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Regular use of pedometer does not enhance beneficial outcomes in a physical activity intervention study in type 2 diabetes mellitus

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Abstract

The aim of the present study was to investigate whether the use of pedometer increases walking and/or enhances beneficial outcomes in a physical intervention study in type 2 diabetes mellitus. Seventy persons with type 2 diabetes mellitus were randomized to a pedometer and a nonpedometer group (P and non-P groups). All participants were seen by a nurse at a baseline visit (V1), after 1 month, after 3 months, and after 6 months and were then encouraged to increase walking. Subjects in the P group additionally registered pedometer steps 3 days twice per month for 6 months. After V1 and the visit at 6 months, aerobic capacity (VO_{2peak}) was measured; and subjects reported perceived physical fitness and activity. Twenty-two subjects did not complete the study (dropouts). The VO_{2peak} at V1 was lower in dropouts than in subjects who completed the study (completers) ($P = .003$). In the P group, the number of steps per day did not increase from month 1 to month 6 ($P = .65$). In completers, taken together, there was a decrease in body weight ($P = .005$), hemoglobin A_{1c} ($P = .034$), fasting blood glucose ($P = .033$), triglycerides ($P = .002$), and diastolic blood pressure ($P = .048$) and an increase in high-density lipoprotein cholesterol ($P < .001$), with no difference between the P group and non-P group for these variables (all P values >.38). Perceived improvement in physical and mental state correlated with improvement in VO_{2peak} ($r = 0.45$, $P = .008$ and $r = 0.38$, $P = .03$, respectively; n = 34). We conclude that the use of pedometer did not increase walking or enhance beneficial metabolic outcomes. The low aerobic capacity in dropouts indicates that persons most needy of physical exercise are the least compliant in exercise programs.

1. Introduction

There is strong evidence for beneficial health effects of physical activity in people with type 2 diabetes mellitus (T2DM) [1-7]. However, although physical activity is presented as a cornerstone in the treatment, people with T2DM often find it difficult to incorporate structured exercise into their daily lives [8,9]. Walking is a simple activity that has been shown to have beneficial health effects [10-14]. Walking can be quantified accurately by the use of pedometers (step counters) [15-17]. Pedometer-registered activity seems to reflect aerobic fitness in nondiabetic [18,19] and diabetic [7] people. The use of pedometers may lead to a realistic perception of physical activity [7], which, in turn, could motivate people to strive for physical fitness. Therefore, the use of pedometers could possibly increase the success of programs aimed to increase physical activity in T2DM subjects. However, controversies exist whether the use of pedometers does increase walking in people with T2DM [10,12,20].

We conducted a randomized controlled trial with the aim to promote physical activity in T2DM subjects and to test whether regular use of pedometer increases walking and/or enhances health-related beneficial effects.

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2. Materials and methods

2.1. Subjects

Subjects with T2DM (age <80 years) were recruited from the outpatient clinic at the Department of Endocrinology, University Hospital of Trondheim, from February to October 2005 and by one advertisement in the local newspaper. Exclusion criteria were pregnancy, disabling long-term complications of diabetes, serious cardiovascular disease or cancer, or any limitations for walking. The protocol was approved by the Regional Ethics Committee. Written informed consent was obtained from all participants.

2.2. Procedures

Participants met with the study nurse at a baseline visit (visit 1, V1), after 1 month (V2), after 3 months (V3), and after 6 months (V4). At each visit, weight, waist-hip ratio, and blood pressure (BP) were measured; fasting blood tests were obtained; medication was reported; and participants were asked if they had experienced chest pain or any health-related limitation for walking. All participants were informed of the favorable effect of physical activity. In a questionnaire, they reported clinical data, perceived physical fitness, and everyday activity graded from 1 (very low) to 5 (high). Participants were randomly allocated to a pedometer group (P group) or a nonpedometer group (non-P group). Subjects in the P group registered ambulatory activity by pedometer (Yamax Digi-Walker ML AW-320, Yamax Corp, Tokyo, Japan) 3 weekdays twice per month. Both groups kept a logbook of all major physical activities. Registrations in the logbook were discussed with the nurse at each visit, and individual strategies to increase walking were established. Participants who used pedometers were encouraged to increase their daily step count from one visit to the next. The targeted increase in steps was based on the mean number of steps during month 1. If the subject walked the targeted number of steps, he/she was encouraged to increase the step number further until the next visit. Participants who did not use pedometer were encouraged to increase the average daily time spent walking from one visit to another, guided by the logbook. Step data collection and logbook registration of activity were scheduled (ahead of registration) in agreement with the study nurse at each visit. The nurse was careful to set realistic and individual targets in agreement with the participants and in consideration of each person's health and perceived ability, and to encourage subjects to increase walking as part of their daily routine. In addition, visits included the following: During V1, subjects in the P group were instructed how to wear and use the pedometer as described previously [7]. After V1, all participants underwent exercise electrocardiogram (ECG) performed on an electronically braked bicycle ergometer (Ergometrics 900; Ergoline, BTL Industries, London, United Kingdom) as described previously [7].

2.2.1. Work economy and peak oxygen consumption

Exercise testing was performed on a treadmill with gradually increasing resistance according to the Oslo protocol [21] after V1 (test 1) and V4 (test 2) under the supervision of an exercise physiologist. A cardiologist was present in a nearby room. After being familiarized with walking on the treadmill, the subjects completed a 10-minute individualized warm-up program (speed, 3-6 km/h; incline, 0%-5%). Afterward, a face mask was placed on the subjects' face for metabolic measurements (Metamax II; Cortex, Leipzig, Germany). Heart rate was continuously recorded (Polar 410; Polar Electro, Kempele, Finland). After the warm-up was completed, each subject's work economy at submaximal intensity was determined (speed, 3-5 km/h; incline, 0%-5%). Within 3 minutes, all subjects reached stable values; and speed or incline was then increased for the next step. The last 30 seconds of the first step was defined as *work economy*. Thereafter, the speed was constant; and incline was increased by 2% every minute until exhaustion. The 30 seconds with the highest oxygen uptake was defined as VO_{2peak}. The intention of the individualized speed and incline was to bring the subjects to VO_{2peak} after 6 to 10 minutes. The first step to detect changes in work economy was the same before and after the intervention. No complication occurred during the treadmill tests.

At V2, V3, and V4, the participants' recordings of physical activity were discussed with the nurse; and goals for increasing physical activity were set. At V4, they answered the following in a questionnaire:

1. Do you recognize any change in your physical fitness during the study?
2. Do you recognize any change in your mental state during the study?

Answers were graded from 1 (no change) to 5 (considerable improvement).

2.3. Laboratory methods

Plasma glucose, hemoglobin A_{1c} (HbA_{1c}), serum creatinine, and lipids were analyzed by standard methods at the Department of Clinical Chemistry, University Hospital of Trondheim. The reference range of HbA_{1c} was 4.3% to 5.6% (interassay coefficient of variation [CV], <1.6%; intraassay CV, <3%). Insulin C-peptide (reference range, 0.3-1.3 nmol/L; interassay CV, 3.2%-5.6%; intraassay CV, 10.3%) was analyzed by competitive enzyme immunoassay (Diagnostic Products, Los Angeles, CA).

2.4. Statistics

Data are expressed as mean ± SD, unless otherwise indicated. Normally distributed variables were compared between groups with independent-samples Student *t* test, and within-subject differences were analyzed with paired-samples Student *t* test. Non-normally distributed variables were compared between groups with Mann-Whitney test,

and dichotomous variables were tested with Fisher exact test. Normality of data was examined by inspection of the normal Q-Q plot. Repeated-measures analysis of variance with Bonferroni correction for multiple comparisons was applied to investigate changes over time. Missing values were handled by pairwise deletions. Relations between continuous variables were analyzed by Pearson or Spearman correlation coefficients. Two-sided P values < .05 were considered significant. Statistical analyses were performed with SPSS version 14.0 (SPSS, Chicago, IL).

3. Results

3.1. Baseline characteristics and dropouts

Seventy persons met at V1. One subject in the P group was excluded after V1 because of an abnormal exercise ECG, and 21 subjects (9 in P group and 12 in non-P group) did not complete the study (dropouts). Most of these subjects dropped out after V1 or V2. Reasons for withdrawal were illness (11 subjects), work commitment (3 subjects), and personal circumstances (7 subjects). Twenty-three subjects in the P group and 25 in the non-P group completed the study (completers).

Aerobic capacity (in milliliters per kilogram per minute and liters per minute) was lower in dropouts than in completers ($P = .003$ and $P = .026$, respectively). Otherwise, clinical and laboratory data were similar in completers and dropouts (Tables 1 and 2). Significant correlations were found between perceived physical fitness and aerobic capacity (in milliliters per kilogram per minute and liters per minute) ($r = 0.46$, $P < .001$, n = 58 and $r = 0.28$, $P = .029$, n = 59, respectively).

Table 1
Background data in the P group, non-P group, and dropouts

	P group (n = 23)	Non-P group (n = 25)	Dropouts[a,b] (n = 22)
Women/men	9/14	8/17	8/14
Never smokers	12	12	12
Current smokers	1	4	4
Employed	13	13	11
Pensioners (old age)	6	9	8
Other metabolic disease	6	8	9
Other diseases	12	14	8
No antidiabetic medication	7	10	9
MET only	9	2	5
SU + MET	2	5	4
Insulin only	0	4	1
Insulin + SU or MET	3	4	2
Repaglinide	1	0	0
Rosiglitazone + SU +MET	1	1	1
Insulin + MET+ repaglinide	0	1	0
Other medication	17	21	18

MET indicates metformin; SU, sulfonylurea.
[a] Ten subjects in the P group.
[b] One subject was excluded because of abnormal exercise ECG.

Table 2
Clinical and laboratory variables at visit 1[a,b] in the P group, non-P group, and dropouts

	P group (n = 23)	Non-P group (n = 25)	Dropouts (n = 22)
Age (y)	56.4 ± 11.0	61.2 ± 9.7	57.7 ± 14.0
Weight (kg)	94.8 ± 19.3	95.2 ± 16.6	94.3 ± 14.3
BMI (kg/m^2)	31.2 ± 5.3	31.5 ± 5.6	31.0 ± 4.4
Waist-hip ratio	0.98 ± 0.09	0.98 ± 0.08	1.01 ± 0.07
Diabetes duration (y)	4.6 ± 5.2	7.4 ± 5.4	5.9 ± 6.1
Systolic BP (mm Hg)	146 ± 13	150 ± 16	141 ± 18
Diastolic BP (mm Hg)	94 ± 11	93 ± 9	88 ± 12
FPG (mmol/L)	8.0 ± 1.6	8.7 ± 2.6	7.5 ± 1.9
HbA_{1c} (%)	7.4 ± 1.1	7.7 ± 1.4	7.3 ± 1.1
Insulin C-peptide (nmol/L)	1.1 ± 0.5	1.1 ± 0.6	1.3 ± 0.5
Cholesterol (mmol/L)	5.0 ± 1.2	5.0 ± 0.8	4.8 ± 1.2
HDL cholesterol (mmol/L)	1.28 ± 0.38	1.17 ± 0.32	1.12 ± 0.24
Triglycerides (mmol/L)	2.0 ± 1.0	2.0 ± 1.0	2.2 ± 1.2
Serum creatinine (μmol/L)	76 ± 19	80 ± 18	80 ± 22
VO_{2peak} (L/min)	2.70 ± 0.70	2.65 ± 0.88	2.19 ± 0.60
VO_{2peak} (mL/[kg min])	29.6 ± 8.3	28.1 ± 7.5	22.4 ± 5.3
Work economy (mL/[kg min])	17.7 ± 3.29	18.9 ± 3.35	16.5 ± 3.38

FPG indicates fasting plasma glucose.
[a] Mean ± SD.
[b] The VO_{2peak} (in liters per minute and milliliters per kilogram per minute) was lower in dropouts than in the pooled P group and non-P group ($P = .003$ and $P = .026$, respectively).

3.2. Results in completers

Clinical and laboratory variables at baseline were similar in the P and non-P groups (Tables 1 and 2). The average scores for perceived physical fitness and activity were not different in the 2 groups (P values > .80). Health problems limiting physical activity were reported by 9 subjects in the P group and 9 subjects in the non-P group at V1 through V4. Thirteen subjects (6 in P group) did not meet for test 2. During the study, 4 subjects (3 in P group) started with, or increased the dose of, statins. Two subjects in the non-P group started with antihypertensive medication. Four subjects (1 in P group) reduced the insulin dose by 34% (15%-62%) (median [range]), and 5 subjects (2 in P group) increased the dose by 28% (4%-160%). Four subjects (3 in P group) reduced metformin by 575 (500-1000) mg/d, and 3 subjects in the non-P group increased metformin by 850 (500-2000) mg/d. All changes in medication were prescribed by the primary physician.

All but one subject in the P group delivered a diary with pedometer registrations. Three subjects lacked pedometer registrations for 3 months or more. Pedometer data from these subjects were excluded from the analyses. The mean number of pedometer registrations (days) per month varied between 5.4 and 5.9. The number of steps per day did not increase from study month 1 to 6 ($P = .65$) (Table 3).

3.2.1. Effects on clinical and laboratory variables

In all completers, taken together, body weight, HbA_{1c}, fasting blood glucose, triglycerides, and diastolic BP

Table 3
Pedometer registered activity (steps per day) during the study (n = 19)

	Mean no. of steps per day			
	Minimum	Maximum	Mean	SD
Month 1	1809	16417	7628	3715
Month 2	1409	14465	7606	3830
Month 3	1394	12421	7116	3477
Month 4	1492	17802	7852	4544
Month 5	1448	23348	8380	4838
Month 6	2834	15046	8022	3368

decreased significantly, whereas high-density lipoprotein (HDL) cholesterol increased (Tables 4 and 5, Fig. 1). We found no difference between groups for any of these variables (all P values > .64). From V1 to V4, there were no changes in VO_{2peak} in all completers taken together or in the P group (all P values > .46). In the non-P group, there was an increase in VO_{2peak} (in milliliters per kilogram per minute) (P = .036); and when expressed as liters per minute, the increase was borderline significant (P = .066).The score for perceived improvement in physical fitness was 3.4 ± 1.2 in the P group and 2.9 ± 1.1 in the non-P group, and the score for improvement in mental state was 1.9 ± 1.3 in the P group and 1.9 ± 1.2 in the non-P group. These scores were not significantly different between the 2 groups (all P values > .17).

3.2.2. Relations between clinical and laboratory data: visit 1

In completers, an inverse relationship was found between VO_{2peak} (in liters per minute) and serum cholesterol (r = −0.34, P = .03, n = 43) and between VO_{2peak} (in milliliters per kilogram per minute) and triglycerides (r = −0.36, P = .02, n = 43). In the P group, step count in month 1 correlated positively with work economy (r = 0.66, P = .002, n = 19) and with borderline significance with VO_{2peak} (in milliliters per kilogram per minute) (r = 0.42, P = .080, n = 18). Inverse correlations were found between step count and weight, BMI, and insulin C-peptide (r = −0.44, P = .06; r = −0.43, P = .067; and r = −0.37, P = .043, respectively; n = 19).

Table 5
Repeated-measures analysis of variance for clinical and laboratory variables from V1 through V4

	n	P	Multiple comparisons, Bonferroni corrected
Weight	48	.005	V1-V3 P = .009, V2-V3 P = .022
Diastolic BP	43	.048	
HbA_{1c}	45	.034	V1-V2 P = .015, V1-V3 P = .049
FPG	42	.033	V1-V2 P = .022
HDL cholesterol	43	<.001	V1-V2 P = .012, V1-V3 P < .001, V1-V4 P = .001
Triglycerides	43	.002	V1-V3 P = .007

3.2.3. Relations between changes in clinical and laboratory data during the study

Perceived improvement in physical fitness correlated with increase in VO_{2peak} (in milliliters per kilogram per minute and liters per minute) (r = 0.45, P = .008 and r = 0.45, P = .007, respectively; n = 34). Perceived improvement in mental state correlated with increase in VO_{2peak} (in milliliters per kilogram per minute and liters per minute) (r = 0.38, P = .03 and r = 0.45, P = .008, respectively; n = 34). Improvement in VO_{2peak} (in milliliters per minute) was significantly correlated with an increase in HDL cholesterol (r = 0.44, P = .012, n = 31) and with a decrease in diastolic BP (r = −0.41, P = .019, n = 33) and nonsignificantly correlated with a decrease in weight (r = −0.29, P = .097, n = 34). There were no significant correlations between the change in VO_{2peak} and the change in waist-hip ratio, HbA_{1c}, fasting plasma glucose, systolic BP, total cholesterol, or triglycerides.

4. Discussion

The main finding of our trial is that subjects who used pedometer did not increase walking during the study and health benefits were not enhanced by the use of pedometer. Our findings are in accordance with, or extending, results

Table 4
Changes in clinical and laboratory variables[a] from visit 1 to visit 4 in subjects who completed the study (completers), the P group, and the non-P group

	Completers		P group		Non-P group	
	Change	n	Change	n	Change	n
Weight (kg)	−1.2 ± 3.4	48	−1.1 ± 3.3	23	−1.4 ± 3.5	25
Systolic BP (mm Hg)	−3.6 ± 21.9	46	−2.8 ± 17.3	21	−4.2 ± 25.5	25
Diastolic BP (mm Hg)	−5.3 ± 14.5	46	−2.9 ± 14.0	21	−7.4 ± 14.8	25
HbA_{1c} (%)	−0.19 ± 1.10	46	−0.15 ± 0.76	22	−0.23 ± 1.35	24
FPG (mmol/L)	−0.57 ± 2.20	43	−0.31 ± 2.05	19	−0.78 ± 2.34	24
Cholesterol (mmol/L)	−0.01 ± 0.71	44	0.17 ± 0.84	20	−0.15 ± 0.56	24
HDL cholesterol (mmol/L)	0.08 ± 0.14	44	0.06 ± 0.13	20	0.10 ± 0.15	24
Triglycerides (mmol/L)	−0.17 ± 0.62	44	−0.11 ± 0.60	20	−0.23 ± 0.64	24
VO_{2peak} (L/min)	0.07 ± 0.25	34	0.03 ± 0.29	16	0.10 ± 0.22	18
VO_{2peak} (mL/[kg min])	0.78 ± 2.87	34	0.19 ± 3.30	16	1.3 ± 2.4	18
Work capacity (mL/[kg min])	0.63 ± 2.45	34	0.39 ± 2.16	17	0.86 ± 2.76	17

[a] Mean ± SD.

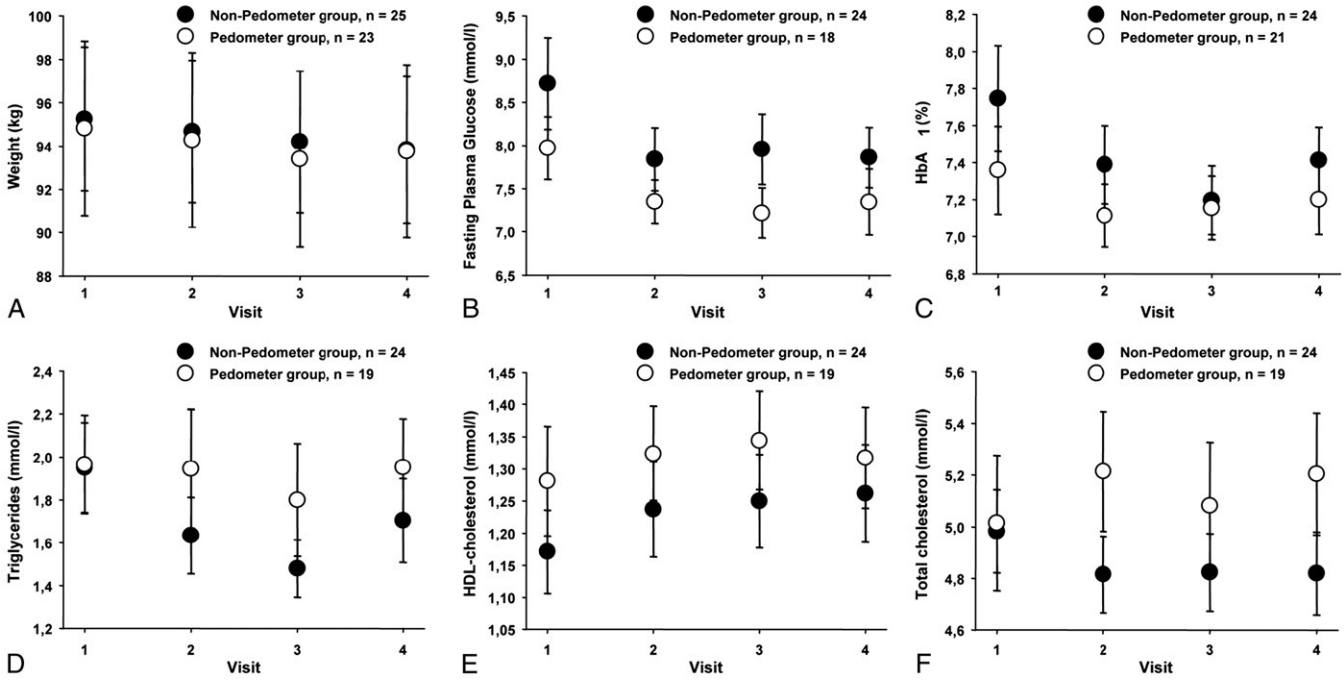

Fig. 1. A to F, Body weight, fasting plasma glucose, HbA_{1c}, triglycerides, HDL cholesterol, and total cholesterol at visit 1 through visit 4. Data are mean and SEM.

from other controlled trials [12,22]. Engel and Lindner [12], studying older adults with T2DM, found that the coaching-only group spent more time walking than the pedometer group. In another trial [22], 23 low-active adolescent girls who used pedometer increased their step count slightly after 6 weeks; but after 12 weeks of intervention, the use of pedometer was not superior to setting daily time-based goals for physical activity. Araiza et al [23], in a 6-week trial in middle-aged patients with T2DM, demonstrated an increase in step count in the pedometer group. However, subjects using pedometer were instructed to walk 10 000 steps on 5 or more days of the week; and control subjects were instructed to maintain their normal habits of walking during the intervention. Hence, in that study [23], as well as in another controlled trial in persons with T2DM [20] and in one noncontrolled trial in 18 nondiabetic women [10], an increase in step count may be attributed to regular counseling and goal setting, and not to the use of pedometer per se.

In the present study, one may argue that no baseline registration of physical activity was obtained because all participants were encouraged to increase walking from the start. Indeed, the daily number of steps in our P group during month 1 was higher than that in control subjects with similar clinical characteristics in 2 previous studies [7,10]. In view of this, and of the health benefits observed, subjects in the P group may have walked more already in month 1 than before enrolment. However, use of pedometer did not promote increased walking from months 1 through 6, which was the target.

In completers, taken together, aerobic capacity did not increase during the study. Improvement in VO_{2max} seems to depend on the intensity of the exercise [6], and self-paced walking speed in subjects with T2DM may be too low to entail increase in aerobic capacity [24]. Increasing the walking speed was associated with increased cardiovascular fitness in a trial that included 8 subjects with T2DM [25]. However, on a larger scale, it may be difficult for middle-aged, overweight subjects with T2DM to increase their self-paced walking speed. Indeed, Fritz et al [11], prescribing "brisk walking" for 45 to 60 minutes 3 times weekly in 26 such subjects, found no effect on aerobic capacity.

The long duration is a major strength of our study. Beneficial effects of physical activity demonstrated in programs with a shorter duration [3-5,7,10,13,23] may not sustain long term. In addition, the randomized controlled design and giving the same amount of coaching to both groups enabled us to test specifically the effects of pedometer as an adjunct to counseling to increase physical activity.

As in our previous study [7], we found positive correlations between perceived physical fitness and activity and VO_{2peak} at baseline. In addition, improvement in VO_{2peak} was associated with perceived improvement in physical and mental health, underscoring the importance of physical activity for health-related quality of life [26-28].

The high dropout rate is a concern in the present study as in several previous studies promoting physical activity in T2DM and other sedentary groups [3,4,7,20,22,29,30]. However, the number of dropouts was approximately equal

between the 2 study groups, minimizing a possible bias between groups. Nevertheless, the fact that we did not perform an intent-to-treat analysis is an obvious limitation of our findings.

To our knowledge, this is the first study to demonstrate lower VO_{2peak} in dropouts than in subjects adhering to the protocol. Aerobic capacity has predictive power for cardiovascular mortality [31], and dropouts in the present study may be at increased risk because of their minimally active lifestyle.

We have shown that a simple intervention program with the aim to increase walking behavior has moderate health benefits in middle-aged, overweight subjects with T2DM. The phenotype of participating subjects can be viewed as typical of T2DM in Scandinavia and representative for at least a large segment of this population. The health benefits demonstrated are in accordance with previous findings [2-7,10-14,20,23,29] and cannot be explained by slight changes in medication in few subjects during the intervention program. In contrast to other intervention studies [3-7], we did not offer supervised exercise. Consequently, our program was rather inexpensive and could therefore be adapted to any community setting.

In conclusion, the use of pedometer did not increase walking or enhance beneficial outcomes in this physical activity intervention study. The low aerobic capacity in dropouts indicates that persons most needy of physical activity are the least compliant in exercise programs. Creative strategies are needed to motivate subjects with T2DM to increase their physical activity.

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