24 ($p < 0.05$).

Social cognitive scores. For all but one SCT scale, there was a significant treatment-by-time effect. The mean scores on these scales increased more between baseline and weeks 12 and 24 in the PED+ group than in the PED-only group ($p < 0.05$), which suggested improvements in these attributes. There was no treatment-by-time effect on the negative outcome expectations subscale, but there were treatment and time effects. The mean score on this subscale increased over time in the two groups ($p = 0.001$), which suggested that participants expected fewer negative outcomes from participating in physical activity at follow-up than at baseline, and the mean score was higher in the PED+ group than in the PED-only group across data collection weeks ($p = 0.008$).

HRQoL. There were no treatment, time, or interaction effects for any HRQoL parameters, except for a time effect ($p = 0.04$) for the daily life activity scale, which measures ability in doing activities such as hobbies and sports. The mean score on the scale improved from baseline to weeks 12 and 24 in both groups.

Discussion

This study is the first evaluation of a pedometer-based intervention in Indonesia. The recruitment, retention, and adherence data indicated that the intervention to promote physical activity levels among Indonesian T2DM is feasible. The study findings also showed meaningful increases over the intervention period in daily step counts, with greater increases in the PED+ versus the PED-only group. PED+ participants also spent more times per week walking and doing MVPA compared to participants in the PED-only group, although the study was not powered to detect between-group differences in these activities. Overall results, therefore, provide preliminary evidence that the WW-DIAB was more effective than the provision of a pedometer in increasing physical activity levels in this target population.

Improvements by the PED+ and PED-only groups in daily steps are consistent with those found in previous pedometer-based programmes in T2DM patients, although these were conducted in Western populations.[6,16–18,30,31] The findings of this study also support the conclusion of a recent systematic review conducted by De Vries et al.[32] that showed physical activity programmes with activity monitoring increase physical activity in individuals who were overweight, as were participants in this study.

Physical activity outcomes continued to improve during the maintenance phase of the intervention (weeks 12–24) in the PED+ group but not in the PED-only group, which experienced slight reductions during that phase. This trend could reflect differences between groups in changes over time in social cognitive processing, as measured by the SCT scales. Scale scores improved significantly in the PED+ group across the intervention period but worsened in the PED-only group, suggesting a mediating effect of social cognitive processes. A larger sample, however, is required to confirm whether changes in SCT constructs mediate changes in walking and physical activity more generally. Overall findings, however, indicate the potential benefit of the WW-DIAB intervention

Table 3. Summary of the mean predicted values [95% CI] of the study outcomes.

Outcomes	Group	Baseline	Week 12	Week 24	Treatment	Time	Time × treatment
Physical activity							
Daily steps	PED-only	4625 [3776, 5473]	6027 [4835, 7219]	5898 [4630, 7166]	0.025	<0.001	0.056
	PED+	4876 [3975, 5778]	8096 [6901, 9292]	8214 [6878, 9550]			
Walking (min/week)	PED-only	32 [13, 51]	107 [52, 162]	93 [41, 145]	0.277	<0.001	0.337
	PED+	34 [7, 62]	138 [82, 193]	162 [89, 235]			
MVPA (min/week)	PED-only	95 [60, 130]	148 [91, 205]	146 [96, 193]	0.11	<0.001	0.289
	PED+	102 [76, 128]	201 [143, 257]	219 [147, 291]			
Glycaemic parameters							
Hba1c (%)	PED-only	7.75 [6.76, 8.73]	7.31 [6.66, 7.95]	7.22 [6.56, 7.88]	0.873	0.003	0.835
	PED+	7.85 [6.92, 8.79]	7.43 [6.72, 8.15]	7.24 [6.67, 7.8]			
Fasting plasma glucose (mg/dL)	PED-only	137 [108, 167]	126 [108, 144]	116 [103, 129]	0.69	0.031	0.794
	PED+	137 [113, 162]	133 [106, 159]	126 [109, 143]			
2-h plasma glucose (mg/dL)	PED-only	201 [155, 247]	178 [150, 206]	154 [133, 175]	0.519	<0.001	0.993
	PED+	215 [182, 249]	193 [155, 231]	167 [131, 203]			
Social cognitive measures							
Self-efficacy	PED-only	3.49 [3.20, 3.78]	3.44 [3.23, 3.64]	3.41 [3.16, 3.66]	0.004	0.067	0.017
	PED+	3.58 [3.24, 3.92]	4.12 [3.84, 4.40]	3.99 [3.73, 4.24]			
Positive outcome expectations	PED-only	3.75 [3.51, 3.99]	3.51 [3.30. 3.72]	3.61 [3.43, 3.78]	0.001	0.655	0.002
	PED+	3.85 [3.62, 4.07]	4.19 [3.99, 4.39]	4.13 [3.87, 4.39]			
Negative outcome expectations	PED-only	3.88 [3.72, 4.05]	4.16 [3.99, 4.33]	4.00 [3.86, 4.15]	0.008	0.001	0.164
	PED+	4.14 [3.97, 4.32]	4.42 [4.26, 4.59]	4.26 [4.12, 4.41]			
Goal setting	PED-only	3.21 [2.88, 3.53]	3.23 [2.85, 3.61]	3.05 [2.57, 3.52]	0.001	0.004	0.008
	PED+	3.28 [2.97, 3.59]	4.14 [3.95, 4.32]	3.85 [3.65, 4.05]			
Planning and scheduling	PED-only	3.38 [3.15, 3.61]	3.35 [3.11, 3.59]	3.14 [2.86, 3.42]	<0.001	0.142	0.002
	PED+	3.50 [3.23, 3.76]	3.91 [3.76, 4.06]	3.94 [3.78, 4.10]			
Reward and punishment	PED-only	3.82 [3.60, 4.04]	3.61 [3.42, 3.79]	3.67 [3.44, 3.90]	0.011	0.272	0.001
	PED+	3.67 [3.39, 3.94]	4.17 [3.97, 4.37]	4.07 [3.86, 4.27]			
Encouragement and participation	PED-only	3.15 [2.83, 3.48]	3.10 [2.71, 3.48]	3.01 [2.76, 3.25]	0.003	0.023	0.002
	PED+	3.16 [2.83, 3.49]	3.86 [3.69, 4.03]	3.72 [3.48, 3.95]			
Quality of life							
Visual analogue scale	PED-only	79 [75, 83]	78 [74, 81]	80 [76, 84]	0.201	0.137	0.082
	PED+	77 [72, 81]	83 [80, 85]	83 [80, 86]			
Mobility	PED-only	1.32 [1.12, 1.51]	1.36 [1.16, 1.56]	1.14 [0.99, 1.28]	0.113	0.617	0.06
	PED+	1.14 [0.99, 1.29]	1.05 [0.95, 1.14]	1.2 [1.02, 1.37]			
Self-care	PED-only	1.05 [0.96, 1.13]	1.14 [0.99, 1.28]	1.00 [1.00, 1.00]	0.441	0.352	0.231
	PED+	1.00 [1.00, 1.00]	1.05 [0.95, 1.15]	1.05 [0.95, 1.15]			
Daily activity	PED-only	1.27 [1.09, 1.46]	1.09 [0.97, 1.21]	1.18 [1.02, 1.34]	0.124	0.043	0.269
	PED+	1.10 [0.97, 1.22]	1.05 [0.95, 1.14]	1.05 [0.95, 1.14]			
Pain	PED-only	1.50 [1.29, 1.71]	1.41 [1.20, 1.61]	1.14 [0.99, 1.28]	0.357	0.08	0.111
	PED+	1.24 [1.06, 1.42]	1.30 [1.10, 1.49]	1.25 [1.06, 1.44]			
Anxiety	PED-only	1.27 [1.09, 1.46]	1.27 [1.09, 1.46]	1.14 [0.99, 1.28]	0.731	0.664	0.626
	PED+	1.19 [1.02, 1.36]	1.19 [1.02, 1.37]	1.15 [0.99, 1.30]			

CI: confidence interval; MVPA: moderate-to-vigorous-intensity physical activity.

over the provision of only a pedometer in influencing SCT constructs and increasing and maintaining physical activity behaviour.

The increases in physical activity levels in the two groups may have been responsible for the clinically meaningful glycaemic control improvements seen in both groups, as studies suggest that physical activity strongly correlates with improvements in glycaemic regulation.[4] Pedometers are novel in Indonesia, and their introduction to participants may have been adequate for increasing physical activity levels sufficiently to result in improved glycaemic control.

The glycaemic control improvements in this study did not require a 4000-step improvement, which, as previous research has suggested, is required for glycaemic control improvements to occur.[10] The discrepancy between our results and previous findings may be due to factors not measured in this

study. HbA1c is not only regulated by physical activity levels but also by other factors, such as medication use, stress levels, and diet. Therefore, to accurately measure the effect of a physical activity programme on HbA1c, future studies should control for those factors.

The significant glycaemic control improvements in this study were not followed by improvements in HRQoL. The cause of this may be that, although participants improved their HbA1c significantly, they did not achieve the recommended level of ⩽6.5% at week 24, and this change may not have been sufficient to positively impact HRQoL. It is also possible that longer observation periods are needed to detect meaningful and significant changes in HRQoL.

Strengths and limitations of this study should be recognised. A key strength was the testing of a pedometer-based intervention in a non-Western population, as most such studies have been conducted in Western countries. Another strength was that the intervention was underpinned by a behaviour change theory, SCT, and developed based on findings from a formative study in the target population. Moreover, the retention rate was high (97%), suggesting the acceptability of the intervention to participants. A major limitation was that all participants were recruited from the same setting, thereby increasing the risk of intervention design contamination. Another limitation was the sample size. The sample was powered to detect treatment-by-time effects in daily step counts, and therefore lack of significant findings for other outcomes could reflect a lack of adequate power to detect differences. The findings of this study, however, will be useful for adequately powering large studies that test the effectiveness of the WW-DIAB across multiple behavioural and health outcomes. Also, the long-term effectiveness of the intervention (beyond 24 weeks) was not assessed due to resource and time limitations. As with other physical activity trials, this study likely attracted people who were in the 'preparation stage' of change, and therefore the effectiveness of the programme in less motivated populations is unknown.

Therefore, prior to recommending the use of only the provision of pedometers in this population, those limitations need to be addressed. We recommend the use of a larger, clustered RCT that evaluates the long-term effects of the programme for future study.

Conclusion

Based on the participants' recruitment, retention, and adherence to step recording and monitoring, this study provides preliminary evidence that a pedometer plus support programme (WW-DIAB) is feasible to be implemented in T2DM patients in the Indonesian diabetes clinic setting. The findings further indicate that the programme is more effective in increasing daily steps in T2DM patients compared with the provision of only a pedometer. The findings also provide preliminary evidence that both programmes lead to increases in self-reported physical activity and improvements in glycaemic control. Therefore, in settings like diabetes clinics in developing countries that have few resources available for offering behaviour change programmes, the provision of pedometers to T2DM patients may be sufficient for improving physical activities to levels that improve glucose control. However, a more comprehensive evaluation of the effectiveness of the intervention is warranted before the simple provision of pedometers can be recommended.

Acknowledgements

We would like to thank the participants for taking the time to participate in this study and to the Institute of Health and Biomedical Innovation, Queensland University of Technology statistician team for providing support and advice in statistical analysis. Principal responsibility for study design was assumed by NIA. T.L.W. and K.C.H. contributed to the development of the intervention and study design. N.I.A. was responsible for the conduct of the intervention and data analysis, in consultation with T.L.W., B.M.W.K., and K.C.H. T.L.W. and K.C.H. contributed to the interpretation of findings. N.I.A. drafted the manuscript with contributions from K.C.H. All the authors made substantive revisions to manuscript drafts and approved the final manuscript.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval and trial registration

This study was approved by the Queensland University of Technology Human Research Ethics Committee, with approval no. 1500000562. Participants' personal information was collected, shared, and maintained to protect confidentiality before, during, and after the trial. All participants were fully informed and provided written informed consent. The trial was registered to the Australian and New Zealand Clinical Trial Registry, with the trial registration no. ACTRN12615001006538.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study received funding from the Indonesian Research and Higher Education Ministry (University Unggulan Grant 25/UPT/UN34.21/2016). The lead author was funded by an Australian Award Scholarship. The funders had no involvement in the collection, management, analysis, and interpretation of data; writing of the manuscripts about the study findings; or in the decision to submit reports of the study findings for publication.

Informed consent

Written informed consent was obtained from all subjects before the study.

Trial registration

This trial was registered at the Australia New Zealand Clinical Trial Registry (ACTRN12615001006538).

ORCID iD

Novita Intan Arovah https://orcid.org/0000-0002-0779-3344

References

1. International Diabetes Federation. *IDF Diabetes Atlas 7th edition (2015)*. Brussels: International Diabetes Federation, 2015.
2. Fountaine T, Lembong J, Nair R, et al. *Tackling Indonesia's diabetes challenge: eight approaches from around the world*. Singapore: McKinsey Center for Healthcare Research and Innovation (CHRI), 2016.
3. Soewondo P, Ferrario A and Tahapary DL. Challenges in diabetes management in Indonesia: a literature review. *Global Health* 2013; 9: 63.
4. Umpierre D, Ribeiro PA, Kramer CK, et al. Physical activity advice only or structured exercise training and association with HbA1c levels in type 2 diabetes: a systematic review and meta-analysis. *JAMA* 2011; 305: 1790–1799.
5. Kaizu S, Kishimoto H, Iwase M, et al. Impact of leisure-time physical activity on glycemic control and cardiovascular risk factors in Japanese patients with type 2 diabetes mellitus: the Fukuoka Diabetes Registry. *PLoS ONE* 2014; 9: e98768.
6. De Greef, Deforche B, Tudor-Locke C, et al. A cognitive-behavioural pedometer-based group intervention on physical activity and sedentary behaviour in individuals with type 2 diabetes. *Health Educ Res* 2010; 25: 724–736.
7. Sluik D, Buijsse B, Muckelbauer R, et al. Physical activity and mortality in individuals with diabetes mellitus: a prospective study and meta-analysis. *Arch Intern Med* 2012; 172: 1285–1295.
8. Abadi FH, Muhamad TA and Salamuddin N. Energy expenditure through walking: meta analysis on gender and age. *Procedia Soc Behav Sci* 2010; 7: 512–521.
9. Tudor-Locke C and Bassett DR Jr. How many steps/day are enough? Preliminary pedometer indices for public health. *Sports Med* 2004; 34: 1–8.
10. Van Dyck D, De Greef K, Deforche B, et al. The relationship between changes in steps/day and health outcomes after a pedometer-based physical activity intervention with telephone support in type 2 diabetes patients. *Health Educ Res* 2013; 28: 539–545.
11. Avery L, Flynn D, van Wersch A, et al. Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. *Diabetes Care* 2012; 35: 2681–2689.
12. Tudor-Locke C, Williams JE, Reis JP, et al. Utility of pedometers for assessing physical activity: convergent validity. *Sports Med* 2002; 32: 795–808.
13. Bravata DM, Smith-Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: a systematic review. *JAMA* 2007; 298: 2296–2304.
14. Qiu S, Cai X, Chen X, et al. Step counter use in type 2 diabetes: a meta-analysis of randomized controlled trials. *BMC Med* 2014; 12: 36.
15. Allen NA. Social cognitive theory in diabetes exercise research: an integrative literature review. *Diabetes Educ* 2004; 30: 805–819.
16. Araiza P, Hewes H, Gashetewa C, et al. Efficacy of a pedometer-based physical activity program on parameters of diabetes control in type 2 diabetes mellitus. *Metabolism* 2006; 55: 1382–1387.
17. Johnson ST, Mundt C, Qiu W, et al. Increase in daily steps after an exercise specialist led lifestyle intervention for adults with type 2 diabetes in primary care: a controlled implementation trial. *J Phys Act Health* 2015; 12: 1492–1499.
18. Tudor-Locke C, Bell RC, Myers AM, et al. Controlled outcome evaluation of the First Step Program: a daily physical activity intervention for individuals with type II diabetes. *Int J Obes Relat Metab Disord* 2004; 28: 113–119.
19. Kesehatan BPdP. *Riset kesehatan dasar (RISKESDAS) 2013*. Jakarta, Indonesia: Kemenkes RI, Indonesian Ministry of Health, 2013.
20. Seligman HK, Wallace AS, DeWalt DA, et al. Facilitating behavior change with low-literacy patient education materials. *Am J Health Behav* 2007; 31: S69–S78.
21. Agboola S, Jethwani K, Lopez L, et al. Text to move: a randomized controlled trial of a text-messaging program to improve physical activity behaviors in patients with type 2 diabetes mellitus. *J Med Internet Res* 2016; 18: e307.
22. Skytrait-Gabe Brandao. *Random numbers generator*. Aberdeen, MD: Skytrait, 2015.
23. Crouter SE, Schneider PL, Karabulut M, et al. Validity of ten electronic pedometers for measuring steps, distance, and kcals. *Med Sci Sports Exerc* 2003; 35: S283.
24. Sallis JF, Buono MJ, Roby JJ, et al. Seven-day recall and other physical activity self-reports in children and adolescents. *Med Sci Sports Exerc* 1993; 25: 99–108.
25. Marcus BH, Selby VC, Niaura RS, et al. Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport* 1992; 63: 60–66.
26. Rovniak LS, Anderson ES, Winett RA, et al. Social cognitive determinants of physical activity in young adults: a prospective structural equation analysis. *Ann Behav Med* 2002; 24: 149–156.
27. Sallis JF, Grossman RM, Pinski RB, et al. The development of scales to measure social support for diet and exercise behaviors. *Prev Med* 1987; 16: 825–836.
28. EuroQol Group. *EQ-5D-Y user guide: basic information on how to use the EQ-5D-3L instrument*. Rotterdam: EuroQol Research Foundation, 2015.
29. Barba C, Cavalli-Sforza T, Cutter J, et al. Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies. *Lancet* 2004; 363: 157–163.
30. De Greef KP, Deforche BI, Ruige JB, et al. The effects of a pedometer-based behavioral modification program with telephone support on physical activity and sedentary behavior in type 2 diabetes patients. *Patient Educ Couns* 2011; 84: 275–279.
31. De Greef K, Deforche B, Tudor-Locke C, et al. Increasing physical activity in Belgian type 2 diabetes patients: a three-arm randomized controlled trial. *Int J Behav Med* 2011; 18: 188–198.
32. De Vries HJ, Kooiman TJ, van Ittersum MW, et al. Do activity monitors increase physical activity in adults with overweight or obesity? A systematic review and meta-analysis. *Obesity* 2016; 24: 2078–2091.

c4-Walking with Diabetes (WW-DIAB) programme a walking programme

ORIGINALITY REPORT

5%	7%	2%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	eprints.qut.edu.au Internet Source	5%

Exclude quotes	On	Exclude matches	< 2%
Exclude bibliography	On		

c4-Walking with Diabetes (WW-DIAB) programme a walking programme

GRADEMARK REPORT

FINAL GRADE

/100

GENERAL COMMENTS

Instructor

PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8

PAGE 9

PAGE 10