

“Active Guide” Brochure Reduces Sedentary Behavior of Elderly People: A Randomized Controlled Trial

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The aim of this study was to examine in a randomized controlled trial how much the sedentary behavior (sitting time) of community-dwelling elderly Japanese subjects decreased as a result of using the “Active Guide” brochure published by the Ministry of Health, Labour and Welfare (2013) and additional documents related to the benefits of reducing sedentary behavior. A total of 86 elderly people who participated in health-club activities for one year were randomly allocated to two groups. Subjects in the intervention group received explanations of the importance of physical activity using the “Active Guide” brochure (n = 42) and additional documents, while subjects in the control group did not (n = 44). Physical activity was measured using a triaxial accelerometer for two weeks at baseline and again after one year. After one year of intervention, the difference in the sedentary behavior rate from baseline was -2.2% for the intervention group (n = 40) and +2.5% for controls (n = 40) (Welch's *t*-test, *p* = 0.007). Use of the “Active Guide” brochure and additional documents may reduce the sedentary behavior of community dwelling elderly people in Japan.

Key words: Active Guide, sedentary behavior, elderly people, randomized controlled trial, health promotion

In contemporary societies, sedentary behavior has been incorporated into many aspects of both work and home life [1]. The amount of sedentary behavior in the Japanese population is the highest in the world [2, 3]. Sedentary behavior increases with age [4], and is a risk factor for various adverse health outcomes [5, 6]. Here, sedentary behavior is defined not as “physical inactivity” (the definition of the World Health Organization (WHO) [7]), but as “any waking behavior characterized by an energy expenditure ≤ 1.5 METs while in a sitting or reclining posture” [8].

Many approaches have been proposed to reduce sedentary behavior; however, there have not been many randomized controlled trials (RCTs) [9-17], especially in Japan. These previous studies demon-

strated significant improvements due to interventions in some behavior indicators such as sitting time at work, television viewing time, and times sitting longer than 30 min compared with control groups. However, these intervention studies were short-term (1 to 13 weeks) [9-17], and the long-term (over one year or more) effectiveness of such interventions has not been established. Moreover, the intervention methods were difficult for the participants to follow. Finally, there have been few studies examining community-dwelling elderly people in Japan [18].

The key recommendation of the “Active Guide” brochure, published by the Ministry of Health, Labour and Welfare (2013) to promote health in Japan, is to add 10 min of exercise per day. The “Plus 10” recommendation is supported by scientific evidence, and is

feasible and efficient for the Japanese population [18].

Therefore, in this RCT, we examined the long-term effects of using the “Active Guide” brochure and additional documents that explain the benefits of reducing sedentary behavior in community-dwelling elderly people in Japan.

Methods

Study design. This RCT included two groups of community-dwelling elderly people in Japan. The subjects were volunteers drawn from among members of the college health club in Utazu-cho, Kagawa, Japan (population approx. 18,450) in 2016. The health club sessions took place once a month for 2 h, and mainly consisted of lectures to promote good health. At baseline, a researcher who was blinded to and not involved in the intervention generated random numbers with Microsoft Excel, and these were assigned to the subjects. Another researcher then assigned the subjects to either an intervention group or a control group, and each participant was made aware of the group to which they were assigned. The intervention group received the “Active Guide” brochure (Ministry of Health, Labour and Welfare) (<http://www.nibiohn.go.jp/eiken/info/pdf/active2013-e.pdf>, <http://www.nibiohn.go.jp/eiken/info/pdf/active2013.pdf> [in Japanese] (accessed January 13, 2019) and additional documents explaining the benefits of reducing sedentary behavior (“Let’s pay attention to time spent sitting”), along with the results of their baseline examination. The “Active Guide”, which was based on the “Physical Activity reference 2013,” introduced the tagline “Plus 10” to describe its recommended strategy for promoting daily physical activity. The “Plus 10” concept is to increase one’s daily physical activity, especially walking, by 10 min. For people over the age of 65, the “Active Guide” recommends standing, walking, or performing daily chores to meet the Plus 10 goal. Members of the control group received only the results of their baseline examination. The subjects in both groups who participated in more than 75% of the 12 sessions during the trial period were used in the final analysis. Of the total of 112 subjects, 90 met this condition, and 86 of these 90 people participated in the final analysis.

We obtained approval from the Shikoku Medical College Ethics Screening Committee (approval number: H27-3), and written informed consent was obtained

from each subject. The study was registered as an RCT with the University Hospital Medical Information Network (UMIN): registration number UMIN 000027781. The trial lasted from 20 July 2016 (the start of the trial and baseline examinations) to 15 September 2017 (the end of the follow-up examinations).

Sample size. We calculated the sample size using the significance level, power, difference between the two groups, and standard deviation (SD) in a paired *t*-test. In accordance with similar previous studies, the significance level used was α : 0.05, and the power used was 0.8. The difference between the 2 groups was derived as follows: Wen *et al.* found that every additional 15 min of daily exercise beyond the minimum amount of 15 min per day reduced all-cause mortality by 4% [19], and the WHO recommended exercising for 30 min a day for good health [20]. Therefore, we adopted the average of 22.5 min of exercise as the target value: (15 min + 30 min)/2. There is a reported trade-off relationship between exercising time and sitting time; increasing exercising time decreases sitting time [21]. Thus, we set the difference between the mean values of the 2 groups as 22.5 min of sitting time (sedentary behavior). In addition, Honda *et al.* [22] reported that the time spent sitting by elderly Japanese (average age 73.1 years) was 486.9 min per day. Reducing sitting time by 22.5 min is thus a 4.62% reduction ($22.5/486.9 \times 100$). As a result, the minimal clinically important difference in the percentage of sitting time (sedentary behavior) was estimated to be 4.62%. Gorman *et al.* [23] reported that the average sedentary time per day was 68%, with an SD of 7.8% (5.9-8.0). As a result, the final sample size (in each group) was 39. We decided to include 43 participants in each group (total 86), in anticipation of a 10% loss to follow-up.

Clinical parameters and measurements. Subjects were evaluated based on the following parameters: age (years), height (cm), body mass index: BMI (kg/m^2), working hours (h/day), and psychological distress by K6 score [24]. Health behaviors included sleeping time (h/day), spouse (%), exercise limitation (presence) (%) (based on a doctor’s diagnosis), pain in locomotive organs (presence) (%), and smoking (%) and drinking habits (%). Smoking and drinking habits were based on the definitions in specific health checkup questionnaires produced by the Ministry of Health and Welfare (<http://www.mhlw.go.jp/bunya/kenkou/seikatsu/pdf/02b.pdf>

[in Japanese] (accessed January 13, 2019).

Physical activity and sedentary behavior. In this study, we recorded physical activity using a triaxial accelerometer (Active Style Pro HJA-750C; Omron Healthcare, Japan) for 14 consecutive days, as previously described [25]. Subjects were asked to wear the accelerometer at their waist at all times, except when impossible such as during swimming and bathing. The SD in the data recorded over a period of 10 seconds was defined as the average value of acceleration. Subjects wore the accelerometer for 10 h or more each day in this analysis. Physical activity was evaluated using Σ [metabolic equivalents \times h per week (METs \cdot h/week)], daily step counts (steps/day), daily step hours (h/day), walking time (min/day), and physical activity (≤ 1.5 METs, 1.6-2.9 METs, 3-5.9 METs) (min/day). Because the mean of physical activity did not exhibit a normal distribution, we adopted the median. Measurements of physical activity and sedentary behavior were evaluated at baseline and after one year.

Statistical analysis. Data analysis was conducted by a researcher blinded to the allocation of the participants. Continuous variables were presented as the mean \pm SD and categorical variables as percentages. We used Welch's *t*-test to compare the averages of continuous variables such as age, and we used χ^2 tests to compare the proportions of categorical variables, such as sex, between the groups. If there were variables that could affect the results, we adjusted those results by these variables before intervention. The threshold for significance was $p < 0.05$. All calculations were performed using STATA, version 14 (STATA, College

Station, TX).

Results

Among the 86 subjects, 3 were lost to follow-up, 2 were hospitalized, and 1 was rejected (Fig. 1). After excluding these patients, we used the data from 24 men (72.3 \pm 5.4 years) and 56 women (73.1 \pm 5.6 years) (Fig. 1). At the randomized group assignment and at baseline, the 2 groups were homogenous except for BMI, as shown in Tables 1 and 2.

At baseline, the sedentary behavior rate was 54.9 \pm 9.7%/day [35.4-75.5%/day] in the intervention group and 55.2 \pm 10.2%/day [38.3-79.9%/day] in the control group ($p=0.856$). As shown in Table 2, there were no significant differences in sedentary behavior between the 2 groups at baseline.

During the follow-up period, the differences in the changes in sedentary behavior (%), *i.e.*, the differences in parameters between before and after intervention, were $-2.2 \pm 5.9\%$ /day [8.0% to -16.6% /day] in the intervention group and $2.5 \pm 8.8\%$ /day [23.3% to -8.6% /day] in the controls ($p=0.007$). There was a significant difference in changes in sedentary behavior (%) between the 2 groups during the follow-up period. A difference in BMI at follow-up was also noted. The sedentary behavior rate was 52.7 \pm 10.9%/day [35.4-75.5%/day] in the intervention group and 57.7 \pm 9.8%/day [36.5-74.3%/day] in the controls ($p=0.033$) at follow-up (Table 3). The changes in sedentary behavior (%) between the 2 groups remained significant even after adjusting for BMI.

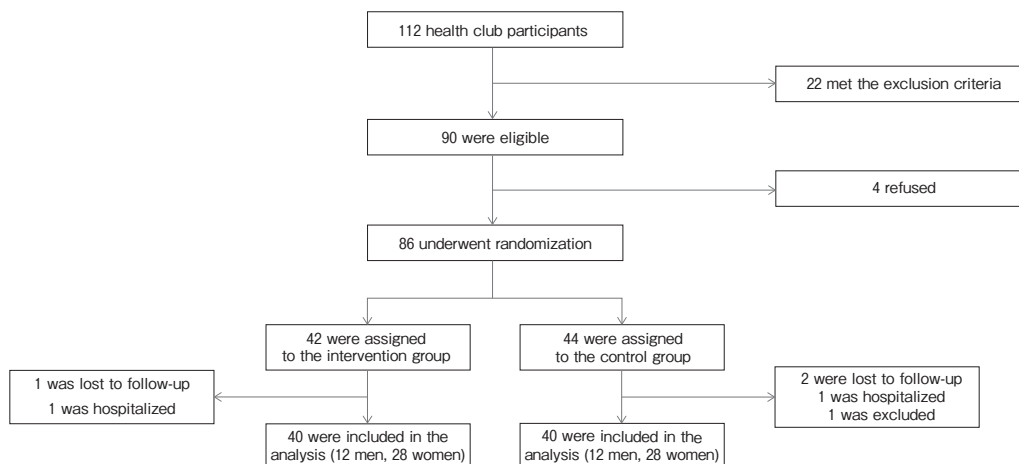


Fig. 1 Randomization and follow-up.

Table 1 Randomized assignment (Clinical characteristics of enrolled subjects)

	Intervention group			Control group			<i>p</i> value
	Mean ± SD	Minimum	Maximum	Mean ± SD	Minimum	Maximum	
Number of subjects	42 (12 men, 30 Women)			44 (14 men, 30 women)			
Age (years)	72.2 ± 5.6	65	85	71.3 ± 5.4	65	85	
Height (cm)	155.6 ± 9.0	138.3	178.4	158.4 ± 8.8	140.1	175.6	
BMI (kg/m ²)	21.8 ± 2.5	14.9	26.7	23.4 ± 2.7	18.7	29.1	< 0.001
Working hours (hours/day)	1.4 ± 2.4	0	8	2.2 ± 3.3	0	10	
Exercise (METs · h/w)	5.2 ± 2.2	0.4	9.7	5.2 ± 2.1	1.6	9.7	
Number of steps (steps/day)	5,602.7 ± 2,743.0	569.9	12,230.1	5,783.0 ± 2,320.5	1,585.4	10,915.9	
Walking time (minutes/day)	82.5 ± 37.6	20.9	177.7	87.7 ± 26.0	31.3	146.7	
≤ 1.5 METs (%/day)	53.8 ± 10.2	35.4	75.5	56.0 ± 9.7	38.3	79.9	
1.6~2.9 METs (%/day)	36.3 ± 7.5	19.4	49.0	34.3 ± 7.9	16.9	52.3	
3~5.9 METs (%/day)	9.4 ± 3.9	0.8	17.0	8.9 ± 3.7	2.8	15.6	
K6 scores	2.3 ± 3.3	0	14	2.9 ± 3.4	0	13	
Sleep time (hours/day)	6.5 ± 1.2	4	10	6.5 ± 0.9	4	8	
Social participation (Presence) (%)	83.7			86.1			
Spouse (Presence) (%)	70.0			81.4			
Exercise limitation (Presence) (%)	9.3			11.6			
Pain in limbs (Presence) (%)	74.4			76.7			
Smoking status (Smoker) (%)	4.7			4.7			
Alcohol drinking status (Drinker) (%)	32.6			25.6			

BMI, body mass index (kg/m²); METs, metabolic equivalents. Bold values are significant (*p* < 0.05).

Table 2 Baseline (Clinical characteristics of enrolled subjects)

	Intervention group			Control group			<i>p</i> value
	Mean ± SD	Minimum	Maximum	Mean ± SD	Minimum	Maximum	
Number of subjects	40 (12 men, 28 women)			40 (12 men, 28 women)			
Age (years)	72.6 ± 5.5	65	85	71.1 ± 5.5	65	85	
Height (cm)	156.2 ± 9.2	138.3	178.4	158.2 ± 9.2	140.1	175.6	
BMI (kg/m ²)	21.8 ± 2.6	14.9	26.7	23.5 ± 2.7	18.7	29.1	< 0.001
Working hours (hours/day)	1.6 ± 2.7	0	8	2.2 ± 3.3	0	10	
Exercise (METs · h/w)	5.1 ± 2.2	0.4	9.7	5.2 ± 2.2	1.6	9.7	
Number of steps (steps/day)	5,728.2 ± 2,818.4	569.9	12,230.1	5,746.5 ± 2,338.9	1,585.4	10,915.9	
Walking time (minutes/day)	83.2 ± 38.3	20.9	177.7	87.4 ± 26.9	31.3	146.7	
≤ 1.5 METs (%/day)	54.9 ± 9.7	35.4	75.5	55.2 ± 10.2	38.3	79.9	
1.6~2.9 METs (%/day)	35.5 ± 7.0	19.4	49.0	34.9 ± 8.5	16.9	52.3	
3~5.9 METs (%/day)	8.9 ± 3.9	2.8	17.0	9.2 ± 3.5	0.8	15.6	
K6 scores	2.2 ± 3.3	0	14	2.6 ± 2.6	0	7	
Sleep time (hours/day)	6.6 ± 1.2	4	10	6.5 ± 0.9	4	8	
Social participation (Presence) (%)	82.5			85.0			
Spouse (Presence) (%)	70.0			80.0			
Exercise limitation (Presence) (%)	7.5			10.0			
Pain in limbs (Presence) (%)	77.5			72.5			
Smoking status (Smoker) (%)	5.0			5.0			
Alcohol drinking status (Drinker) (%)	32.5			30.0			

BMI, body mass index (kg/m²); METs, metabolic equivalents. Bold values are significant (*p* < 0.05).

Discussion

In this RCT study, sedentary behavior was significantly reduced in community-dwelling elderly Japanese subjects by using the “Active Guide” brochure and additional documents. There was a significant difference in the changes in sedentary behavior (%) between the two groups. The changes in sedentary behavior were -2.2%

for the intervention group and +2.5% for the control group during the study period. Sedentary behavior is generally thought to increase with aging. However, our study demonstrated that the “Active Guide” brochure and additional documents explaining the importance of reducing sedentary behavior (“Let’s pay attention to time spent sitting”) reduced the sedentary behavior of community-dwelling elderly people in Japan. This sim-

Table 3 Follow-up (Clinical characteristics of enrolled subjects)

	Intervention group			Control group			<i>p</i> value
	Mean ± SD	Minimum	Maximum	Mean ± SD	Minimum	Maximum	
Number of subjects	40 (12 men, 28 women)			40 (12 men, 28 women)			
Age (years)							
Height (cm)	156.2 ± 9.2	138.3	178.4	158.2 ± 9.2	140.1	175.6	0.277
BMI (kg/m ²)	21.9 ± 2.7	14.9	26.7	23.3 ± 2.6	19.1	29.1	< 0.001
Working hours (hours/day)	1.4 ± 2.6	0	8	2.6 ± 3.7	0	12	0.091
Exercise (METs · h/w)	5.5 ± 2.8	0.5	10.9	5.0 ± 2.5	0.9	10.7	0.340
Number of steps (steps/day)	6,138.5 ± 3,187.8	845.1	13,973.3	5,784.3 ± 2,503	985.4	11,291.0	0.582
Walking time (minutes/day)	87.3 ± 42.8	32.7	192.1	84.3 ± 31.5	38.6	167.4	0.717
≤ 1.5 METs (%/day)	52.7 ± 10.9	35.4	75.5	57.7 ± 9.8	36.5	74.3	0.033
Changes in ≤ 1.5 METs (%/day)	-2.2 ± 5.9	16.6	8	2.5 ± 8.8	-8.6	23.3	0.007
1.6~2.9 METs (%/day)	36.4 ± 8.0	19.4	49.0	33.7 ± 7.4	19.6	47.4	0.117
Changes in 1.6~2.9 METs (%/day)	0.9 ± 4.1	2.6	-1.9	-1.2 ± 6.3	-2.4	1.1	0.098
3~5.9 METs (%/day)	10.3 ± 4.6	2.8	17.0	8.5 ± 4.0	1.9	15.8	0.067
Changes in 3~5.9 METs (%/day)	1.4 ± 2.2	-0.4	0.2	-0.7 ± 1.9	-1.8	1.3	0.061
K6 scores	1.9 ± 3.0	0	14	3.2 ± 3.1	0	11	0.052
Sleep time (hours/day)	6.7 ± 1.1	4	10	6.6 ± 0.8	5	8	0.488
Social participation (Presence) (%)	67.5			85.0			0.369
Spouse (Presence) (%)	70.0			80.0			0.168
Exercise limitation (Presence) (%)	5.0			10.0			0.468
Pain in limbs (Presence) (%)	77.5			72.5			0.443
Smoking status (Smoker) (%)	5.0			5.0			0.816
Alcohol drinking status (Drinker) (%)	30.0			30.0			0.817

BMI, body mass index (kg/m²); METs, metabolic equivalents. Bold values are significant (*p* < 0.05).

ple intervention offers a strategy for reducing sedentary behavior among community-dwelling Japanese elderly people in clinical practice.

Most of the previous studies on interventions to reduce sedentary behavior [9-17] have focused on the short-term effects (1-13 weeks) of interventions, whereas long-term effects such as those observed in our study have not been fully explored. Most subjects in previous studies were full-time employees (mean age: 41.9 to 54.1 years), rather than community-dwelling elderly people. Some studies showed significant differences in sedentary behavior resulting from interventions [12-16], while others did not [9-11, 17]. The intervention methods used in previous reports were personal interviews, a combination of personal interviews and written support, smartphone support, interruption stimulation by personal computers, and improvements in facilities at the workplace. A few studies of the elderly [26-28] also used personal interviews, a combination of personal interviews and written support, and smartphone support as means of intervention. These interventions would be relatively difficult to perform in clinical practice.

Our study targeted community-dwelling elderly people in Japan. The long-term effects of intervention using the “Active Guide” brochure and additional documents

were analyzed using objective measurements of sedentary behavior. The subjects only received the “Active Guide” brochure and encouragement (“Let’s pay attention to time spent sitting”). The intervention method was simple and easy to perform in clinical practice.

Several limitations of this study should be acknowledged. First, our study did not use random sampling but rather random allocation. The subjects in this study were members of a health club, and thus were likely to be more health-conscious than average. In fact, the subjects at baseline had rather low sedentary behavior (%) (56.4-53.8), and high social participation (%) (83.7-86.1). In addition, their K6 scores were thought to be comparatively low (2.3-2.9). Because the group was relatively active, had high social participation, and had low K6 scores, the effect of intervention may have been smaller than it would be in a more general population. Second, although simple random assignment was performed, there was a significant difference in BMI between the intervention group and the control group. Third, the sample size was small. Although the difference in changes in sedentary behavior (%) between the groups was significant, the final statistical power was 78%. Post hoc calculations indicated that 41 subjects per group would be required for 80% power. Finally, we did not consider the interruption of sedentary behavior,

although some studies have suggested that the interruption of sedentary behavior improves the quality of life [29,30]. Taken together, these findings suggest that, especially to improve the 78% statistical power, further intervention studies of other populations are required in the future.

In conclusion, the “Active Guide” brochure and documents explaining the importance of reducing sedentary behavior (“Let’s pay attention to time spent sitting”) reduced the sedentary behavior of community-dwelling elderly people in Japan.

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