Fifteen-Month Lifestyle Intervention Program to Improve Cardiovascular Risk Factors in a Community Population in Japan

YASUO HARUYAMA,¹ TAKASHI MUTO,¹ MAKIKO NAKADE,² EMIKO KOBAYASHI,³ KAORI ISHISAKI³ and AKIKO YAMASAKI³

¹Department of Public Health, Dokkyo Medical University School of Medicine, Tochigi, Japan

²Graduate School of Medicine, the University of Tokyo, Tokyo, Japan

³Soka City Health Center, Saitama, Japan

Morbidity and mortality associated with cardiovascular disease remain primary public health problems in Japan. We developed a large-scale community-based 15-month intervention program, and evaluated its long-term effects on improving lifestyle and cardiovascular risk. Of 549 participants, 436 (46 males and 186 females in intervention group and 72 males and 132 females in control group) completed the study. The intervention program consisted of a 6-month program including 15 sessions, with one lecture and individual counseling, two workshops and nutrition educations, and nine exercises (total 29 hours) and a 9-month maintenance program including 4 sessions of individual counseling, workshop, nutrition, and exercise (total 7 hours). Changes from the baseline to 15 months were significantly different between intervention and control groups by gender: the proportion of subjects who walked more than 6,000 steps/day (+39% vs. +2% for males; +17% vs. +1% for females), exercised more than 20 min/day and 3 times/week (+22% vs. +1% for males; +22% vs. +8% for females), ate vegetables at every meal (+18% vs. +4% for females), and consumed less salt (+9% vs. +3% for females); and the changes in body weight (−1.0 vs. −0.1 kg for males; −1.8 vs. −0.6 kg for females). Other changes detected only in females were body mass index (−0.8 vs. −0.3 kg/m²), systolic blood pressure (−6.6 vs. −2.4 mmHg), total cholesterol (−2.2 vs. +1.5 mg/dl), and the total risk scores (−0.5 vs. −0.1 points). The 15-month intervention program effectively improves and maintains lifestyle and cardiovascular risk, with greater effects of the long-term intervention in females. ——— Lifestyle; Cardiovascular risk; Intervention; Community; Exercise.

Tohoku J. Exp. Med., 2009, **217** (4), 259-269. © 2009 Tohoku University Medical Press

Morbidity and mortality due to cardiovascular disease are now the leading public health problems in industrialized countries, including Japan (World Health Organization 2008; Health and Welfare Statistics Association 2006). In Japan, mortality from cardiovascular disease accounts for approximately 15% of all deaths, being the second highest after malignant tumors (Health and Welfare Statistics Association 2006). It is well-known that cardiovascular diseases develop from common and important risk factors such as being overweight, high blood pressure, and high serum levels of lipoprotein cholesterol and glucose (Castelli et al. 1986; Pechere-Bertschi et al. 2005; Daousi et al. 2006; Ridderstrale et al. 2006; Wang et al. 2006). These risk factors are associated with various lifestyle-related parameters, including physical activity levels, dietary habits, and smoking; therefore, lifestyle improvement is considered to be important to prevent these diseases (Bautista-Castano et al. 2004; Hu et al. 2005; Arai et al. 2006; Pitsavos et al. 2007).

In the United States and Europe, many community-based intervention studies, which focused on lifestyle changes and were mainly conducted for three to six months,

demonstrated an effect on reducing blood pressure, body weight, blood lipid, and blood glucose levels (Winkleby et al. 1996; Appel et al. 1997, 2003; Diehl 1998; Lindstrom et al. 2003; Aldana et al. 2006; Burke et al. 2008). Some of these studies followed the participants after intervention, and reported that the intervention effect was sustained during the follow-up period, but also reported that a part of the benefits regarding improved cardiovascular risk factors or lifestyle was gradually lost over time (Winkleby et al. 1996; Lindstrom et al. 2003; Cappuccio et al. 2006). These results suggest the necessity for continuous intervention after the main intervention to sustain the intervention effects. Wister et al. (2007) conducted a maintenance intervention aimed at reducing the risk of cardiovascular disease, and showed the successful maintenance of a reduced cardiovascular disease risk even by a low-intensity maintenance intervention program.

In Japan, there have been some community-based three- or six-month intervention studies focusing on lifestyle modification (Miura et al. 2006; Noda et al. 2006; Egawa et al. 2007; Kai et al. 2007). However, few studies

Received October 29, 2008; revision accepted for publication February 20, 2009.

Correspondence: Yasuo Haruyama, 880 Kitakobayashi, Mibu-City, Tochigi 321-0293, Japan.

e-mail: yasuo-h@dokkyomed.ac.jp

implemented a maintenance intervention after that. Considering that the intervention effect is gradually lost after short-term intervention, long-term interventions which combine main and maintenance phases are needed for effective lifestyle modification.

The Ministry of Health, Labour and Welfare (MHLW) in Japan started the "Health-Up Model Project" in 2002. In this project, specified municipalities are encouraged to develop their own health-promotion programs, and programs showing long-term effectiveness will become models of evidence-based, standardized, health-promotion programs in the community. Soka City in Saitama Prefecture of Japan, with a population of about 233,000, was selected as a Health-Up Model Project Site in 2004, and an original 15-month lifestyle intervention program consisting of a 6-month main program and 9-month maintenance program was developed.

The purpose of this study was to evaluate the effect of this long-term lifestyle intervention program on lifestyles and cardiovascular risk factors.

METHODS

Organization, study design, and subjects

Under the instructions of Soka City Government, a board and working team were organized in 2003. The board managed and supervised the project and devised a strategy for the protection of personal information and ethics. The working team consisted of doctors in a local hospital, public health nurses and registered dietitians of a health center in Soka City, instructors of a sports association in the city, and experts in public health. The study protocol was approved by the Soka City Board and the Ministry of Health, Labour and Welfare in Japan. Written informed consent to participate in this study was obtained from all subjects. The identities of subjects remained anonymous, in compliance with the Ethical Guidelines for Epidemiological Research (Ministry of Education, Culture, Sports, Science and Technology, and Ministry of Health, Labour and Welfare, Japan, 2002).

The present study employed a non-randomized controlled trial design. The program was provided from July 2004 to September 2005. As shown in Figure 1, 7,875 inhabitants aged 39-71 years old (yr) who underwent health checkups in 2003 were informed of the study by direct mail. Of the recruited 636 subjects, 87 were excluded from the study because they did not satisfy the following two protocol criteria: (1) At least one of the following was detected: systolic blood pressure (SBP) ≥ 130 mmHg, diastolic blood pressure (DBP) ≥ 85 mmHg, body mass index (BMI) ≥ 25 kg/m², total cholesterol (TC) ≥ 200 mg/dl (females and subjects aged 50 yr and over: ≥ 220 mg/dl), high-density lipoprotein cholesterol (HDL-C) <40 mg/dl, low-density lipoprotein cholesterol (LDL-C) ≥ 120 mg/dl, triglycerides (TG) ≥ 150 mg/dl, fasting blood glucose (FBG) ≥ 110 mg/dl, or HbA_{1c} $\geq 5.6\%$, according to the Guideline of Diabetes and Cardiovascular Diseases in Health Care of Aged (Japan Public Health Association, 2002), Adult Treatment Panel III criteria, and the National Cholesterol Education Program (NCEP-ATP III, 2002). (2) No self-reported medication prescribed for an abnormality, with verification by local physicians. The remaining 549 subjects were allocated into either the intervention or control group at the participants' requests. The number of subjects in intervention and control groups was 305 (74 males and

231 females) and 244 (86 males and 158 females), respectively.

Intervention

As shown in Fig. 1, all subjects in the intervention and control groups were given 3 health checkups and 3 underwent lifestyle surveys at the baseline, 6 months, and 15 months. The common program consisted of a lecture regarding the purpose of health promotion (2 hours, one time) at the baseline, and newsletters about general health information (5 times by direct mail) provided by local community health workers during the 15-month period.

For the intervention group, a comprehensive program, consisting of a 6-month main program and 9-month maintenance program, was provided. The 6-month main program included individual counseling and a group session in addition to the common program. As shown in Fig. 1, individual counseling was conducted based on the results of health checkups and health assessment charts on physical activity, nutrient intake, and lifestyle at the baseline (60 minutes per person). The group session consisted of 2 sessions for the workshop about goal-setting for the modification of lifestyle; 2 sessions for the provision of nutrition education and cooking classes by registered dietitians, encouraging the subjects to eat more vegetables and less animal fat and salt; 9 sessions for exercise such as aerobic exercises, stretching, walking, and water-based exercise in a sports gym, as well as local health and community centers. Every session was conducted for 2 hours. Subjects in the intervention group were divided into 9 small groups (30 to 35 people in each group) who participated in the program. The same program was provided during the daytime and at night, and subjects were allowed to participate in any group they wished.

In the 9-month maintenance period, there was one individual counseling session and one session each for the workshop, nutrition education, and exercise.

Measurements

Fasting blood samples from all subjects were obtained at the baseline, and after 6 and 15 months. TC, TG, HDL-C, LDL-C, FBG, and HbA_{1c} were measured at a laboratory (Saitama, Japan). The height was measured using the scale VL65 (Yagami INC., Nagoya, Japan) without shoes. The percentage body fat and body weight were measured while subjects were lightly clothed and without shoes using the scale TBF110 (Tanita INC., Tokyo, Japan). The BMI was calculated as the body weight (kg) divided by the square of the height (m²). SBP and DBP were measured using an auto-manometer (Omron Co., Tokyo, Japan) after the subjects had been seated for 3-5 minutes. If the first measurement value was high, it was taken again after the subjects had remained still for 3 minutes, and the lower value was recorded. The total risk score was calculated by adding the number of abnormalities in the BMI, SBP/DBP, TC, HDL-C, LDL-C, FBG, and HbA_{1c}.

Information on lifestyles such as smoking, drinking alcohol, physical activity, eating behaviors, medical history, and the current use of medication was obtained by a self-administered questionnaire at the baseline, 6, and 15 months. The number of walking steps was self-reported using a pedometer. In this study, desirable lifestyle-related behaviors were defined as follows: the number of walking steps is more than 6,000 or 10,000 steps/day, the frequency of physical activity is more than 3 times/week, eating vegetables at every meal, eating less salt and animal fat, drinking alcohol at a rate of less than 20 g/day and 6 day/week, and not smoking.

Statistical analysis

Anthropometrical and biological data were compared using Student's *t*-test. Comparisons of lifestyle variables between the intervention and control groups at the baseline, 6 months, and 15 months, and between subjects who did and did not drop out were conducted by the chi-square test. Forty-four subjects were identified as taking medicine during the intervention period: 21 subjects used anti-hypertensive, 5 subjects used anti-hyperglycemic, and 26 subjects used anti-hyperlipidemic drugs. Thus, the mean differences in changes in anthropometrical and biological data and the risk factor scores at 6 and 15 months between the intervention and control groups were assessed after excluding those taking drugs by ANCOVA adjusting for baseline values and age. Statistical significance was considered at $p < 0.05$. All statistical analyses were conducted using the statistical software package SPSS 15.0 for Windows (SPSS Japan Inc., Tokyo, Japan).

RESULTS

Of the 549 subjects, 20.6% ($n = 113$; 73 in the intervention group and 40 in the control group) dropped out during the 15-month intervention period (Fig. 1). The main reason for dropping out was a loss of interest in the program according to a telephone interview after the intervention. No relocation or death occurred during the program. The remaining 436 participants who completed the program were 62.7 (SD7.0) yr, ranging from 40 to 72 yr, and 49.3% were over 65 yr. The intervention and control groups consisted of 46 males (over 65 yr: 58.7%) and 186 females (over 65 yr: 43.9%), and 72 males (over 65 yr: 58.3%) and 132 females (over 65 yr: 47.3%), respectively.

Fig. 1. Flow chart of the study protocol.

TABLE 1. Comparison of the baseline health checkup results between intervention and control groups.

	Intervention	Control	<i>p</i> -value ^a
	Mean $\pm$ S.D.	Mean $\pm$ S.D.	
Males, <i>n</i>	74	86	
Age, yr	60.5 $\pm$ 9.3	61.1 $\pm$ 8.6	NS
Height, cm	166.3 $\pm$ 6.2	165.3 $\pm$ 6.0	NS
Weight, kg	68.5 $\pm$ 8.8	65.1 $\pm$ 10.0	0.026
Body mass index, kg/m ²	24.7 $\pm$ 2.5	23.8 $\pm$ 2.9	0.028
Body fat, %	23.3 $\pm$ 4.6	21.4 $\pm$ 4.7	0.010
Systolic blood pressure, mmHg	138.5 $\pm$ 12.9	138.4 $\pm$ 14.1	NS
Diastolic blood pressure, mmHg	82.4 $\pm$ 9.2	82.6 $\pm$ 10.5	NS
Total cholesterol, mg/dl	214.5 $\pm$ 31.8	208.5 $\pm$ 29.4	NS
HDL cholesterol, mg/dl	54.0 $\pm$ 13.0	55.3 $\pm$ 14.9	NS
LDL cholesterol, mg/dl	138.8 $\pm$ 29.8	129.7 $\pm$ 28.2	0.049
Triglycerides, mg/dl	129.2 $\pm$ 69.8	126.5 $\pm$ 70.7	NS
Fasting blood glucose, mg/dl	103.9 $\pm$ 21.0	102.4 $\pm$ 16.5	NS
HbA _{1c} , %	5.34 $\pm$ 0.72	5.30 $\pm$ 0.77	NS
Total risk score ^b	3.8 $\pm$ 1.4	3.6 $\pm$ 1.6	NS
Females, <i>n</i>	231	158	
Age, yr	61.5 $\pm$ 6.2	60.9 $\pm$ 6.8	NS
Height, cm	152.1 $\pm$ 5.1	152.6 $\pm$ 5.5	NS
Weight, kg	54.8 $\pm$ 8.7	54.0 $\pm$ 8.6	NS
Body mass index, kg/m ²	23.7 $\pm$ 3.6	23.2 $\pm$ 3.4	NS
Body fat, %	29.5 $\pm$ 6.3	28.8 $\pm$ 7.0	NS
Systolic blood pressure, mmHg	135.0 $\pm$ 16.5	135.1 $\pm$ 17.1	NS
Diastolic blood pressure, mmHg	79.2 $\pm$ 10.3	79.2 $\pm$ 10.4	NS
Total cholesterol, mg/dl	230.8 $\pm$ 34.0	236.0 $\pm$ 30.9	NS
HDL cholesterol, mg/dl	65.9 $\pm$ 15.1	67.5 $\pm$ 15.4	NS
LDL cholesterol, mg/dl	148.1 $\pm$ 33.6	151.7 $\pm$ 30.7	NS
Triglycerides, mg/dl	98.6 $\pm$ 49.3	98.7 $\pm$ 47.8	NS
Fasting blood glucose, mg/dl	98.8 $\pm$ 19.2	97.3 $\pm$ 13.6	NS
HbA _{1c} , %	5.26 $\pm$ 0.65	5.24 $\pm$ 0.49	NS
Total risk score ^b	3.3 $\pm$ 1.4	3.2 $\pm$ 1.4	NS

^a Using Student's *t*-test^b Total risk score includes BMI $\geq$ 25 kg/m², SBP/DBP $\geq$ 130/85 mmHg, HDL-C < 40 mg/dl, LDL-C $\geq$ 120 mg/dl, TG $\geq$ 150 mg/dl, FBG $\geq$ 110 mg/dl, and HbA_{1c} $\geq$ 5.6%

NS, not significant

Baseline characteristics of subjects in intervention and control groups

A comparison of health checkup data at the baseline between the intervention and control groups is shown in Table 1. In males, the means of weight, BMI, body fat, and LDL-C in the intervention group were significantly higher than those in the control group, although significant differences were not seen in anthropometrical and biological data in females. There was no significant difference in lifestyle parameters between the two groups in both males and females (Table 2).

Comparison between the subjects who dropped out and those who completed the program

Baseline health checkup data in those who dropped out

or completed the program are shown in Table 3. Compared with the subjects who finished the program, subjects who dropped out showed significantly higher values for height and TC in males. There were no significant differences in health checkup data in females between the subjects who dropped out and those who did not. Regarding lifestyles, there were no significant differences between the two groups in both males and females, except for drinking alcohol (< 20 g/day and 6 days/week) in females (Table 4).

Change in lifestyle after 6 and 15 months

As shown in Table 5, the proportion of subjects who walked more than 6,000 steps per day and exercised for over 20 minutes per day and more than 3 times/week in the intervention group increased by +15.3% and +17.0% for

TABLE 2. Comparison of the baseline lifestyle characteristics between intervention and control groups.

	Intervention		Control		<i>p</i> -value ^a
	<i>n</i>	%	<i>n</i>	%	
Males, <i>n</i>	74		86		
Walking steps per day					
< 6,000 steps/day	56	75.7	61	70.9	
6,000 to 9,999 steps/day	12	16.2	20	23.3	NS
≥ 10,000 steps/day	6	8.1	5	5.8	
Physical activity over 20 min, ≥ 3 times /week	35	47.3	39	45.3	NS
Eating vegetables at every meal, yes	39	52.7	54	62.8	NS
Eating less salt, yes	39	52.7	56	65.1	NS
Eating less animal fat, yes	41	55.4	51	59.3	NS
Drinking alcohol (< 20 g/day, < 6 days/week), yes	59	79.7	66	76.7	NS
Current smoker, yes	28	37.8	24	27.9	NS
Females, <i>n</i>	230 ^b		158		
Walking steps per day					
< 6,000 steps/day	176	76.5	111	70.3	
6,000 to 9,999 steps/day	46	20.0	38	24.1	NS
≥ 10,000 steps/day	8	3.5	9	5.7	
Physical activity over 20 min, ≥ 3 times /week	105	45.7	66	41.8	NS
Eating vegetables at every meal, yes	150	65.2	103	65.2	NS
Eating less salt, yes	189	82.2	130	82.3	NS
Eating less animal fat, yes	170	73.9	120	75.9	NS
Drinking alcohol (< 20 g/day, < 6 days/week), yes	226	98.3	155	98.1	NS
Current smoker, yes	15	6.5	9	5.7	NS

^a *p*-value is calculated using Chi-square test^b One subject did not answer the questionnaire

NS, not significant

males, and +11.4% and +14.9% for females, respectively, at 6 months. At 15 months, the intervention group, compared with the control group, showed a significant improvement in the proportion of subjects who walked more than 6,000 steps per day (males: +39.1% vs. +1.5%, females: +17.2% vs. +0.7%, respectively) and exercised for over 20 minutes per day and more than 3 times/week (males: +21.7% vs. +1.4%, females: +22.1% vs. +7.6%, respectively). However, the proportion of subjects who walked more than 10,000 steps per day in the intervention group did not change after 6 or 15 months in both gender groups.

Regarding eating behavior in the intervention group, there were no significant differences in males and females compared with the control group. At 15 months, the intervention group, compared with the control group, showed a significant improvement in the proportion of females subjects who stated that they ate vegetables at every meal and less salt: +18.3% vs. +3.8%, and +8.6% vs. +3.0%, respectively.

There were no significant changes in drinking and smoking habits in both males and females at 6 and 15 months.

Change in cardiovascular risk factors during the program

The changes in cardiovascular risk factors in subjects are shown in Table 6. At 6 months males in the intervention group, compared with the control group, showed a significant improvement in weight (−0.4 kg vs. +0.7 kg), BMI (−0.1 kg/m² vs. +0.3 kg/m²), DBP (−2.0 mmHg vs. +0.6 mmHg), HbA_{1c} (−0.12% vs. −0.05%), and the total risk scores: (−0.04 points vs. +0.46 points) respectively; for females values were: weight (−0.7 kg vs. +0.05 kg), BMI (−0.3 kg/m² vs. +0.03 kg/m²), FBG (−3.2 mg/dl vs. −0.5 mg/dl), and HbA_{1c} (−0.15% vs. −0.07%) respectively, after adjusting for baseline values and age.

During the 9-month maintenance period, the values of weight, BMI, body fat, SBP/DBP, TC, LDL-C, FBG, and the total risk score excluding HDL-C, TG, and HbA_{1c} were maintained or improved continuously in both males and females. At 15 months, the intervention group, compared with the control group, showed a more significant improvement in weight for males (−1.0 kg vs. −0.1 kg); for females significant improvements were noted in weight (−1.8 kg vs. −0.6 kg), BMI (−0.8 kg/m² vs. −0.3 kg/m²), body fat (−1.7% vs. −0.6%), SBP (−6.6 mmHg vs. −2.4 mmHg), TC (−2.2 mg/dl vs. +1.5 mg/dl), and the total risk scores (−0.51 points

TABLE 3. Baseline comparison of outcome variables between subjects who dropped out and completed the intervention.

	Dropped out	Completed	<i>p</i> -value ^a
	Mean ± S.D.	Mean ± S.D.	
Males, <i>n</i>	42	118	
Age, yr	59.0 ± 9.6	61.4 ± 8.6	NS
Height, cm	167.5 ± 6.1	165.1 ± 6.1	0.031
Weight, kg	68.0 ± 8.5	66.2 ± 9.9	NS
Body mass index, kg/m ²	24.2 ± 2.6	24.2 ± 2.8	NS
Body fat, %	23.4 ± 5.1	21.8 ± 4.5	NS
Systolic blood pressure, mmHg	137.2 ± 13.8	138.9 ± 13.4	NS
Diastolic blood pressure, mmHg	81.4 ± 10.3	83.0 ± 9.8	NS
Total cholesterol, mg/dl	220.6 ± 37.2	207.9 ± 27.2	0.020
HDL cholesterol, mg/dl	57.4 ± 14.2	53.7 ± 13.9	NS
LDL cholesterol, mg/dl	137.9 ± 36.7	132.5 ± 26.0	NS
Triglycerides, mg/dl	140.5 ± 73.1	123.2 ± 68.7	NS
Fasting blood glucose, mg/dl	107.5 ± 29.8	101.5 ± 12.3	NS
HbA _{1c} , %	5.55 ± 1.14	5.24 ± 0.52	NS
Total risk score ^b	3.8 ± 1.6	3.6 ± 1.4	NS
Females, <i>n</i>	71	318	
Age, yr	60.0 ± 6.8	61.6 ± 6.3	NS
Height, cm	152.6 ± 5.2	152.2 ± 5.3	NS
Weight, kg	54.3 ± 9.0	54.5 ± 8.6	NS
Body mass index, kg/m ²	23.3 ± 3.7	23.5 ± 3.5	NS
Body fat, %	29.4 ± 6.9	29.2 ± 6.5	NS
Systolic blood pressure, mmHg	132.2 ± 16.1	135.6 ± 16.8	NS
Diastolic blood pressure, mmHg	78.4 ± 10.2	79.4 ± 10.4	NS
Total cholesterol, mg/dl	233.4 ± 30.2	232.9 ± 33.4	NS
HDL cholesterol, mg/dl	65.7 ± 15.7	66.7 ± 15.1	NS
LDL cholesterol, mg/dl	149.5 ± 28.8	149.6 ± 33.2	NS
Triglycerides, mg/dl	103.0 ± 60.1	97.7 ± 45.7	NS
Fasting blood glucose, mg/dl	96.7 ± 12.7	98.5 ± 18.0	NS
HbA _{1c} , %	5.23 ± 0.59	5.25 ± 0.60	NS
Total risk score ^b	3.2 ± 1.4	3.2 ± 1.3	NS

^a Using Student's *t*-test^b Total risk score includes BMI ≥ 25 kg/m², SBP/DBP ≥ 130/85 mmHg, HDL-C < 40 mg/dl, LDL-C ≥ 120 mg/dl, TG ≥ 150 mg/dl, FBG ≥ 110 mg/dl, and HbA_{1c} ≥ 5.6%

NS, not significant

vs. -0.09 points), respectively, after adjusting for baseline values and age.

DISCUSSION

The present study identified significant reductions of several cardiovascular risk factors such as weight, BMI, and HbA_{1c} in males and females, DBP and the total risk in males, and FBG in females after the 6-month main intervention period. At the same time, they also showed an increase in the frequency of physical activity, the number of walking steps, and desirable eating behaviors. In previous studies, increasing physical activity, eating more vegetables, and reduced intakes of animal fat and salt were related to the improvement of obesity, blood lipid levels, and blood pres-

sure (Appel et al. 1997, 2003; Diehl 1998; Aldana et al. 2006; Miura et al. 2006; Noda et al. 2006). Furthermore, Pazoki et al. (2007) reported SBP reduction in subjects after performing 20 minutes of physical activity more than three days a week. Mosca et al. (2000) reported that moderate-intensity physical activity was associated with a risk reduction of heart disease in a dose-response manner. These previous results are consistent with our findings. Therefore, the main intervention period of this study is suggested to be useful to improve lifestyle-related and cardiovascular risk factors.

To maintain these effects achieved by the from 6-month main intervention, a low-intensity intervention which included a total of 4 sessions (total: 7 hours) involv-

TABLE 4. Baseline comparison of lifestyles between subjects who dropped out and completed the intervention.

	Dropped out		Completed		<i>p</i> -value ^a
	<i>n</i>	%	<i>n</i>	%	
Males, <i>n</i>	42		118		
Walking steps per day					
< 6,000 steps/day	31	73.8	86	72.9	
6,000 to 9,999 steps/day	8	19.0	24	20.3	NS
≥ 10,000 steps/day	3	7.1	8	6.8	
Physical activity over 20 min, ≥ 3 times /week	20	47.6	54	45.8	NS
Eating vegetables at every meal, yes	22	52.4	71	60.2	NS
Eating less salt, yes	25	59.5	70	59.3	NS
Eating less animal fat, yes	23	54.8	69	58.5	NS
Drinking alcohol (< 20 g/day, < 6 days/week), yes	32	76.2	93	78.8	NS
Current smoker, yes	16	38.1	36	30.5	NS
Females, <i>n</i>	70 ^b		318		
Walking steps per day					
< 6,000 steps/day	50	71.4	237	74.5	
6,000 to 9,999 steps/day	17	24.3	67	21.1	NS
≥ 10,000 steps/day	3	4.3	14	4.4	
Physical activity over 20 min, ≥ 3 times /week	27	38.6	144	45.1	NS
Eating vegetables at every meal, yes	41	58.6	212	66.7	NS
Eating less salt, yes	52	74.3	267	84.0	NS
Eating less animal fat, yes	52	74.3	238	74.8	NS
Drinking alcohol (< 20 g/day, < 6 days/week), yes	66	94.3	315	99.1	0.022
Current smoker, yes	5	7.1	19	6.0	NS

^a *p*-value is calculated using Chi-square test^b One subject did not answer the questionnaire

NS, not significant

ing counseling, a workshop, nutrition education, and exercise, was conducted during the 9-month maintenance period. As a result, we found that the proportions of subjects who improved their lifestyle, anthropometrical, and biological data such as weight, BMI, body fat, SBP/DBP, TC, LDL-C, FBG, and the total risk score were maintained or continued to improve in the intervention group during the 9-month maintenance period. In particular, compared with the control group, the intervention group showed a marked effect regarding weight in males and females, and BMI, body fat, TC, SBP, and the total risk score in females at the end of the program. Compared with the 15 sessions (total: 29 hours) of the 6-month main program, the 9-month maintenance program spent only one quarter of the time for intervention. This frequency and intensity of intervention were lower than those of other programs (Winkleby et al. 1996; Cappuccio et al. 2006). These results suggest that low-intensity intervention may have a favorable effect on reducing cardiovascular risk factors and maintaining long-term lifestyle improvements.

The strength of this study was that we evaluated the long-term effectiveness of a lifestyle-intervention program which combined main intervention with low-intensity maintenance intervention in a community setting with a relative-

ly large sample size, and 3 health checkups and lifestyle assessment were conducted at the baseline, 6, and 15 months. To the best of our knowledge, this is the first long-term and large-scale study to evaluate cardiovascular disease risk factors in a Japanese community setting. Furthermore, to avoid the bias of gender and medication, the analysis was stratified by gender, excluding those who took any prescribed medication. Moreover, the data were analyzed by researchers blinded to the intervention. These steps contributed to an unbiased evaluation of the long-term effectiveness of this study.

In this study, 237 (76.1%) subjects in the intervention group completed the 15-month program; this completion rate was similar to or higher than those in other programs conducted over 6 months (Lingfors et al. 2001, 2003; Miura et al. 2006; Noda et al. 2006). This low dropout rate may have been achieved by the variety of continuous intervention methods including lectures, group sessions, and exercise/cooking classes, as well as individual counseling and newsletters. The program was conducted during both the daytime and at night, and this flexibility in the schedule may also have increased the completion rate.

Improvements in lifestyle- and cardiovascular diseases-related factors were seen in this study, but the degree of

TABLE 5. Changes in physical activity, eating, alcohol, and smoking habits after 6- and 15-month intervention.

	Baseline to 6 months			Baseline to 15 months		
	Intervention	Control	<i>p</i> -value ^a	Intervention	Control	<i>p</i> -value ^a
	%	%		%	%	
Males, <i>n</i>	59	79		46	72	
Walking steps,						
≥ 6,000 steps/per day	+15.3	+10.1	0.976	+39.1	+1.5	0.002
≥ 10,000 steps/per day	+1.7	−1.2	0.252	+6.5	−1.3	0.154
Physical activity over 20 min, ≥ 3 times /week	+17.0	+3.8	0.035	+21.7	+1.4	0.001
Eating vegetables at every meal, yes	+1.7	+8.9	0.018	+14.9	0	0.525
Eating less salt, yes	+23.8	+7.6	0.480	+28.3	+9.7	0.196
Eating less animal fat, yes	+11.9	+7.6	0.742	+13.1	0	0.489
Drinking alcohol, < 20 g/day, < 6 days/week, yes	−15.3	−12.6	0.670	−6.5	−16.7	0.152
Non-smoker, yes	0	+2.5	0.086	+4.4	+4.2	0.411
Females, <i>n</i>	202	138		186	132	
Walking steps,						
≥ 6,000 steps/per day	+11.4	0	0.532	+17.2	+0.7	0.048
≥ 10,000 steps/per day	+2.4	0	0.956	+3.8	−1.6	0.368
Physical activity over 20 min, ≥ 3 times /week	+14.9	+13.7	0.445	+22.1	+7.6	0.001
Eating vegetables at every meal, yes	+9.4	+2.2	0.078	+18.3	+3.8	0.001
Eating less salt, yes	+8.9	+4.4	0.129	+8.6	+3.0	0.019
Eating less animal fat, yes	+11.3	+6.5	0.449	+11.9	+6.8	0.249
Drinking alcohol, < 20 g/day, < 6 days/week, yes	−1.0	−1.4	0.354	−2.2	−1.5	0.336
Non-smoker, yes	+0.9	0	0.732	+1.1	0	0.633

^a Using Chi-square test to analyze differences between intervention and control groups at 6 and 15 months

improvement was not as pronounced as in other intervention trials (Appel et al. 1997, 2003). Two reasons can be considered for this. First, included subjects aged over 65 yr accounted for 49.7%, and the mean age was 62 yr (range: 40 to 72 yr) at 15 months; these are higher than those of other studies (Appel et al. 1997, 2003; Mosca et al. 2000; Pazoki et al. 2007). Lifestyle changes, especially increasing physical activity, might be difficult for aged subjects (Sit et al. 2007). For example, the present program recommended a goal to increase the number of walking steps to 10,000 steps per day, but the number of subjects who accomplished this goal increased by only 6.5% in males and 3.8% in females at 15 months. Second, aging might influence the degree of improvement in risk factors. Hasegawa et al. reported that aging could be a major factor related to the occurrence of multiple health risks in Japanese subjects (Hasegawa et al. 2005). The age-related deterioration of cardiovascular risk factors was also reported by previous large-scale epidemiological studies in general Japanese populations (Yamamoto et al. 2003a, 2003b; Arai et al. 2006). We also reported that the deterioration of cardiovascular risk factors may be mostly due to aging in another five-year follow-up study (Fukuda et al. 2007). Considering the impact of aged participants and aging, the present study results could be representative of populations with a high average age.

There are some limitations in the present study. First, it was not a randomized controlled trial. Although there were no differences in the lifestyle and risk factors at the baseline between the intervention and control groups in females, we cannot deny the possibility that attitudes towards lifestyle or how to approach health-related activities might be different between the two groups. Second, male participants in this study were fewer. In addition, because some younger males dropped out during the 15-month intervention, 58% of the remaining male subjects were over 65 yr. Therefore, marked improvements in the risk factors might not have been possible. Third, another limitation was information disclosure in the community-based intervention (Luepker et al. 1996; Korhonen et al. 1998; Tudor-Smith et al. 1998; Lingfors et al. 2003). Because all of the participants lived in the same city, those in the control group had access to the same information about the contents of the intervention program as those in the intervention group. However, this free-flow of information would actually weaken the findings. Thus, in the absence of such a situation, the differences between the two groups may be more pronounced than the results of the present study. Fourth, because lifestyle assessment was made by a self-reported questionnaire, except for the number of walking steps counted by a pedometer, reporting bias may exist.

TABLE 6. Comparison of changes in cardiovascular risk factors between intervention and control groups.

	Baseline to 6 months		<i>p</i> -value ^a	Baseline to 15 months		<i>p</i> -value ^a
	Intervention	Control		Intervention	Control	
	Mean ± S.D.	Mean ± S.D.		Mean ± S.D.	Mean ± S.D.	
Males, <i>n</i>	59	79		46	72	
Weight, kg	−0.4 ± 1.7	0.7 ± 1.3	0.001	−1.0 ± 2.2	−0.1 ± 1.7	0.013
Body mass index, kg/m ²	−0.1 ± 0.6	0.3 ± 0.5	0.001	−0.3 ± 0.8	−0.1 ± 0.7	0.162
Body fat, %	2.2 ± 2.3	2.6 ± 2.0	0.229	−1.4 ± 3.2	−0.2 ± 2.3	0.063
Systolic blood pressure, mmHg	−0.6 ± 13.1	3.0 ± 13.6	0.156	−4.9 ± 11.5	−1.5 ± 12.9	0.191
Diastolic blood pressure, mmHg	−2.0 ± 8.1	0.6 ± 8.1	0.050	−1.4 ± 6.0	1.1 ± 8.3	0.053
Total cholesterol, mg/dl	6.2 ± 19.2	9.3 ± 20.6	0.387	−1.7 ± 19.5	2.0 ± 20.6	0.320
HDL cholesterol, mg/dl	1.7 ± 6.4	1.1 ± 6.4	0.744	−0.1 ± 5.3	0.4 ± 6.5	0.558
LDL cholesterol, mg/dl	−0.5 ± 17.5	5.7 ± 17.7	0.078	−12.4 ± 15.8	−8.9 ± 18.0	0.456
Triglycerides, mg/dl	−4.0 ± 47.5	0.3 ± 64.1	0.725	−2.0 ± 49.0	11.2 ± 52.9	0.146
Fasting blood glucose, mg/dl	0.3 ± 7.5	0.6 ± 8.5	0.836	−1.7 ± 8.0	−1.0 ± 7.8	0.620
HbA _{1c} , %	−0.12 ± 0.19	−0.05 ± 0.17	0.014	0.02 ± 0.16	0.05 ± 0.14	0.249
Total risk score ^b	−0.04 ± 1.3	0.46 ± 1.2	0.049	−0.33 ± 1.5	−0.12 ± 1.3	0.545
Females, <i>n</i>	202	138		186	132	
Weight, kg	−0.7 ± 1.6	0.05 ± 2.6	0.002	−1.8 ± 2.0	−0.6 ± 3.1	0.001
Body mass index, kg/m ²	−0.3 ± 0.8	0.03 ± 1.1	0.001	−0.8 ± 0.9	−0.3 ± 1.3	0.001
Body fat, %	0.8 ± 2.3	1.1 ± 2.6	0.324	−1.7 ± 2.8	−0.6 ± 2.6	0.001
Systolic blood pressure, mmHg	−1.8 ± 11.9	−0.9 ± 13.4	0.350	−6.6 ± 13.1	−2.4 ± 13.8	0.003
Diastolic blood pressure, mmHg	−1.1 ± 8.0	−1.3 ± 8.4	0.951	−2.1 ± 7.2	−0.6 ± 7.6	0.064
Total cholesterol, mg/dl	1.0 ± 24.1	5.1 ± 23.1	0.054	−2.2 ± 22.4	1.5 ± 22.1	0.041
HDL cholesterol, mg/dl	1.1 ± 8.8	2.0 ± 7.6	0.307	−0.4 ± 7.2	0.7 ± 7.5	0.206
LDL cholesterol, mg/dl	−5.3 ± 21.1	−1.3 ± 20.1	0.058	−13.6 ± 19.0	−11.9 ± 19.1	0.272
Triglycerides, mg/dl	−7.7 ± 38.5	−5.6 ± 36.1	0.493	9.3 ± 100.1	4.4 ± 42.8	0.584
Fasting blood glucose, mg/dl	−3.2 ± 9.2	−0.5 ± 11.6	0.012	−3.4 ± 7.3	−2.1 ± 9.3	0.125
HbA _{1c} , %	−0.15 ± 0.3	−0.07 ± 0.25	0.001	0.02 ± 0.16	0.01 ± 0.23	0.873
Total risk score ^b	−0.27 ± 1.2	−0.03 ± 1.3	0.108	−0.51 ± 1.1	−0.09 ± 1.4	0.005

^a Using ANCOVA adjusted for baseline values and age^b Total risk score includes BMI ≥ 25 kg/m², SBP/DBP ≥ 130/85 mmHg, HDL-C < 40 mg/dl, LDL-C ≥ 120 mg/dl, TG ≥ 150 mg/dl, FBG ≥ 110 mg/dl, and HbA_{1c} ≥ 5.6%

In conclusion, a 15-month comprehensive program consisting of a main part and maintenance period showed long-term effects on lifestyle modification, such as increased physical activity, improved eating behaviors, and lowered blood pressure, weight, BMI, body fat, and total cardiovascular risk factors, with greater effects of the long-term intervention in females.

Acknowledgments

This project was supported by grants from the Ministry of Health, Labour and Welfare, Japan (No1217003). The authors wish to thank the many staff who worked in the Health-up model project and the citizens of Soka City who cooperated.

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