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Original Article

Effects of a Japan Diet Intake Program on Metabolic Parameters in Middle-Aged Men:

A Pilot Study

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Aim: We conducted a pilot study to clarify the effects of the Japan Diet nutritional education program on metabolic risk factors for atherosclerotic cardiovascular disease in middle-aged men who were brought up in the westernized dietary environment of modern Japan.
Methods: Thirty-three men, 30–49 years of age, attended a nutrition education class to learn food items and recommended volumes comprising the Japan Diet (more fish, soybeans and soy products, vegetables, seaweed, mushrooms and unrefined cereals, and less animal fat, meat and poultry with fat, sweets, desserts and snacks, and alcoholic drinks), and were encouraged to consume the Japan Diet for 6 weeks. Anthropometric and biochemical parameters were measured and 3-day weighted dietary records were kept before and at completion of the intervention.
Results: Ninety-one percent of participants showed improvements in more than one cardiovascular risk factor after 6 weeks. Body weight, serum low density lipoprotein (LDL) cholesterol, malondialdehyde modified (MDA)-LDL and triglyceride concentrations decreased significantly, while high density lipoprotein cholesterol was unchanged. Fish, soy, and sum of seaweed, mushrooms and konjak intakes doubled, and green and yellow vegetable intakes also increased as compared to baseline. Meanwhile, intakes of refined cereals, meat and poultry, sweets, desserts and snacks, and margarine and shortening decreased. Total energy, lipid, and saturated and monounsaturated fatty acid intakes decreased, while n-3 polyunsaturated fatty acid, dietary fiber, beta-carotene, vitamins D and K, potassium, and magnesium increased, with no change in sodium intake.
Conclusions: The Japan Diet is suggested to improve atherosclerotic cardiovascular disease risk factors in middle-aged Japanese men.
The clinical trial registration number: UMIN000020639.

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Key words: Japan Diet, Soy, Fish, Seaweed, MDA-LDL

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Introduction

Primary prevention of cardiovascular disease risks such as obesity, dyslipidemia, hypertension and impaired glucose tolerance (diabetes) is an urgent global issue. Habitual consumption of the traditional Japanese diet during the 1960s and 70s was recognized as providing protection from cardiovascular disease, as demonstrated in the Seven Countries study[1-4].

The characteristic features of this diet included consuming more fish and other seafood products, and soy, as well as less animal meat, poultry and dairy foods than in Western countries, resulting in low energy, saturated fatty acid (SFA) and cholesterol intakes with high dietary fiber consumption. Thereafter, evidence of the efficacy of higher intakes of fish and plant foods was reconfirmed, with the benefits of reduced intakes of refined carbohydrates and animal fat on coronary artery disease prevention being reported in Japanese cohort studies conducted in the last two decades of the 20th century[5, 6]. Thus, the Japan Atherosclerosis Society recommended the so-called Japan Diet for the prevention of atherosclerotic cardiovascular diseases in its guidelines[7].

However, the Japanese lifestyle and social environment, including familial dynamics, have changed markedly with westernization and diversification over the past four decades[8, 9], making it difficult to prepare daily meals consistent with the Japan Diet concept. In fact, animal meat consumption has risen, while intakes of fish and plant foods have steadily decreased. Therefore, a simple and reliable educational program designed to make eating according to the Japan Diet a lifelong habit is urgently needed.

The Mediterranean and Dietary Approach to Stop Hypertension (DASH) Diet patterns are recommended in the Dietary Guidelines as an effective means of reducing the onset of and death from diet-related chronic diseases with numerous studies supporting this approach[10]. A prospective study is now necessary to provide corroborating evidence and to motivate implementing the Japan Diet as a therapeutic anti-atherogenic eating pattern.

Aim

We conducted a single arm pilot study to obtain preliminary data on the effects of the Japan Diet nutritional education program, and the practical challenges of designing a randomized clinical trial for this diet. We aimed to clarify the effects of the Japan Diet on risk factors for atherosclerotic cardiovascular disease in men 30–49 years of age who had been brought up in the highly westernized dietary environment of modern Japan.

Methods

Study Design and Subjects

The study period was 6 weeks in a single arm design. Sample size was calculated using A'Hern's formula[11]. For the Japan Diet to be regarded as effectively improving metabolic disorders, we expected a success rate of at least 90%. A success rate of 70% or less was taken to indicate failure to improve atherosclerotic parameters. With 0.05 for the alpha and 0.20 for the beta error, 28 participants were calculated to be required to allow assessment of whether the proportion of participants with a successful intervention outcome was below $<$70% or $>$90%. The necessary sample size was 33 subjects, taking possible drop-outs into consideration.

The participants were recruited via e-mail and posters. Inclusion criteria were male gender, age between 30 and 49 years, a body mass index (BMI) over 22 kg/m^2, and non-smoker status. As serum cholesterol concentrations vary with menstrual cycle phases, women were excluded. Participants were excluded if a disease had been detected at their most recent medical check-up and treated with medication. Users of dietary supplements or health food products were also excluded. After being given a detailed explanation of the program, 34 subjects consented to participate.

The present study was conducted according to the guidelines of the Declaration of Helsinki, and all procedures were approved by the ethics committee of Japan Women's University (No. 209). Written informed consent was obtained from all subjects prior to participation. The clinical trial registration number is UMIN000020639.

Intervention Program

Participants attended a one-hour educational session concerning coronary artery disease risk factors and preventive lifestyle strategies, focusing on easy ways to consume the foods classified as constituting the Japan Diet. The group work session involved 1) calculating ideal body weight and comparing this value to the subjects' current body weights, 2) calculating energy and nutrient intakes based on typical dishes consumed habitually and comparing the results with recommended nutrient intakes, 3) learning food items and recommended volumes comprising the Japan Diet (more fish, soybeans and soy products, vegetables, seaweed, mushrooms, konjak and unrefined cereals, and less animal fat, meat and poultry with fat, sweets, desserts and snacks, and alcoholic drinks), and 4) calculating the energy and nutrient intakes obtained from the participants' selected dishes for the Japan Diet and comparing these values to the recommended nutrient intakes. Then, the participants were encouraged to set goals and devise action plans aimed at changing their dietary behaviors. Each participant was required to record their personal goals and action plans on a self-monitoring sheet. They were then encouraged to keep a daily record of their body weight and performance in terms of the intakes of foods comprising the Japan Diet for 6 weeks. The records had to be e-mailed to the instructor at 2 and 4 weeks, and each participant then received supportive individual advice by e-mail. The subjects were instructed to maintain their habitual physical activity during the study period.

Measurements

Anthropometric measurements and fasting blood collection were conducted on the first day and after 6 weeks in the morning following a 12-hour fast. Height, weight, and waist circumference of the subjects were measured. BMI was calculated as weight (kg)/height (m)^2. Waist circumference was determined with a tape measure during the late exhalation phase in the standing position. Blood pressure was measured using an automatic blood pressure manometer with the subject in the seated position. Plasma and serum samples were obtained and stored at −80℃ until analysis and concentration measurements were conducted as follows: plasma glucose (hexokinase UV method), serum insulin (chemiluminescent enzyme immunoassay (CLEIA)) method, serum total cholesterol (cholesterol dehydrogenase UV method), low density lipoprotein (LDL)-cholesterol and high density lipoprotein (HDL)-cholesterol (direct method), malondialdehyde modified (MDA)-LDL (enzyme-linked immunosorbent assay method), triglyceride (TG) concentration (enzymatic method), aspartate amino transferase, alanine amino transferase and γ-glutamyl transferase (Japan Society of Clinical Chemistry compliant method) in the laboratory of SRL Inc., Tokyo, Japan, and leptin and adiponectin (enzyme-linked immunosorbent assay method) in the laboratory of Biomarker Science Co. Ltd., Kyoto, Japan. The homeostasis model assessment (HOMA-IR) for insulin resistance was calculated as plasma glucose (mg/dL) × insulin (IRI) (μU/mL) ÷ 405.

Dietary Data Collection

Three-day weighted dietary records were kept at baseline and at the end of the 6-week study period, and then collected after confirmation by interview with a trained staff member. Participants were encouraged to submit photos of meals and nutrition labeling of the prepared foods that they had consumed. Nutrient intakes were calculated employing Excel-Eiyokun Ver.6, (Kenpaku-sha Co., Ltd., Tokyo, Japan) software. The volume of foods consumed was summarized into food groups based on the Standard Table of Food Composition in Japan 2010 (the Science and Technology Agency of Japan). Alcoholic drinks were summarized as total ethanol intake. Participants answered a questionnaire focusing on their motivation and ability to adhere to the Japan Diet.

Statistical Analysis

Statistical analyses were carried out using SPSS for Windows (version 16.0J; SPSS Japan, Inc.). All values are presented as means with standard deviations. The statistical significance of differences in values obtained at baseline and after 6 weeks were assessed using the non-parametric Wilcoxon matched pair's signed-rank test. Spearman correlation analyses were performed to identify correlations among anthropometric, biochemical and nutrient parameters. $p < 0.05$ was considered to indicate a statistically significant difference.

Results

One of the 34 enrolled participants was hospitalized for an acute illness and had to drop out. Thus, 33 Japanese men completed this program.

The body weight, BMI, and waist circumference values decreased 1.3 ± 1.9 kg, 0.4 ± 0.6, and 2.1 ± 2.4 cm, respectively, with a decrease in the serum leptin concentration. Serum LDL-cholesterol, MDA-LDL, and TG concentrations decreased significantly, while HDL-cholesterol was unchanged. Mean decreases in serum LDL-cholesterol and MDA-LDL were 7.9 % and 18.3 %, respectively (**Table 1**). Changes in body weight correlated with changes in the concentrations of leptin ($r = 0.823$, $p < 0.001$), LDL-cholesterol ($r = 0.526$, $p = 0.002$), insulin ($r = 0.374$, $p = 0.032$), and HOMA-IR ($r = 0.372$, $p = 0.033$). Changes in MDA-LDL correlated only with changes in LDL-cholesterol ($r = 0.460$, $p = 0.007$), among the biochemical parameters examined. There were six participants with LDL-cholesterol above 140 mg/dL at baseline, half of whom showed a decrease of 25 % in their LDL-cholesterol levels. Tendencies for decreases in plasma glucose and serum insulin concentrations to be associated with lower HOMA-IR were noted.

All of the participants had at least one cardiovascular risk factor at baseline. This pilot educational program focusing on the Japan Diet showed significant effectiveness, with 90.9 percent of participants showing improvements in their cardiovascular risk factor parameters to within the reference ranges after 6 weeks (**Table 2**).

At baseline, participants consumed 49.0 g of fish and 39.8 g of soybeans and soy products, accounting in volume for only two-thirds of the sum of meat and poultry intakes which totaled 134.3 g. Total vegetable intake including vegetable juice was only 262 g, and the sum of seaweed, mushroom, and konjak intakes

Table 1. Anthropometric variables, blood pressure and blood biochemical parameter concentrations at baseline and after the 6-week intervention

	Baseline	After 6 week	p
Body weight (kg)	75.2 ± 10.2	73.9 ± 9.9	< 0.001
Body Mass Index	25.3 ± 3.4	24.8 ± 3.2	< 0.001
Waist Circumference (cm)	88.3 ± 9.1	86.2 ± 8.5	< 0.001
Systolic blood pressure (mmHg)	130 ± 13	125 ± 9	0.004
Diastolic blood pressure (mmHg)	84 ± 10	81 ± 8	0.036
Total cholesterol (mg/dL)	198 ± 28	192 ± 31	0.207
LDL-cholesterol (mg/dL)	126 ± 26	116 ± 25	0.038
MDA-LDL (U/L)	142 ± 39	116 ± 29	< 0.001
HDL-cholesterol (mg/dL)	53 ± 9	52 ± 10	0.726
Triglyceride (mg/dL)	112 ± 51	108 ± 105	0.041
Glucose (mg/dL)	105 ± 16	101 ± 12	0.056
Insulin (μU/mL)	6.8 ± 4.0	5.8 ± 3.7	0.091
HOMA-IR	1.8 ± 1.2	1.5 ± 1.1	0.075
Aspartate amino transferase (U/L)	22 ± 6	23 ± 6	0.205
Alanine amino transferase (U/L)	26 ± 15	28 ± 17	0.257
γ-glutamyl transferase (U/L)	36 ± 19	35 ± 29	0.147
Leptin (ng/mL)	5.1 ± 4.9	4.0 ± 3.5	0.012
Adiponectin (μg/mL)	2.7 ± 1.1	2.6 ± 1.0	0.330

n = 33, Values are expressed as means ± SD.
MDA-LDL: malondialdehyde modified-low density lipoprotein
HOMA-IR: homeostasis model assessment for insulin resistance

Table 2. Numbers of participants with baseline cardiovascular risk factors and showing improvements after 6 weeks

	Risk factor at baseline	Improved to reference range	(%)§
At least one cardiovascular risk factor	33	30	(90.9)
Body mass index ≧ 25	12	4	(33.3)
Waist circumference ≧ 85 cm	20	11	(55.0)
Systolic blood pressure ≧ 130 mmHg	14	7	(50.0)
Diastolic blood pressure ≧ 85 mmHg	15	8	(53.3)
LDL-cholesterol ≧ 140 mg/dL	6	3	(50.0)
HDL-cholesterol < 40 mg/dL	3	2	(66.7)
Triglyceride ≧ 150 mg/dL	6	5	(83.3)
Glucose ≧ 100 mg/dL	24	10	(41.7)
Insulin ≧ 15 μU/mL	3	2	(66.7)
HOMA-IR > 1.6	16	10	(62.5)

n = 33
§: Data are the percentages of participants with values outside of the reference range at baseline and those who showed improvement at the end of the 6-week intervention.
HOMA-IR: homeostasis model assessment for insulin resistance

was 24.7 g. At the end of the intervention period, intakes of recommended foods, such as fish, soy, and sum of seaweed, mushrooms and konjak had doubled, and green and yellow vegetable intakes were also increased as compared to the baseline. Meanwhile, intakes of refined cereals, meat and poultry, sweets, desserts and snacks, and margarine and shortening which participants had been advised to avoid, decreased. Thus, the total food intake volume was unchanged (**Table 3**).

Table 3. Intake volumes of foods at baseline and at the end of the 6-week intervention

	Baseline (g)	6 weeks (g)	p
Total food volume[§]	1364.1 ± 294.7	1431.3 ± 351.6	0.416
Unrefined cereals	32.2 ± 42.4	58.5 ± 85.0	0.136
Refined cereals	384.0 ± 183.1	291.1 ± 141.3	0.007
Potatoes and other starches	36.7 ± 26.1	32.5 ± 36.6	0.374
Sweets, desserts and snacks	78.3 ± 60.3	36.3 ± 47.1	0.001
Beverages with sugar	124.5 ± 194.4	67.8 ± 117.2	0.106
Fish	49.0 ± 35.1	98.0 ± 58.0	< 0.001
Shellfish, prawns, shrimp, crab, squid, octopus, fish eggs, and viscera	15.1 ± 19.2	21.0 ± 25.9	0.281
Soybeans and other soy products	39.8 ± 41.3	86.5 ± 66.4	< 0.001
Milk and other dairy products	99.6 ± 112.0	69.1 ± 66.3	0.193
Meat and poultry	134.3 ± 52.3	95.4 ± 73.0	0.011
Eggs	46.3 ± 29.4	41.7 ± 42.3	0.268
Animal fats	2.3 ± 3.0	1.9 ± 3.3	0.264
Vegetable oils	32.6 ± 13.1	28.1 ± 13.7	0.118
Margarine and shortening	0.9 ± 2.5	0.2 ± 0.6	0.048
Nuts	3.6 ± 5.4	2.2 ± 2.6	0.531
Total Vegetables	247.6 ± 103.7	303.1 ± 107.2	0.030
Green and yellow vegetables	91.0 ± 56.3	116.3 ± 67.5	0.015
Other vegetables	156.6 ± 64.6	186.8 ± 76.6	0.136
Vegetable juice	14.3 ± 43.8	84.7 ± 169.0	0.013
Fruits	51.1 ± 60.3	48.8 ± 69.1	0.411
Fruit juice	22.1 ± 51.8	25.5 ± 83.2	0.746
Seaweed, mushrooms and konjac	24.7 ± 22.0	58.2 ± 51.0	0.002
Seaweed	9.6 ± 9.2	33.4 ± 34.0	< 0.001
Mushrooms	12.6 ± 15.6	16.7 ± 24.6	0.369
Konjac	2.6 ± 6.0	8.1 ± 28.4	0.733
Alcoholic beverages[§§]	20.6 ± 18.3	19.4 ± 34.5	0.230

n = 33, Values are expressed as means ± SD.
§: All food volumes except beverages, seasonings and spices are summarized.
§§: Calculated as pure ethanol.

Reduced lipid and carbohydrate intakes lead to decreased energy intake. Changes in energy intake correlated with changes in the concentrations of insulin (r=0.564, p=0.001), glucose (r=0.441, p=0.010), HOMA-IR (r=0.563, p=0.001), triglyceride (r=0.385, p=0.027), and body weight (r=0.349, p=0.046), but did not correlate with changes in the concentrations of LDL-cholesterol or MDA-LDL.

Mean (minimum, maximum) energy intakes derived from lipids and SFAs were 31.4 (23.7, 42.9) % and 8.8 (5.61, 15.0) % at baseline and had decreased to 30.6 (18.4, 44.9) % and to 7.8 (3.6, 14.2) %, respectively, at completion of the study. Monounsaturated fatty acid intake was also decreased, while n-3 polyunsaturated fatty acid (PUFA) intake increased from 3.10 (1.36, 5.13) g to 3.72 (1.29, 7.30) g. Dietary fiber intake increased, due mostly to insoluble dietary fiber consumption. Beta-carotene, vitamin D, and vitamin K intakes were found to be increased. Potassium and magnesium intakes increased, while sodium intake did not change during the intervention (**Table 4**).

Two-thirds of participants were sedentary workers, and 27 % lived alone. Those preparing daily meals by themselves and having their food made by a family member accounted for 21 % and 79 % of the participants, respectively. At the end of the intervention, 85 % of the participants had a good impression of practicing the Japan Diet. The participants believed daily consumption of fish, soybeans and soy products, and other vegetables to be easy, while eating green and yellow vegetables, and sum of seaweed, mushrooms and konjak was deemed to be moderately easy. Consumption of unrefined cereals was, however, considered to be difficult. Fatty meats were recognized as easy foods to particularly be avoided. Factors making the Japan Diet difficult to implement included limitations in personal skills and the social environment such as the

Table 4. Energy and nutrient intakes at baseline and the end of the 6-week intervention

	Baseline	6 weeks	*p*
Energy (kcal)	2526 ± 464	2150 ± 510	0.002
Lipid (g)	87.4 ± 16.3	73.4 ± 23.8	0.005
(%E)	31.4 ± 4.7	30.6 ± 5.9	0.013
SFA (g)	24.59 ± 7.17	18.87 ± 8.95	0.003
(%E)	8.80 ± 2.10	7.80 ± 2.60	0.005
MUFA (g)	32.58 ± 6.93	27.01 ± 9.52	0.008
n-3PUFA (g)	3.10 ± 1.01	3.72 ± 1.48	0.036
n-6PUFA (g)	15.13 ± 3.10	13.76 ± 3.59	0.067
PUFA/SFA	0.80 0.30	1.10 0.40	0.001
Cholesterol (mg)	453 ± 140	429 ± 249	0.357
Carbohydrate (g)	298.1 ± 67.5	243.3 ± 63.5	< 0.001
(%E)	47.1 ± 6.4	46.0 ± 10.2	< 0.001
Total dietary fiber (g)	15.4 ± 4.2	18.9 ± 6.5	0.006
Soluble dietary fiber (g)	3.9 ± 1.5	4.3 ± 1.7	0.155
Insoluble dietary fiber (g)	10.8 ± 2.9	13.0 ± 4.5	0.013
Protein (g)	89.2 ± 14.8	92.3 ± 24.8	0.675
(%E)	14.3 ± 2.4	17.2 ± 2.5	0.623
Thiamine (mg)	3.99 ± 15.32	1.30 ± 0.57	0.437
Riboflavin (mg)	1.69 ± 0.69	1.69 ± 0.66	0.893
Niacin equivalents (mgNE)	42.0 ± 7.4	45.0 ± 13.6	0.313
Pantothenic acid (mg)	7.81 ± 2.61	8.11 ± 2.83	0.503
Ascorbic acid (mg)	113 ± 49	127 ± 56	0.313
β-Carotene equivalents§ (μg)	4116 ± 2692	7047 ± 6019	< 0.001
α-Tocopherol (mg)	12.8 ± 16.7	10.7 ± 3.5	0.367
Vitamin D (μg)	6.9 ± 4.9	13.4 ± 7.8	< 0.001
Vitamin K (μg)	253 ± 107	389 ± 200	< 0.001
Sodium (mg)	4831 ± 976	4924 ± 1243	0.458
Potassium (mg)	3006 ± 583	3415 ± 944	0.017
Calcium (mg)	556 ± 204	606 ± 169	0.081
Magnesium (mg)	319 ± 76	376 ± 101	0.000

$n = 33$, Values are expressed as means ± SD.
SFA: saturated fatty acids, MUFA: monounsaturated fatty acids, PUFA; polyunsaturated fatty acids, PUFA/SFA: ratio of PUFA to SFA
§: β-Carotene(μg) + 1/2α-Carotene(μg) + 1/2β-Cryptoxanthin

accessibility of food and meals (**Table 5**).

Discussion

Consumption of meat in amounts exceeding the sum of fish and soy intakes was confirmed to expose participants to high SFA intakes. The food and nutrient intakes at baseline were essentially equivalent to the results of the last report of the National Health and Nutrition Survey in Japan[12]. We found that total lipid and SFA intake levels have become increasingly westernized in the last 25 years, with levels now having reached peaks corresponding to the highest quintile intake group of the subjects during the baseline period of a cohort study conducted in the 1980s[13]. Lack of fish and vegetable intake has also been recognized as a major problem in the younger generation[12], and similar results were obtained in our current study participants.

Our 1-hour educational session including group work and follow-up e-mail advice based on the participant's self-monitoring supported their food intake changes facilitating successful implementation of the Japan Diet. A 6-week trial aimed at implementing changes in daily food intakes resulted in significant decreases in body weight, BMI, blood pressure, serum LDL-cholesterol, MDA-LDL, TG, and glycemic markers. Those showing improvements in some metabolic disorders in response to the Japan Diet consumption accounted for 90.9 % of participants. Thus,

Table 5. Confidence in the Japan Diet experienced by participants at the end of the intervention

	number§	(%)
The Japan Diet implementation		
very good	7	(21.2)
good	21	(63.6)
occasional failure	5	(15.2)
complete failure	0	(0.0)
Practical application		
daily intakes of		
fish	25	(75.8)
soy and soy products	26	(78.8)
green & yellow vegetables	23	(69.7)
other vegetables	32	(97.0)
seaweed, mushrooms, konjak	22	(66.7)
unrefined cereals	15	(45.5)
avoidance of		
fatty meats	28	(84.8)
alcohol	16	(48.5)
sweets, desserts and snacks	20	(60.6)
Reason for difficulty implementing the Japan Diet		
attending parties with Western or Chinese dishes	14	(42.4)
troublesome to prepare	10	(30.3)
lack of favorite foods	9	(27.2)
few restaurants	7	(21.2)
lack of a supportive family member	7	(21.2)
expensive	7	(21.2)
dislike the food	0	(0.0)

n=33
§: Multiple answers allowed.

the present program was regarded as being effective.

Low energy diets have been recommended for body weight reduction[14, 15]. The Japan Diet reduces energy intake without changing total food volume intake. Typical plant foods featured in the Japan Diet are soybeans, seaweed, mushrooms, and konjak. Most notably seaweed, mushrooms, and konjak, all of which are very low energy foods, have traditionally been consumed in Japan. These foods are also major sources of dietary fiber. Consuming these plant foods contributes to decreases in energy density, and might thus be beneficial for increasing satiety and promoting the elimination of lipids and carbohydrates via the bowels. In addition, replacing meat with fish and/or soy-based products reduces SFA intake and increases n-3 and n-6 PUFA intake, possibly contributing to elevated diet-induced thermogenesis[16]. Thus, the Japan Diet was demonstrated to be beneficial for losing weight.

Notably, serum LDL-cholesterol and MDA-LDL decreased 7.9 % and 18.3 %, respectively, in 6 weeks. SFA intake has been shown to correlate strongly with blood cholesterol concentrations[17] and replacing SFA intake with PUFA intake was associated with LDL-cholesterol reduction[18]. We observed no correlation between changes in LDL-cholesterol concentrations and changes in SFA or PUFA intake. The decrease in SFA intake was small, but statistically significant, because the participants were not instructed to restrict the quantity of food in their daily meals with this program. Soybean protein and viscous fiber are well known to have positive impacts on serum cholesterol reduction, and the serum LDL-cholesterol lowering effect of plant-based diets has also been emphasized[19, 20]. Increased intake of soybean-based and fiber rich foods, such as seaweed, mushrooms, and konjak, as well as vegetables, might also contribute to lowering serum cholesterol concentrations. Our results indicate that single nutrients or foods may not have detectable effects, while the overall food intake characteristic of the Japan Diet pattern may effectively lower serum LDL-cholesterol with MDA-LDL reduction.

Increased consumption in green and yellow vegetables and vegetable juice raised beta-carotene and magnesium intakes in this study. Fruit and vegetable intakes reportedly showed a significant association with reduced risk of cardiovascular disease in Japan[21]. Fruit and vegetable intakes, as well as those of related nutrients such as beta-carotene and magnesium, were reported to be independently associated with a reduction in oxidized LDL[22, 23], and significant inverse associations with heart disease were seen for beta-carotene and magnesium[24]. Favorable changes in MDA-LDL are mainly the result of decreases in LDL particles. Furthermore, the Japan Diet may provide an abundance of beneficial antioxidants. Further study is needed to confirm the effects of anti-oxidant components derived from the Japan Diet on levels of oxidative stress.

High salt intake is associated with blood pressure elevation and significantly increased risks of stroke and total cardiovascular disease[25]. A diet that includes modest salt restriction while increasing potassium intake can prevent or control hypertension and decrease cardiovascular morbidity and mortality[26, 27]. The participants in this study showed blood pressure reductions with increased potassium intake, obtained from the high vegetable and seaweed consumptions recommended.

This study has limitations. First, as the study design was single-arm, the actual effects on changes in the parameters assessed could not be demonstrated. We observed that energy intake decreased significantly in the participants consuming the Japan Diet. However, various factors such as physical activity, climate, and media impacts on the public's perception of healthy foods and meals would have influenced food intake. Moreover, as the participants attended this educational program of their own free will, they had ample incentive to improve their diets, aiming for healthier consumption, such that the issue of sampling bias should be considered when interpreting the findings of this study. High-quality evidence of the effects of the Japan Diet on metabolic parameters must be obtained from randomized controlled trials with larger numbers of subjects. Second, changes in serum lipid concentrations in the hyperlipidemic participants were minimal, such that detecting significant effects on those with risk factors for atherosclerotic cardiovascular diseases requires further study in a larger cohort. Third, the study duration was 6 weeks, similar to those in previous studies. Thus, the effects and practical application of habitual Japan Diet intake should be confirmed over a longer period. Our results provide useful information for designing a randomized controlled trial on the effects of the Japan Diet. If participants could be persuaded to consume unrefined cereals rich in viscous fiber, and avoid eating out and/or improve their skills in selecting and preparing healthy meals, these changes would facilitate obtaining more effective outcomes, in terms of metabolic parameters, in response to implementing habitual use of the Japan Diet.

Conclusion

The Japan Diet was suggested to be a beneficial dietary pattern in terms of body weight reduction and improving metabolic disorders in middle-aged men who had been brought up in the westernized dietary environment of modern Japan. A simple and reliable educational program, aimed at making implementation of the Japan Diet a lifelong eating habit, is urgently needed.

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COI

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References

1) Keys A, Menotti A, Karvonen MJ, Aravanis C, Blackburn H, Buzina R, Djordjevic BS, Dontas AS, Fidanza F, Keys MH, Kromhout D, Nedeljkovic S, Punsar S, Seccareccia F, Toshima H: The diet and 15-year death rate in the seven countries study. Am J Epidemiol, 1986; 24: 903-915
2) Kromhout D, Keys A, Aravanis C, Buzina R, Fidanza F, Giampaoli S, Jansen A, Menotti A, Nedeljkovic S, Pekkarinen M, Simic BS, Toshima H: Food consumption patterns in the 1960s in seven countries. Am J Clin Nutr, 1989; 49: 889-894
3) Kromhout D, Menotti A, Bloemberg B, Aravanis C, Blackburn H, Buzina R, Dontas AS, Fidanza F, Giampaoli S, Jansen A: Karvonen M, Katan M, Nissinen A, Nedeljkovic S, Pekkarinen J, Pekkarinen M, Punsar A, Rasanen L, Simic B, Toshima H: Dietary saturated and trans fatty acids and cholesterol and 25-year mortality from coronary heart disease: the Seven Countries Study. Prev Med, 1995; 24: 308-315
4) Menotti A, Kromhout D, Blackburn H, Fidanza F, Buzina R, Nissinen A: For the Seven Countries Study Research Group: Food intake patterns and 25-year mortality from coronary heart disease: cross-cultural correlations in the Seven Countries Study. The Seven Countries Study Research Group. Eur J Epidemiol, 1999; 15: 507-515
5) Tada N, Maruyama C, Koba S, Tanaka H, Birou S, Tera-

moto T, Sasaki J: Japanese dietary lifestyle and cardiovascular disease. J Atheroscler Thromb, 2011; 18: 723-374
6) Shimazu T, Kuriyama S, Hozawa A, Ohmori K, Sato Y, Nakaya N, Nishino Y, Tsubono Y, Tsuji I: Dietary patterns and cardiovascular disease mortality in Japan: a prospective cohort study. Int J Epidemiol, 2007; 36: 600-609
7) Teramoto T, Sasaki J, Ishibashi S, Birou S, Daida H, Dohi S, Egusa G, Hiro T, Hirobe K, Iida M, Kihara S, Kinoshita M, Maruyama C, Ohta T, Okamura T, Yamashita S, Yokode M, Yokote K: Treatment A) lifestyle modification: executive summary of the Japan Atherosclerosis Society (JAS) guidelines for the diagnosis and prevention of atherosclerotic cardiovascular diseases in Japan--2012 version. J Atheroscler Thromb, 2013; 20: 835-849
8) Cabinet Office, Government of Japan: White Paper on the National Lifestyle 2007. http://www5.cao.go.jp/seikatsu/whitepaper/h19/10_pdf/01_honpen/
9) Kumagai F: Forty years of family change in Japan: a society experiencing population aging and declining fertility. Journal of Comparative Family Studies, SUMMER 2010; 41: 581-610
10) Eckel RH, Jakicic JM, Ard JD, de Jesus JM, Houston Miller N, Hubbard VS, Lee IM, Lichtenstein AH, Loria CM, Millen BE, Nonas CA, Sacks FM, Smith SC Jr, Svetkey LP, Wadden TA, Yanovski SZ; American College of Cardiology/American Heart Association Task Force on Practice Guidelines: 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol, 2014; 63: 2960-2984
11) A'Hern R P: Sample size tables for exact single-stage phase II designs. Statist, Med 2001; 20: 859-866
12) Ministry of Health, Labor and Welfare: The National Health and Nutrition Survey in Japan, 2014. http://www.mhlw.go.jp/bunya/kenkou/eiyou/h26-houkoku.html
13) Yamagishi K, Iso H, Yatsuya H, Tanabe N, Date C, Kikuchi S, Yamamoto A, Inaba Y, Tamakoshi A; JACC Study Group: Dietary intake of saturated fatty acids and mortality from cardiovascular disease in Japanese: the Japan Collaborative Cohort Study for Evaluation of Cancer Risk (JACC) Study. Am J Clin Nutr, 2010; 92: 759-765
14) Anderson JW, Konz EC, Frederich RC, Wood CL: Long-term weight-loss maintenance: a meta-analysis of US studies. Am J Clin Nutr, 2001; 74: 579-584
15) Johansson K, Neovius M, Hemmingsson E: Energy intake reduction could lose body weight Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomized controlled trials. Am J Clin Nutr, 2014; 99: 14-23
16) Takeuchi H, Matsuo T, Tokuyama K, Shimomura Y, Suzuki M: Diet-induced thermogenesis is lower in rats fed a lard diet than in those fed a high oleic acid safflower oil diet, a safflower oil diet or a linseed oil diet. J Nutr, 1995; 125: 920-925
17) Grundy SM, Denke MA. Dietary influences on serum lipids and lipoproteins. J Lipid Res, 1990; 31: 1149-1172
18) Hodson L, Skeaff CM, Chisholm WA: The effect of replacing dietary saturated fat with polyunsaturated or monounsaturated fat on plasma lipids in free-living young adults. Eur J Clin Nutr, 2001; 55: 908-915
19) Gardner CD, Coulston A, Chatterjee L, Rigby A, Spiller G, Farquhar JW: The effect of a plant-based diet on plasma lipids in hypercholesterolemic adults: a randomized trial. Ann Intern Med, 2005; 142: 725-733
20) Malhotra A, Shafiq N, Arora A, Singh M, Kumar R, Malhotra S: Dietary interventions (plant sterols, stanols, omega-3 fatty acids, soy protein and dietary fibers) for familial hypercholesterolaemia. Cochrane Database Syst Rev, 2014 10; 6: CD001918
21) Okuda N, Miura K, Okayama A, Okamura T, Abbott RD, Nishi N, Fujiyoshi A, Kita Y, Nakamura Y, Miyagawa N, Hayakawa T, Ohkubo T, Kiyohara Y, Ueshima H; NIPPON DATA80 Research Group: Fruit and vegetable intake and mortality from cardiovascular disease in Japan: a 24-year follow-up of the NIPPON DATA80 Study. Eur J Clin Nutr, 2015; 69: 482-488
22) Cocate PG, Natali AJ, Oliveira Ad, Longo GZ, Alfenas Rde C, Peluzio Mdo C, Santos EC, Buthers JM, Oliveira LL, Hermsdorff HH: Fruit and vegetable intake and related nutrients are associated with oxidative stress markers in middle-aged men. Nutrition, 2014; 30: 660-665
23) Esfahani A, Wong JM, Truan J, Villa CR, Mirrahimi A, Srichaikul K, Kendall CW: Health effects of mixed fruit and vegetable concentrates: a systematic review of the clinical interventions. J Am Coll Nutr, 2011; 30: 285-294
24) Tucker KL, Hallfrisch J, Qiao N, Muller D, Andres R, Fleg JL; Baltimore Longitudinal Study of Aging: The combination of high fruit and vegetable and low saturated fat intakes is more protective against mortality in aging men than is either alone: the Baltimore Longitudinal Study of Aging. J Nutr, 2005; 135: 556-561
25) Ando K, Kawarazaki H, Miura K, Matsuura H, Watanabe Y, Yoshita K, Kawamura M, Kusaka M, Kai H, Tsuchihashi T, Kawano Y: [Scientific statement] Report of the Salt Reduction Committee of the Japanese Society of Hypertension (1) Role of salt in hypertension and cardiovascular diseases. Hypertens Res, 2013; 36: 1009-1019
26) Umesawa M, Iso H, Date C, Yamamoto A, Toyoshima H, Watanabe Y, Kikuchi S, Koizumi A, Kondo T, Inaba Y, Tanabe N, Tamakoshi A; JACC Study Group: Relations between dietary sodium and potassium intakes and mortality from cardiovascular disease: the Japan Collaborative Cohort Study for Evaluation of Cancer Risks. Am J Clin Nutr, 2008; 88: 195-202
27) Aaron KJ, Sanders PW: Role of dietary salt and potassium intake in cardiovascular health and disease: a review of the evidence. Mayo Clin Proc, 2013; 88: 987-995