Original article:

Pedometer-based walking intervention with and without group support among sedentary adults in primary care patients in north-east Malaysia: a randomized controlled trial.

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Abstract

Background: Many studies have shown that pedometer is an effective motivational tool to promote walking however there is lack of evidence which combines pedometer and group support in motivating patient to increase their physical activity ***Objective:*** To determine the effectiveness of pedometer and group support versus pedometer only on physical activity level and cardiovascular risk factors among sedentary adults in north-east Malay ***Methods:*** This was a prospective randomized comparative trial. Eighty participants were randomly assigned to pedometer-based walking program plus group support (N=40) or pedometer-based walking program only (N=40) for 12 weeks. Both groups received physical activity counselling. The intervention group had monthly group meeting for support, motivation and also walking activities. Measurements for step-counts, 7-day physical activity recall, body mass, BMI, waist and hip circumference, blood pressure, total cholesterol, HDL cholesterol and fasting blood sugar were taken at baseline and at week 12. Analyses were performed using repeated measures ANOVA and analysis of co-variance (ANCOVA). ***Results and Discussion:*** Sixty two participants completed the study. The mean age in the intervention group were 48 (4.43) years old and 47 (5.08) years old in the control group. There were significant improvements in the intervention group in terms of step-counts ($p < 0.001$), weight ($P<0.05$) and BMI ($p>0.05$) compared to control group. However there was no significant difference in term of other health outcome. ***Conclusion*** A pedometer-based walking program, incorporating a physical activity consultation and group support, is effective in promoting walking and improving health outcome in community based individuals. Studies of longer duration need to be done to see the sustainability of the above intervention.

Keyword : pedometer, group support, physical activity, sedentary adult

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Introduction:

Physical inactivity is the fourth leading risk factor for global mortality and non communicable disease[1]. Globally 31% of adults aged more than 15 years old were inactive and about 3.2 million deaths each year is caused by physical inactivity. Many physical activity intervention and health promotion messages have promoted walking as a healthy form of physical activity. However, despite the importance of physical activity, many people fail to maintain appropriate level of activity. A review of current research findings regarding the determinants of exercise behaviour stated that social support is an important correlate of physical activity[2].

Pedometer is a low cost motion sensor which is typically worn on a belt and waist band and responds to vertical acceleration of the hip during gait cycle[3]. It is a valid tracking device for steps counting and has benefit as a feedback tool to the user in research[4] It is a valid tracking device for steps counting and has benefit as a feedback tool to assess physical activity level. Many researchers have shown that this device significantly increase physical activity and also associated with decreased in body mass index, blood pressure and reduction of waist circumference [5, 6 ,7].

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studies have been conducted on physical activity using pedometer or other tracking device, to our knowledge there is limited published reports on randomized controlled trial on the effects of group support together with these tracking device especially in our region of the world. Therefore, we hypothesized that group support is important to increase physical activity level on top of having tracking device to monitor the physical activity level. In this study, we compare the mean of physical activity level measured by step counts and using 7 Day Physical Activity Recall questionnaire and cardiovascular outcomes (blood pressure, weight, waist circumference, body mass index, fasting blood glucose and fasting lipid profile) between subjects who received group social support and pedometer and the subjects who received pedometer only.

Materials and methods:

Study design and setting

This is a randomised-controlled study aim to compare the effects of pedometer, with or without group support on the physical activity level and cardiovascular risk factor among sedentary adults. The participants are recruited from a primary care clinic at a tertiary hospital located in a north-eastern part of Malaysia. The study was carried out from June 2013 to September 2014.

Participants and instruments

The study participants included those aged 35 – 45 years old who were determined to lead a sedentary lifestyle based on the 7 day physical activity questionnaire (7DPAR) and who have no chronic illness. The study excluded those with history of coronary artery disease and those with physical disability. Informed consent was obtained once they agreed to participate in the study. Having satisfied the inclusion and exclusion criteria, the patients were then randomly placed into two groups using a computer-generated table of random numbers based on block of four randomization.

All participants had a baseline physical examination to determine their height, weight, body mass index, waist circumference and blood pressure reading. The total daily energy expenditure (TDEE) was also calculated from the 7 day Physical Activity recall questionnaire and baseline investigation for fasting blood sugar and fasting lipid profile were also taken. The intervention group received physical activity counselling, pedometer and assigned into three groups of 10 -15 people, while the control group was given physical activity counselling and pedometer and were not assigned into any group. All of the participants were counselled to increase their daily steps with the aim of 10,000 steps per day. Log diaries were given to document the steps. They were instructed to document the step count for three consecutive days in each week.

The intervention groups then had a monthly meeting for three months with their respective group member and the researcher. During the meeting, the researcher went through the log diaries and gave them motivation to increase their physical activity. The control group was only given the log diaries to document their daily physical activity for three months. At the end of the three months, the physical examination and investigations was repeated for all participants. All the log diaries were also collected for assessment and patient was asked to answer the 7DPAR questionnaire again.

Statistical analysis

The study's sample size calculations were based on power and sample size calculation software for the comparison of two means (α =0.05, Power= 0.8). A sample size of 33 in each group was needed to detect the increase in steps count by 3846 with standard deviation of 2680 (8). Forty patients in each group were enrolled to allow for 2% dropout. Per protocol analysis was done using SPSS version 20.0. Randomized groups were compared in order to recognize possible differences at baseline using independent-T, and Pearson chi-square. To determine the differences in the outcome parameters between the groups based on different months, repeated measure Anova (RM-ANOVA) was used. Changes were reported as estimated marginal means with the confidence interval (CI) adjusted at 95%. In addition, ANCOVA had been used to compare mean and other parameters post intervention. All reported *p*-values were 2-tailed with values less than 0.05 considered significant.

The protocol of the study was approved by the Research Ethics Committee of university sains Malaysia[Ref: USMKK/PPP/JEPeM—[253.3.(16)] and the study have been conducted in accordance to the ethical standards laid down in the '1964 Declaration of Helsinki' revised in the year 2000.

Results

62 patients completed the study. Nine participants in each group failed to complete the study, for various reasons. In the intervention group, two patients were loss to follow up and the other seven dropped out of the study due to personal reasons. In the control group, four were loss to follow up and the other five dropped out of the study due to personal reasons.

The mean age were 48 (4.43) years old in the intervention group and 47 (5.08) years old in the control group. There was more female subject than men however both were equally distributed in each group. The sociodemographic characteristics of both groups showed no statistical difference (Table 1).

Table1: Sociodemographic of study subjects. (n=62)

Variables		Intervention n=31 (%)	Control n=31(%)	p-value
Age		48.3 (4.43)[a]	47.1 (5.08)[a]	0.29[b]
Gender				
Female		24 (77.4)	22 (70.9)	0.562[c]
Male		7 (22.6)	9 (29.1)	
Education				
secondary		16 (51.6)	15(48.3)	0.799[c]
tertiary		15 (48.3)	16 (51.6)	
Medical illness				
Hypertension	yes	5 (16.1)	9 (29.0)	0.224[c]
	no	26(83.9)	22 (71.0)	
Diabetes	yes	3(9.7)	5 (16.1)	0.449[c]
	no	28 (90.3)	26(83.9)	
Hyperlipidemia	yes	1 (3.2)	4 (12.9)	0.162[c]
	no	30(96.8)	27(87.1)	
Employment				
Housewife		2 (6.5)	5 (16.1)	0.245[c]
Full time employment		29(93.5)	26 (83.9)	

a = Mean (S.D)

b=independent t-test c=pearson chi square test

There was no significant difference between the clinical characteristic except in the total daily energy expenditure calculated (TDEE) from the 7 day Physical Activity recall questionnaire (Table 2).

Table2: Clinical characteristic at baseline for intervention and control group.

Variable	Intervention (n=31)		Control (n=31)		P value [a]
	Mean	(SD)	Mean	(SD)	
Weight (kg)	65.7	12.63	68.9	11.21	0.300
BMI(kg/m^2)	26.3	4.46	27.8	3.71	0.165
SBP (mmHg)	123.2	8.08	125.3	16.38	0.513
DBP (mmHg)	78.5	7.36	78.6	10.24	0.955
WC (cm)	83.9	9.75	85.6	8.32	0.452
FBS (mmol/L)	5.1	0.84	5.9	2.40	0.064
TC (mmol/L)	5.5	0.88	5.9	1.10	0.149
LDL (mmol/L)	3.3	0.74	3.7	1.11	0.139
HDL (mmol/L)	1.4	0.37	1.4	0.26	0.711
TG (mmol/L)	1.6	0.81	1.4	0.74	0.575
TDEE (cal/day)	2594.5	591.99	2210.4	432.49	0.005

[a] independent t-test

Table 3 showed difference in pedometer step count between intervention and control group. The intervention groups have significantly higher pedometer step counts in month 2 and month 3.

Table 3: Pedometer step count between intervention and control group based on time.

Variables	Intervention n=31 Mean (SD)	Control n=31 Mean (SD)	Mean difference (95% CI)	t-stat (df)	p-value[a]
Month 1	8528.71 (2212.65)	7635.03 (1915.51)	-893.67 (-1945.10, 157.75)	-1.700 (60)	0.094
Month 2	8897.84 (2426.66)	7732.84 (8897.84)	-1165.00 (-22.93.23, -36.76)	-2.065 (60)	0.043*
Month3	9159.97 (2081.51)	7540.97 (1703.11)	-1619.00 (-2585.23, -652.76)	-3.352 (60)	0.001*

[a] RM ANOVA

*significant at p<0.05.(2-tailed)

The weight and Body Mass Index (BMI) has significant difference over 3 months period for intervention group compare to control group (Table 4). The mean weight in the intervention group reduced from 70.59 kg to 63.4kg. This also makes the BMI reduced significantly from 28.27kg/m^2 to 25.02 kg/m^2. However the other clinical characteristic comparing the two groups were not significantly different over time.

Table 4. Comparison of clinical characteristic between groups at three months.

Variables	Intervention		Control		Mean diff	(95%CI)	F stat	*P* value
	Adj mean[a]	(95% CI)	Adj mean[a]	(95% CI)				
Weight (kg)	63.4	(59.69, 67.28)	70.59	(66.74, 74.43)	7.14	(1.51, 12.78)	6.45	**0.014**[b*]
BMI (kg/m^2)	25.02	(23.20, 26.84)	28.27	(26.45,30.09)	3.25	(0.57, 5.92)	5.93	**0.018**[b*]
SBP (mmHg)	127.72	(121.19, 134.24)	128.18	(122.67,133.69)	0.46	(16.1, 7.1)	0.02	0.889[c]
DBP (mmHg)	76.55	(72.15, 80.95)	78.36	(74.64, 82.07)	1.80	(-2.68, 6.29)	0.651	0.423[c]
WC (cm)	82.65	(79.04, 85.48)	85.79	(82.57, 89.02)	3.53	(-1.19, 8.25)	2.24	0.140[b]
FBS (mmol/L)	6.22	(5.40, 7.03)	6.7	(5.98, 7.41)	0.48	(-0.41, 1.37)	1.16	0.285[b]
TC (mmol/L)	5.30	(4.94, 5.66)	5.72	(5.36, 6.08)	0.42	(-0.12, 0.95)	-2.41	0.126[d]
LDL (mmol/L)	3.45	(3.12, 3.77)	3.69	(3.36, 4.01)	0.24	(-0.24, 0.72)	1.00	0.322[d]
HDL (mmol/L)	1.26	(1.17, 1.36)	1.24	(1.14, 1.33)	-0.02	(-0.16, 0.11)	0.15	0.694[d]
TG (mmol/L)	1.45	(1.19, 1.70)	1.44	(1.18, 1.69)	-0.01	(-0.39, 0.37)	0.003	0.954[d]

[a] Bonferonni adjustment applied

[b] Analysis of covariance (ANCOVA) after adjusted for baseline value and age

[c] Analysis of covariance (ANCOVA) after adjusted for baseline value, diabetes, hypertension,

[d] Analysis of covariance (ANCOVA) after adjusted for baseline value,Hyperlipidemia,diabetes,

*significant at p<0.05 (2 tailed)

Discussion

This study showed that group support and pedometerpedometer use with support group has beneficial effect to the physical activity level compared to pedometer alone. Our exercise and support group program resulted in improvement in number of steps count at the end of the three months study period. The participants' weight and body mass index also showed significant improvement compared to control.

BothAlthough both groups haves significant increase in step count initially during the study period, however those with support groups were muchsignificantly better and . In fact, the step count in the pedometer only group went down in the third monthwere able to sustain the level of physical activity up to three months. However, those who received both group support and pedometer, the steps count continue increasing up to the third month The step count in the control group initially increased, however the participants in this group were unable to sustain the step count.. This showed that group support is important for not only escalating the physical activity level but probably in maintaining it as well. The RM analysis also showed significant monthly increment in the step count between the two groups. Therefore, the possibility that participants increased their physical activity levels only during week 12 in order to achieve their final target is unlikely to be true. Although the TDEE was not statistically significant, however there was a difference of 30 calories per day between the groups based on 7 day Physical Activity recall questionnaire.This finding is supported by the findings of a systemic review of intervention in physical activity where engaging social support does increase physical activity (2). This meta-analysis which included 19 studies with 4572 participants showed that interventions to promote walking in groups are efficacious at increasing physical activity. The results from our study suggest that having social support may have improved adherence to the exercise prescription. Adherence is a key to derive beneficial effects on any exercise program. Although retention in the trial was generally good, the adherence to the exercise was not optimal with the dropout rate of around 20% to the exercise sessions. Motivating sedentary adults to adhere to exercise programs may be particularly important because of their potential for increased weight gain and, it is well-known that sustaining weight loss requires a long-term commitment to regular exercise in addition to having a healthy diet. Thus, future interventions should develop specific strategies to enhance adherence in this group of people.

In this study the participants were counselled to aim for 10,000 steps in a day. Previous studies have used different target for walking exercise. Although the steps count at three month fail to achieve the target of 10,000 steps, we believe that having a target is a useful motivating tool for participants. This is supported by a review which stated that studies employing a step goal (5), and in particular a 10,000 steps/day goal (9), appear to have had the greatest impact on increasing physical activity.

The increase in pedometer steps count in the intervention group may be due to motivated subject that are more than willing to changes their lifestyles. During the support group meeting, the subjects were seen individually to review the steps count progress. It also has allowed the participants to communicate on the problems that arise during using the pedometer. Therefore the researcher and subjects were able to discuss and find conclusions on the problems. In this study the reduction of weight and body mass index were significant in the support group. This finding is also similar to a study by Negri et al on patient with type 2 diabetes where those in the support group has reduction of weight and significant overall improvement of physical activity[10]. Similarly, reduction of mean weight was noted at the end of intervention in the study by Wallace in sedentary African American women (11). Meanwhile, in a systemic review on intervention component by Greaves et al [12], interventions which are done in research produce meaningful weight loss and increase physical activity compare to control. Positive changes in the body weight may have also motivated the participants to increase their step count.

Our study fail to show significant changes in the other cardiovascular markers namely the blood pressure, fasting blood sugar and fasting lipid profile. This is supported by findings by Negri et al[10] and K. De Greef et al[13], where they fail to show significant improvement in the blood parameters. However, a systemic review of 26 studies by Bravata et al showed a significant decreased of systolic blood pressure by 3.8 mmHg and diastolic reduction of 0.3mmHg[(5)]. This difference in result could be due to the fact that participants in the review has higher baseline blood pressure. Correspondingly, fasting blood glucose and serum lipid levels were not significantly reduced due to fairly normal values at baseline and due to short duration of study.

Although our study showed the beneficial effect of pedometer use with group support, our study has several limitations. The analysis was done per protocol and not intention-to-treat analysis. Therefore the effect of the intervention in real world setting was not determined. The number of the participant is not very large and this may have influenced the results of the study. There are also few dropouts during the research. However, the drop out was equally distributed among the intervention and the control group and thus, not expected to influence the results. The participants in the intervention group were also given brief counselling by the researcher at each group activity. This may have augmented the effect of the intervention. It is not possible to disentangle the respective contributions of the physical activity consultation from the benefits of the pedometer-based goals of the walking program.

The study duration is also fairly short to see significant changes in the clinical characteristic. It is recommended that longer study duration is required to see the changes in the other health parameters and also the sustainability of the intervention.

Conclusion

Pedometer use with group support is effective in increasing physical activity level of sedentary adults as well as improving their weight and body mass index. We recommend that the use of support group should be integrated in any physical activity program using pedometer to enhance its effectiveness.

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