Table 3
Mortality rate ratios (MRR) in women, 1988–2003, Japan.

	Univariate				Multivariate			
	MRR	95% CI		p	MRR	95% CI		p
Area-level interest in screening (per 1 percentage point)	0.97	0.95	0.99	0.001	0.98	0.97	1.00	0.038
Age (per 1 year)	1.12	1.11	1.12	<0.001	1.11	1.11	1.12	<0.001
Interest in health screening								
High and moderate	0.79	0.74	0.85	<0.001	0.87	0.81	0.94	<0.001
Low	Reference				Reference			
No	1.85	1.57	2.17	<0.001	1.10	0.93	1.30	0.251
Attendance in past year in health screening	0.90	0.85	0.96	0.001	0.89	0.84	0.95	<0.001
Past history of stroke	3.81	3.26	4.45	<0.001	1.82	1.56	2.14	<0.001
Past history of hypertension	1.95	1.84	2.06	<0.001	1.21	1.14	1.28	<0.001
Past history of ischemic heart disease	2.18	1.91	2.50	<0.001	1.25	1.10	1.44	0.001
Past history of diabetes	2.49	2.26	2.75	<0.001	1.59	1.44	1.76	<0.001
Past history of cancer	2.16	1.85	2.51	<0.001	1.64	1.41	1.91	<0.001
Smoking status								
Never smoker	Reference				Reference			
Current smoker	1.36	1.21	1.52	<0.001	1.48	1.32	1.67	<0.001
Former smoker	1.80	1.49	2.17	<0.001	1.29	1.07	1.56	0.009
Missing	1.27	1.17	1.38	<0.001	0.99	0.90	1.09	0.841
Alcohol intake								
Non-habitual drinker	Reference				Reference			
Habitual drinker	0.69	0.65	0.75	<0.001	0.92	0.85	0.99	0.025
Former habitual drinker	1.51	1.28	1.79	<0.001	1.26	1.06	1.50	0.008
Missing	1.30	1.19	1.42	<0.001	1.16	1.05	1.28	0.005
Walking hours per day								
<0.5	Reference				Reference			
≥1.0	0.70	0.64	0.76	<0.001	0.71	0.65	0.78	<0.001
0.6–0.9	0.81	0.73	0.89	<0.001	0.78	0.71	0.87	<0.001
0.5	0.85	0.77	0.94	0.002	0.79	0.72	0.88	<0.001
Missing	0.87	0.76	1.00	0.057	0.69	0.60	0.79	<0.001
Type of recruit								
Health examinees or volunteers	Reference				Reference			
Population based	1.86	1.40	2.48	<0.001	1.07	0.86	1.33	0.517
Regional random variance (SE)	0.14*	(0.50)			0.030	(0.062)		
−2Loglikelihood	39638*				33706			

*Regional random variance and −2loglikelihood of the univariate model were derived from the univariate model of are-level interest in screening.

Several limitations of the present study warrant mention. First, although we adjusted for selected individual factors that might potentially be associated with mortality, residual confounding would be present at both the individual and area levels. Socioeconomic characteristics of an area and of individuals are associated with participation in screening and health (Fukuda, Nakamura, & Takano, 2004, 2005a, b), but these relationships were difficult to interpret in the present study. A previous multilevel analysis using a nationally representative sample of Japanese reported that living in a metropolitan area and per capita income were associated with a reduced likelihood of cancer screening, while having a higher individual income were associated with a higher likelihood of cancer screening (Fukuda, Nakamura, & Takano, 2005b). The impact of residual confounding of socioeconomic factors at both the area and individual level on the present results is uncertain. Second, we did not ascertain the type of screening programmes, with regard to either individual attendance or area-level interest in screening. Although the effects of screening might differ between types at the individual level, it may be reasonable to measure area-level interest in screening programmes in general terms rather than with regard to each type of screening, such as stomach cancer screening, breast cancer screening and others. Third, although the model included attendance at health screening, this was baseline data. Thus, we assume that the model adjusted for the individual's attitude and health consciousness rather than for the opportunity to detect diseases.

In conclusion, this study showed that area-level and individual interest for health screening appear to be independent predictor of 15-year mortality in this national Japanese study. This effect benefited all people who lived in these areas, whether they participated in health screening or not. The present findings may support public health practices to promote knowledge of and participation in health screening programmes.

Conflict of interest statement
The authors declare that there are no conflicts of interest.

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Original Article

Behavioral change during weight loss program and one-year follow-up: Saku Control Obesity Program (SCOP) in Japan

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This study evaluated effects of a behavioral approach which placed emphasis on tailored behavior counseling, diet, weight loss and weight maintenance. A one-year randomized controlled trial was conducted among 235 overweight/obese adults in Japan. The intervention group (n=119) received individual-based counseling using a behavioral approach and the changes made in the diet and physical activity were dependent on each participant as much as possible. One year later, the intervention group lost significantly more weight than the control group (-5.0 kg vs. 0.1 kg for men and -3.9 kg vs. -0.2 kg for women). Compared to the control group, the male intervention group reduced overall energy, cereals and dairy products consumption significantly, while increasing green and yellow vegetable intake, and the female intervention group significantly reduced intake of dairy products. Regarding behaviors, both male and female intervention groups increased the number of walking steps and women improved their irregular eating habits compared to those in the control groups. Behavior changes were related to weight loss; participants who maintained the action/maintenance stage or moved to later stages lost significantly more weight than participants who remained in the pre-contemplation/contemplation/preparation stages or regressed to earlier stages. After one-year follow-up, the intervention group maintained significantly lower weights, lower energy intakes and improvements in irregular eating habits. Our behavioral approach led to diet and behavior modification, weight loss and maintenance. Because modified variables differed between men and women, gender-specific approaches may be necessary.

Key Words: behavior therapy, body weight changes, randomized controlled trial, follow-up studies, diet

INTRODUCTION

It is well known that obesity is a risk factor for various diseases such as hypertension, hyperglycemia, dyslipidemia, hyperuricemia and some cancers.[1] In 2003, the International Obesity Task Force estimated that at least 1.1 billion people around the world were overweight (body mass index (BMI) ≥25 kg/m^2), including 312 million who were obese (BMI ≥30 kg/m^2), and that the prevalence of obesity had doubled or risen threefold in less than two decades.[2] Japan is no exception in that mean BMI values have consistently increased over the past 50 years in all age groups for men, and women aged 60.[3] To make matters worse, large epidemiological studies reported that the cardiovascular disease risk in the Japanese population greatly increased, even in those with BMI values less than 30 kg/m^2.[4,5] This indicates the need to decide on strategies for weight loss as people are overweight in Japan.

Weight loss improves obesity-related risk factors and the benefits persist as long as the weight loss is maintained.[6-8] To date, many weight loss trials have been conducted and short-term treatment efficacy has dramatically improved over recent decades.[9] A behavioral approach is one technique used in obesity treatment,[10] and this approach has been incorporated into weight loss programs not only in Europe and the United States, but also in Japan.[11-21] Follow-up studies have also been conducted, but it was reported that the subjects gradually regained their weight.[14-16] These data suggest that improved behaviors might revert to the baseline levels during the follow-up period. However, it is not clear which improved behaviors easily reverted or were maintained in the long term.

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We developed a weight loss program based on a behavioral approach with dietary and exercise intervention (Saku Control Obesity Program (SCOP)) in Japan. In the program, several behavioral approaches such as goal setting and self-monitoring were used, and because it was suggested that therapeutic support of weight reduction should be continued for at least one year for successful weight reduction,[22] the duration of the program was set for one year. However, frequency of intervention was minimized as much as possible to save manpower. In addition, our program has a unique feature. Although many other weight loss programs give uniform advice, such as recommending a low-fat diet or low-carbohydrate diet to the subjects, such uniform advice may not necessary fit all of the subjects. Thus, in this program, we placed emphasis on tailored counseling, instead of uniform instruction, and the changes made in the diet and physical activity were dependent on each participant.

In this study, we evaluated the effect of SCOP program on weight loss and weight maintenance in Japanese male and female overweight/obese populations by means of a randomized controlled trial. In addition, we focused on changes in behaviors during the intervention and follow-up periods, and examined which behaviors were easily improved and maintained, and whether or not the behavioral change was different in terms of sex.

MATERIALS AND METHODS

Study subjects

Recruitment was conducted by the Saku Health Dock Center in Nagano prefecture in 2006.[23] A letter was sent directly to 976 people aged 40 to 64 who visited the Dock Center from 2000 and were in the top 5% (≥28.4 kg/m^2) in terms of the result of the latest BMI screening. A total of 265 people applied to join this program. Exclusion criteria were psychiatric conditions or physical conditions that would preclude full participation in the study (i.e., significant hepatic or renal dysfunction and cardiovascular diseases), current treatment for obesity and current treatments known to affect eating or weight (e.g., medications). Finally, 235 people met the inclusion criteria and they were randomly assigned to either an intervention (n=119; 59 men and 60 women) or a waiting-list control (n=116; 57 men and 59 women) group. Written information including the purpose of study, assurance of refusal, and security of personal information was handled to each participant, and written informed consent was obtained from all participants. The study protocol was approved by the ethics committee of the National Institute of Health and Nutrition. This study was partly supported by a fund from a Research-in-Aid Grant for Cardiovascular Diseases from the Ministry of Health, Labor and Welfare.

Saku Control Obesity Program (SCOP)

This program was a one-year lifestyle intervention for weight loss based on a behavioral approach (Figure 1). The program was conducted at the Saku Health Dock Center from July, 2006. The participants in the intervention group received individual counseling (30 minutes) and group sessions about effective exercise (20 minutes) provided by registered dietitians and exercise instructors at baseline and at 1, 3, 6 and 9 months. In the exercise group session, an exercise instructor taught participants effective exercises for weight loss, such as how to stretch and walk, by providing examples, and participants mimicked the motions. In the individual counseling sessions, the participants discussed lifestyle habits (diet, dietary habit and physical activities) that needed improvement and set monthly plans to modify them with the support of dietitians and exercise instructors. At least one objective for each energy intake (diet/eating behavior) and energy expenditure (exercise) parameter was set for each month. In addition, they were instructed to self-monitor daily weight, daily step counts, diet and implementation of the plans using a self-monitoring sheet (Appendix). Participants wrote down in the remarks column of the sheet if they attended an event such as a drinking party. The months between these five face-to-face counseling sessions (that is, at 2, 4, 5, 7, 8, 10 and 11 months), participants reported their progress for the previous month and their new plans for the following month by mailing the records to the dietitians. The dietitians checked these and sent back comments to each participant.

Fifteen dietitians, who usually worked as registered dietitians in their own places of employment participated on every counseling day in this program. To standardize the intervention, they received training in advance (for example, we advised them to respect participants' thoughts when setting objectives and to set easier objectives in the beginning of the program, etc). In the program, dietitians explained adequate % fat and carbohydrate intake compared with each participant's actual intake as assessed by the diet history questionnaire. However, dietary instruction, such as to lower the fat or carbohydrate intake were not forced on the participants. When setting objectives, the dietitians considered the stage of change for each participant and judged whether or not the objective was appropriate. The dietitians encouraged the participants throughout the program and each dietitian continuously supported the same participants as much as possible.

Participants in the control group did not receive any support for one year. Participants in the intervention group were followed for one year after the intervention, but we did not offer any support for them during the follow-up period.

Outcome measures

Assessments were conducted at the Saku Health Dock Center at baseline and 12 months. Only participants in the intervention group visited the dock center at 24 months again and received the same assessment except for stage of change.

Anthropometric and biological data

Height was measured with shoes off, and body weight and percentage of body fat were measured with light clothes in the fasting state in the morning. Body weight and percentage of body fat were measured by Bioelectrical Impedance Analysis (TB-220, Tanita Co., Japan). BMI was calculated from the body weight (kg) divided by the height squared (m^2) of each subject. Waist circumference was measured twice in the upright position. The mean value of waist circumference was used in the analysis. Visceral fat areas were assessed by a computed tomo-

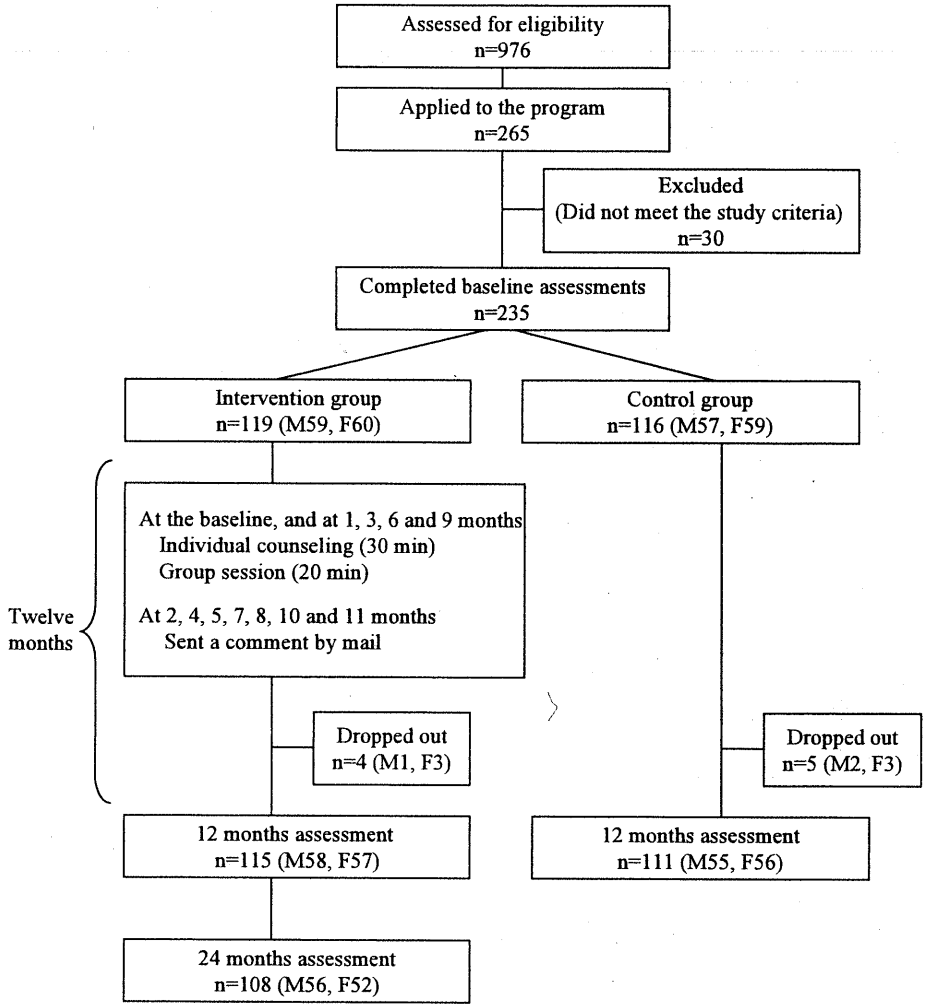

Figure 1. Flowchart of the SCOP program

graphy scan at the level of the umbilicus, with the subjects in the supine position, and calculated using commercially available software (Fat Scan; N2 System Corp., Osaka, Japan).

The systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured by an automatic manometer (HEM907, Omron Co., Japan) after the subject had sat at rest. Blood samples were collected from the anterior cubital vein from the subjects in an overnight fasting state, and the HDL cholesterol (HDL-C), LDL cholesterol (LDL-C), triglyceride (TG) and fasting plasma glucose (FPG) levels were analyzed. The metabolic syndrome was defined by the metabolic syndrome diagnostic criteria for the Japanese: a waist circumference of ≥85 cm for males and ≥90 cm for females, and two or more of the following criteria: (1) TG ≥150 mg/dL and/or HDL-C <40 mg/dL or current treatment, (2) SBP ≥130 mmHg and/or DBP ≥85 mmHg or current treatment and (3) FPG ≥110 mg/dL or current treatment.[24]

Physical activity

Daily step counts were assessed using a uniaxial accelerometer (Suzuken Co., Japan). Each participant wore a uniaxial accelerometer on his or her belt from the time of waking to going to bed for two weeks.[25] We used the mean step counts for two weeks in the analysis.

Diet and eating behavior

Dietary intake in the previous month was assessed by a self-administered diet history questionnaire (DHQ) that has been validated.[26-28] Food groups and nutrient intake were calculated using an ad hoc computer program for DHQ, which was based on the food composition table in Japan. Eating behaviors were assessed by a questionnaire by the Japan Society for the Study of Obesity.[29] This questionnaire included 51 items based on the statements given by the obese participants in a clinical survey. A four-point Likert scale (strongly disagree/disagree/agree/strongly agree) was used in the questionnaire. Based on these items, scores were calculated for the following eight eating behavior categories: 1) irregularity of eating (example of included item; "I often eat between meals"), 2) perception gap about the feelings of fullness and hunger (e.g. "I can eat my favorite foods even if I feel full"), 3) preference for unhealthy foods (e.g. "I often eat out and have food delivered"), 4) eating on unexpected occasions (e.g. "I always keep food around"), 5) perception gap about constitution and weight (e.g. "I don't satisfied un-

less I eat my fill''), 6) eating quickly (e.g. ''I eat a meal fast''), 7) motivation for eating (e.g. ''I can't sleep when I feel hungry''), and 8) total score. A higher score indicated that the participants had more features characteristic of obese people.

Stages of change

Only the intervention group answered a questionnaire about stages of change to improve lifestyles. In the questionnaire, participants chose one of the five stages developed by Prochaska *et al.*: *pre-contemplation* (participants are not seriously considering changing behavior), *contemplation* (participants are considering changing behavior, but they have no intention of carrying this out within the next month), *preparation* (participants are considering changing behavior and they will carry this out within the next month), *action* (participants have already changed behavior within the last 6 months) and *maintenance* (participants have already changed behavior for at least 6 months).[30,31]

Statistical analysis

Analyses were based on data from 226 participants who participated at both the baseline and 12-month assessments. Baseline anthropometric data and the prevalence of hyperglycemia, dyslipidemia, hypertension and the metabolic syndrome between the intervention and control groups were compared by t-test or chi-square test. Changes in anthropometrical data, daily step counts, eating behaviors and dietary intake over the trial period were analyzed using a paired t-test and mixed model procedure (PROC MIXED, SAS). In the mixed model analysis, the model had fixed effects (group assignment, time, and group and time interaction, with age as a covariate) and random effects (individual). A significant group-by-time interaction indicated that, for the given outcome measures, changes from the baseline differed significantly between the two groups. Changes in the proportions of participants in the five stages were examined by Wilcoxon's signed-rank test. Furthermore, the participants were divided into three groups according to how they changed stages: 1) participants who remained in the pre-contemplation/ contemplation/preparation stage both at baseline and after 12 months or who went back to an earlier stage from action/maintenance to pre-contemplation/contemplation/ preparation after 12 months, 2) participants who remained in the action/maintenance stage both at baseline and after 12 months and 3) participants who improved the stage from pre-contemplation/contemplation/preparation to action/maintenance after 12 months. Because only 4 participants went back to an earlier stage, they were included in the participants who remained in the pre-contemplation/contemplation/preparation stage. Mean weight loss among the three groups was compared by analysis of covariance (ANCOVA) adjusting for age, sex and baseline weight.

To examine changes in anthropometrical data, daily step counts, eating behaviors and dietary intake during the follow-up, paired t-test between the values at baseline and 24 months was conducted. A p-value of less than 0.05 is considered significant. An analysis using a mixed model was conducted using the SAS (version 9.2; SAS Institute, Cary, NC) software, and the other analyses were carried out using the SPSS for Windows (version 12.0; SPSS Inc., Japan) software.

RESULTS

Characteristics of the study participants

Participation and dropouts are shown in Figure 1. A total of 4 participants in the intervention group (3.4%) and 5 in the control group (4.3%) dropped out during the study period. Thus, 115 participants in the intervention group (58 men and 57 women) and 111 participants in the control group (55 men and 56 women) completed both baseline and 12-month assessments.

The mean ages of the men in the intervention and control groups were 53.6±6.7 yr and 53.7±6.3 yr, and the mean ages of the women were 55.1±6.4 yr and 54.2±6.2 yr, respectively. Mean age was not significantly different between the groups in men or women.

Table 1 shows comparisons of the baseline anthropometric data and the prevalence of hyperglycemia, dyslipidemia, hypertension and the metabolic syndrome between the intervention and control groups. Although the baseline % body fat in females in the control group was significantly higher than that in the intervention group (p=0.04), there were no significant differences in any of the other anthropometric data and the prevalence of hyperglycemia, dyslipidemia, hypertension and the metabolic syndrome.

Changes in anthropometric data and dietary intake

Results of baseline, 12-month and 24-month measurements for the intervention and control groups are shown in Table 2. The intervention group significantly improved with regard to all of the anthropometric data, while the control group showed little change in these variables after 12 months. Mean weight loss in the intervention and control groups were -5.0 kg (BMI -1.7 kg/m^2) and 0.1 kg (BMI -0.04 kg/m^2) for men and -3.9 kg (BMI -1.6 kg/m^2) and -0.2 kg (BMI -0.1 kg/m^2) for women, respectively. Significant differences (interaction between group and time) were seen in change in weight, BMI, body fat, waist circumference and visceral fat in both sexes. At 24 months, male and female participants in the intervention group still maintained significantly lower weight, BMI, waist circumference and visceral fat compared with baseline values. Men in the intervention group also maintained significantly lower percentage of body fat from baseline.

Tables 3 and 4 show changes in nutrient and food intakes. During the program, the male intervention group showed a larger reduction in energy and macronutrient intake than those in the control group, and significant group-by-time interactions were seen in energy, protein and carbohydrate intake. As for food group intake, the male intervention group significantly reduced intakes of cereals and dairy products and increased intake of green and yellow vegetables (p<0.01, p<0.01 and p=0.02 for group×time interaction, respectively). The female intervention group significantly reduced intake of energy and macronutrients at 12 months, but the subjects in the control group also significantly reduced intakes of most of these nutrients, thus there were no significant group-by-

Table 1. Baseline characteristics of participants

	Men			Women		
	Intervention group (n=58)	Control group (n=55)	p-value‡	Intervention group (n=57)	Control group (n=56)	p-value‡
Weight (kg)	84.1 ± 8.4	87.0 ± 11.7	0.13	74.4 ± 8.5	75.0 ± 10.2	0.70
BMI (kg/m^2)	29.8 ± 2.3	30.5 ± 3.7	0.22	30.9 ± 3.0	31.1 ± 3.1	0.72
Body fat (%)	28.4 ± 3.6	29.3 ± 4.8	0.28	39.5 ± 5.4	41.7 ± 5.4	0.04
Waist circumference (cm)	100 ± 6.4	102 ± 8.8	0.17	103 ± 7.9	104 ± 8.9	0.88
Visceral fat (cm^2)	150 ± 47.6	162 ± 47.9	0.17	128 ± 46.5	133 ± 47.9	0.58
Hyperglycemia§ n (%)	20 (34.5)	25 (45.5)	0.23	21 (36.8)	25 (44.6)	0.40
Dyslipidemia§ n (%)	37 (63.8)	33 (60.0)	0.68	24 (42.1)	33 (58.9)	0.07
Hypertension§ n (%)	40 (69.0)	40 (72.7)	0.66	37 (64.9)	40 (71.4)	0.46
Metabolic syndrome§ n (%)	33 (56.9)	38 (69.1)	0.18	26 (45.6)	35 (62.5)	0.07

Values are means±SD.
‡T-test or chi-square test.
§Hyperglycemia (plasma glucose level ≥110 mg/dL in the fasting state or current treatment), dyslipidemia (plasma triglyceride level ≥150 mg/dL and/or plasma HDL cholesterol level <40 mg/dL or current treatment), hypertension (systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥85 mmHg or current treatment) and the metabolic syndrome (waist circumstances ≥85 cm for men and ≥90 cm for women and having two and more above risk factors).

Table 2. Anthropometrical data at baseline, 12 months and 24 months later

	Intervention group (n=58)					Control group (n=55)			Group×time
Men	Baseline	12 months	24 months	p-value‡	p-value§	Baseline	12 months	p-value‡	p-value¶
Weight (kg)	84.1 ± 8.4	79.1 ± 8.7	80.5 ± 8.8	<0.01	<0.01	87.0 ± 11.7	87.2 ± 12.6	0.77	<0.01
BMI (kg/m^2)	29.8 ± 2.3	28.1 ± 2.5	28.5 ± 2.6	<0.01	<0.01	30.5 ± 3.7	30.5 ± 4.1	0.78	<0.01
Body fat (%)	28.4 ± 3.6	26.7 ± 4.5	26.7 ± 4.5	<0.01	<0.01	29.3 ± 4.8	29.7 ± 5.3	0.44	<0.11
Waist circumference (cm)	100 ± 6.4	95.9 ± 7.5	96.7 ± 7.3	<0.01	<0.01	102 ± 8.8	103 ± 9.0	0.75	<0.01
Visceral fat (cm^2)	150 ± 47.6	125 ± 46.7	133 ± 46.2	<0.01	<0.01	162 ± 47.9	157 ± 46.6	0.26	<0.01
	Intervention group (n=57)					Control group (n=56)			Group×time
Women	Baseline	12 months	24 months	p-value‡	p-value§	Baseline	12 months	p-value‡	p-value¶
Weight (kg)	74.4 ± 8.5	70.4 ± 9.2	71.9 ± 9.2	<0.01	<0.01	75.0 ± 10.2	74.9 ± 10.8	0.61	<0.01
BMI (kg/m^2)	30.9 ± 3.0	29.2 ± 3.4	29.9 ± 3.3	<0.01	<0.01	31.1 ± 3.1	30.9 ± 3.2	0.41	<0.01
Body fat (%)	39.5 ± 5.4	37.5 ± 5.9	38.7 ± 5.9	<0.01	0.10	41.7 ± 5.4	41.6 ± 5.8	0.82	<0.01
Waist circumference (cm)	103 ± 7.9	99.2 ± 9.4	101 ± 9.2	<0.01	<0.01	104 ± 8.9	104 ± 8.9	0.36	<0.01
Visceral fat (cm^2)	128 ± 46.5	103 ± 37.4	104 ± 38.4	<0.01	<0.01	133 ± 47.9	128 ± 46.1	0.77	<0.01

Values are means±SD.
‡Paired t-test between values at the baseline and 12 months later.
§Paired t-test between values at the baseline and 24 months later.
¶Mixed model analysis after adjusting for age.
††Abbreviation: BMI, body mass index.

Table 3. Dietary intake estimated by a self-administered diet history questionnaire at baseline, 12 months and 24 months later in men

	Intervention group (n=58)				Control group (n=55)			Group×time
Men	Baseline	12 months	24 months	p-value‡	p-value§	Baseline	12 months	p-value‡	p-value¶
Energy (kcal/day)	2718 ± 761	2267 ± 588	2376 ± 590	<0.01	<0.01	2680 ± 791	2501 ± 709	0.01	0.02
Protein (g/day)	99.5 ± 26.9	79.9 ± 23.7	80.2 ± 23.9	<0.01	<0.01	92.8 ± 32.7	85.7 ± 31.0	0.01	0.01
Fat (g/day)	75.7 ± 29.2	66.6 ± 24.3	68.6 ± 25.8	0.02	0.04	76.1 ± 35.9	72.3 ± 31.4	0.26	0.30
Carbohydrate (g/day)	351 ± 105	286 ± 74.9	296 ± 73.4	<0.01	<0.01	332 ± 94.5	324 ± 92.1	0.33	<0.01
Cereals (g/day)	609 ± 234	502 ± 147	537 ± 148	<0.01	<0.01	573 ± 198	580 ± 192	0.75	<0.01
Nuts	3.1 ± 5.4	3.0 ± 5.3	4.8 ± 16.0	0.90	0.48	3.5 ± 5.5	4.0 ± 5.8	0.56	0.64
Potatoes	27.8 ± 22.5	29.1 ± 22.2	24.1 ± 21.4	0.63	0.24	32.0 ± 26.2	35.6 ± 44.8	0.50	0.70
Sugars	13.0 ± 8.4	12.1 ± 6.4	12.2 ± 5.4	0.45	0.55	14.2 ± 9.4	13.7 ± 8.6	0.65	0.86
Confectionaries	56.7 ± 44.7	60.6 ± 47.5	59.0 ± 54.4	0.47	0.69	64.0 ± 42.8	68.2 ± 42.7	0.41	0.97
Vegetable oil	27.1 ± 13.8	25.5 ± 14.1	27.6 ± 14.3	0.51	0.90	30.4 ± 22.2	27.2 ± 17.9	0.26	0.67
Pulses	60.6 ± 43.4	70.8 ± 43.3	63.7 ± 40.2	0.08	0.56	64.0 ± 31.9	62.1 ± 36.1	0.66	0.09
Fruits	121 ± 165	104 ± 88.8	89.5 ± 74.8	0.44	0.19	88.3 ± 80.7	92.2 ± 107	0.73	0.40
Green and yellow vegetables	105 ± 75.9	130 ± 77.4	109 ± 60.0	0.01	0.82	112 ± 80.6	107 ± 84.4	0.54	0.02
Other vegetables	157 ± 85.8	157 ± 80.6	157 ± 63.4	0.97	0.91	168 ± 101	155 ± 103	0.14	0.32
Mushrooms	12.5 ± 12.4	17.6 ± 22.4	13.9 ± 15.8	0.06	0.53	12.0 ± 12.1	16.1 ± 18.9	0.06	0.76
Seaweeds	11.8 ± 12.0	13.9 ± 12.9	11.7 ± 11.2	0.32	0.82	13.5 ± 9.5	12.1 ± 11.1	0.37	0.19
Alcoholic beverages	261 ± 316	183 ± 208	256 ± 374	0.01	0.79	391 ± 502	273 ± 310	0.02	0.48
Fish and shellfish	108 ± 57.7	104 ± 58.9	103 ± 61.7	0.65	0.53	121 ± 79.3	121 ± 71.7	0.99	0.73
Meats	83.3 ± 61.7	71.0 ± 42.0	74.5 ± 51.1	0.10	0.23	84.1 ± 69.6	80.3 ± 54.7	0.61	0.40
Eggs	46.6 ± 31.5	45.6 ± 41.0	40.3 ± 34.3	0.79	0.28	41.2 ± 28.1	41.1 ± 25.0	0.99	0.85
Dairy products	526 ± 122	133 ± 103	150 ± 112	<0.01	<0.01	281 ± 145	104 ± 110	<0.01	<0.01

Values are means±SD.
‡Paired t-test between values at the baseline and 12 months later.
§Paired t-test between values at the baseline and 24 months later.
¶Mixed model analysis after adjusting for age.

Table 4. Dietary intake estimated by a self-administered diet history questionnaire at baseline, 12 months and 24 months later in women

	Intervention group (n=57)				Control group (n=56)			Group×time
Women	Baseline	12 months	24 months	*p*-value‡	*p*-value§	Baseline	12 months	*p*-value‡	*p*-value¶
Energy (kcal/day)	2217 ± 889	1848 ± 582	1832 ± 571	<0.01	<0.01	2182 ± 750	1918 ± 590	<0.01	0.21
Protein (g/day)	87.2 ± 34.1	68.3 ± 25.4	66.8 ± 25.1	<0.01	<0.01	82.3 ± 27.4	70.0 ± 22.1	<0.01	0.13
Fat (g/day)	71.4 ± 37.1	57.1 ± 25.8	56.0 ± 25.9	<0.01	<0.01	68.8 ± 36.7	58.8 ± 25.2	<0.01	0.18
Carbohydrate (g/day)	300 ± 114	261 ± 72.1	260 ± 68.8	<0.01	<0.01	301 ± 93.6	271 ± 77.8	<0.01	0.46
Cereals (g/day)	411 ± 129	400 ± 90.3	396 ± 84.8	0.50	0.19	427 ± 113	416 ± 109	0.45	0.88
Nuts	3.3 ± 6.1	2.3 ± 4.6	1.9 ± 3.4	0.15	0.03	4.6 ± 11.6	2.7 ± 4.3	0.19	0.60
Potatoes	38.8 ± 63.0	29.3 ± 27.3	27.4 ± 25.2	0.16	0.19	35.5 ± 25.7	34.2 ± 27.3	0.70	0.34
Sugars	13.2 ± 8.8	12.0 ± 8.3	12.5 ± 7.6	0.25	0.26	12.5 ± 5.7	14.4 ± 12.0	0.26	0.11
Confectionaries	105 ± 79.4	85.0 ± 63.6	90.5 ± 63.1	0.04	0.07	91.0 ± 88.7	79.8 ± 69.8	0.10	0.39
Vegetable oil	29.5 ± 22.9	21.9 ± 14.0	20.8 ± 13.4	0.02	0.01	26.8 ± 23.8	23.0 ± 15.0	0.12	0.08
Pulses	56.7 ± 37.1	59.6 ± 33.0	57.6 ± 39.2	0.53	0.81	63.4 ± 37.8	56.1 ± 33.6	0.03	0.06
Fruits	129 ± 154	116 ± 117	124 ± 95.4	0.45	0.62	158 ± 215	118 ± 115	0.19	0.49
Green and yellow vegetables	130 ± 96.9	149 ± 95.2	128 ± 99.2	0.05	0.99	136 ± 77.2	130 ± 85.5	0.61	0.13
Other vegetables	188 ± 183	189 ± 100	154 ± 84.4	0.97	0.02	192 ± 91.4	166 ± 76.0	0.04	0.30
Mushrooms	17.4 ± 14.3	19.4 ± 16.8	15.2 ± 11.8	0.29	0.34	18.3 ± 15.1	17.4 ± 14.4	0.64	0.43
Seaweeds	18.5 ± 23.3	17.5 ± 17.2	13.0 ± 11.8	0.61	0.06	21.0 ± 14.0	15.0 ± 11.2	<0.01	0.16
Alcoholic beverages	35.6 ± 97.4	19.0 ± 48.7	16.3 ± 51.4	0.10	0.18	63.9 ± 139	35.9 ± 76.4	0.03	0.48
Fish and shellfish	99.5 ± 68.0	90.7 ± 70.3	86.7 ± 55.6	0.37	0.13	97.1 ± 60.2	90.1 ± 52.8	0.23	0.95
Meats	54.5 ± 49.7	45.6 ± 31.9	46.9 ± 41.0	0.12	0.06	51.4 ± 32.3	48.7 ± 29.6	0.47	0.34
Eggs	33.3 ± 23.9	28.7 ± 22.8	30.9 ± 22.2	0.18	0.27	31.8 ± 20.5	27.1 ± 20.4	0.08	0.67
Dairy products	494 ± 113	143 ± 106	137 ± 101	<0.01	<0.01	333 ± 186	151 ± 108	<0.01	<0.01

Values are means±SD.
‡Paired t-test between values at the baseline and 12 months later.
§Paired t-test between values at the baseline and 24 months later.
¶Mixed model analysis after adjusting for age.

Table 5. Eating and physical activity behavior at baseline, 12 months and 24 months later.

Men	Intervention group (n=58)			p-value‡	p-value§	Control group (n=55)		p-value‡	Group×time p-value¶
	Baseline	12 months	24 months			Baseline	12 months		
Total score (points out of 188)	100.0 ± 23.5	91.1 ± 21.5	88.8 ± 20.5	<0.01	<0.01	103.0 ± 19.7	98.0 ± 18.9	0.07	0.11
Irregularity of eating (points out of 32)	16.0 ± 5.1	15.5 ± 4.3	15.1 ± 4.4	0.25	0.28	17.3 ± 4.8	16.5 ± 4.3	0.50	0.63
Perception gap about feeling of fullness and hunger (points out of 16)	8.2 ± 2.8	7.4 ± 2.3	7.3 ± 2.3	0.03	0.01	8.1 ± 2.5	7.9 ± 2.1	0.03	0.17
Preference for unhealthy foods (points out of 36)	17.1 ± 5.2	15.6 ± 4.3	14.7 ± 3.8	<0.01	<0.01	17.5 ± 3.6	16.7 ± 3.6	0.48	0.17
Eating on unexpected occasion (points out of 16)	6.6 ± 2.5	6.1 ± 2.3	6.2 ± 2.4	0.14	0.29	6.2 ± 2.1	6.0 ± 2.1	0.10	0.41
Perception gap about constitution and weight (points out of 28)	18.0 ± 3.9	16.7 ± 4.2	16.1 ± 3.6	0.02	<0.01	18.7 ± 4.3	18.0 ± 3.7	0.03	0.35
Eating quickly (points out of 20)	12.8 ± 3.8	11.0 ± 3.7	10.7 ± 3.8	<0.01	<0.01	13.4 ± 4.0	12.6 ± 3.8	<0.01	0.07
Motivation for eating (points out of 40)	21.3 ± 6.7	18.8 ± 6.1	18.8 ± 5.6	<0.01	<0.01	21.8 ± 5.8	20.2 ± 5.4	0.10	0.22
Daily step counts (steps/day)	7058 ± 2885	8489 ± 3371	7482 ± 2743	<0.01	0.08	8337 ± 3651	8771 ± 3655	0.10	0.04
Women	**Intervention group (n=57)**					**Control group (n=56)**			
	Baseline	12 months	24 months			Baseline	12 months		
Total score (points out of 180)	95.6 ± 17.5	89.6 ± 18.7	90.4 ± 17.3	<0.01	0.02	96.3 ± 18.4	96.7 ± 18.7	0.82	0.01
Irregularity of eating (points out of 32)	16.0 ± 3.8	14.3 ± 3.3	14.9 ± 3.8	<0.01	<0.01	15.9 ± 4.1	16.2 ± 4.3	0.50	<0.01
Perception gap about feeling of fullness and hunger (points out of 24)	11.4 ± 3.0	10.9 ± 3.2	10.7 ± 2.8	0.29	0.12	11.5 ± 2.9	11.8 ± 3.0	0.35	0.14
Preference for unhealthy foods (points out of 28)	11.1 ± 3.0	10.7 ± 2.9	10.8 ± 2.8	0.12	0.41	10.9 ± 2.8	11.1 ± 3.0	0.58	0.11
Eating on unexpected occasion (points out of 16)	7.8 ± 2.9	7.9 ± 3.0	7.9 ± 3.0	0.77	0.95	7.9 ± 2.9	8.2 ± 2.8	0.26	0.52
Perception gap about constitution and weight (points out of 24)	17.4 ± 3.1	16.0 ± 3.6	15.9 ± 3.4	<0.01	<0.01	17.0 ± 3.2	16.9 ± 3.3	0.72	0.07
Eating quickly (points out of 20)	11.5 ± 3.6	10.7 ± 3.5	11.0 ± 3.7	0.03	0.48	12.4 ± 3.4	11.6 ± 3.4	0.01	0.98
Motivation for eating (points out of 36)	20.3 ± 5.5	19.1 ± 5.1	19.3 ± 4.9	0.05	0.26	20.7 ± 5.2	20.9 ± 5.5	0.68	0.07
Daily step counts (steps/day)	8122 ± 2928	9847 ± 3932	8821 ± 3101	<0.01	0.08	7984 ± 3376	8218 ± 3075	0.68	<0.01

Values are means±SD.
‡Paired t-test between values at the baseline and 12 months later.
§Paired t-test between values at the baseline and 24 months later.
¶Mixed model analysis after adjusting for age.

time interactions in change of nutrient intake (Table 4). As well as nutrient intake, changes in intake of food groups were not significantly different between the groups, except for dairy products. The female intervention group decreased intake of daily products more than that of the control group ($p<0.01$ for group-by-time interaction).

During the follow-up period, the male intervention group maintained food and nutrient intakes, which improved during the program, except that for intakes of green and yellow vegetables (Table 3). In women, the participants in the intervention group still maintained lower intake of energy, macronutrients and dairy products from baseline (Table 4).

Changes in behaviors of eating and physical activity

We evaluated changes in eating and physical activity behaviors during the program and follow-up (Table 5). In terms of eating behavior, both men and women showed intermediate scores of each maximum score at baseline. Most of the scores in the male and female intervention group decreased (that is, eating behavior was improved) during the program, and significant group-by-time interactions in total score ($p=0.01$) and the score for "irregularity of eating" ($p<0.01$) in women were seen. In addition to improvement of eating behavior, the intervention group walked more after the 12 months, at 1,413 and 1,789 step counts on average for men and women, respectively, than at the beginning of the program, and significant group-by-time interactions were seen in both sexes ($p=0.04$ for group-by-time interaction in men and $p<0.01$ in women). During the follow-up period, although mean number of walking steps decreased in both sexes and was closer to the baseline level, total score and the score for "irregularity of eating" in women were maintained even at 24 months.

Stages of the transtheoretical model

Because some behavior change was seen in the intervention group, we evaluated changes in the proportion of the participants at each stage and examined the relationship between stage change and degree of weight loss during the program.

At baseline, 66.0% of men and 68.6% of women were in the preparation stage. However, the proportion at this stage decreased by 42.6% in men and 47.0% in women and the participants in the action or maintenance stages increased to 74.5% in total in both men and women at 12 months (Wilcoxon signed-rank test; $p<0.01$ in both men and women). A total of 52 male and female participants (71.2%) among those who were in the pre-contemplation/contemplation/preparation stage at the baseline changed to the action/maintenance stage after 12 months, and 21 participants (84.0%) among the participants who were in the action/maintenance stage at the baseline remained in that stage after 12 months. On the other hand, only 25 participants (28.2%) among the participants who were in the pre-contemplation/contemplation/preparation stage maintained the stage or went back a stage from the action/maintenance to the pre-contemplation/contemplation/preparation stage after 12 months. Mean body weight loss of the participants who remained in the action/maintenance stage or who moved to the next stage was significantly higher than that of the participants who remained in the pre-contemplation/ contemplation/preparation stage or went back a stage (Figure 2).

Attendance of SCOP program

The participation rate at each face-to-face intervention

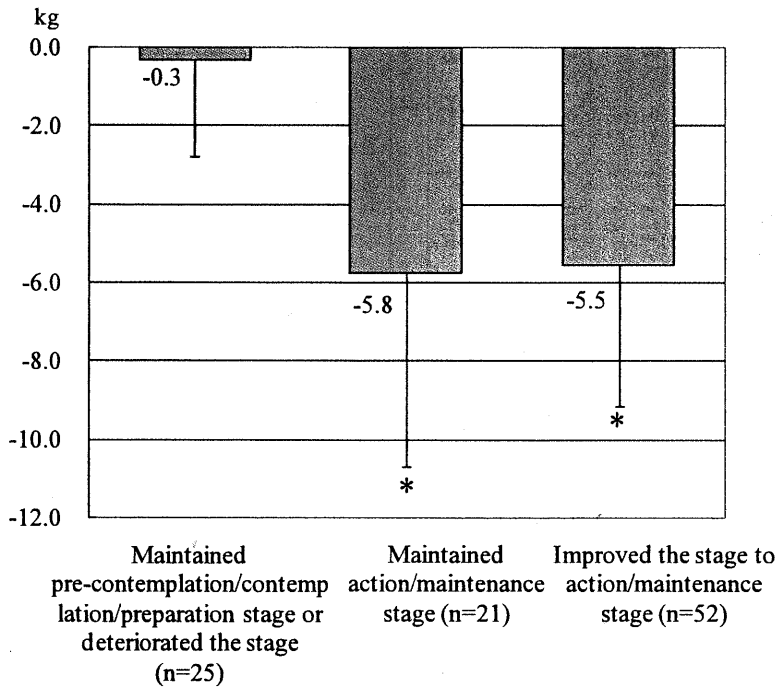

Figure 2. Mean weight change according to the changes in five stages. *Significantly different from the participants who maintained pre-contemplation/contemplation/preparation stage or deteriorated in terms of stage, $p<0.05$. Error bars represent standard deviation.

(that is, at 1, 3, 6, and 9 months) was 98.3%, 98.3%, 97.4% and 95.8%, respectively. The percentage of participants who mailed records to the dietitians at 2, 4, 5, 7, 8, 10 and 11 months were 88.2%, 83.2%, 76.5% ,79.0%, 69.7%, 74.8%, and 65.5%, respectively (data not shown).

DISCUSSION

We conducted a randomized controlled study to evaluate the effect of our behavior weight loss program which placed emphasis on tailored counseling on participants' diet, behavior, body weight and weight maintenance.

Despite one year of intervention, only four participants dropped out and participation rate was high in the intervention group. Behavioral treatment provided motivation essential to maintain adherence to a healthier lifestyle.[32] Rapport-building, which is establishing a harmonious relationship between a therapist and a client, is key to sustaining treatment adherence.[33] In this program, dietitians contacted the participants regularly and each dietitian continuously supported the same participants as much as possible. Thus, these are thought to have promoted rapport-building and prevented dropout. In addition, because we had some spare days at each intervention and the participants could choose the date that suited their convenience, this also contributed to the high participation rate.

Participants in the intervention group showed a mean weight reduction of -5.0 kg (BMI -1.7 kg/m^2) in men and -3.9 kg (BMI -1.6 kg/m^2) in women after the program. In previous studies, Oldroyd *et al.* conducted individual counseling (a total of 105-140 minutes) and the subjects reduced their BMI scores by 0.56 kg/m^2 after 6-month intervention (this indicates 188-250 minutes were needed to reduce BMI by 1.0 kg/m^2).[12] Lindström *et al.* implemented seven individual face-to-face consultations (a total of 210-420 minutes) and overweight subjects showed a -1.6 kg/m^2 BMI reduction after 1 year (requiring 131-262 minutes to reduce BMI by 1.0 kg/m^2). However, in this program, a very-low-calorie diet was used in some cases to boost weight loss.[13] In Japan, Kai *et al.* conducted a 4-month behavioral change intervention, which included lectures, group work and individual counseling (a total of 280 minutes), and obese participants reduced their BMI scores by 1.2 kg/m^2 at the end of the intervention (requiring 233 minutes to reduce BMI by 1.0 kg/m^2).[20] Egawa *et al.* conducted an intervention (a total of 1,080 minutes) consisting of a lecture, group session and individual counseling with goal setting and self-monitoring for 9 months and the intervention group showed a -1.9 kg/m^2 BMI reduction (requiring 568 minutes to reduce BMI by 1.0 kg/m^2).[17] Noda *et al.* reported that a 6-month intensive intervention with individual dietary and exercise counseling (three times a week) with self-monitoring of weight, diet and physical activity led to a weight reduction of -1.9 kg (although the time spent on this intervention was not shown, as many as 72 interventions were conducted during the program).[21] In this program, we had only 5 face-to-face interventions (a total of 250 minutes) consisting of individual counseling and exercise group sessions, and dietitians spent a total of 105 minutes (15 minutes per session, 7 times in all) to check and comment on the participants' records. Because male and female participants showed mean BMI reductions of -1.7 kg/m^2 and -1.6 kg/m^2, respectively, it is estimated that 208 minutes for men and 221 minutes for women were spent to reduce BMI by 1.0 kg/m^2. Considering the time spent on the intervention and participants' BMI reduction in our study, the SCOP program achieved great results with relatively little work.

In the SCOP program, we used several behavioral approaches such as goal setting and self-monitoring. Goal setting was suggested to be effective in focusing the attention of a participant on behavior change.[34] Consistent self-monitoring of weight allowed individuals to notice how specific situations or patterns of behaviors related to body weight changes.[35] Weight monitoring also provides an opportunity for positive reinforcement when changes in behavior correspond to weight loss or avoidance of weight gain.[35] In this program, dietitians supported participants to find problems in their lifestyle and set goals by themselves, and this was thought to have motivated participants to change their behavior. In addition, because participants in this program recorded their weight, daily step counts and implementation of plans and events, linking these to weight change may have led participants to recognize how eating and physical activity behaviors were related to weight loss or gain, and methods to prevent weight gain. In fact, the intervention group improved in terms of various eating and lifestyle behaviors after the program. Women in the intervention group improved "irregularity of eating". It was reported that irregular eating such as eating late at night was positively associated with being overweight/obesity.[36] In the SCOP program, the participants set goals about irregularity of eating (eg "stop eating between meals, including eating at night", etc.) thus, change in this eating behaviors may be associated with weight loss in women.

Along with the change in eating behaviors, men and women in the intervention group increased daily step counts, and men in the intervention group decreased intake of energy and cereals, and increased intake of green and yellow vegetables more than those of the control group. These changes in physical activity and diet that promoted energy expenditure and less energy intake were suggested to enhance participants' weight loss. Although women in the intervention group did not show any significant differences in terms of diet compared with the control group, careful attention is required when interpreting the results; women in the control group improved in terms of diet similar to the intervention group. This indicated that the baseline assessment triggered lifestyle improvements in the female control group, although we did not provide any support to them for one year.

Participants' lifestyle changes were also reflected in the stages of the transtheoretical model.[31] In the intervention group, the participants' stage advanced and 74.5% of the female and male participants were in the action or maintenance stages at the end of the program. Moreover, the mean weight loss of the participants who remained in the action/maintenance stage or who moved to the next stage was significantly greater than that of the participants who remained in the pre-contemplation/contemplation/preparation stages or went back a stage. Although we did not assess the behavioral stage in the control group, these

results indicated that a behavioral approach combined with diet and exercise intervention induced behavioral changes in the participants and that practicing a desirable lifestyle led to weight loss.

We followed the participants for one year after the program. At the 24-month assessment, the participants still maintained significantly lower weight, BMI, waist circumference and visceral fat compared with baseline values. According to NIH Technology Assessment Conference Panel, one-third to two-thirds of the lost weight is regained within 1 year.[37] In addition, it was reported that participants who received behavior therapy regained approximately 70% of lost weight during one year of follow-up.[15] In this study, although the participants regained their weight, 28% of lost weight for men and 37% for women, the degree of weight regained was similar or slightly less than the results of previous studies. At 24 months, intake of green and yellow vegetables had returned to the baseline level, but the participants still maintained a lower energy intake and the improved eating behaviors. The one unfortunate feature is that both men and women could not maintain the increase of walking step counts. Being physically active was suggested to be one of the factors that related to long-term weight maintenance.[38] Thus, methods to maintain improved physical activity over the long term is an issue for the future, and to that end, examination of the cause of a decrease of physical activity is needed.

There are several limitations to this study. First, it was possible that participants in the control group changed their lifestyles after the baseline assessment and this may have affected the results. Second, we could not evaluate whether or not the participants totally met their objectives, because the objectives varied for each participant, and the participants changed objectives according to their progress during the previous month. Third, because stages of change were evaluated only in the intervention group, we could not compare the results between the intervention and control groups. In addition, we could not assess the stages at 24 months. However, we showed that participants' stage changed following intervention and the degree of weight loss was different by stage.

In conclusion, the findings of this study suggested that a behavioral approach which placed emphasis on tailored counseling was effective for the advancement of self-management, behavior modification, losing weight and weight maintenance for both men and women. Because modified variables were different in terms of sex, sex-specific approaches may be necessary when losing weight and for weight maintenance.

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AUTHOR DISCLOSURES

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Appendix. Example of self-management sheet

Month		August						
Day		1	2	3	4	5	6	7
	kg	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Goal of weight loss -1 kg Goal of number of walking steps 8500 steps	80.0 79.5 79.0 78.5 78.0 77.5							
Body weight (kg)		79.6	79.3	78.5	78.8	79.3	79.1	79.0
Number of walking steps (steps)		8679	9823	8795	7568	7326	10182	8543
Goal	1. To stop drinking alcohol	○	○	○	○	×	○	○
	2. To eat more vegetables	○	×	×	○	×	○	○
Event						Drinking party		

○: Participant accomplished the goal. ×: Participant did not accomplish the goal.

Original Article

Behavioral change during weight loss program and one-year follow-up: Saku Control Obesity Program (SCOP) in Japan

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減重計畫期間及一年追蹤期的行為改變：日本的 Saku 控制肥胖計畫(SCOP)

此研究為評估行為改變的效應，在行為改善對策中強調個別的行為諮詢、飲食、減重、及體重的維持。有 235 位過重或肥胖的日本成人，參與為期一年的隨機對照試驗。其中介入組(119 位)接受個人諮詢，利用行為改善對策，儘可能依據參與者個別情況，建議其飲食及體能活動的改變。一年後，介入組顯著比對照組下降更多體重(男性介入組減 5 公斤，對照組增 0.1 公斤；女性則兩組分別減 3.9 公斤與 0.2 公斤)。與對照組相比，介入組的男性顯著地減少總能量、穀類及乳製品的攝取，同時增加綠色及黃色蔬菜的攝取；而介入組女性則顯著地減少乳製品的攝取。在行為方面，相較於對照組，介入組男女性皆增加走路的步數，另外介入組女性改善了不規律的飲食習慣。行為的改變與體重降低具有相關；介入組的參與者若保持在行動或持續行動，或進展至行動階段，相較於仍處於未考慮、考慮或準備階段或退回至行動前階段的參與者，體重下降較顯著。試驗期後追蹤一年，介入組顯著比對照組，維持較低體重、低能量攝取及改善不規律飲食習慣。本研究的行為改善對策，促使飲食及行為的改變、體重減輕並且維持。由於男女性改善的變項不同，顯示可能需要依性別，採取專一的行為改善對策。

關鍵字：行為治療、體重改變、隨機對照試驗、追蹤研究、飲食

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