

Do Pedometers Increase Physical Activity in Sedentary Older Women? A Randomized Controlled Trial

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OBJECTIVES: To determine the effectiveness of a behavior change intervention (BCI) with or without a pedometer in increasing physical activity in sedentary older women.

DESIGN: Prospective randomized controlled trial.

SETTING: Primary care, City of Dundee, Scotland.

PARTICIPANTS: Two hundred four sedentary women aged 70 and older.

INTERVENTIONS: Six months of BCI, BCI plus pedometer (pedometer plus), or usual care.

MEASUREMENTS: Primary outcome: change in daily activity counts measured by accelerometry. Secondary outcomes: Short Physical Performance Battery, health-related quality of life, depression and anxiety, falls, and National Health Service resource use.

RESULTS: One hundred seventy-nine of 204 (88%) women completed the 6-month trial. Withdrawals were highest from the BCI group (15/68) followed by the pedometer plus group (8/68) and then the control group (2/64). After adjustment for baseline differences, accelerometry counts increased significantly more in the BCI group at 3 months than in the control group ($P = .002$) and the pedometer plus group ($P = .04$). By 6 months, accelerometry counts in both intervention groups had fallen to levels that were no longer statistically significantly different from baseline. There were no significant changes in the secondary outcomes.

CONCLUSION: The BCI was effective in objectively increasing physical activity in sedentary older women. Provision of a pedometer yielded no additional benefit in physical activity, but may have motivated participants to remain in the trial. *J Am Geriatr Soc* 58:2099–2106, 2010.

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KEY WORDS: randomized controlled trial; pedometer; physical activity; elderly

Despite compelling evidence of the benefits of physical activity in later life and numerous public health recommendations, older people remain the most sedentary segment of the population.¹ Because of their high burden of chronic disease, disability levels, and healthcare usage, older people arguably have the most to gain from participating in regular physical activity, yet identifying effective strategies to increase physical activity levels remains a global public health challenge.²

The development of complex behavior change interventions (BCIs) should be based on scientific theory, and interventions should use evidence-based behavior change techniques such as goal setting, planning, and self-monitoring.^{3–5} Pedometers are attracting increasing interest as a potential means of enhancing the effectiveness of interventions promoting physical activity, yet surprisingly few randomized trials have been conducted.⁶ Finding practical, easy-to-use methods of assessing physical activity is a major stumbling block in this field of research. The limitations of self-reporting and diaries are well documented, particularly their lack of sensitivity to walking.⁷ Motion sensors, including pedometers and accelerometers, are an objective way to assess physical activity. Pedometers are pager-sized devices worn at the hip or around the waist that count the number of steps walked per day. They are considerably less expensive than accelerometers, which need hardware and software. Spring-levered pedometers accurately assess walking at speeds of 3 mph or greater but are less accurate at slower speeds. Pilot work has shown them to be acceptable to community-dwelling older people.⁸ The hypothesis was that the provision of a pedometer with a BCI would confer an advantage over a BCI alone in objectively increasing physical activity levels in sedentary older women. Women were specifically targeted, because inactivity is an

established modifiable predictor of functional decline in older women.⁹

METHODS

Participants

Eligibility criteria included community-dwelling, aged 70 and older, and considered inactive (no participation in moderate-intensity physical activity of at least 30 minutes 5 days per week or at least 20 minutes of continuous vigorous-intensity physical activity 3 or more times a week).¹⁰ Participants were excluded if they lived in an institution, were housebound or wheelchair bound (thus unable to increase outdoor walking), had moderate to severe cognitive impairment (Mini-Mental State Examination (MMSE) score <18) precluding informed consent, or had significant visual impairment and so were unable to read the pedometer count screen.

Participants were recruited between February 2008 and March 2009 from four local General Practices in Dundee, Scotland, United Kingdom, through the Scottish Primary Care Research Network. The principal general practitioner (GP) at each practice provided a list of all women aged 70 and older, excluding those who should not be approached because of terminal illness, recent bereavement, severe heart failure, chronic obstructive disease, or dementia or because they were lived in a nursing home. The GP wrote to the women inviting them to take part in the study, including a prepaid reply envelope. The study coordinator telephoned those accepting the invitation and checked for eligibility. At the first face-to-face visit, the MMSE was administered if cognitive impairment was suspected.

Ethics

The Tayside Committee on Medical Research Ethics approved the study (REC 07/S1402/33), which was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each participant.

Outcome Measures

The primary outcome measure was change in daily activity levels, measured objectively using accelerometry (RT3 Accelerometry Research Tracker, Stay Healthy, Inc., Monrovia, CA). This is a pager-sized device worn on the waistband during waking hours for a 7-day period and validated for use in an older population.¹¹ Participants wore the accelerometer for two consecutive 7-day periods at the start of the study. Data from the first 7 days were discarded to establish a baseline to minimize the effect on baseline readings of any uncharacteristic increases in physical activity triggered by the novelty of wearing an activity measuring device. Tri-axial data were collected in 1-minute epochs, counts (<250 or >3,000 vector maximums) were discarded as not walking.¹² Counts were totalled over each 24-hour period (midnight to midnight), the first set of 24-hour data was discarded (incomplete day), and missing days were excluded from analysis. Counts per minute per day for valid days (within vector maximum) were recorded, and minutes spent walking per day were estimated.

Secondary outcome measures were lower extremity function according to the Short Physical Performance Bat-

tery (SPPB), which consists of three 0- to 4-point scales summarizing performance on gait speed, chair stands, and tandem balance tests;¹³ health-related quality of life (Euro-QoL);¹⁴ depression and anxiety (Hospital Anxiety and Depression Scale);¹⁵ and falls. Falls were recorded prospectively using the validated daily diary method; diaries were mailed to participants and returned monthly.¹⁶ A fall was defined as an unexpected event in which the participant comes to rest on the floor, ground, or lower level.¹⁶

Health service resource use of participants (GP visits, nurse visits, inpatient and outpatient care, day hospital attendance, community therapy and chiropody, outpatient investigations, imaging, calls to a telephone- and Web-based source of health information and self-care advice that provides out-of-hours services) was based on self-report and recorded by questionnaire at baseline (for the previous 3 months) and again at 12 and 24 weeks. Costs were based on Personal Social Services Research Unit figures for 2005/06 in United Kingdom and inflated by 5% to give costs for 2007.¹⁷

Outcome measures were assessed before randomization at baseline and at 12 and 24 weeks. Adverse events were investigated at each assessment. Age, social deprivation (Scottish Index of Multiple Deprivation), number of prescribed medicines, and living circumstances were recorded at baseline.

Randomization and Blinding

Randomization was performed off-site using the Health Services Research Unit's automated telephone randomization service at the University of Aberdeen. Participants were allocated at random to one of three groups: no intervention (control), a pedometer plus a BCI (pedometer plus group), and only a BCI (BCI group). An independent research assistant who was not otherwise involved in the study and remained "blind" to group allocation performed outcome assessments. Participants were firmly briefed not to reveal which group they were in.

Intervention

The Omron HJ-113 piezoelectric pedometer (Omron Healthcare UK Ltd, Milton Keynes, UK) was selected for use based on the result of pilot work.⁸ It has a 7-day memory, which avoids the need for participants to record their own daily step counts. It contains a horizontal cantilevered beam with a weight at the end that compresses a piezoelectric crystal when subjected to movement.

After randomization, each participant in the pedometer plus group was asked to read the step count screen of the device and to walk 50 and 100 steps at their usual pace wearing two pedometers, one on their waistband and one around their neck. The more-accurate position was recommended for use, although the manufacturer recommends both positions. Participants recorded their step count each day during waking hours. Before the intervention took place, participants in the pedometer plus group were asked to wear a pedometer for a week and record daily steps counts, those in the BCI alone group were asked to record minutes spent walking outdoors per day for a week. The average daily pedometer step count or average daily minutes walked outdoors from at least 3 days (at baseline

before the intervention) was used to set a target of achieving a 20% increase in step counts or minutes walked during the first month. If participants succeeded in meeting their target, it was increased a further 20% at the end of the first and second months. If targets were not being met, the target remained unchanged and was reviewed the following month.

The BCI was based on self-regulation theory, which emphasizes the role of goal setting, planning, and self-monitoring behavior change.¹⁸ Theory-based advice was given to each participant in the pedometer plus and BCI alone groups in the form of individualized activity action plans and plans to address barriers to action. Procedures and materials were based on previous evidence, and the protocol for this was developed during a previous study.⁸ The intervention consisted of a brief education session focusing on beliefs and motivation for walking followed by a self-regulation intervention based on goal setting, action and coping planning, self-monitoring, and feedback. The intervention material and full protocol can be obtained from the authors. First, each participant was given brief advice verbally and in pamphlet form about the health benefits of increasing physical activity. Then action plans and coping plans¹⁹ were discussed and written with each participant in her home. The action plans were designed to increase participants' physical activity levels (mainly through walking), and the coping plans were to identify how to cope with possible barriers to increasing their walking.⁸ A graded goal-setting approach to increase walking was given, with clear advice on when and where to walk and how to schedule time for physical activity. Participants were given monthly daily activity diaries to complete with logs of pedometer step counts or minutes spent walking outdoors. The diaries were mailed to participants monthly and returned to the study coordinator in stamped addressed envelope. Adherence to diary keeping was recorded.

Each participant was contacted over the telephone once a week for the first month, then every 2 weeks for 2 months, and then monthly until the end of the 6-month study to provide motivation and encouragement and to troubleshoot any problems. The study coordinators (JS, IA) delivered the intervention after the baseline data had been collected. Both received training from two experienced health psychologists (DWJ and FFS).

Statistical Power

Based on a total sample of 210 (70 per group) and a dropout rate of 20%, it was predicted that the inclusion of 171 participants would give the study 80% power to detect a difference in change in mean accelerometry between the groups of 15,364 counts at 12 weeks based on the data obtained in a pilot study.⁸

Statistical Analysis

Statistical analysis was performed on an intention-to-treat basis, in line with CONSORT guidelines. All participants with valid consent who fulfilled the entry criteria were included in the analysis. Six participants dropped out before starting and therefore had no measurements and were not included in the analysis.

Descriptive data are displayed as means and standard deviations or, if the data were skewed, as medians and ranges for continuous variables and as numbers and percentages for categorical variables. The primary outcome was change in accelerometer count between baseline and 3 months and was analyzed using regression modeling of 3-month means with adjustment for baseline mean level. Comparisons were made between the pedometer plus group and controls and the BCI group and controls using dummy variables in the model. In addition, further variables that showed imbalance at baseline were added as covariates. Multiple imputation assuming data that were missing at random was carried out for the missing data, because the dropout rate was different between the three arms of the trial. All analyses were implemented in SPSS version 17 (SPSS, Inc., Chicago, IL). One of the study coordinators (JS) entered the data, and an individual not involved in the study checked 10% of the data entered for errors. For the primary outcome, 100% of the data was checked.

RESULTS

There were 3,144 women aged 70 and older registered in the four Scottish Primary Care Research Network practices from which participants were recruited. Practice GPs sent letters of invitation to 1,631 women, of whom 19% (313) accepted the invitation to participate. From this group, 210 eligible women were recruited, but six withdrew before randomization, leaving 204 for statistical analysis. Figure 1 shows the progression of participants through the trial. The overall dropout rate was 25 (12.3; 22.1% from the BCI group, 11.8% from the pedometer plus group, and 2.9% from the control group). The study was not powered to detect differential dropout rates between the three arms of the trial. The characteristics of the three trial arms were generally well balanced for baseline factors such as seasonality,²⁰ age, previous falls, and previous use of a pedometer (Table 1). There was evidence of differences in marital status, living alone, finding daily stairs difficult, and proportion with an illness and slight differences in deprivation distribution. In addition, there were some differences in baseline measures of accelerometer results, as shown in Figure 2, and in NHS costs within the 3 months before baseline (Table 1). Mean baseline pedometer step count was $4,115 \pm 2,235$ (range 711–13,080) step counts per day, compatible with the sedentary category as defined according to pedometer step counts per day ($<5,000$).²¹ Trial retention was good, with only 31 (15%) participants dropping out, less than the predicted dropout rate of 20%. The highest dropout rate (15, 22%) was from the BCI group—almost double the dropout rate of the pedometer plus group. No specific check for preservation of blinding integrity was made.

Table 2 presents the means and standard errors of the changes in outcomes between 3 months and baseline. The pedometer plus group (mean increase 3.9%, ratio of the increase in activity counts divided by the baseline activity count $5,504/139,879$, $P = .02$) and the BCI group (mean increase 10.6%, ratio of the increase in activity counts divided by the baseline activity count $13,305/125,038$, $P = .01$) had increases in activity counts from baseline to 3 months, compared with a slight decrease for controls (mean

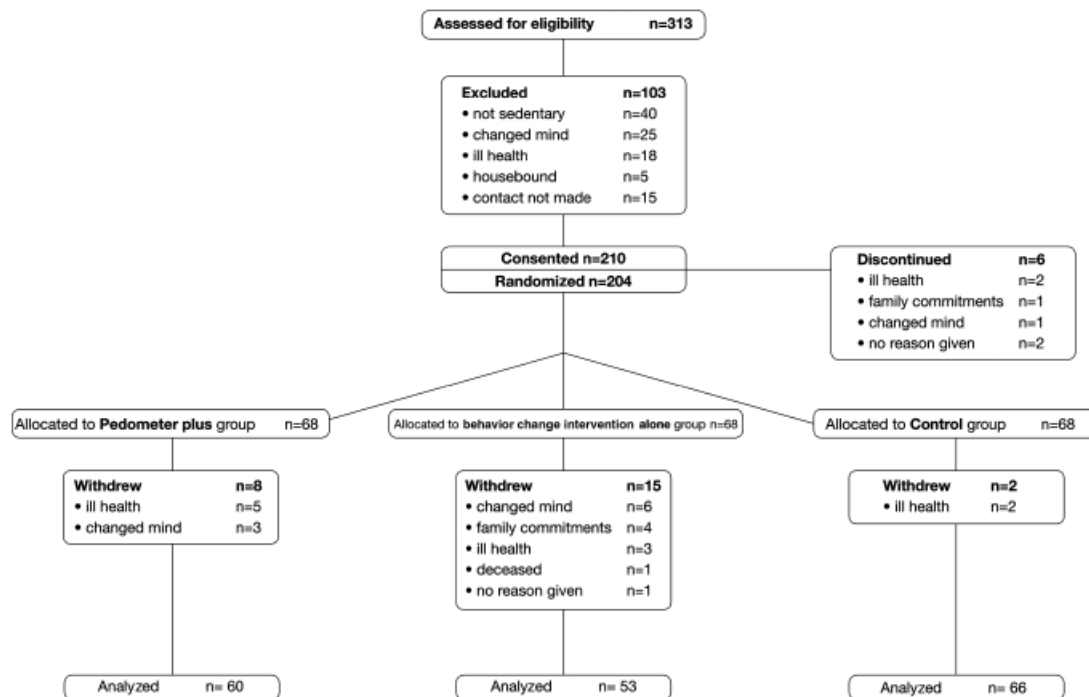


Figure 1. Patient flow through the trial.

decrease 1.8%, 2,290/126,785, $P = .54$). The BCI group increased minutes spent walking, in contrast with the pedometer plus group, which had a small decrease, and the control group, which declined. There were no significant between-group differences in the secondary outcome measures. There was a greater increase in SPPB scores with the pedometer plus group than in the other two groups and a greater reduction in health service costs, although neither of these differences were statistically significant. There were no significant differences in falls between the groups, providing reassurance that this method of promoting physical activity participation in older women does not increase falls, in contrast to other reports.^{22,23} NHS costs were calculated for each individual using Personal Social Services Research Unit–derived figures (2007).¹⁷ The median reduction in NHS costs was greatest for the pedometer plus group (£17.45) but not significantly different from the other groups ($P = .96$) (£1 ~ US\$1.6).

A regression model predicting missing accelerometer results at 3 months was derived, and five sets of data with imputed values were created using Markov Chain Monte Carlo methods, assuming missing at random. These multiple imputed datasets were then analyzed as above, with multiple regression modelling adjusting for other imbalances at baseline, and the pooled results are given in Table 3. After multiple imputation and adjustment, the pedometer plus and BCI groups had significantly higher accelerometer counts at 3 months than the controls. There was no significant difference between the pedometer plus group and the BCI group ($P = .58$). The results were similar for minutes of accelerometer activity, although the difference between pedometer plus group and the other two groups did not quite reach statistical significance for this outcome ($P = .20$). By 6 months, accelerometry counts in both inter-

vention groups had declined to near baseline levels after withdrawal of the intervention.

There was exemplary 100% adherence to activity action plan and coping plan completion. Mean adherence to diary completion was 96% (58–100%) in the pedometer plus group and 95% (65–100%) in BCI alone group. More adverse events were recorded in both intervention groups than in the control group, which had six adverse events (diagnosis of malignancy $n = 2$; hospital admission, bereavement, depression, sciatica $n = 1$ each). The BCI group had 16 adverse events (hospital admission $n = 4$; elective surgery and hip or knee pain $n = 2$ each; death, bereavement, stress, sciatica, cellulitis, prolapse, investigations for breathlessness, polymyalgia rheumatica pain $n = 1$ each), and the pedometer plus group had nine adverse events (knee pain $n = 2$; diverticulitis, stress, sciatica, chest infection, increased breathlessness, influenza, vertigo $n = 1$ each). No excess of events was identified in the intervention groups that could plausibly be related to the interventions.

The SPPB score was better ($P = .03$), and finding use of stairs difficult ($P = .03$) was less common in those who completed 3 months of the study than in those who dropped out.

DISCUSSION

These results show that the use of a theory- and evidence-based behavioral change intervention with or without a pedometer was effective in objectively increasing physical activity in sedentary older women at 3 months but that this increase reverted to baseline level over the following 3 months as the frequency of intervention contacts waned. The result was surprising, because it had been anticipated that the combination of pedometer plus BCI would be more

Table 1. Baseline Characteristics

Characteristics	All (n = 210)	Pedometer Plus BCI (n = 68)	BCI Alone (n = 68)	Controls (n = 68)
Age, mean ± SD	77.3 ± 5.0	77.1 ± 4.9	77.6 ± 5.4	77.0 ± 4.9
Marital status, n (%)				
Married	91 (43.3)	26 (38.2)	34 (50.0)	29 (42.6)
Widowed	96 (45.7)	36 (52.9)	22 (32.4)	33 (48.5)
Single	23 (10.9)	6 (8.8)	12 (17.6)	5 (7.4)
Deciles of Scottish Index of Multiple Deprivation, n (%)				
1–5 (most deprived)	83 (39.5)	22 (32.3)	35 (51.4)	23 (33.8)
6–10 (most affluent)	125 (59.5)	46 (67.6)	32 (47.0)	44 (64.7)
Used pedometer before, n (%)				
No	196 (93.3)	63 (92.6)	64 (94.1)	63 (92.6)
Yes	14 (6.7)	5 (7.4)	4 (5.9)	5 (7.4)
Fall in 12 months before study, total (range)	100 (0–6)	32 (0–5)	34 (0–6)	30 (0–3)
Car access, n (%)				
No	72 (34.3)	23 (33.8)	24 (35.3)	22 (32.4)
Yes	138 (65.7)	45 (66.2)	44 (64.7)	46 (67.6)
Long-standing illness that limits activity, n (%)				
No	146 (69.5)	45 (66.2)	43 (63.2)	53 (77.9)
Yes	64 (30.5)	23 (33.8)	25 (36.8)	15 (22.1)
Daily stair use, n (%)				
No	84 (40.0)	23 (33.8)	28 (41.2)	30 (44.1)
Yes	126 (60.0)	45 (66.2)	40 (58.8)	30 (55.9)
Stairs difficult, n (%)				
No	143 (68.1)	48 (70.6)	48 (70.6)	45 (66.2)
Yes	67 (31.9)	20 (29.4)	20 (29.4)	23 (33.8)
Voluntary work, n (%)				
No	149 (71.0)	49 (72.1)	50 (73.4)	45 (66.2)
Yes	61 (29.0)	19 (27.9)	18 (26.5)	23 (33.8)
Own shopping, n (%)				
No	10 (4.8)	2 (2.9)	3 (4.4)	5 (7.4)
Yes	200 (95.2)	66 (97.1)	65 (95.6)	63 (92.6)
Season entered, n (%)				
Winter	82 (39.0)	29 (42.6)	26 (38.2)	26 (38.2)
Spring	69 (32.9)	20 (29.4)	24 (35.3)	23 (33.8)
Summer	40 (19.0)	14 (20.6)	11 (16.2)	13 (19.1)
Autumn	19 (9.0)	5 (7.4)	7 (10.3)	6 (8.8)
Lives with, n (%)				
Alone	113 (53.8)	39 (57.4)	31 (45.6)	38 (55.9)
With someone	2 (1.0)	29 (42.6)	37 (54.4)	30 (44.1)
No. of drugs, mean ± SD	4.4 ± 3.5	4.9 ± 3.6	4.2 ± 3.3	4.0 ± 3.5
Falls in last 3 months, n (%)				
1st 3 months of study				
0	172 (81.9)	58 (85.30)	52 (76.5)	62 (91.2)
1	7 (3.3)	0 (0.0)	4 (5.9)	3 (4.4)
≥2	8 (3.9)	4 (5.9)	3 (4.4)	1 (1.5)
2nd 3 months of study				
0	165 (78.6)	57 (83.8)	51 (75.0)	57 (83.8)
1	17 (8.1)	4 (5.9)	6 (8.8)	7 (10.3)
≥2	5 (2.4)	2 (2.9)	1 (1.5)	2 (3.0)
Vector maximum accelerometry counts, mean ± SD		137,623 ± 50,642	123,456 ± 48,713	123,560 ± 46,190
Accelerometer minutes of activity, mean ± SD		180.2 ± 68.0	160.9 ± 69.1	159.6 ± 63.2
Short Physical Performance Battery, mean ± SD		8.2 ± 2.6	8.6 ± 2.2	8.7 ± 2.2
EuroQOL, mean ± SD		0.82 ± 0.19	0.83 ± 0.18	0.83 ± 0.19
Hospital and Anxiety Depression Scale score				
Depression, mean ± SD		3.1 ± 3.0	2.76 ± 2.48	2.62 ± 2.29
Anxiety, mean ± SD		4.48 ± 3.23	3.9 ± 3.0	3.5 ± 2.7
National Health Service Costs in previous 3 months, £, mean ± SD		213.4 ± 300.4	284.8 ± 873.0	193.7 ± 326.3

1£ ~ US\$1.6.

BCI = behavior change intervention; SD = standard deviation.

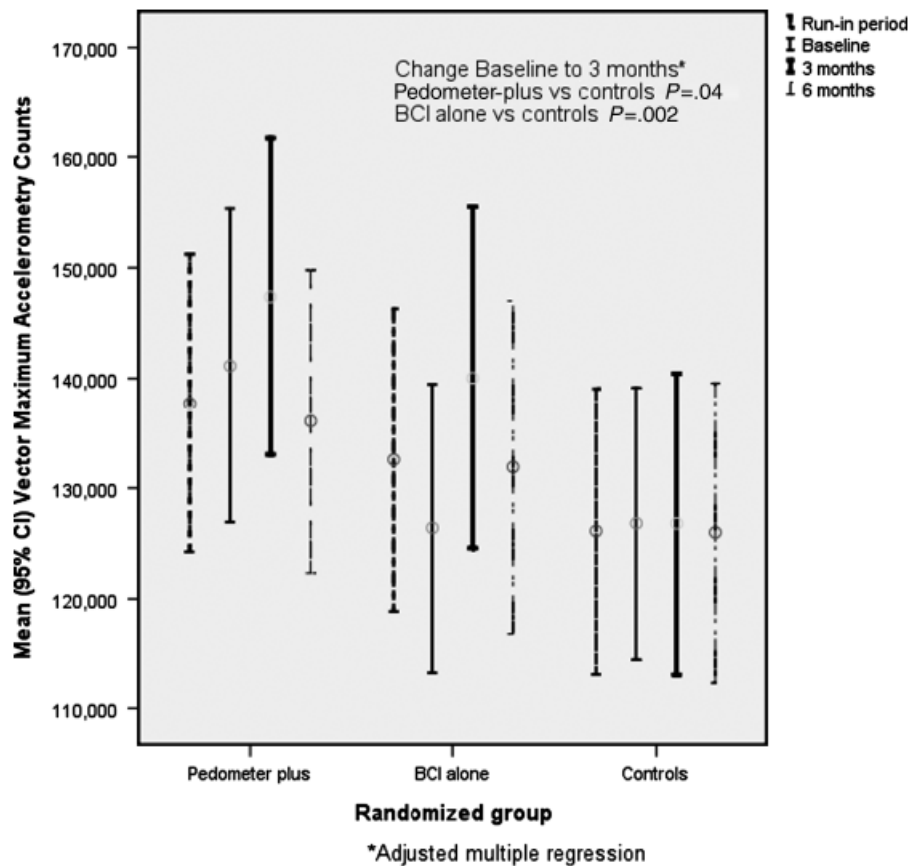


Figure 2. Means and 95% confidence intervals (CIs) for accelerometer readings at all time points according to randomization group. BCI = behavior change intervention.

effective than BCI alone. The addition of a pedometer to the BCI intervention conferred no additional physical activity advantage, although the dropout rate was much lower in the pedometer plus group than the BCI group, raising the possibility that the provision of a pedometer may have motivated participants to remain in the trial.

Strengths and Limitations

This is the first trial to use pedometers as part of a complex behavior change intervention evaluated using accelerometry rather than using pedometers both as an intervention and a tool to measure physical activity. To the authors' knowledge, this trial is the largest involving pedometers,

Table 2. Unadjusted Comparison of Changes in Outcomes from Baseline to 3 Months According to Randomized Group

Outcome	Pedometer Plus BCI	BCI Alone	Controls	P-Value (One-Way Analysis of Variance)
Accelerometry vector maximum, mean (SE)	5,504 (4,465)	13,305 (5,142)	-2,290 (3,715)	.049
Minutes walking	-1.31 (5.74)	14.27 (6.42)	-5.86 (5.67)	.05
Short Physical Performance Battery, mean (SE)	0.39 (0.21)	0.12 (0.21)	0.33 (0.21)	.66
*EuroQOL, median (range)				
Score	0 (-0.84-0.38)	0 (-0.61-0.48)	0 (-0.72-0.53)	.85
Scale	0 (-75-50)	0 (-45-33)	5 (-30-33)	.42
Hospital Anxiety and Depression Scale score				
Depression, mean (SE)	-0.56 (0.33)	-0.16 (0.29)	-0.55 (0.29)	.58
Anxiety, median (range)	-0.82 (0.32)	-0.47 (0.34)	-0.33 (0.33)	.55
Health costs, £, median (range)	-17.4 (-1,309.1-1,299.3)	-15.6 (-2,868.5-701.4)	-15.6 (-2,280.3-411.5)	.96

*EuroQOL is a standard European Quality of Life measure used in research and many trials. It is based on five questions and gives a score generally from 0 = death to 1 = perfect health, although it is possible to have a negative value in some circumstances (quality of life worse than death). In addition, it has a separate visual analogue scale in the form of a thermometer that the patient marks, and this gives a scale of 0 to 100.

£1 ~ US\$1.6.

BCI = behavior change intervention; SE = standard error.

Table 3. Multiple Linear Regression on Accelerometer Counts Between Intervention Groups and Controls Based on Pooling of Five Multiple Imputations (n = 202)

Factor	Regression Coefficients			
	Beta	Standard Error	t	P-Value
Intercept	89,394	47,664	1.88	.06
Pedometer plus vs control	13,154	6,168	2.13	.04
BCI vs control	18,374	5,929	3.10	.002
Baseline accelerometry vector maximum (+1)	0.749	0.065	11.54	<.001
Age (+1 year)	– 1,331	541	– 2.46	.01
Short Physical Performance Battery total at baseline (+1)	4,124	1,235	3.34	.001
Stairs difficult (yes vs. no)	7,148	6,053	1.18	.24
Total number of drugs (+1)	– 940	763	– 1.23	.22
Living alone (yes vs. no)	6,399	4,977	1.29	.20
National Health Service health costs at baseline (+1£)	14.774	6.026	2.45	.03

and the focus on older women, the objective measurement of activity levels, consideration of the effect of seasonality, blinding of outcome assessments, and its use of intention-to-treat analysis are all strengths. Self-reported measures of physical activity levels have been used in many trials but are notoriously inaccurate, particularly in their lack of sensitivity to walking activities.⁷ Surprisingly few high-quality randomized controlled trials of pedometer use have been published. A recent systematic review, for example, identified only eight randomized control trials and 18 observation studies, with a mean participant age of 49.⁶ The behavior-change intervention incorporated the setting of graded step goals and use of self-monitoring step diaries, both of which were identified in the review as being predictors of increased physical activity. Other active components of the intervention were based on evidence and sound psychological theory.⁶

In contrast to the existing literature, a strength of the current trial was its target population of women aged 70 and older. Older people were targeted, because functional impairment afflicts a large number of older adults. Older women in particular were targeted, because physical activity is a modifiable predictor of functional decline in older women.²⁴ Findings from the Women's Health and Aging Study that small amounts of regular walking can confer protection from further mobility loss further supported the decision to target women.²⁵

A further strength of the trial is that adverse events, including falls, were recorded. Potential risks of increasing activity participation have been inadequately recorded in the past, and some interventions have been associated with an increase in falls.^{22,23} Unlike previous trials that have relied on recall of falls, a method known to be inaccurate,²⁶ falls were recorded prospectively using a validated daily diary method. The findings provide reassurance that this method of promoting physical activity participation in older women does not increase falls.

It was decided to have a 2-week recording period of activity levels before randomization and to reject the first week of recording (the run-in period) to minimize the effect on baseline readings of any uncharacteristic increases in physical activity triggered by the novelty of wearing an ac-

tivity measuring device. Although accelerometry counts fell in the BCI group and remained static in the control group, activity levels started from a higher level and rose higher still during the 2-week period of prerandomization recording for the pedometer plus group. Because the randomization procedure was off-site and produced well-balanced baseline characteristics, it is likely that this is simply a quirk of the randomization, although its effect may have reduced the increment achieved in the pedometer plus group. Nevertheless, after imputing missing values and adjusting for baseline differences, the pedometer plus group recorded significantly greater activity than the controls.

Meaning of Study: Possible Implications and Explanations

These findings may dampen the enthusiasm for pedometers that currently prevails, at least for sedentary older women. Pedometers appear attractive as inexpensive aids for potentially increasing activity levels through self-monitoring and adherence. This trial in sedentary older women found that pedometer use was not superior to a theory-based intervention based on time-based goal setting, planning, and self-monitoring. The findings do not provide support for the adoption of pedometers other than possibly as a means of motivating participants to remain in a trial.

Unanswered Questions and Future Research

The BCI was effective in objectively increasing activity levels at 3 months. After 3 months, no further target setting was done with participants, and telephone calls of encouragement decreased in frequency. Further work is now required to establish what additional support, for example, "booster sessions,"²⁷ would be required to sustain that increase in the longer term, to measure the cost effectiveness and clinical effect of this approach, and to determine whether it is possible to use psychological measures to predict who is most likely to respond to a such an intervention.

CONCLUSION

A BCI was effective in significantly increasing objectively measured physical activity participation by sedentary older

women at 3 months, but physical activity reverted to baseline after withdrawal of the intervention. The addition of a pedometer to the BCI conferred no additional advantage.

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