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Effect of Six Months Lifestyle Intervention in Japanese Men with Metabolic Syndrome: Randomized Controlled Trial

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Abstract: Effect of Six Months Lifestyle Intervention in Japanese Men with Metabolic Syndrome: Randomized Controlled Trial: Akiko Nanri, *et al.* Department of Epidemiology and Prevention, International Clinical Research Center, National Center for Global Health and Medicine—Objectives: The prevalence of metabolic syndrome (MS) has been remarkably increasing worldwide. However, few studies have examined the effect of lifestyle intervention among subjects with MS. We investigated the effect of a six-month lifestyle modification program on the prevalence of MS and its associated biomarkers among Japanese men with MS. **Methods:** Subjects were randomly assigned to either the intervention (n=53) or control (n=54) group. Subjects in the intervention group received a lifestyle modification program focused on exercise and diet behavior from a trained occupational health nurse at the baseline and at one and three months. The effect of intervention was assessed by differences in changes in the prevalence of MS, its components and associated biomarkers between the two groups. **Results:** Of the 107 participants, 102 completed the survey at the end of six months (intervention group, n=49; control group, n=53). During the study period, the prevalence of MS decreased to 65.3% and 62.3% in the intervention group and control group, respectively. However, the difference between the two groups was not statistically significant (p=0.75). A significant reduction in body weight, waist circumference and glycated hemoglobin was observed in the intervention group compared with the control group. In the intervention group, time spent on physical activity was increased by nearly one hour per week, and the intakes of cereals and sugar and sweeteners were significantly decreased. **Conclusions:** Although the tailor-made lifestyle modification program among men with MS did not provide an additional benefit in decreasing the prevalence of MS, it may help weight control and improve glucose metabolism.
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Key words: Intervention, Lifestyle, Metabolic syndrome

Metabolic syndrome (MS), which consists of abdominal obesity, hypertension, hyperglycemia and hyperlipidemia, is associated with increased risk of type 2 diabetes and cardiovascular disease. The prevalence of MS has been remarkably increasing worldwide over the past two decades[1]. In Japan, in particular, the prevalence of MS was 26.9% for adult men and 9.9% for adult women in 2007[2]. Therefore, an effective strategy against MS is urgently needed.

Lifestyle modification against overweight, physical inactivity and an atherogenic diet have been recommended as a foundation for management of MS[1]. A few controlled-intervention studies among subjects with MS have examined the effect of lifestyle intervention. In a Korean study among subjects with MS[3], the prevalence of MS did not significantly differ between intervention and control groups after six months. On the other hand, in an Italian study among subjects with MS and those who had two MS components and a high level of high-sensitivity C-reactive protein (hs-CRP)[4], the intervention group showed a significantly greater reduction in the prevalence of MS than the control group. In some Japanese studies, lifestyle intervention in adults who had an unfavorable profile in terms of cardiometabolic risk factors[5–7] has been shown to improve components of MS. To our knowledge, however, no study has examined the effect of intervention among subjects who met the Japanese definition of MS in Japan.

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Here, to examine the effect of lifestyle intervention on MS, its components and its associated biomarkers including glycated hemoglobin and hs-CRP, we conducted a six-month lifestyle intervention study among Japanese men with MS.

Subjects and Methods

Study design

We conducted a six-month randomized controlled trial to investigate the effect of a behavioral modification program among Japanese men with MS. The protocol of the study was approved by the ethics committee of the National Center for Global Health and Medicine, and written informed consent was obtained from each participant. This study was registered in the UMIN Clinical Trials Registry (trial number: UMIN000000915).

Subjects

Study subjects were recruited from among male employees of a company in Kanagawa Prefecture, Japan (Fig. 1). Of the 3,277 men who participated into worker health examinations from September 2007 through May 2008, 740 were diagnosed, according to the Japanese definition[8], as having MS with waist circumference of ≥85 cm plus two or more of the following factors: 1) fasting blood glucose of ≥110 mg/d*l* and/or medication for diabetes, 2) high-density lipoprotein (HDL) cholesterol of <40 mg/d*l* and/or triglyceride of ≥150 mg/d*l* and/or medication for dyslipidemia and 3) systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥85 mmHg and/or medication for hypertension. Of these, 225 subjects who met any of the following criteria were excluded: 1) subjects who reported a history of serious disease including cancer, cerebrovascular disease and myocardial infarction (n=24), 2) subjects who received therapy of diet and exercise or medication for type 2 diabetes treatment or subjects with fasting blood glucose of ≥140 mg/d*l* in this health check-up (n=138), 3) subjects with a systolic blood pressure ≥180 mmHg and/or diastolic blood pressure ≥110 mmHg and/or triglyceride ≥1,000 mg/d*l* (n=14), 4) subjects unable to exercise due to an orthopedic problem (n=8) and 5) others (n=41). We sent the remaining 515 men with MS an invitation letter asking them to participate in the study through the internal mailing system of the company. Of these, 405 declined to participate or did not respond. Finally, 110 men agreed to participate and were assigned to either the intervention or control group by using block randomization (intervention group, n=55; control group, n=55). Because three subjects were found to not satisfy the MS criteria at study entry, they were excluded from the present analysis (intervention group, n=2; control group, n=1).

Intervention

For participants in the intervention group, a lifestyle modification program based on behavioral theory was

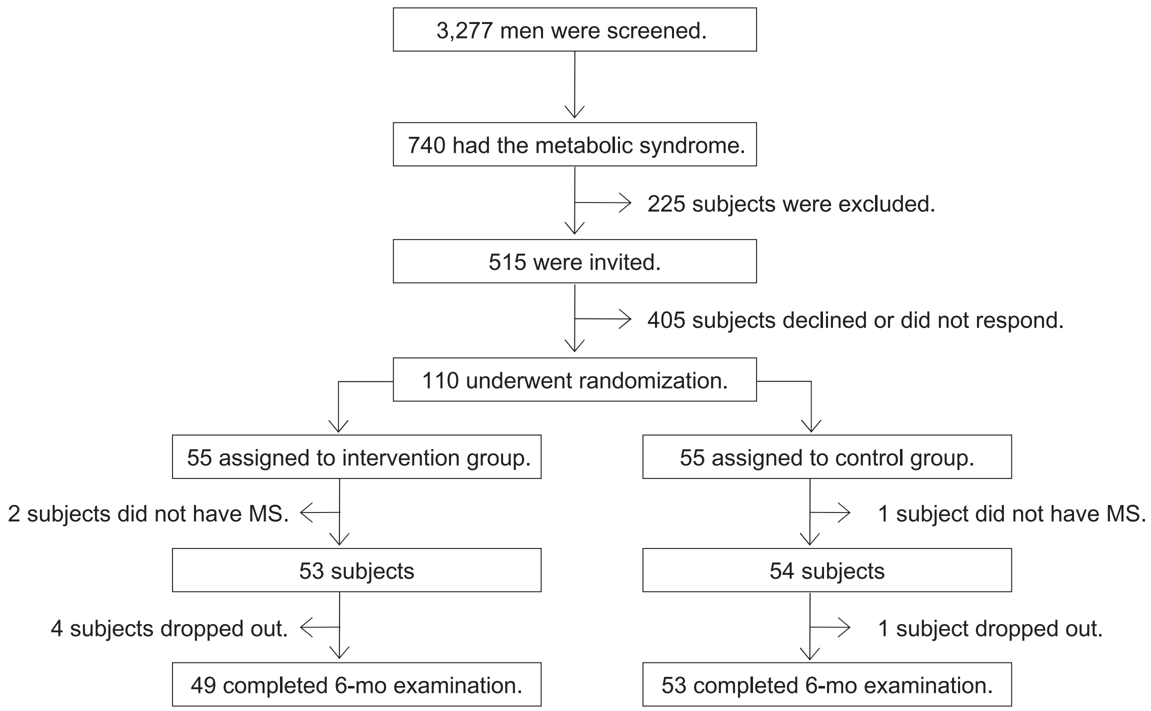

Fig. 1. Flow chart of study protocol.

provided at the baseline and at one and three months. At the baseline, a trained occupational health nurse and the participants discussed about their unfavorable health-related lifestyles that might have caused weight increase. Then, with advice from the health nurse, the participants set a goal for their body weight in six months and three to five goals for health-related behaviors including both physical activity and diet. To facilitate behavior change, each participant received a pedometer, weight scale, leaflet and diary to record behavioral performance and body weight. The participant was instructed to measure his body weight every morning and evening during the study period and record it, together with whether or not he performed the targeted behaviors, on a specified sheet or his personal diary. At one month, the participant attended a follow-up meeting with the health nurse, who confirmed whether and how the participant had complied with targeted behaviors and checked whether the participant had experienced any health and safety problem related to behavioral changes. The goals of lifestyle behaviors set at baseline were modified, if necessary. Additionally, the health nurse recommended to increase intakes of vegetables, fruit and dairy products and to consume alcohol in moderation. At three months, a third meeting was held in a manner similar to the second one and to encourage the participants to maintain their targeted behaviors during the study period. Participants in the control group were given standard health guidance by an occupational health nurse using a leaflet at the baseline.

Measurements

At the time of health guidance at baseline and during the month before the six-month health guidance, participants completed a health survey consisting of anthropometric and blood pressure measurements and a lifestyle questionnaire and were subjected to venous blood drawing and urine sampling. Body height and body weight were measured using an automated scale (AD-6225A; A&D, Tokyo, Japan), and body mass index was calculated as weight in kilograms divided by squared height in meters. Waist circumference was measured with a measuring tape at the umbilical level by laboratory technicians. Blood pressure was measured using an automated sphygmomanometer (TM-2655P; A&D) after the subjects had rested for 15 min. Body height, body weight, waist circumference and blood pressure at the baseline were obtained from worker health examination data. Blood was taken in three vacuum tubes; two were immediately sent to a laboratory to measure biochemical data (described below), and the remaining one was centrifuged, with the serum being separated in an aliquot and stored in a deep freezer at –80°C. Blood concentrations of total cholesterol, HDL-cholesterol, triglyceride, glucose and glycated hemoglobin were measured by enzymatic assay, and hs-CRP was measured using the latex agglutination nephelometry method at an external laboratory (Mitsubishi Chemical Medience Corporation, Tokyo, Japan). Because most participants attended baseline health guidance in a nonfasting condition, we used biochemical data (except glycated hemoglobin and hs-CRP) that were measured in a fasting condition at the most recent health examination (within 3 months before the initial health guidance) as the baseline data. Physical activity, smoking status and alcohol consumption were ascertained by using a self-administered survey questionnaire. Diet during the preceding one-month period was assessed using a validated 56-item brief-type self-administered diet history questionnaire (BDHQ)[9], and dietary intake for energy and selected nutrients were estimated using an ad hoc computer algorithm for the BDHQ, with reference to the Standard Tables of Food Composition in Japan[10, 11]. According to the validation study of the BDHQ using 16-day weighed dietary records as the gold standard, Pearson correlation coefficients for food groups in 92 men and 92 women of 31–76 yr of age were 0.21 to 0.83 and 0.14 to 0.82, respectively[12].

Endpoints

The primary outcome of the present study was the prevalence of MS at six months. Secondary outcomes included the change in the prevalence of each component of MS including abdominal obesity, dyslipidemia, hypertension and hyperglycemia and the mean change in metabolic parameters including waist circumference, body weight, body mass index, systolic blood pressure, diastolic blood pressure, total cholesterol, HDL cholesterol, triglyceride, blood glucose, glycated hemoglobin and change in hs-CRP between the baseline and six-month surveys.

Statistical analysis

Analysis was performed according to intention-to-treat. Data are presented as means ± standard deviation or proportions. For variables other than triglyceride, hs-CRP, time spent on physical activity and dietary intake, baseline differences in means and proportions between groups were assessed by using an independent *t*-test and chi-square test or Fisher exact test, respectively. Differences between the baseline and six months in each group were tested by using a paired *t*-test for continuous variables and chi-square test for categorical variables. Two-factor repeated-measures analysis of covariance (ANCOVA) was performed to assess time × group interactions, with time and intervention as factors. For triglyceride, hs-CRP, time spent on physical activity and dietary intake, for which the data were highly skewed, the differences between groups and between the baseline and at six months were assessed by using the Wilcoxon rank-sum test. Two-sided p values of less than 0.05 were regarded as statistical significant. All analyses were performed with the Statistical Analysis System (SAS) software version 9.1 (SAS Institute, Cary, NC, USA).

Results

Of the 107 participants at the baseline, 102 completed the six-month survey (intervention group, n=49; control group, n=53) (Fig. 1). The mean age of the 102 participants was 53.2 (standard deviation: 6.8) yr old (range: 38–68). The baseline characteristics of the two groups are shown in Table 1. Subjects who had three components of MS were more frequently observed in the intervention group compared with the control group (30.6 versus 13.2%; p=0.03). For other characteristics including age, body mass index, waist circumference, blood pressure, blood lipid, blood glucose, glycated hemoglobin and hs-CRP, there were no significant differences between the two groups.

Changes in physical activity, dietary intake, smoking and alcohol consumption between the baseline and six-month surveys are shown in Table 2. During the six-month period, mean time spent on physical activity was significantly increased, by 57 min per week, in the intervention group (p<0.001), whereas it did not change in the control group (p=0.99). In particular, in the intervention group, walking, jogging, golf, weight training and swimming were common. Alcohol consumption was significantly decreased in both groups (p=0.048 in the intervention group and

Table 1. Baseline characteristics of subjects

	Intervention	Control	p value[a]
Number of subjects	49	53	
Age (yr)	53.7 (6.1)[b]	52.8 (7.4)	0.55
Body weight (kg)	76.1 (7.7)	73.7 (7.5)	0.12
Body mass index (kg/m^2)	26.0 (2.4)	25.6 (2.3)	0.39
Waist circumference (cm)	92.1 (5.1)	92.2 (4.9)	0.96
Systolic blood pressure (mmHg)	135.7 (11.4)	135.6 (14.3)	0.98
Diastolic blood pressure (mmHg)	87.9 (9.4)	88.4 (7.9)	0.79
Total cholesterol (mg/d*l*)	221.6 (33.8)	229.6 (26.9)	0.19
HDL cholesterol (mg/d*l*)	52.7 (12.6)	57.2 (14.9)	0.10
Triglyceride (mg/d*l*)	202.3 (120.3)	181.6 (63.3)	0.92
Glucose (mg/d*l*)	109.6 (14.2)	106.5 (13.2)	0.26
Glycated hemoglobin[c] (%)	5.8 (0.5)	5.7 (0.5)	0.40
High-sensitivity CRP[d] (mg/d*l*)	0.078 (0.086)	0.077 (0.083)	0.97
Components of metabolic syndrome[e] (%)			
Abdominal obesity	100	100	
Dyslipidemia	73.5	81.1	0.35
Hypertension	98.0	86.8	0.06
Hyperglycemia	59.2	45.3	0.16
Number of components[f] (%)			
2	69.4	86.8	0.03
3	30.6	13.2	

CRP: C-reactive protein.
[a]Based on an indepentent t-test for continuous variables excluding triglycerides and CRP, for which the Wilcoxon rank-sum test was used, and the chi-squared test and Fisher exact test for categorical variables. [b]The figures in the table are means (standard deviation) unless otherwise stated. [c]Measurements of glycated hemoglobin were transformed from Japan Diabetes Society into National Glycohemoglobin Standardization Program values. [d]Subjects with high-sensitivity CRP of ≥0.5 mg/d*l* were excluded (intervention group, n=3; control group, n=1). [e]Abdominal obesity: waist circumference of ≥85 cm. Dyslipidemia: HDL cholesterol of <40 mg/d*l* and/or triglycerides of ≥150 mg/d*l*. Hypertension: systolic blood pressure of ≥130 mmHg and/or diastolic blood pressure of ≥85 mmHg and/or current medical care for hypertension. Hyperglycemia: fasting blood glucose of ≥110 mg/d*l*. [f]Number of subjects having dyslipidemia, hypertension or hyperglycemia.

Table 2. Change in dietary intake, physical activity and smoking status between the baseline and six-month follow-up surveys

	Intervention group (n=49)				Control group (n=53)			
	Baseline	At six months	Difference[a]	*p* value[b]	Baseline	At six months	Difference[a]	*p* value[b]
Physical activity (min/wk)	148 (172)[c]	205 (172)	57.0	<0.001	124 (116)	130 (160)	5.4	0.99
Current smoker (%)	32.7	30.6		0.83	24.5	22.6		0.82
Alcohol consumption (gou/day)	1.6 (1.4)	1.3 (1.2)	–0.23	0.048	1.5 (1.3)	1.3 (1.3)	–0.16	0.01
Dietary intake (g/day)								
Cereal	490.3 (155.4)	420.3 (128.9)	–70.1	0.002	462.1 (151.4)	434.8 (166.3)	–27.4	0.21
Potato	39.0 (39.8)	44.3 (44.5)	5.3	0.61	41.1 (37.2)	43.4 (38.1)	2.3	0.70
Pulse	60.8 (30.1)	64.5 (39.6)	3.8	0.96	66.5 (41.0)	68.5 (38.2)	2.0	0.55
Dark green and yellow vegetable	79.2 (65.6)	86.6 (60.8)	7.4	0.54	73.2 (46.4)	79.3 (49.4)	6.1	0.10
Other vegetable	142.7 (80.5)	138.8 (78.7)	–3.9	0.75	137.9 (73.3)	152.8 (84.5)	15.0	0.28
Fruit	69.4 (59.5)	56.2 (45.6)	–13.2	0.17	62.3 (62.9)	70.8 (66.3)	8.5	0.06
Fish and shellfish	82.5 (41.9)	92.5 (51.1)	10.0	0.18	81.4 (47.1)	96.4 (65.6)	15.0	0.047
Meat	66.2 (32.8)	66.1 (36.6)	–0.1	0.96	67.2 (34.1)	68.6 (32.4)	1.4	0.58
Egg	35.0 (25.9)	33.1 (25.7)	–1.9	0.53	35.4 (25.0)	34.2 (24.6)	–1.2	0.70
Milk	121.0 (111.6)	122.2 (78.4)	1.2	0.43	134.2 (95.9)	141.7 (107.5)	7.4	0.48
Fat and oil	22.3 (10.7)	21.0 (10.1)	–1.3	0.31	22.6 (9.4)	23.7 (9.7)	1.2	0.22
Confectionery	32.2 (34.4)	26.9 (26.6)	–5.2	0.11	31.7 (27.7)	31.1 (22.6)	–0.6	0.60
Sugar and sweetener	7.3 (6.9)	4.7 (4.3)	–2.63	0.002	6.8 (7.6)	5.9 (5.8)	–0.8	0.35
Soft drink	55.8 (99.3)	35.2 (47.1)	–20.5	0.53	49.4 (68.3)	52.5 (90.0)	3.1	0.52

[a]Difference between the baseline and six-month follow-up surveys. [b]Based on the Wilcoxon rank-sum test for paired samples for continuous variables and the chi-squared test for categorical variables. [c]The figures in the table are means (standard deviation) unless otherwise stated.

p=0.01 in the control group). In the intervention group, the intakes of cereals and sugar and sweeteners were significantly decreased; of note, rice intake substantially decreased from 357 to 297 g (*p*=0.004). In the control group, fish and shellfish intake was increased. Vegetables, fruit and milk intakes as well as smoking did not change in either group.

Changes in the prevalence of MS and its components during the six-month period are shown in Table 3. At six months, the prevalence of MS did not significantly differ between the two groups: it was 65.3% in the intervention group and 62.3% in the control group (*p*=0.75). Body weight and waist circumference were decreased by 2 kg and 2.5 cm, respectively, in the intervention group and by 0.3 kg and 1.1 cm, respectively, in the control group after six months. The changes were significantly larger in the intervention group than in the control group. Glycated hemoglobin was also significantly decreased in the intervention group compared with the control group: it was –0.17% in the intervention group and –0.04% in the control group (*p*=0.005). Although the prevalence of hypertension in the intervention group and the prevalence of dyslipidemia in the control group were significantly decreased at six months, there were no statistically significant differences with regard to these changes between the two groups. Hs-CRP concentrations were not significantly decreased in either group.

Discussion

In this randomized control trial of lifestyle intervention among Japanese men with MS, a six-month lifestyle modification program did not decrease the prevalence of MS more than standard health guidance did. However, compared with the control group, body weight, waist circumference and glycated hemoglobin were significantly decreased in the intervention group. During the six months, time spent on physical activity was increased, and intake of cereals and sugar and sweeteners was decreased in the intervention group. To our knowledge, this is the first study among Japanese adults with MS to assess the effect of lifestyle modification intervention.

In the present study, although the prevalence of MS decreased in both the intervention and control groups, the size of the reduction did not significantly differ between the two groups. A similar result was reported in a Korean study of 52 women with MS[3)]; the prevalence of MS decreased to 55% in a six-month lifestyle modification intervention group and 57% in the control group. In our study, body weight, waist circumference and glycated hemoglobin were significantly decreased in intervention group compared with the control group, whereas the changes in blood pressure, total cholesterol, HDL cholesterol, triglycerides and glucose did not differ between the two groups. This finding is also consistent with some previous studies. In the Korean study[3)], blood pressure, fast-

Table 3. Change in the prevalence of metabolic syndrome and cardiometabolic risk factors between the baseline and six-month follow-up surveys

	Intervention group (n=49)				Control group (n=53)				p value[c]
	Baseline	At six months	Difference[a]	p value[b]	Baseline	At six months	Difference[a]	p value[b]	
Metabolic syndrome (%)	100	65.3		<0.001	100	62.3		<0.001	
Components of metabolic syndrome[d] (%)									
Abdominal obesity	100	79.6		<0.001	100	90.6		0.02	
Dyslipidemia	73.5	63.3		0.28	81.1	49.1		<0.001	
Hypertension	98.0	83.7		0.01	86.8	86.8		1.00	
Hyperglycemia	59.2	44.9		0.16	45.3	47.2		0.85	
Number of components[e] (%)									
0	0.0	2.0			0.0	1.9			
1	0.0	26.5			0.0	28.3			
2	69.4	49.0			86.8	54.7			
3	30.6	22.4			13.2	15.1			
Mean of number of components	2.3 (0.5)[f]	1.9 (0.8)	–0.4	<0.001	2.1 (0.3)	1.8 (0.7)	–0.3	0.002	0.50
Body weight (kg)	76.1 (7.7)	74.1 (8.1)	–2.01	<0.001	73.7 (7.5)	73.4 (8.1)	–0.28	0.29	<0.001
Body mass index (kg/m^2)	26.0 (2.4)	25.3 (2.7)	–0.67	<0.001	25.6 (2.3)	25.5 (2.5)	–0.10	0.26	0.001
Waist circumference (cm)	92.1 (5.1)	89.6 (5.9)	–2.51	<0.001	92.2 (4.9)	91.1 (5.5)	–1.10	0.004	0.02
Systolic blood pressure (mmHg)	135.7 (11.4)	133.8 (13.5)	–1.86	0.34	135.6 (14.3)	136.1 (15.9)	0.43	0.82	0.40
Diastolic blood pressure (mmHg)	87.9 (9.4)	88.2 (8.9)	0.31	0.81	88.4 (7.9)	91.2 (11.4)	2.79	0.03	0.17
Total cholesterol (mg/d*l*)	221.6 (33.8)	209.6 (29.7)	–12.02	0.003	229.6 (26.9)	217.0 (31.1)	–12.58	<0.001	0.91
HDL cholesterol (mg/d*l*)	52.7 (12.6)	53.5 (11.0)	0.74	0.47	57.2 (14.9)	55.5 (14.0)	–1.73	0.06	0.07
Triglyceride (mg/d*l*)	202.3 (120.3)	164.9 (89.9)	–37.33	0.007	181.6 (63.3)	143.5 (52.8)	–38.13	<0.001	0.96
Glucose (mg/d*l*)	109.6 (14.2)	108.8 (14.2)	–0.82	0.56	106.5 (13.2)	107.9 (13.9)	1.36	0.23	0.23
Glycated hemoglobin[g] (%)	5.8 (0.5)	5.6 (0.4)	–0.17	<0.001	5.7 (0.5)	5.7 (0.4)	–0.04	0.12	0.005
High-sensitivity CRP[h] (mg/d*l*)	0.078 (0.086)	0.072 (0.087)	–0.006	0.74	0.077 (0.083)	0.066 (0.063)	–0.011	0.33	0.76

CRP: C-reactive protein.
[a]Difference between the baseline and six-month follow-up surveys. [b]Based on a paired *t*-test for continuous variables excluding triglycerides and CRP, for which the Wilcoxon rank-sum test for paired samples was used, and the chi-squared test for categorical variables. [c]Based on two-factor repeated-measured analysis of covariance. [d]Abdominal obesity: waist circumference of ≥85 cm. Dyslipidemia: HDL cholesterol of <40 mg/d*l* and/or triglycerides of ≥150 mg/d*l*. Hypertension: systolic blood pressure of ≥130 mmHg and/or diastolic blood pressure of ≥85 mmHg and/or current medical care for hypertension. Hyperglycemia: fasting blood glucose of ≥110 mg/d*l* and/or current medical care for diabetes. [e]Number of subjects having dyslipidemia, hypertension or hyperglycemia. [f]The figures in the table are means (standard deviation) unless otherwise stated. [g]Measurements of glycated hemoglobin were transformed from Japan Diabetes Society into National Glycohemoglobin Standardization Program values. [h]Subjects with high-sensitivity CRP of ≥0.5 mg/d*l* at baseline or six months were excluded (intervention group, n=3; control group, n=2).

ing glucose, HDL cholesterol, and triglycerides were not significantly improved in the intervention group compared with the control group, in spite of a greater reduction in body weight and waist circumference observed in the intervention group[3]. In a US study among 279 adult men and women with MS, only body weight and waist circumference were significantly decreased by a 12-month computer-based intervention of physical activity and diet[13]. Similarly, Japanese studies among subjects who had at least one component of MS have also observed significant decreases in body weight, fasting glucose or glycated hemoglobin in intervention groups; however, a beneficial effect of intervention on blood pressure, total cholesterol or triglyceride has not been observed[5–7]. Among persons with MS, lifestyle intervention was focused on weight control, although physical activity and diet may have a favorable effect on body weight, waist circumference and glucose metabolism but have no or limited effect on blood pressure and lipid profile.

The observed decrease in body weight, waist circumference and glycated hemoglobin in the intervention group might be ascribed to the changes in lifestyle including increased physical activity and decreased intake of cereals (mainly rice) and sugars and sweeteners. In some controlled studies among overweight or obese subjects, an intervention of increase physical activity significantly decreased body weight and waist circumference[14–16]. White rice, the most highly consumed cereal in Japan, has a high glycemic index[17], which has been shown to be positively associated with body mass index, waist circumference and glycated hemoglobin[18–20]. Moreover, white rice intake was associated with increased risk of type 2 diabetes[21]. Sugar and sweeteners were mainly derived from added sugar to coffee and tea, soft drinks, and sweet foods. A cross-sectional study observed that glycated hemoglobin was higher among participants who added sugar to coffee or tea than those who did not add sugar[22]. Moreover, a dietary pattern characterized by high intakes of foods including sweets and desserts was associated with increased risk of type 2 diabetes[23–25]. Thus, a combination of increased physical activity and a low-calorie and low-glycemic index diet might have contributed to a decrease in body weight, waist circumference and glycated hemoglobin in the present intervention group.

A major strength of the present study is its randomized controlled design, with most subjects having completed the six-month survey. Moreover, tailor-made interventions can achieve better compliance to self-set goals for health-related behaviors than conventional interventions. The present study also had some limitations. First, although we observed a favorable effect of lifestyle modification on body weight, waist circumference and glycated hemoglobin, it is unclear which component of lifestyle change was the most effective in improving these outcomes. Second, we did not obtain detailed information on the compliance among subjects in the intervention group. However, we confirmed changes in physical activity and dietary intake using a questionnaire. Third, 79% of the subjects refused to participate in the study. Although there might be differences in characteristics between subjects who participated in this study and those who refused, we could not compare the characteristics because we could not obtain information among subjects who refused to participate in the study. Because the study subjects might have been more health consciousness than nonparticipants, the possibility of selection bias could not be denied. Fourth, in this study, although participants were assigned to either the intervention or control group by using block randomization, the prevalence of subjects with two or three components of MS significantly differed between the two groups at baseline. It is possible that the randomization might not have been successfully performed. However, the mean of systolic blood pressure, diastolic blood pressure, waist circumference, total cholesterol, HDL cholesterol, triglycerides and glucose did not differ between the two groups at baseline. Fifth, although the tailor-made lifestyle modification program improved some health indicators including lifestyle and body weight, the benefit of such intensive intervention needs to be assessed in terms of cost effectiveness. Finally, because the study subjects were male employees of a company in Japan, the present findings may not be generalized to women or men with a different background.

In conclusion, a six-month lifestyle modification program did not lead to a greater decrease in the prevalence of MS compared with standard health guidance. However, waist circumference, body weight and glycated hemoglobin were significantly decreased in the intervention group compared with the control group. These results suggest that a tailor-made lifestyle modification program may have a beneficial effect on abdominal obesity and glycemic control. Further investigations are required to confirm whether the effect of lifestyle modification is sustained after an extended follow-up period.

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