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Randomized controlled trial to evaluate the effect of a physical activity intervention program based on behavioral medicine

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Abstract

In spite of health benefits of physical activity, a large part of the population keeps a sedentary lifestyle. Thus, it remains an important public health challenge to develop intervention programs to promote physical activity. In this study, the effect of a physical activity program using behavioral approaches was examined by 8-month randomized controlled trial (2 months intensive intervention+6 months follow-up). Subjects were 86 sedentary women, aged from 47 to 68 years old, and were randomly classified into two groups, an intervention group and a control group. Results showed that the intervention group increased their total energy expenditure by a significantly large degree compared with the control group in both the short-term (2 months) and long-term (8 months) ($p=0.038$ and $p=0.014$, respectively). According to the analysis of physical activity intensity, these increases were mainly due to the increase of moderate activity. Some other measures of physical fitness and body composition were significantly improved in the intervention group compared with the control group. In conclusion, the present program based on behavioral medicine was effective to promote physical activity and to improve physical fitness and body composition over 8 months.

Introduction

It is well documented that regular physical activity is beneficial for reduction of mortality[1], for prevention of cardiovascular disease[2], diabetes[3], and some kinds of cancer[4], and for maintenance of physical function in older adults[5]. These evidences were widely accepted, and were summarized as recommendation statements on physical activity[6)-8]. However, a large part of the population is not sufficiently active. In the United States, more than 60% of people are not sufficiently active[9)10]. In Japan, only 30.2% of men and 27.5% of women engage in 20 minutes or more of exercise two or more times per week[11]. Thus, it remains a public health challenge to promote physical activity for prevention and control of chronic diseases, and the development of physical activity promotion methods is eagerly awaited.

Given this background, behavioral theories and models such as the learning theory[12] the social cognitive theory[13], the relapse prevention model[14], and the transtheoretical model[15)16], are expected to be applied for physical activity interventions. These theories and models of human behavior are useful for understanding health behavior[17] and have played important roles in the development and refinement of intervention programs for smoking cessation and other health behaviors. Recently, applications of these theories to physical activity programs have begun to spread, and the results of some intervention trials have been reported in the United States[18)19]. Review articles on 127 intervention studies concluded that intervention based on behavioral science is an effective and recommended method to promote physical activity[20)21]. However, applications of behavior theories and models to physical activity programs are still in development, and further studies to

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examine the effects of programs are needed, especially in Japan. In this study, a physical activity program was developed based in large part on the transtheoretical model, a model spreading to heath education, and the effects of the program on sedentary middle-aged and senior women were examined by a randomized controlled trial.

Methods

This study was conducted with the permission of the Ethics Committee of Tokyo Medical University.

1. Study design

The study design was an eight-month randomized controlled trial, conducted from April through December, 2001. The eight months consisted of a 2-month intensive intervention period and a 6-month follow-up period.

2. Subjects

Participant flow is shown in Fig. 1. Women with obesity and hyperlipidemia were recruited by newspaper advertisements. Inclusion criteria were: 1) sedentary women aged from 45 to 69 years old who engage in exercise less than once a week as of the occasion of the explanation of the project, 2) meeting the criteria for serum total cholesterol <280 mg/dl, triglyceride <400 mg/dl, fasting plasma glucose <126 mg/dl, resting blood pressure $<160/100$ mmHg, 3) taking no medications affecting lipid metabolism such as antihyperlipidemic drugs, antihypertensive drugs, etc., 4) no cardiovascular or orthopedic disorders limiting participation in an exercise program, 5) others. Women with obesity or hyperlipidemia were given priority for participation. A total of 237 women applied for participation in this study. Initial screening was done through application forms, and 195 women were invited to a research explanation meeting. Of the 157 participants, 156 signed informed consent forms. After a second screening conducted at the meeting, 90 women were invited for baseline assessment. At baseline assessment, including exercise test and blood sampling, one woman had exercise-induced arrhythmia, and three had cholesterol levels higher than the inclusion criteria. These four subjects were excluded. Finally, 86 participants were confirmed as subjects of this study and were randomized into two groups, 42 females in the control group and 44 females in the intervention group.

3. Measurements

Assessments were conducted three times, at baseline, immediately after intensive intervention (at 2 months), and after 6-month follow-up period (at 8 months) for all measurements.

1) Measurements of physical activity energy expenditure, exercise behavior, physical fitness, and nutrition

Physical activity energy expenditure

For physical activity energy expenditure assessment, a 24-hour physical activity record was used. Participants were asked to record all kinds of physical activities that they did every ten minutes for seven consecutive days. The intensity of each activity was self-classified into one of 5 categories: intensity 1 - sleeping, intensity 2 - sedentary activity mainly in a sitting position, intensity 3 -

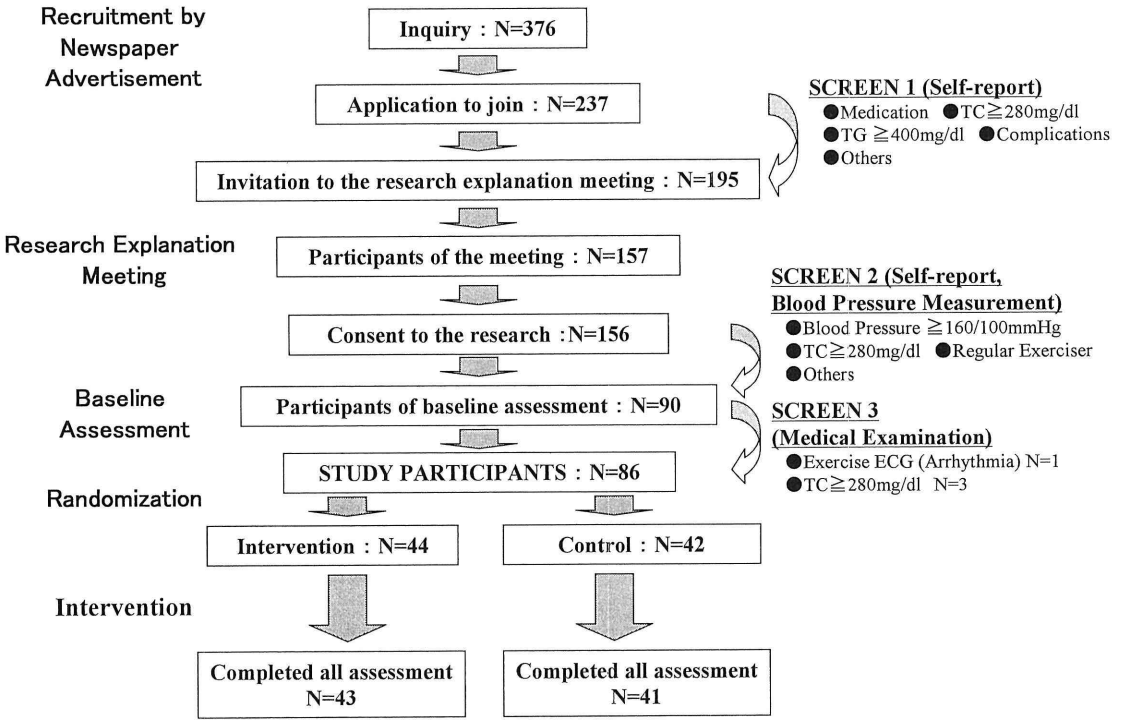

Fig. 1 Participant flow

light activity in a standing position, intensity 4 - moderate activity (3-6 metabolic equivalents : METs), intensity 5 - vigorous activity (>6 METs). To help subjects to classify the intensity, face to face instruction was given to each subject. In addition, a table of concrete examples of activities and intensities, which was constructed with reference to the compendium of physical activities reported by Ainsworth et al.[22], were provided. The records were confirmed by interviews at collection. Energy expenditure was calculated according the equation below[23].

Energy expenditure (kcal/kg) = Intensity (METs)× Duration(min)×3.5 (ml/min/kg)×0.005 (kcal/ml)

3.5 ml/min/kg : Oxygen uptake for 1 MET

0.005 kcal/ml : Energy expenditure per 1 ml oxygen uptake

On calculation of energy expenditure, METs values of physical activity below were assigned to each intensity category.

Intensity 1 : 0.9 METs, Intensity 2 : 1.5 METs, Intensity 3 : 2.0 METs,

Intensity 4 : 4 METs, Intensity 5 : 7 METs

In this study, 3 measurements of energy expenditure - total energy expenditure (kcal/kg/day), energy expenditure by moderate activity (kcal/kg/day), and energy expenditure by vigorous activity (kcal/kg/day) were used.

Exercise behavior

Three measurements regarding exercise behavior : frequency of exercise per week (times per week), stage of change for exercise behavior, and exercise self-efficacy, were assessed by a self-administered questionnaire.

The stage of change is the main concept of the transtheoretical model proposed by Prochaska and DiClemente[15][16]. It is the scale that estimates motivational readiness of behavior change and consists of 5 stages : Precontemplation (individuals who do not exercise and do not intend to start exercise in the next 6 months), Contemplation (individuals who do not exercise, but intend to start exercising in the next 6 months), Preparation (individuals who do some exercise but not regularly), Action (individuals who exercise regularly, but only began doing so within the last 6 months), and Maintenance (individuals who exercise regularly and have done so for longer than 6 months). Regular exercise was defined as exercising three times per week[24]. People are thought to progress through these stages, moving back and forth before attaining the goal of maintenance. Participants were classified into one of these five stages depending on answers to three questions regarding frequency of exercise, intention to start exercise within the next 6 months, and duration of continuing the current exercise habit.

Self-efficacy is originally a concept in social cognitive theory, proposed by Bandura[13]. It means the perception of one's ability to perform the behavior. The transtheoretical model adopted this concept as one of the predictors of the stage of change[15][16]. This scale is related to the stage of change, meaning that persons in a higher stage have higher self-efficacy[25][26]. In this study, self-efficacy was rated by one question that asked subjects to evaluate their perception of ability to perform exercise on a 11-point scale ranged from "not at all confident"=0% to "very confident"=100%[26][27].

Physical fitness

Physical fitness was estimated by grip strength (kg), sit-ups (times/30 sec.), jumping reaction time (msec.), vertical jump (cm), and sitting trunk flexion (cm). Grip strength, vertical jump, and sitting trunk flexion were tested twice in each subject and the better performances were recorded. Grip strength was expressed as the mean of the right and left hands. Sit-ups were counts of performance over 30 seconds. Jumping reaction time was the duration from the moment of the light signal until jumping, and this was tested 5 times. After maximum and minimum data were excluded, three performances were averaged. A few subjects were unable to perform the tests because of their orthopedic disorders. Therefore, the number of data that could be analyzed varied from 79 to 84 depending on the kind of tests.

Nutrition

As a parameter of nutrition, total energy intake (kcal/day) was calculated by a self-administered questionnaire including questions on frequency and amount of food intake[27].

2) Measurements of physique and blood lipids

Physique measurements included body weight (kg), body mass index (BMI) (kg/m^2), and percent body fat. Percent body fat was measured by the caliper method, and calculated using the Nagamine[29] and Brozek[30] equation. BMI was defined as weight in kilograms divided by the square of height in meters. Fasting blood samples were obtained and analyzed for total serum cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and triglyceride (TG). Samples were analyzed using enzymatic technique (TC, LDL-C, TG) and direct technique (HDL-C).

4. Intervention procedures

The intervention program was conducted at the Tokyo Metropolitan Health Promotion Center. After baseline assessment, results of tests were reported for each subject in both groups. General information including how to interpret the data and recommendation on physical activity was also offered for both groups in 30-minute group lectures. Recommended physical activity was to meet one of three criteria : 1) walking

more than 10,000 steps per day[31], 2) accumulation of 30 minutes or more moderate intensity physical activity more than 5 days a week[6], 3) three times or more exercise a week[24]. The point of recommendation was to increase energy expenditure by either lifestyle activity or structured exercise. In addition to the lecture, subjects in both groups received guidance in the use of facilities of the Tokyo Metropolitan Health Promotion Center, and they were allowed to use the center during the research period. The processes written above were common for both groups. For the control group, no more intervention was conducted

The intervention program for the intervention group aimed for long-term adherence to active lifestyle. The 8-week intensive program and the 6-month follow-up period were set. Eight weeks included eight sessions (one session a week), and each session consisted of one hour of group work and one hour of exercise practice. The program was based on a behavior change model called the "stage of change." The model postulate that the stage-specific intervention is useful. We engaged various behavioral management skills in the program depending on the stage of change shown in Table 1. These skills were originally derived from various theories and models of human behavior[32][33] such as the learning theory[12], the social cognitive theory[13] and the relapse prevention model[14]. For example, self-efficacy is originally the concept of the social cognitive theory and also a component of the transtheoretical model. Stimulus control and reinforcement management are skills derived from the learning theory. Practical educational procedures were prepared based on these skills. The procedures were combined depending on the stage of change (Table 1), and the subjects were trained to use these skills. In practice, the group work was conducted according to the schedule shown in Table 2. Although the concepts and methods of goal setting and self-monitoring were explained in the second week, subjects continued to practice these two skills every week during intensive intervention period. Goal setting was conducted in two forms, short-term (the goal of that week) and long-term (the goal of 8 weeks). Since almost all subjects (92.9%) were in Contemplation (71.4%) and Preparation stages (21.4%), we prepared only one program, a program for the Contemplation/Preparation stage. We included skills for the Contemplation stage and the Preparation stage early in the 8-week period, and skills for the Action stage and the Maintenance stage later in the 8-week period. Although the behavioral approaches were used mainly in group work, exercise practice also included the concepts of behavioral science. For example, we expected that the exercise practice would be a good chance to increase the self-efficacy through enactive attainments, vicarious experiences and verbal persuasions that are pointed out by Bandura as effective in raising self-efficacy[34].

During the 6-month follow-up period, newsletters were mailed to intervention group subjects every 2 months.

5. Data analysis

Analysis of variance with repeated measures was used to test the change of values of all measures, except stage of change, from baseline to 2 months and to 8 months. For the comparison between two groups, analysis of covariance was performed. Covariance factors were age and baseline data for the tests of physical activity energy expenditure, exercise behavior, physical fitness, nutrition, and physique. In the analysis of blood lipids, age, BMI, postmenopausal status and baseline data were adjusted as covariance factors. The χ^2 test was used to compare the distribution change in stage of change between the two groups. All statistical analyses were performed with the SPSS 11.0J for Windows, SPSS Inc., Chicago, USA. A p value of less than 0.05 was taken

Table 1 Combination of behavioral management skills depending on the stage of change for exercise behavior in the present program

Behavioral management strategies	The stage of change				
	Precontemplation	Contemplation	Preparation	Action	Maintenance
Knowledge of physical activity	◎	◎	○		
Sellf-monitoring	○	○	◎	◎	○
Goal setting		○	◎	◎	○
Self-efficacy	○	◎	◎	◎	○
Decisional balance	◎	◎	○		
Stimulus control		○	◎	◎	○
Reinforcement management		○	◎	◎	○
Social support		○	◎	◎	◎
Contracting		○	◎		
Positive self-talk			◎	◎	○
Relapse prevention				◎	◎

◎ : strongly recommended skills, ○ : recommended skills

Table 2 Behavioral management skills taught in group sessions

week 1	Knowledge of physical activity, Recommendation	Explanation of benefits and recommended amounts of physical activity to help participants to have realistic expectations.
week 2	Goal setting	To set concrete goals including the type, place, time and duraton of physical activity.
	Self-monitoring	To record one's own behavior. In the program, activity diary and accerelometer were delivered for self-monitoring.
	Contracting	To agree with the contract to maintain an active lifstyle to enhance commitment. Subjects signed the contract to formalize the agreement.
week 3	Decisional balance	To discuss benefits, costs and barriers of physical activities in order to overcome barriers and to support participants in setting goals with more benefits and with fewer costs.
week 4	Stimulus control	To increase environmental cues or stimuli to do physical activity such as wearing sports shoes in daily life, putting a written note on the wall, having a routine time and place for exercise, etc.
week 5	Social support	To seek support of family, friends and coworkers who understand the subject's effort, encourage participation in physical activity or do physical activity together.
week 6	Reinforcement management	To control reinforcers encouraging physical activity such as giving self-praise, recording the activity chart, setting favorite walking course, etc.
week 7	Positive self-talk	To train positive thinkings in difficult situations in order to maintain the active lifestyle.
	Relapse prevention	To identify high-risk situations for relapse and to prepare ways of coping with them
week 8	Summary	Summary of above skills

to indicate a statistically significant difference.

Results

1. Baseline characteristics and program adherence

In total, 84 subjects participated in all three assessments (follow-up rate: 97.7%). One subject in the intervention group declined to participate in the program due to a disease in the family. However, she did participate in all three assessments. Therefore, according to the intention-to-treat analysis principle, the data were analyzed as the data of the intervention group. Thus, data with regard to 84 women (43 subjects in the intervention group, 41 subjects in the control group) were analyzed.

Baseline characteristics of subjects are shown in Table 3. The mean (SD) age was 57.2 (5.4) years old, ranging from 47 to 68 years old. Almost all (90.5%) engaged in exercise less than once a week and were considered to be sedentary women. The mean (SD) BMI was 22.9 (2.8) kg/m^2. According to the guidelines for diagnosis and treatment of atherosclerotic diseases of the Japan Atherosclerosis Society[35], 50.0% of subjects had high LDL-C level ($\geqq$140 mg/dl), 2.4% had low HDL-C level ($<$40 mg/dl), and 17.9% had high triglyceride level ($\geqq$150 mg/dl). Most of the subjects had normal levels of blood glucose and blood pressure. In all outcome measures, no significant difference between groups was observed at baseline.

Table 3 Baseline characteristics of participants

Variables	n=84
Age, years old	57.2±5.4
Employment (full time worker) rate, %	47.6 (7.1)
Total energy expenditure, kcal/kg/day	39.8±2.7
Stage of change for exercise behavior[#], %	3.6 : 71.4 : 21.4 : 2.4 : 1.2
Frequency of exercise, times/week	0.29±0.91
Height, cm	154.1±5.2
Weight, kg	54.6±7.3
BMI, kg/m^2	22.9±2.8
Body fat, %	30.1±7.7
Total cholesterol, mg/dl	235.9±23.7
HDL-C, mg/dl	66.5±15.7
LDL-C, mg/dl	137.0±21.5
Triglyceride, mg/dl	106.5±59.9
Fasting plasma glucose, mg/dl	92.3±7.0
Systolic blood pressure, mmHg	114.2±14.5
Diastolic blood pressure, mmHg	74.1±8.4
Postmenopausal status, %	88.1

Values are mean±SD except sex, work status, stage of change, and postmenopausal status.
[#]: values indicates distribution of stage in form as Precontemplation : Contemplation : Preparation : Action : Maintenance.
BMI : body mass index,
HDL-C : High density lipoprotein cholesterol
LDL-C : Low density lipoprotein cholesterol

2. Effects on physical activity, exercise behavior, physical fitness, and nutrition

1) Results at 2 months

Table 4 shows mean changes in measures of physical activity, exercise behavior, physical fitness, and nutrition.

Fig. 2 also shows the changes in energy expenditure depending on the intensity of activity. The intervention group significantly increased their total energy expendi-

Table 4 Mean changes in measures of physical activity energy expenditure, exercise behavior, physical fitness, and nutrition

Variables		baseline	Change from baseline after 2 months	Comparison between groups (p value)	Change from baseline after 8 months	Comparison between groups (p value)
Energy expenditure, kcal/kg/day						
Total	Control	40.11±3.07	0.10±2.19	0.38	−1.05±2.43*	0.14
	Intervention	39.53±2.23	1.26±2.20**		0.30±1.95	
Moderate activity	Control	4.24±3.97	−0.81±2.97	.025	−1.58±3.27**	.003
	Intervention	3.19±2.84	0.92±2.71*		0.81±2.93	
Vigorous activity	Control	0.43±1.49	0.02±1.75	.277	−0.27±1.38	.146
	Intervention	0.30±1.02	0.55±2.25		0.03±1.00	
Exercise behavior						
Frequency of exercise, days/week	Control	0.46±1.25	0.57±1.30**	<.001	0.34±1.75	.025
	Intervention	0.13±0.29	1.74±1.39***		1.27±1.09***	
Stage of change for exercise behavior, %	Control	2.4 : 65.9 : 24.4 : 4.9 : 2.4 #	39.0 ##	<.001	34.1 ##	.009
	Intervention	4.7 : 76.7 : 18.6 : 0 : 0 #	81.4 ##		62.8 ##	
Exercise self-efficacy	Control	62.4±19.6	−1.7±22.2	.035	−6.1±20.6	.001
	Intervention	60.0±20.4	8.8±19.5**		8.8±18.8**	
Physical fitness						
Grip strength, kg	Control	23.4±3.9	0.9±2.0**	.459	0.3±2.2	.137
	Intervention	24.6±4.9	0.3±3.0		0.5±2.2	
Sit-ups, times/30 sec.	Control	8.1±4.9	0.0±2.1	.012	1.1±2.9*	.127
	Intervention	8.6±5.7	1.2±2.3**		2.0±3.2***	
Jumping reaction time, msec.	Control	399.7±59.8	15.3±48.6	.025	8.2±41.8	.432
	Intervention	398.2±48.6	−5.0±34.8		2.4±38.5	
Vertical jump, cm	Control	26.8±5.7	0.0±4.5	.039	−0.8±4.8	.190
	Intervention	28.9±5.7	0.5±3.4		−1.0±4.1	
Sitting trunk flexion, cm	Control	11.8±8.3	1.1±3.3*	.230	0.7±4.0	.012
	Intervention	13.8±5.7	1.5±2.4***		1.9±2.3***	
Nutrition						
Total energy intake, kcal/day	Control	1,549±279	−54±235	.541	−85±260*	.138
	Intervention	1,440±242	−20±241		−64±228	

All values without stage of change are expressed as mean±SD.
P values were calculated after adjustment for age and baseline value except Stage of change.
#: values indicate distribution of stage in form as Precontemplation : Contemplation : Preparation : Action : Maintenance.
##: Values indicate the proportion of subjects who improved their stage compared with baseline.
*: $p<0.05$, **: $p<0.01$, ***: $p<0.001$ for the comparison with the baseline

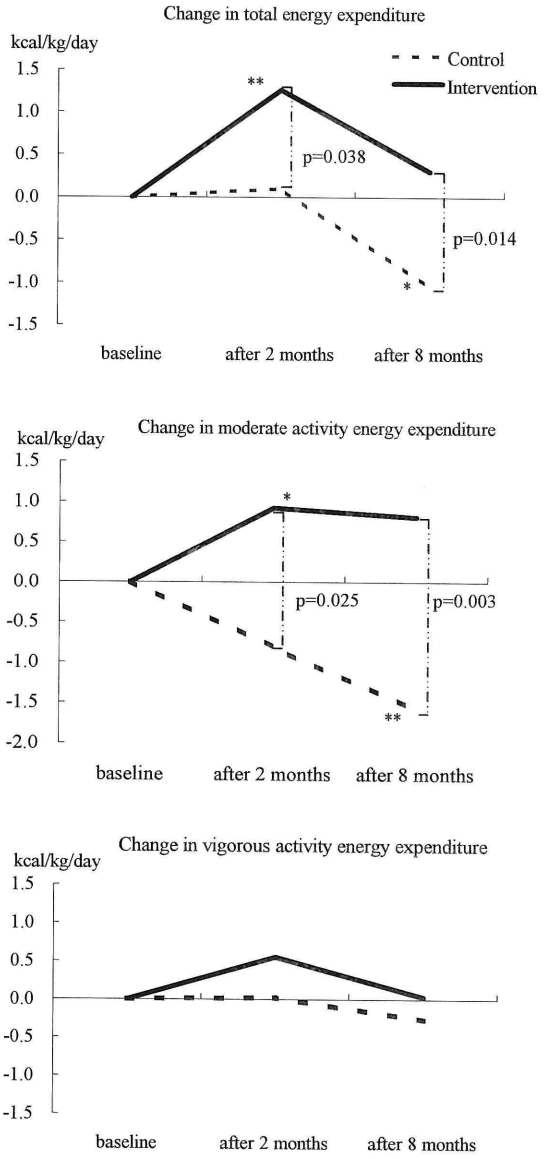

Fig. 2 Changes in energy expenditure depending on the intensity of activity
*: $p<0.05$, **: $p<0.01$ for the comparison with the baseline
p values indicate the results of comparison between groups

ture by 1.26 kcal/kg/day. The amount of increase was significantly larger than the control group ($p=0.038$). Analysis of the components of activity revealed that the intervention group significantly increased their energy expenditure only in moderate activity over time. Also, the amount of increase was significant larger in the intervention group compared with the control group ($p=0.025$). On the other hand, in vigorous activity, no significant difference was observed over time or between groups.

Significant improvements in frequency of exercise, stage of change for exercise behavior, and exercise self-efficacy were also observed in the intervention group at 2 months compared with baseline. Comparison of the changes in these measures between groups also showed significantly more improvement in the intervention group.

In physical fitness, grip strength and sitting trunk flexion in the control group, and sit-ups and sitting trunk flexion in the intervention group were significantly improved from baseline to 2 months. On comparison between the two groups, the intervention group significantly improved performance in sit-ups ($p=0.012$), jumping reaction time ($p=0.026$), and vertical jump ($p=0.039$). Total energy intake was unchanged in both groups.

2) Results at 8 months

Total energy expenditure and moderate activity energy expenditure were significantly decreased from baseline in the control group. In the intervention group, mean changes from baseline were 0.30 kcal/kg/day in total energy expenditure and 0.81 kcal/kg/day in moderate activity energy expenditure, but no significant difference was observed compared with baseline. The amounts of increase in total and moderate activity energy expenditure were significantly higher in the intervention group compared with the control group ($p=0.014$, and $p=0.003$, respectively). The differences in changes of energy expenditure between the two groups were +1.35 kcal/kg/day for total energy expenditure, and +2.39 kcal/kg/day for moderate activity energy expenditure. As observed at 2 months, vigorous activity energy expenditure was not significantly changed at 8 months.

Frequency of exercise, stage of change for exercise behavior, and exercise self-efficacy were improved by significantly large degrees in the intervention group compared with the control group at 8 months ($p=0.025$, $p=0.009$, and $p=0.001$, respectively).

In physical fitness, both groups improved their performance in sit-ups from baseline, but no significant difference between groups was observed. Sitting trunk flexion was significantly improved only in the intervention group. Significant difference between groups was also observed in the amount of improvement of sitting trunk flexion ($p=0.012$).

Total energy intake was significantly decreased in the control group, but there was no significant difference between groups.

3. Effects on physique and blood lipids

1) Results at 2 months

Table 5 shows the mean changes in measures of physique and lipid metabolism. The intervention group significantly decreased body weight and BMI from baseline to 2 months. Comparison between the two groups also showed significantly large decreases in body weight and BMI in the intervention group ($p=0.036$, $p=0.006$, respectively). In blood lipids, the interven-

Table 5 Mean changes in measures of physique and blood lipids

Variables		baseline	Change from baseline after 2 months	Comparison between groups (p value)	Change from baseline after 8 months	Comparison between groups (p value)
Physique						
Weight, kg	Control	54.9±7.7	−0.2±0.9	.036	−0.4±1.5	.184
	Intervention	54.4±6.9	−0.6±1.0***		−0.8±1.5**	
BMI, kg/m²	Control	23.1±3.0	−0.1±0.4	.006	−0.1±0.6	.124
	Intervention	22.8±2.6	−0.3±0.4***		−0.3±0.6**	
Body fat, %	Control	30.0±8.4	0.5±3.5	.056	−0.8±2.8	.002
	Intervention	30.2±7.1	−0.7±2.7		−2.5±3.0***	
Blood Lipids						
Total cholesterol, mg/dl	Control	234.4±27.6	−4.3±21.5	.207	−1.0±22.7	.877
	Intervention	237.3±19.6	−10.8±22.9		−1.7±25.5	
HDL-C, mg/dl	Control	68.7±15.0	−2.2±7.9	.432	−1.4±8.1	.934
	Intervention	64.5±16.2	−2.7±6.5**		−0.8±8.3	
LDL-C, mg/dl	Control	134.1±23.9	8.2±17.4**	.075	10.3±16.7***	.659
	Intervention	139.8±19.0	0.8±14.3		6.6±18.7*	
Triglyceride, mg/dl	Control	101.1±62.0	−8.0±39.3	.761	−13.4±47.9	.374
	Intervention	111.6±58.2	−8.0±63.9		−7.7±51.2	

All values are expressed as mean±SD.
P values were calculated after adjustment for age and baseline value in the enalysis of body weight, BMI, and body fat.
P values were calculated after adjustment for age, BMI, menopausal state and baseline value in the analysis of blood lipids.
* : $p<0.05$, ** : $p<0.01$, *** : $p<0.001$ for the comparison with the baseline

tion group showed a significantly decreased HDL-C level, and the control group showed a significantly increased LDL-C level. However, no significant group difference was seen in any blood lipids.

1) Results at 8 months

The intervention group significantly decreased body weight, BMI, and percent body fat at 8 months compared with baseline, while no significant decrease was observed in the control group. The change in body fat was significantly greater in the intervention group ($p=0.002$). The LDL-C levels in both groups significantly increased, but change values were not statistically significant between the two groups.

Discussion

The major finding of this study is that a developed program based on behavioral science significantly increased physical activity and improved some measures of physical fitness and body composition at 2 months compared with baseline. Furthermore, the effects of intervention were maintained after a 6-month follow-up period.

1. Effects on physical activity and physical fitness

Observed differences in change of total energy expenditure at 8 months between groups was +1.35 kcal/kg/day. By calculation with the assumptions of walking speed=70 m/min, 3 METs in intensity, width of a step=70 cm, and body weight=50 kg, +1.35 kcal/kg/day is parallel to an energy expenditure increase of 2,579 steps per day[23]. This effect is large enough to meet the target of Health Japan 21, an increase of 1,000 steps per day on average in the general population[31]. In this study we used 24-hour physical activity records to evaluate energy expenditure. In this method, all kinds of activities done by subjects were recorded and calculated. It is reported that the physical activity record method has fair to good validity in estimating energy expenditure[36)37]. In fact, a high correlation between total energy expenditure as estimated by 24-hour physical activity record used in this study and as measured by accelerometer ($r=0.68$) supports the validity of physical activity assessment in this study (data not shown).

Although a significant difference was observed in mean change of total energy expenditures between the two groups, the values in both groups were decreased by approximately 1 kcal/kg/day at 8 months compared with 2 months. The reasons for this may include seasonal change of physical activity, decrease of motivation in both groups, etc. Seasonal variation may play an especially important role for this result. Matthews et al. reported that women increased their activity level by 1 METs-hours/day (1.05 kcal/kg/day) during summer in comparison with winter[38]. Supposed that there was a comparable seasonal effect on physical activity in this study, the decrease of energy expenditure from 2 months (July) to 8 months (December) is understandable.

Regarding the intensity of activity, only moderate activity was increased by intervention. No significant change was observed in vigorous activity. In this study, the recommendation of physical activity for both groups emphasized the increase of energy expenditure without reference to intensity. Also, it is likely that moderate activity is more acceptable, easier to start, and easier to maintain for these subjects.

In three measures related to exercise behavior, the intervention group also improved behavioral parameters such as stage of change and self-efficacy in significantly large degrees compared with the control group over 8 months. The parallel increase of self-efficacy with the improvement of stage of change and with the increase in energy expenditure is consistent with the result of past studies[39]. Since self-efficacy is reported to be a strong predictor of behavior change in many studies, the improvement of this scale suggests the maintenance of active lifestyles among the intervention group.

2. Effects on physique and blood lipids

The effects of intervention were also observed in body weight, BMI, and percent body fat, although weight reduction was not the main focus in this program. As such, goal setting and self-monitoring were implemented mostly on physical activity and behavioral skills. These differences in the physique are mainly due to the increase of physical activity, as there was no significant group difference observed in total energy intake. It is thought that the improvement of body composition was due to the sequence of sustained physical activity.

In analysis of blood lipids, there was no significant group difference in change values. Regarding LDL-C, subjects of this study had slightly increased levels of LDL-C, and 50% of them had high levels of LDL-C defined as 140 mg/dl or more at baseline. The result was the same as if the analysis was limited to 42 women with elevated levels of LDL-C. However, this is not surprising, as these results are consistent with past studies. Stefanick reviewed five randomized trials on lipoprotein effects of aerobic exercise in individuals with mean BMI less than 25 kg/m^2 [40]. According to this review, only one of five trials that showed an improvement in LDL-C or TC with exercise involved an additional dietary component. In our study, mean BMI of subjects, 22.9 kg/m^2 was far less than 25 kg/m^2.

3. Limitations of this study and future direction

There are some limitations to this study. First, the limited variety of subjects; all subjects were middle-aged and senior women in a community setting. While 47.7% of subjects had jobs, only 7.1% were full-time workers. For different age groups and sex, there may be different types of barriers to increasing physical

activity, for example barriers such as lack of time due to work or childcare. The acceptability of the program may also be different depending on sex and age. Further studies are needed to examine the effects of the program in other settings and populations. Secondly, subjects in this study were volunteers who had relatively high levels of motivation of behavior change. Distribution of stage of change indicates that 71.4% of subjects had the intention to start exercise at baseline, and that 21.4% were doing some exercise even though the amount was not enough to obtain health benefits. The effects of the program on subjects in the Contemplation and the Preparation stages were the main observations in this study. Further studies are needed for people who have lower levels of motivation and for people in the Precontemplation, Action and Maintenance stages. However, even for people in the Contemplation stage and in the Preparation stage, it is not easy to adopt and maintain the active lifestyle, and practitioners most frequently have the opportunity to educate people in these two stages. Thus the result of this study is quite useful in health education practices. The third limitation is that the effects of elements of the program, i.e. the behavioral group work and the exercise practice, could not be differentiated from each other due to the study design. It may be pointed out that the effects of the program may be mainly due to the exercise practices themselves or due to the frequent contacts with educators (8 times in 8 weeks) even though the behavioral elements was emphasized in this program. What can be concluded from this study design is that the present program was more effective than the treatment for the control group in which subjects received explanations of the results of medical checks and were offered chances to use the exercise facility. According to past studies, however, intervention methods like health risk appraisal, exercise prescription or supervised exercise practice by itself demonstrated small effects to change behavior, while the behavior modification approaches showed large effects[20)21)]. It is likely that behavioral approaches played an important role in promoting physical activity in this program. In the future, studies that differentiate effects of each element in the program are expected to improve the intervention method.

In spite of these limitations, the results of this study suggested the potential of behavioral science in physical activity education. It is worthwhile in the public health context that the program was based on a theoretical framework, since a theoretical framework can guide the application of the program in many other kinds of health promotion practices such as the development of educational materials, the training of health professionals, and the development of modified programs in various settings.

Conclusion

The physical activity program using behavioral approaches effectively increased physical activity, and improved exercise behavior, physical fitness, and body composition over 8 months including a 2-month intensive intervention period and a 6-month follow-up period.

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References

1) Paffenbarger RS, Hyde RT, Wing AL, Hsieh CC : Physical activity, all-cause mortality, and longevity of college alumni. N Engl J Med **314** : 605-613, 1986
2) Kannel WB, Sorlie P : Some health benefits of physical activity : the Framingham study. Arch Intern Med **139** : 857-861, 1979
3) Helmrich SP, Ragland DR, Leung RW, Paffenbarger RS : Physical activity and reduced occurrence of non-insulin-dependent diabetes mellitus. N Engl J Med **325** : 147-152, 1991
4) Leel-M : Physical activity, fitness, and cancer. Physical activity, fitness, and health : international proceedings and consensus statement. (Eds) Bouchard C, Shephard RJ, Stephens T, Human Kinetics, Champaign, IL, 814-831, 1994
5) Buchner DM, Beresford SA, Larson EB, LaCroix AZ, Wargner EH : Effects of physical activity on health status in older adults : Intervention studies, Annu Rev Publ Health **13** : 469-488, 1992
6) Pate RR, Pratt M, Blair SN, Haskell WL, Macera CA, Bouchard C, Buchner D, Ettinger W, Heath GW, King AC, Kriska A, Leon AS, Marcus BH, Morris J, Paffenbarger RS, Patrick K, Pollock ML, Rippe JM, Sallis J, Wilmore JH : Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. JAMA **273** : 402-407, 1995
7) Fletcher GF, Balady G, Blair SN, Blumenthal J, Caspersen C, Chaitman B, Epstein S, Froelicher ESS, Froelicher VF, Pina IL, Pollock ML : Statement on exercise : benefits and recommendation for physical activity program for all Americans-A statement for health professionals by the committee on exercise and cardiac rehabilitation of the council on clinical cardiology, American heart association. Circulation **94** : 857-862, 1996
8) Goldstein LB, Adams R, Becker K, Furberg CD, Gorelick PB, Hademenos G, Hill M, Howard G, Howard VJ, Jacobs B, Levine SR, Mosca L, Sacco RL, Sherman DG, Wolf PA, del Zoppo GJ : Pri-

mary prevention of ischemic stroke-A statement for healthcare professionals from the stroke council of the America Heart Association, Circulation **103**: 163-182, 2001
9) US Department of Heath and Human Services: Patterns and Trends of physical activity. Physical activity and health : A report of the Surgeon General. US Dept of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Diseases Prevention and Health Promotion, Atlanta, GA, 173-207, 1996
10) Pratt M. : Benefits of lifestyle activity vs structured exercise. JAMA **281**: 375-376, 1999
11) The Ministry of Health and Welfare, Health Service Bureau, Community Health, Health Promotion and Nutrition Division, Office for Life-style Related Diseases Control : The 1999 National Nutritional Survey in Japan. Daiichi Publishing Co. Ltd., Tokyo, 2001
12) Skinner BF : Science and human behavior. Macmillan, New York, 1953
13) Bandura A : Social foundations of thought and action : a social-cognitive theory. Prentice-Hall, Englewood Cliffs, NJ, 1986
14) Marlatt GA, Gordon JR : Relapse prevention : maintenance strategies in the treatment of addictive behaviors. Guilford Press, New York, 1985
15) Prochaska JO, DiClemente CC : Transtheoretical therapy : toward a more integrative model of change. Psychotherapy : theory, research, and practice **20**: 161-173, 1982
16) Inoue S, Shimomitsu T : The behavioral approach to promote physical activity-application of the transtheoretical model-. Nippon Rinsho **58** Suppl : 538-544, 2000
17) Wakui S, Shimomitsu T, Odagiri Y, Inoue S, Takamiya T, Ohya Y : Relation of the stages of change for exercise behaviors, self-efficacy, decisional-balance, and diet-related psychobehavioral factors in young Japanese women. J sports med phys fitness **42**: 224-232, 2002
18) Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HW, Blair SN : Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness-A randomized trial. JAMA **281**: 327-334, 1999
19) Calfas KJ, Long BJ, Sallis JF, Wooten WJ, Pratt M, Patrick K : A controlled trial of physician counseling to promote the adoption of physical activity. Preventive medicine **25**: 225-233, 1996
20) Sallis JF, Owen N : Physical activity interventions with individuals. Physical Activity & Behavioral Medicine, Sage Publications, Inc., Thousand Oaks, 135-152, 1999
21) Dishman, RK, Buckworth J : Increasing physical activity : a quantitative synthesis. Med Sci Sports Exrc **28**: 706-719, 1996
22) Ainsworth BE, Haskell WL, Leon AS, Jacobs DR Jr, Montoye HJ, Sallis JF, Paffenbarger RS Jr : Compendium of physical activities : classification of energy costs of human physical activities. Med Sci Sports Exrc **25**: 71-80, 1993
23) American College of Sports Medicine : General principles of exercise prescription. In. ACSM's guidelines for exercise testing and prescription, sixth edition, Lippincott Williams & Wilkins, Philadelphia, PA, 137-164, 2000
24) American College of Sports Medicine Position Stand : The recommended quantity and quality of exercise for developing and maintaining cardiorespiratory and muscular fitness in healthy adults. Med Sci Sports Exerc **22**: 265-274, 1990
25) Sallis JF, Owen N : Determinants of physical activity. Physical Activity & Behavioral Medicine, Sage Publications, Inc., Thousand Oaks, 110-134, 1999
26) Shimomitsu T, Odagiri Y, Wakui S, Inoue S, Takamiya T : Exercise behavior and psychobehavioral factors : cross-sectional study of stage of change for exercise behavior, Descente sports science **20**: 3-19, 1999
27) Inoue S, Shimomitsu T, Ohya Y, Odagiri Y, Takamiya T, Wakui S, Katsumura T : Reliability and validity of exercise self-efficacy scales for Japanese adults. International Journal of Behavioral Medicine 7 Suppl : 142, 2000
28) Morimoto A, Takase S, Hata K, Hosoya N : Evaluation of a "Convenient Method" for the estimation of dietary food consumption. Jap J Nutr **35**: 235-245, 1977
29) Nagamine S : Assessment of obesity from skinfold thickness. Nihon-ishikai-zassi **68**: 919-924, 1972
30) Brozek J : Densitometric analysis of body composition. Revision of some quantitative assumptions. Ann NY Acad Sci **110**: 113-40, 1963
31) Ministry of Health, Labour and Welfare of Japan: Report on "Health Japan 21". Plan Study Committee and "Health Japan 21" Plan Development Committee, 2000
32) American College of Sports Medicine : Methods for changing exercise behaviors. In. ACSM's guidelines for exercise testing and prescription, sixth edition, Lippincott Williams & Wilkins, Philadelphia, PA, 237-257, 2000
33) US Department of Heath and Human Services: Understanding and promoting physical activity. Physical activity and health : A report of the Surgeon General. US Dept of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Diseases Prevention and Health Promotion, Atlanta, GA, 209-259, 1996
34) Bandura A : Self-efficacy : toward a unifying theory of behavioral change. Psychological Review **84**: 191-215, 1977
35) Japan Atherosclerosis Society : Japan Atherosclerosis Society (JAS) guidelines for diagnosis and treatment of atherosclerotic cardiovascular diseases, 2002
36) Montoye HJ, Kemper HCG, Saris WHM, Washburn RA : The diary method. In. Measuring physical

activity and energy expenditure, Human Kinetics, Champaign, IL, 42-71, 1996
37) Naito, Y. : Assessment of physical activity in a large scale cohort study. Research in Exercise Epidemiology **4** : 26-27, 2002
38) Matthews CE, Freedson PS, Hebert JR, Stanek EJ, Merriam PA, Rosal MC, Ebbeling CB, Ockene IS : Seasonal variation in household, occupational, and leisure time physical activity : longitudinal analyses from the seasonal variation of blood cholesterol study. Am J Epidemiol **153** : 172-83, 2001
39) Sallis JF, Hovell MF, Hofstetter CR, Barrington E : Explanation of vigorous physical activity during two years using social learning variables. Social science and medicine **34** : 25-32, 1992
40) Stafanick, ML : Physical activity for preventing and treating obesity-related dyslipoproteinemias. Med Sci Sports Exrc **33** : 609-618, 1999

行動医学を応用した身体活動推進プログラムの効果に関する無作為割付対照試験

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【要旨】 身体活動の健康に対する効果はすでに多くの研究により知られているが、身体活動量を増加させ長期間維持させるような効果的なプログラムは確立されておらず、生活習慣病対策の上で重要な課題となっている。そこで、行動医学を応用した身体活動推進プログラムを開発しその効果を検討することを本研究の目的とした。対象は運動習慣のない中高年女性86名とし、8ヶ月間 (2ヶ月間の集中介入＋6ヶ月間の経過観察) の無作為割付対照試験を実施した。評価指標は24時間活動記録法に基づいた身体活動によるエネルギー消費量、運動に関する行動科学指標、体力、体格・体構成、血中脂質とした。エネルギー消費量は、総エネルギー消費量 (総消費量) に加え、活動強度別に中等度の活動による消費量 (中等度消費量)、高強度の活動による消費量に分けて検討した。評価は介入前、2ヵ月後 (集中介入直後)、8ヶ月後 (経過観察終了後) の3回実施し、その全てに参加した84名 (47～68歳、平均年齢57.2歳) (経過観察率97.7%) を解析の対象とした。その結果、総消費量、中等度消費量の2ヵ月後および8ヵ月後の変化量は対照群と比較して介入群において有意に大きかった。また、運動頻度、運動習慣のステージ、運動習慣の自己効力、一部の体力指標、体脂肪率において介入の効果が認められた。以上より、新たに作成した行動医学的手法を用いた身体活動推進プログラムは、8ヶ月間に渡り身体活動量を増加させ、体力、体脂肪率を改善することに有効であることが明らかとなった。

〈**Key words**〉身体活動、介入、無作為割付対照試験、行動医学