



Rationale and Descriptive Analysis of Specific Health Guidance: the Nationwide Lifestyle Intervention Program Targeting Metabolic Syndrome in Japan

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Aim: All health insurers in Japan are mandated to provide Specific Health Checkups and Specific Health Guidance (SHG) focusing on metabolic syndrome (MetS) in middle-aged adults, beginning in 2008; intensive HG for individuals who have abdominal obesity and two or more additional MetS risk factors, and motivational HG for individuals with one risk factor. The aim of this study is to describe medium-term changes in health indexes for intensive and motivational HG groups using the National Database.

Methods: We compared changes of risk factors and initiation of pharmacological therapy over 3 yr between participants ($n=31,790$) and nonparticipants ($n=189,726$) who were eligible for SHG in 2008.

Results: Body weight reduction in intensive HG was 1.98 kg (participants) vs 0.42 kg (nonparticipants) in men ($p<0.01$) and 2.25 vs 0.68 kg in women ($p<0.01$) after 1 yr. In motivational HG, the respective reduction was 1.40 vs 0.30 kg in men ($p<0.01$) and 1.53 vs 0.42 kg in women ($p<0.01$). Waist circumference reduction was also greatest among participants in intensive HG (2.34 cm in men and 2.98 cm in women). These reductions were fairly unchanged over 3 yr and accompanied greater improvements in MetS risk factors in participants. We also detected significantly smaller percentages of SHG participants who initiated pharmacological therapy compared with nonparticipants.

Conclusion: Participants in SHG showed greater improvements in MetS profiles with proportionally smaller pharmacological treatment initiations than did nonparticipants for 3 yr. Although selection bias may be present, this study suggests SHG would be a feasible strategy to prevent MetS and its sequelae.

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Key words: Metabolic Syndrome, Health checkup, Health Guidance, National Data Base, Health Policy

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Introduction

Japan has been ranked first in life expectancy at

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birth almost consecutively since the mid-1980s¹). A series of government-led public health programs are credited for this achievement, including the universal health insurance (1961) and the nationwide annual health checkup systems in workplaces (1972) and municipalities (1982)²⁻⁵. Early disease detection and pharmacological treatment, along with public health campaign aimed at reducing salt, have been major drivers to reduce leading causes of death, in particular, stroke mortality⁶⁻⁸).

The longevity of the citizens brought Japan a fast-growing aging society. Coupled with a low birth rate, the proportion of people aged 65 yr and older increased from 14.6% in 1995 to 20.2% in 2005⁹⁾ and 26.7% in 2015. Consequently, Japan's total health-care expenditure as a share of gross domestic product gradually rose from 6.4% in 1995 to 8.1% in 2005 and 11.2% in 2015¹⁰⁾. A report by the Organization for Economic Co-operation and Development confirms that a continuing high growth in pharmaceutical spending is a major contributor to the increasing health spending in Japan¹¹⁾.

In terms of population disease burden, slowly increasing prevalence of overweight, type 2 diabetes, and its complications received notices¹²⁾. Although the proportion of adults who are obese is still much lower than that of other industrialized nations¹³⁾, mild abdominal obesity can lead to impaired glucose metabolism and cardiovascular sequelae in Japanese individuals¹⁴⁻¹⁸⁾. In 2005, the new diagnostic criteria of metabolic syndrome (MetS) for Japanese adults were published^{19, 20)}. Unlike the NCEP-ATP III²¹⁾ or the harmonized criteria²²⁾, the Japanese criteria treat abdominal obesity as a necessary factor for diagnosis²³⁻²⁵⁾.

To proactively tackle an impending health-care crisis, the Ministry of Health, Labor and Welfare (MHLW) began formulating a health-care systems reform that would include a new approach to systematically detect hyperglycemia, hypertension, and dyslipidemia earlier, possibly at the preclinical stage. Scientific evidence was already clear that lifestyle modification can be more efficacious than pharmacological treatment for improving MetS risk factors in adults with prediabetes²⁶⁻²⁹⁾. With this knowledge, the Japanese government decided to add a lifestyle intervention component within the health-care system. Using the 2006 Health Care Systems Reform Plan as the base law, the MHLW introduced the Specific Health Checkups (SHC) and the Specific Health Guidance (SHG) in fiscal year 2008. All health insurers in Japan, therefore, were required to provide health checkup programs to all enrollees and their dependents 40 to 74 yr of age and implement lifestyle improvement counseling for nonmedicated participants who have elevated risk factors of MetS^{30, 31)}. There is a new evaluation component for the program, which utilizes the National Database (NDB), an electronic claims dataset containing health information of SHC participants (20–25 million annually for 2008–2011), to facilitate data-driven decision making³²⁾.

Aim

The purpose of this study is to describe changes in waist circumference (WC), body mass index (BMI),

and other risk factors of MetS over 3 yr using the NDB. The present study is the first systematic evaluation of the nationwide SHG by the study group convened by the MHLW.

Methods

Study Design

This study is a population-based longitudinal observational study. We compared changes in SHC health examination data over a 3-yr period between participants and nonparticipants. We defined participants as subjects who fully completed SHG in 2008, and we did not consider whether they participated in SHG in 2009 or 2010. Nonparticipants were defined as subjects who were eligible for SHG in 2008 but never participated in SHG during these 3 yr (2008–2010). Subjects whose hemoglobin A1c (HbA1c) was more than 7.0%, or systolic blood pressure (SBP) was more than 160 mmHg, or diastolic blood pressure (DBP) was more than 100 mmHg at baseline were excluded, because they would be strongly recommended to take medications instead of participating in a prevention program by health insurers.

The Specific Health Checkups

SHC features annual laboratory tests, questionnaire, and physical examination to evaluate MetS risk factors. The laboratory tests and physical examination include measurements of WC, body weight, BMI, SBP, DBP, HbA1c, serum triglycerides (TG), and high-density lipoprotein (HDL) cholesterol. The questionnaire assesses smoking status and whether the participant takes medication for diabetes, hypertension, or dyslipidemia. Measurement methods, cutoff values, and protocols are described in the “Operational Guide to Specific Health Checkups and Specific Health Guidance” by the MHLW³³⁾. Participants in the checkups, aged 40 to 74 yr, are initially classified by obesity indicators (WC and BMI) and then by the number of additional metabolic risk factors, smoking status, and age (**Fig. 1**). Individuals who are on pharmacological therapy for diabetes, hypertension, or dyslipidemia are not eligible for SHG. Medical insurers are asked to recommend eligible members to participate in in-house SHG or SHG provided by outsourced health-care agencies. Compliance rates of SHG recommendation differed from 0% to more than 90%, depending on insurers. Note that participation in SHG is not mandatory for eligible individuals.

The Specific Health Guidance

There are two types of SHG in this program: (1) Intensive HG is offered to those who have two or

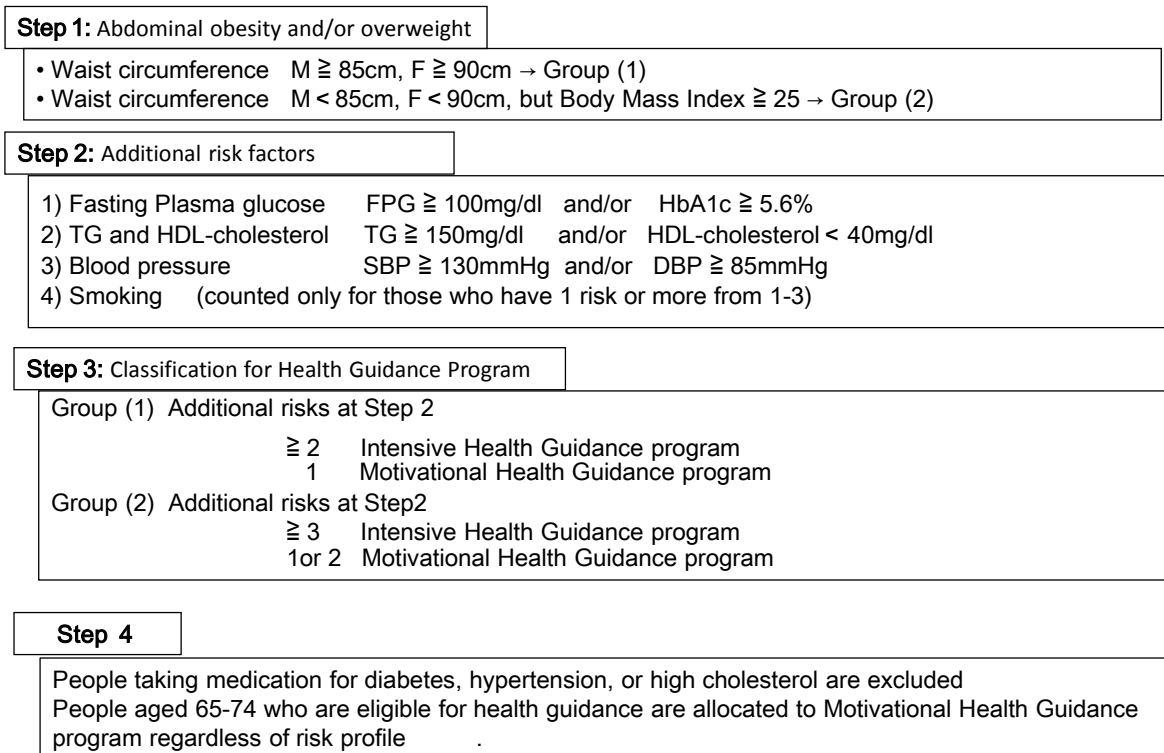


Fig. 1. Participant classification for Specific Health Guidance (SHG) eligibility based on the “Standardized health examination and guidance program” of the Ministry of Health, Labor and Welfare.

Specific Health Checkups participants are initially classified by obesity indicators (Step 1) and then by the number of additional metabolic risk factors and smoking status (Steps 2 and 3). Individuals who are on pharmacological therapy for diabetes, dyslipidemia, or hypertension are not eligible for SHG (Step 4).

more risk factors with abdominal obesity or three or more risk factors with overweight (BMI > 25) but without abdominal obesity. (2) Motivational HG is offered to those who have one risk factor with abdominal obesity or one or two risk factors with overweight without abdominal obesity.

Both types of SHG include initial counseling and final evaluation after 6 months. At initial counseling, participants are briefed about their health condition and lifestyle through a review of their SHC results sheets. They are instructed to set personalized behavioral goals that are achievable. Walking (for instance, walk “extra 10 min” whenever possible) is recommended as a form of physical activity, and participants are encouraged to wear a pedometer. Diet may be adjusted to balance the total energy expenditure. The clinical goals include reductions of body weight by 3%–5% and WC by 3 cm^{34, 35}. The initial counseling session can be one on one for at least 20 min, or group counseling (eight participants or fewer) for at least 80 min. A trained health-care professional (physician, nurse, or dietitian) who has completed the established MHLW training course provides counseling. In the intensive

HG program, participants receive personalized follow-up consultation through e-mail, phone calls, and/or in-person or group sessions at their convenience for at least 3 month and up to 6 months. The motivational HG program does not include continuous support. The programs are considered to be completed when participants received a specific amount of cumulative consultation time, for example, four 15-min phone consultations or five e-mail consultations (intensive HG only), and finished the 6-month evaluation (both intensive and motivational HG). The average per capita cost is about US\$180 (18,000 Japanese yen) for intensive HG and about US\$60 (6,000 Japanese yen) for motivational HG.

Program Participants

The total number of adults who were eligible for the SHC was approximately 51.9 million in 2008, roughly the entire Japanese adult population aged 40 to 74 yr. Of these, approximately 20.2 million (38.9%) participated in the SHC. In this subset, about 4.0 million (19.9%) had elevated MetS risk factors but were not on pharmacological therapy; thus, they became

eligible for SHG.

Because there was systemic shortcoming in linking deidentified health checkup data files and health insurance claims data files owing to inconsistent Japanese alphanumeric data entry methods, we selected 365 insurers (321 National Health Insurances, 2 cooperate insurance societies, and 42 mutual aid associations) who had a data matching rate of 80% or higher in all observation periods.

Analysis Methods

We received anonymized and linkable SHC/SHG data in the standardized extensible markup language from the MHLW. At the end of each year during the follow-up period (2009, 2010, and 2011), we compared changes in MetS risk factors (WC, BMI, body weight, SBP, DBP, HbA1c, TG, and HDL) from baseline (2008) between SHG participants and nonparticipants in the SHC data. We conducted analyses by type of intervention (intensive HG and motivational HG), sex, and age groups of participants. In addition, we analyzed the percentage of people who initiated pharmacological therapy for diabetes, hypertension, or dyslipidemia during the follow-up period using the questionnaire data. The Student *t* test was used to test for statistical significance ($p < 0.05$).

This study was exempt from a review by the ethical review committee, because the study was performed on the purpose of policy evaluation under the Act of Financing Health Care for the Elderly, and we used anonymized secondary data provided by MHLW.

Results

Study Participants

The analysis data set contained a total of 221,516 individuals who were eligible for SHG from 365 insurers; 89,014 met the criteria for intensive HG and 132,502 for motivational HG (**Fig. 2**). The participation rate of SHG was 12.3% (10,942/89,014) for intensive HG and 15.7% (20,848/132,502) for motivational HG. The follow-up retention rates for intensive HG were 84.5% (after 1 yr), 78.7% (after 2 yr), and 72.7% (after 3 yr) in participants and 69.5%, 64.4%, and 61.5% in nonparticipants. The follow-up retention rates for motivational HG were 74.3%, 65.1%, and 57.8% in participants and 63.9%, 57.3%, and 51.6% in nonparticipants.

The baseline characteristics of SHG participants by type of intervention and sex are shown in **Table 1**. We conducted additional age-stratified analyses using 5-yr increments to grasp age-specific changes (**Supplemental Table 1**).

Result of the Intensive HG Program

In intensive HG participants, WC, BMI, body weight, SBP, TG, and HDL cholesterol significantly improved compared with those in nonparticipants (**Table 2a, Fig. 3**). The reduction in body weight/WC from baseline among men in the participants group was 1.98 kg/2.34 cm at the end of the 1 yr, 1.53 kg/1.92 cm after 2 yr, and 1.25 kg/1.48 cm after 3 yr. The extent of body weight and WC reductions was significantly greater than those in nonparticipants (0.42 kg/0.66 cm, 0.43 kg/0.69 cm, and 0.43 kg/0.51 cm, respectively). The reduction in body weight/WC from baseline among women in the participants group was 2.25 kg/2.98 cm at 1 yr, 1.83 kg/2.80 cm at 2 yr, and 1.65 kg/2.66 cm at 3 yr. The extent of body weight and WC reductions was also significantly greater than that in nonparticipants (0.68 kg/1.59 cm, 0.85 kg/1.71 cm, and 0.81 kg/1.55 cm, respectively). In the age-stratified analyses, we found significant reductions in body weight in intensive HG participants compared with nonparticipants in all age subgroups in both sexes (**Supplemental Table 2**).

As for blood pressure and TG, improvements were significantly greater in participants than in nonparticipants, except for DBP in women. HbA1c decreased by 0.01% in men and 0.05% in women in participants but increased by 0.04% in men and 0.02% in women in nonparticipants after 1 yr. In subsequent years, HbA1c moderately increased in both groups, but the group differences remained significant throughout the 3-yr period. HDL cholesterol increased significantly greater in participants.

Results of the Motivational HG Program

In motivational HG participants (aged 40–64 yr), most MetS risk factors also improved significantly compared with those in nonparticipants. The degree of improvement in each risk factor, however, was smaller than that in intensive HG participants (**Table 2b**). In the older motivational HG participants (aged 65–74 yr), significant differences in improvements for at least two consecutive years were observed in WC, body weight, TG, and HDL cholesterol, but not in blood pressure (men and women) and HbA1c (women) (**Table 2c**). In the age-stratified analyses, significant reductions in body weight were found in motivational HG participants compared with those in nonparticipants in all age-subgroups in both sexes.

Starting Pharmacological Therapy

Significantly smaller percentages of SHG participants initiated pharmacological therapy for diabetes, hypertension, or dyslipidemia than nonparticipants during the follow-up period in both types of HG pro-

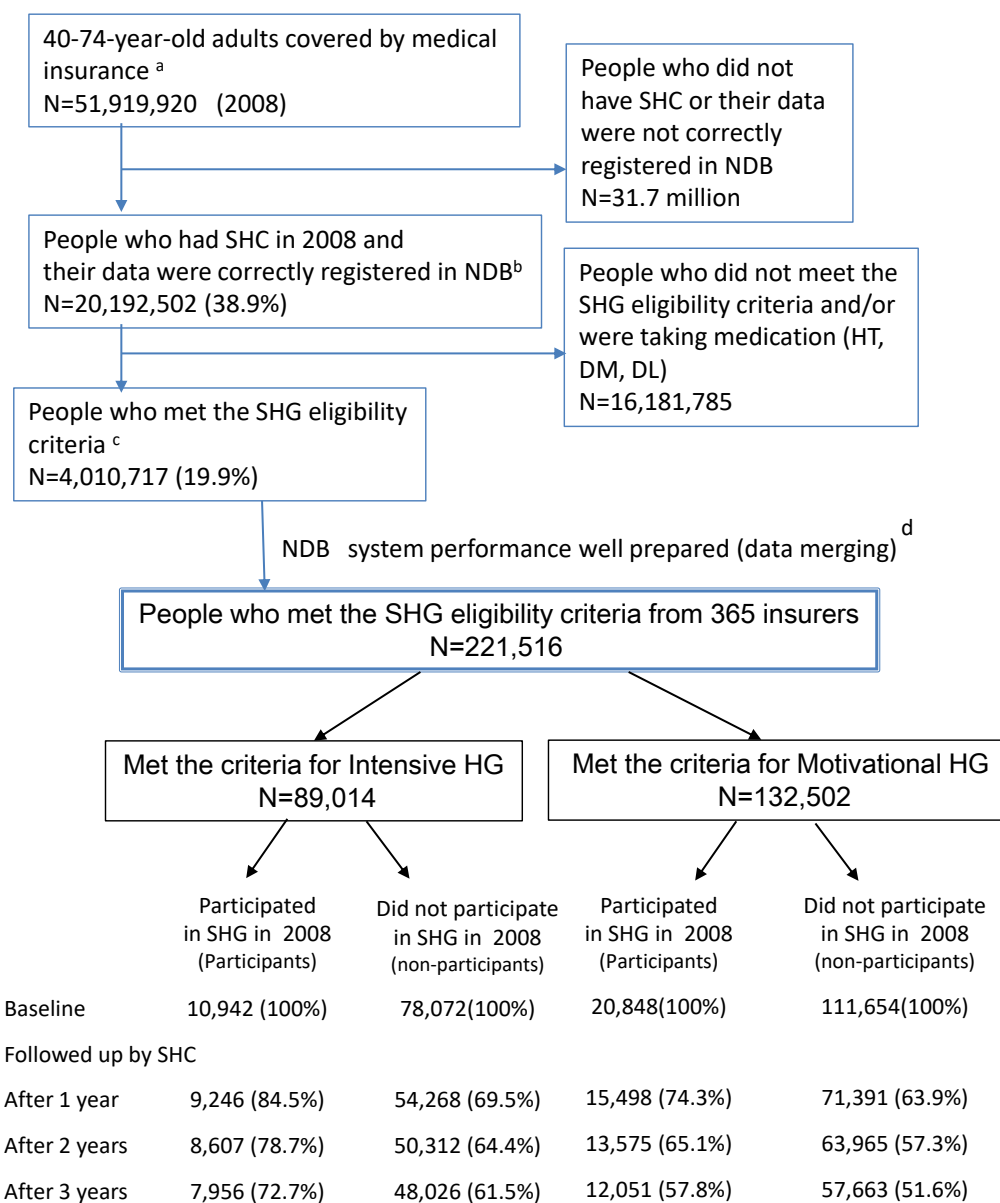


Fig. 2. Number of people who met the eligibility criteria for the Specific Health Guidance (SHG) in 2008, assignment of participants and nonparticipants, and follow-up rate

a. The entire Japanese adult population aged 40–74 yr. b. People who did not have Specific Health Check-ups (SHC) or their data were not correctly registered in the National Database were excluded. c. Participants of SHC were classified by the standard criteria (Fig. 1). d. We analyzed SHC/SHG data from 365 insurers who met specific performance requirements (data merging).

grams (**Fig. 4**).

Discussion

The present study is the first official descriptive analysis of the nationwide lifestyle intervention program to improve risk factors of MetS in nonmedicated adults 40 to 74 yr of age in Japan. We found that the improvements in obesity indices, including WC, BMI,

and body weight, were significantly greater in participants of SHG than in nonparticipants. Body weight reduction in intensive HG participants was 1.98 kg (2.63% reduction) in men and 2.25 kg (3.43%) in women, whereas WC reduction was 2.34 cm in men and 2.98 cm in women, after 1 yr. These reductions were fairly unchanged over the next 3 yr and accompanied similar sustainable improvements in TG, HDL cholesterol, SBP, and initial reduction of HbA1c among

Table 1. Summary baseline values by type of the specific health guidance and sex groups

Intensive Health Guidance aged 40-64	Men		Women	
	Participants <i>n</i> =8,918	Non-ptcptps <i>n</i> =64,503	Participants <i>n</i> =2,024	Non-ptcptps <i>n</i> =13,569
Age, mean (SD), yrs	52.1 (6.8)	52.7 (6.9)**	56.7 (6.3)	55.6 (6.6)**
Waist circumference, mean (SD), cm	91.4 (5.7)	91.4 (6.0)	95.1 (6.5)	94.7 (7.4)*
BMI, mean (SD), kg/m ²	26.0 (2.6)	26.0 (2.7)	27.4 (3.3)	27.5 (3.5)
Body weight, mean (SD), kg	75.3 (8.8)	75.0 (9.1)*	65.6 (8.9)	66.2 (9.2)**
HbA1c, mean (SD), %	5.69 (0.7)	5.71 (0.9)**	5.85 (0.6)	5.85 (1.0)
Systolic blood pressure, mean (SD), mmHg	130 (16)	131 (18)*	134 (16)	134 (18)
Diastolic blood pressure, mean (SD), mmHg	82 (11)	82 (12)*	81 (10)	81 (11)*
Triglyceride, mean (SD), mg/dL	206 (88)	204 (86)	172 (96)	170 (99)

Motivational Health Guidance aged 40-64	Men		Women	
	Participants <i>n</i> =1,882	Non-ptcptps <i>n</i> =24,965	Participants <i>n</i> =3,021	Non-ptcptps <i>n</i> =20,853
Age, mean (SD), yrs	56.1 (6.9)	52.4 (7.0)**	57.6 (6.0)	54.5 (6.0)**
Waist circumference, mean (SD), cm	89.8 (5.5)	89.3 (5.5)**	90.7 (6.5)	89.8 (6.9)**
BMI, mean (SD), kg/m ²	25.4 (2.2)	25.5 (2.4)*	26.4 (2.3)	26.6 (2.6)**
Body weight, mean (SD), kg	71.4 (7.6)	73.3 (7.9)**	62.2 (6.7)	63.7 (7.3)**
HbA1c, mean (SD), %	5.58 (0.5)	5.56 (0.5)	5.70 (0.4)	5.70 (0.6)
Systolic blood pressure, mean (SD), mmHg	127 (15)	127 (16)	130 (16)	130 (17)
Diastolic blood pressure, mean (SD), mmHg	79 (10)	80 (11)*	78 (10)	79 (11)*
Triglyceride, mean (SD), mg/dL	135 (88)	137 (86)	118 (60)	118 (65)

Motivational Health Guidance aged 65-74	Men		Women	
	Participants <i>n</i> =9,617	Non-ptcptps <i>n</i> =39,847	Participants <i>n</i> =6,328	Non-ptcptps <i>n</i> =25,989
Age, mean (SD), yrs	69.1 (2.5)	69.2 (2.5)	69.0 (2.5)	68.9 (2.6)
Waist circumference, mean (SD), cm	90.1 (4.8)	90.0 (4.9)	92.6 (6.1)	92.4 (6.5)
BMI, mean (SD), kg/m ²	25.0 (2.1)	24.9 (2.1)**	26.0 (2.4)	26.0 (2.5)
Body weight, mean (SD), kg	67.7 (6.5)	67.6 (6.6)	59.2 (6.2)	59.1 (6.4)
HbA1c, mean (SD), %	5.75 (0.6)	5.84 (0.75)**	5.76 (0.5)	5.82 (0.6)**
Systolic blood pressure, mean (SD), mmHg	135 (16)	137 (18)**	136 (16)	138 (18)**
Diastolic blood pressure, mean (SD), mmHg	80 (10)	81 (11)**	78 (10)	79 (11)**
Triglyceride, mean (SD), mg/dL	147 (83)	150 (93)**	132 (70)	135 (72)**

Values are mean (SD). **p*<0.05, ***p*<0.01, compared participants with non-participants in each category
 SI conversion factors: To convert Triglyceride to mmol/L, multiply value by 0.0113, Non-ptcptps: non-participants

SHG participants. Furthermore, the proportion of individuals who started pharmacological therapy in each follow-up year was significantly smaller in SHG participants than in nonparticipants. These results support that a large scale, policy-driven lifestyle intervention program could produce measureable improvements in MetS risks, and that small reductions in body weight (3%–5%) and WC (3 cm) would be feasible program goals for high-risk Japanese adults.

For the interpretation of these results, we have to consider several limitations. We could not control self-selection bias. There is a possibility that participants

in SHG were more health conscious than nonparticipants were. Health insurers' attitude and readiness might have affected individual participation, as implementation rates differed substantially among health insurers. Further investigation will be needed when more detailed background data become available. Second, a relatively low follow-up retention rate could also introduce potential bias. The loss to follow-up was caused primarily by participants' migration into different health insurers owing to a shift in age eligibility (into the elderly insurance plan), relocation, job change/loss, or retirement. Study subjects who belonged to insurers of the

Table 2. Change in clinical indicators (waist circumference, BMI, body weight, HbA1c, systolic blood pressure, diastolic blood pressure, triglyceride and HDL cholesterol) from baseline to subsequent three years in each Health Guidance participants and non-participants. 2a. Intensive Health Guidance aged 40-64, 2b. Motivational Health Guidance aged 40-64, 2c. Motivational Health Guidance aged 65-74

Intensive Health Guidance	Men aged 40-64			Women aged 40-64		
	Participants <i>n</i> =8,918	Non-ptcpts <i>n</i> =64,503	<i>P</i>	Participants <i>n</i> =2,024	Non-ptcpts <i>n</i> =13,569	<i>P</i>
Δ Waist circumference, mean (SE), cm						
one year	-2.34 (0.04)	-0.66 (0.01)	<0.01	-2.98 (0.12)	-1.59 (0.05)	<0.01
two years	-1.92 (0.05)	-0.69 (0.02)	<0.01	-2.80 (0.12)	-1.71 (0.05)	<0.01
three years	-1.48 (0.05)	-0.51 (0.02)	<0.01	-2.66 (0.12)	-1.55 (0.05)	<0.01
Δ BMI, mean (SE), kg/m ²						
one year	-0.66 (0.01)	-0.13 (0.00)	<0.01	-0.92 (0.04)	-0.24 (0.01)	<0.01
two years	-0.48 (0.01)	-0.11 (0.01)	<0.01	-0.71 (0.04)	-0.28 (0.01)	<0.01
three years	-0.38 (0.01)	-0.09 (0.01)	<0.01	-0.61 (0.04)	-0.23 (0.01)	<0.01
Δ Body weight, mean (SE), kg						
one year	-1.98 (0.03)	-0.42 (0.01)	<0.01	-2.25 (0.07)	-0.68 (0.02)	<0.01
two years	-1.53 (0.04)	-0.43 (0.01)	<0.01	-1.83 (0.08)	-0.85 (0.03)	<0.01
three years	-1.25 (0.04)	-0.43 (0.02)	<0.01	-1.65 (0.08)	-0.81 (0.03)	<0.01
Δ HbA1c, mean (SE), %						
one year	-0.01 (0.00)	0.04 (0.00)	<0.01	-0.05 (0.01)	0.02 (0.00)	<0.01
two years	0.06 (0.00)	0.09 (0.00)	<0.01	0.01 (0.01)	0.07 (0.00)	<0.01
three years	0.07 (0.00)	0.10 (0.00)	<0.01	0.02 (0.01)	0.09 (0.00)	<0.01
Δ Systolic BP, mean (SE), mmHg						
one year	-2.12 (0.13)	-0.87 (0.05)	<0.01	-3.31 (0.31)	-1.75 (0.12)	<0.01
two years	-1.19 (0.15)	-0.39 (0.05)	<0.01	-3.16 (0.33)	-1.95 (0.12)	<0.01
three years	-0.72 (0.15)	-0.13 (0.06)	<0.01	-2.95 (0.34)	-1.94 (0.13)	<0.05
Δ Diastolic BP, mean (SE), mmHg						
one year	-1.34 (0.09)	-0.39 (0.04)	<0.01	-2.11 (0.21)	-1.43 (0.08)	<0.05
two years	-0.64 (0.10)	-0.28 (0.04)	<0.01	-2.31 (0.21)	-1.75 (0.08)	NS
three years	-0.47 (0.10)	-0.14 (0.04)	<0.05	-2.45 (0.22)	-2.04 (0.09)	NS
Δ Triglyceride, mean (SE), mg/dL						
one year	-35.8 (1.22)	-15.1 (0.49)	<0.01	-27.5 (1.79)	-17.2 (0.71)	<0.01
two years	-29.4 (1.26)	-18.3 (0.50)	<0.01	-26.8 (1.87)	-17.6 (0.72)	<0.01
three years	-31.3 (1.27)	-22.2 (0.51)	<0.01	-26.2 (2.00)	-19.7 (0.72)	<0.05
Δ HDL cholesterol, mean (SE), mg/dL						
one year	1.93 (0.07)	0.58 (0.03)	<0.01	1.69 (0.17)	1.08 (0.07)	<0.01
two years	2.10 (0.08)	0.96 (0.03)	<0.01	2.00 (0.18)	0.98 (0.08)	<0.01
three years	2.37 (0.08)	1.29 (0.03)	<0.01	2.33 (0.19)	1.38 (0.08)	<0.01

Values are Mean (SE). *P* values are comparison between participants and non-participants in each category.

SI conversion factors: To convert Triglyceride to mmol/L, multiply value by 0.0113, and to convert cholesterol to mmol/L, multiply values by 0.0259, Non-ptcpts: non-participants

National Health Insurance were more likely to skip health checkups than were those who belonged to occupational health insurers; thus, the former had lower follow-up rates. It is necessary to conduct an additional study with a more representative sample or all insurers' data after revamping the NDB linkage system.

Despite these limitations, this study generated

valuable information as being one of a very few population-level observational studies that systematically analyze public health programs for prevention of non-communicable diseases (NCDs)³⁶. The nationwide extent of the program, a large number of study subjects involving 221,516 individuals, 3-yr longitudinal design, and availability of a wide range of laboratory,

(Cont Table 2)

Table 2b

Motivational Health Guidance	Men aged 40-64			Women aged 40-64		
	Participants <i>n</i> =1,882	Non-ptcpts <i>n</i> =24,965	<i>P</i>	Participants <i>n</i> =3,021	Non-ptcpts <i>n</i> =20,853	<i>P</i>
ΔWaist circumference, mean (SE), cm						
one year	-1.87 (0.09)	-0.44 (0.02)	<0.01	-1.70 (0.10)	-0.54 (0.04)	<0.01
two years	-1.73 (0.09)	-0.49 (0.03)	<0.01	-1.69 (0.10)	-0.55 (0.04)	<0.01
three years	-1.54 (0.10)	-0.31 (0.03)	<0.01	-1.54 (0.10)	-0.35 (0.04)	<0.01
ΔBMI, mean (SE), kg/m ²						
one year	-0.47 (0.02)	-0.09 (0.01)	<0.01	-0.60 (0.02)	-0.16 (0.01)	<0.01
two years	-0.37 (0.03)	-0.08 (0.01)	<0.01	-0.51 (0.02)	-0.21 (0.02)	<0.01
three years	-0.31 (0.03)	-0.06 (0.01)	<0.01	-0.46 (0.02)	-0.15 (0.02)	<0.01
ΔBody weight, mean (SE), kg						
one year	-1.40 (0.07)	-0.30 (0.02)	<0.01	-1.53 (0.05)	-0.42 (0.02)	<0.01
two years	-1.21 (0.08)	-0.30 (0.02)	<0.01	-1.40 (0.05)	-0.61 (0.02)	<0.01
three years	-1.09 (0.08)	-0.29 (0.03)	<0.01	-1.34 (0.06)	-0.52 (0.03)	<0.01
ΔHbA1c, mean (SE), %						
one year	0.00 (0.00)	0.03 (0.00)	<0.01	0.00 (0.00)	0.02 (0.00)	<0.01
two years	0.03 (0.01)	0.07 (0.00)	<0.01	0.01 (0.00)	0.06 (0.00)	<0.01
three years	0.04 (0.01)	0.07 (0.00)	<0.01	0.01 (0.01)	0.06 (0.00)	<0.01
ΔSystolic BP, mean (SE), mmHg						
one year	-0.64 (0.30)	0.49 (0.08)	<0.01	-0.81 (0.24)	-0.33 (0.09)	NS
two years	0.19 (0.32)	0.96 (0.08)	NS	-0.58 (0.25)	0.00 (0.10)	NS
three years	0.24 (0.32)	1.38 (0.09)	<0.01	0.04 (0.26)	0.36 (0.10)	NS
ΔDiastolic BP, mean (SE), mmHg						
one year	-0.21 (0.21)	0.45 (0.06)	<0.05	-0.7 (0.17)	-0.49 (0.06)	NS
two years	-0.04 (0.23)	0.57 (0.06)	<0.05	-1.12 (0.17)	-0.45 (0.07)	<0.01
three years	-0.48 (0.23)	0.77 (0.06)	<0.01	-1.03 (0.18)	-0.33 (0.07)	<0.01
ΔTriglyceride, mean (SE), mg/dL						
one year	-7.77 (1.68)	0.78 (0.50)	<0.01	-7.03 (0.99)	-0.94 (0.41)	<0.01
two years	-11.3 (1.99)	-0.70 (0.50)	<0.01	-6.41 (1.00)	-2.36 (0.42)	<0.01
three years	-8.79 (1.96)	-1.87 (0.51)	<0.01	-6.46 (0.99)	-1.32 (0.41)	<0.01
ΔHDL cholesterol, mean (SE), mg/dL						
one year	0.97 (0.21)	0.18 (0.00)	<0.01	0.98 (0.14)	0.24 (0.06)	<0.01
two years	1.23 (0.20)	0.38 (0.00)	<0.01	0.98 (0.15)	0.38 (0.07)	<0.01
three years	1.21 (0.22)	0.66 (0.00)	<0.05	1.33 (0.15)	0.70 (0.07)	<0.01

Values are Mean (SE). *P* values are comparison between participants and non-participants in each category.

SI conversion factors: To convert Triglyceride to mmol/L, multiply value by 0.0113, and to convert cholesterol to mmol/L, multiply values by 0.0259, Non-ptcpts: non-participants

anthropometric, and pharmacological data from the NDB are major strengths of this study. There are only a few existing studies that have a comparable participant size and follow-up duration in the real-world setting, and our findings are fairly consistent with those studies' findings. The MOVE! program by the United States Veterans Health Administration reports that veterans who participated in the lifestyle intervention program in an "intensive and sustained" manner lost 2.2% of body weight in 3 yr (*n*=19,367), compared with

less active participants (-0.64%, *n*=219,173) and non-participants (+0.46%, *n*=1,606,257)³⁷. The MOVE! program included individuals with diabetes, cardiovascular disease, and other chronic conditions; and 87% of participants were men. Meta-analyses of Diabetes Prevention Programs (DPP) also report similar weight reduction and cardio-metabolic risk improvements. Dunkley *et al.*'s study, which included 22 DPP studies worldwide (pooled *n*=5,500), found a mean weight loss of 2.32 kg at 12 months³⁸, and Mudaliar *et al.*'s

(Cont Table 2)

Table 2c

Motivational Health Guidance	Men aged 65-74			Women aged 65-74		
	Participants <i>n</i> =9,617	Non-ptcpts <i>n</i> =39,847	<i>P</i>	Participants <i>n</i> =6,328	Non-ptcpts <i>n</i> =25,989	<i>P</i>
Δ Waist circumference, mean (SE), cm						
one year	-1.95 (0.04)	-0.95 (0.02)	<0.01	-2.36 (0.07)	-1.45 (0.04)	<0.01
two years	-1.78 (0.04)	-1.06 (0.02)	<0.01	-2.44 (0.07)	-1.85 (0.04)	<0.01
three years	-1.65 (0.04)	-0.97 (0.02)	<0.01	-2.23 (0.07)	-1.75 (0.04)	<0.01
Δ BMI, mean (SE), kg/m ²						
one year	-0.44 (0.01)	-0.14 (0.00)	<0.01	-0.61 (0.01)	-0.23 (0.00)	<0.01
two years	-0.38 (0.01)	-0.18 (0.01)	<0.01	-0.54 (0.02)	-0.28 (0.01)	<0.01
three years	-0.36 (0.01)	-0.19 (0.01)	<0.01	-0.48 (0.02)	-0.28 (0.01)	<0.01
Δ Body weight, mean (SE), kg						
one year	-1.30 (0.03)	-0.43 (0.01)	<0.01	-1.51 (0.03)	-0.64 (0.01)	<0.01
two years	-1.20 (0.03)	-0.62 (0.01)	<0.01	-1.48 (0.03)	-0.90 (0.02)	<0.01
three years	-1.22 (0.03)	-0.74 (0.02)	<0.01	-1.49 (0.04)	-1.02 (0.02)	<0.01
Δ HbA1c, mean (SE), %						
one year	0.00 (0.00)	0.01 (0.00)	<0.01	-0.01 (0.00)	0.00 (0.00)	NS
two years	0.02 (0.00)	0.04 (0.00)	<0.01	0.01 (0.00)	0.02 (0.00)	NS
three years	0.03 (0.00)	0.04 (0.00)	<0.05	0.02 (0.00)	0.02 (0.00)	NS
Δ Systolic BP, mean (SE), mmHg						
one year	-1.20 (0.14)	-0.55 (0.07)	<0.01	-0.89 (0.17)	-0.61 (0.09)	NS
two years	-0.96 (0.15)	-0.78 (0.07)	NS	-1.29 (0.18)	-0.68 (0.09)	<0.05
three years	-0.90 (0.15)	-0.88 (0.08)	NS	-0.95 (0.18)	-0.92 (0.10)	NS
Δ Diastolic BP, mean (SE), mmHg						
one year	-1.40 (0.10)	-1.05 (0.05)	<0.01	-1.41 (0.12)	-1.09 (0.06)	<0.05
two years	-1.67 (0.10)	-1.67 (0.05)	NS	-2.01 (0.12)	-1.70 (0.06)	NS
three years	-2.04 (0.10)	-1.93 (0.05)	NS	-2.47 (0.12)	-2.20 (0.06)	NS
Δ Triglyceride, mean (SE), mg/dL						
one year	-13.5 (0.77)	-7.9 (0.40)	<0.01	-11.3 (0.76)	-7.3 (0.39)	<0.01
two years	-15.7 (0.73)	-10.4 (0.41)	<0.01	-12.5 (0.78)	-9.5 (0.40)	<0.01
three years	-16.1 (0.79)	-12.4 (0.43)	<0.01	-12.0 (0.77)	-10.9 (0.40)	NS
Δ HDL cholesterol, mean (SE), mg/dL						
one year	1.13 (0.08)	0.14 (0.04)	<0.01	1.01 (0.12)	0.54 (0.05)	<0.01
two years	1.25 (0.08)	0.17 (0.05)	<0.01	0.96 (0.13)	0.55 (0.05)	<0.01
three years	1.59 (0.08)	0.56 (0.05)	<0.01	1.58 (0.13)	1.07 (0.05)	<0.01

Values are Mean (SE). *P* values are comparison between participants and non-participants in each category.

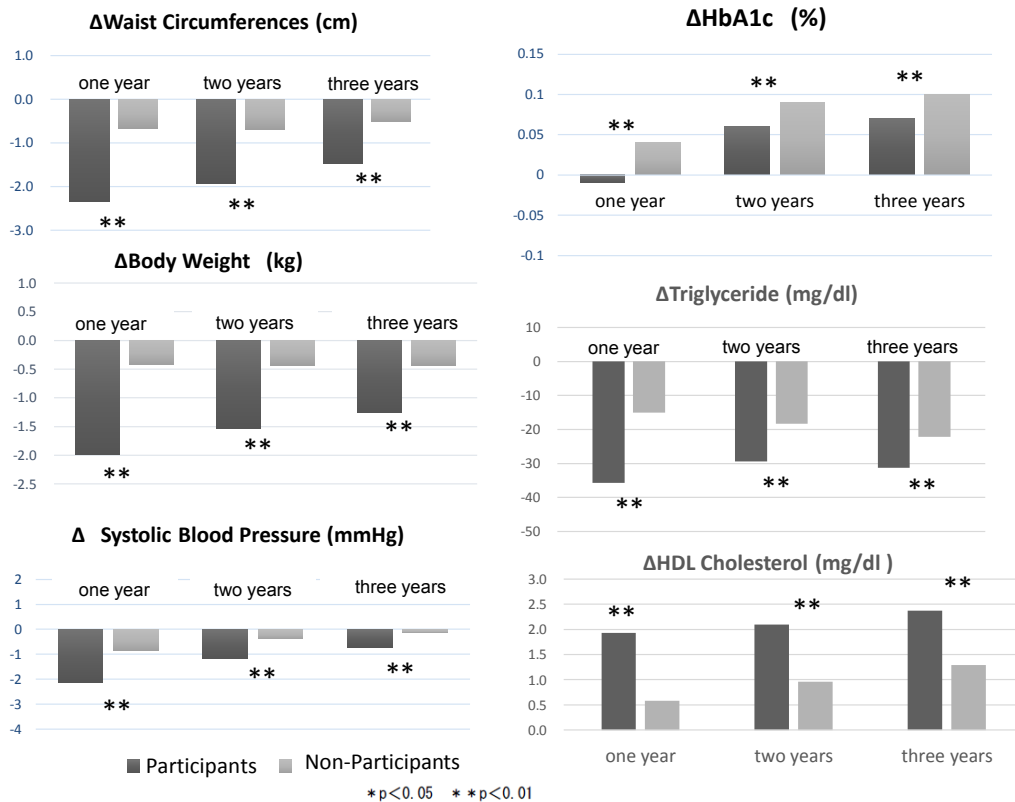
SI conversion factors: To convert Triglyceride to mmol/L, multiply value by 0.0113, and to convert cholesterol to mmol/L, multiply values by 0.0259, Non-ptcpts: non-participants

study, which included 44 DPP studies in the United States (pooled *n*=8,995), found a mean weight loss of 3.77 kg, a mean HbA1c reduction of 0.21%, and a mean HDL increase of 0.85 mg/dL, with an average follow-up of 9.3 months³⁹). The 2014 United States Preventive Service Task Force's (USPSTF's) meta-analysis of lifestyle improvement counseling trials reports that medium- to high-intensity behavioral counseling for persons with elevated cardiovascular risks resulted in consistent improvements across a variety of health

outcomes⁴⁰). The USPSTF also supports the notion that the effectiveness of counseling interventions largely depends on their availability and real-world adherence to those interventions. Unlike the existing lifestyle intervention models⁴¹), SHG does not come with a formulaic curriculum. Health insurers had great flexibility to tailor their programs on the basis of the demographics, occupations, local culture, and specific health needs of their enrollees.

Looking back, SHC/SHG was planned after the

3-a



3-b

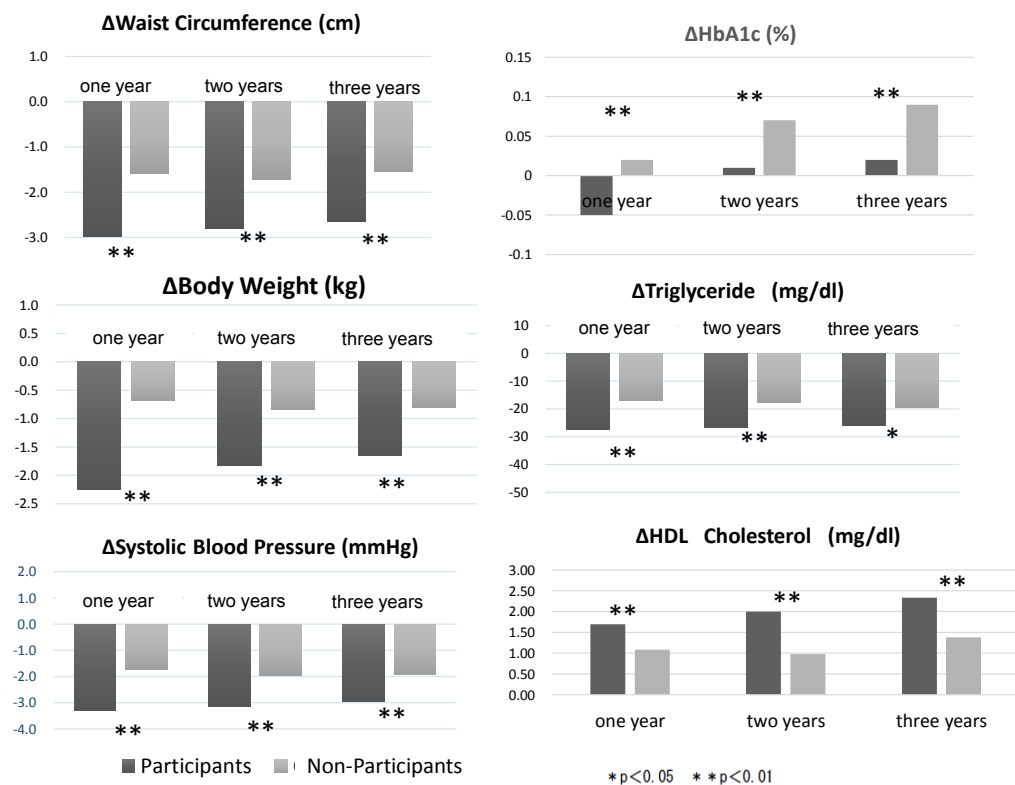


Fig. 3. Change in clinical indicators (waist circumference, body weight, systolic blood pressure, hemoglobin A1c, triglyceride, and high-density lipoprotein cholesterol) from baseline (2008) to subsequent 3 yr (2009, 2010, and 2011) in participants and nonparticipants. (a) Men aged 40–64. (b) Women aged 40–64. **p*<0.05, ***p*<0.01: differences between participants and the control.

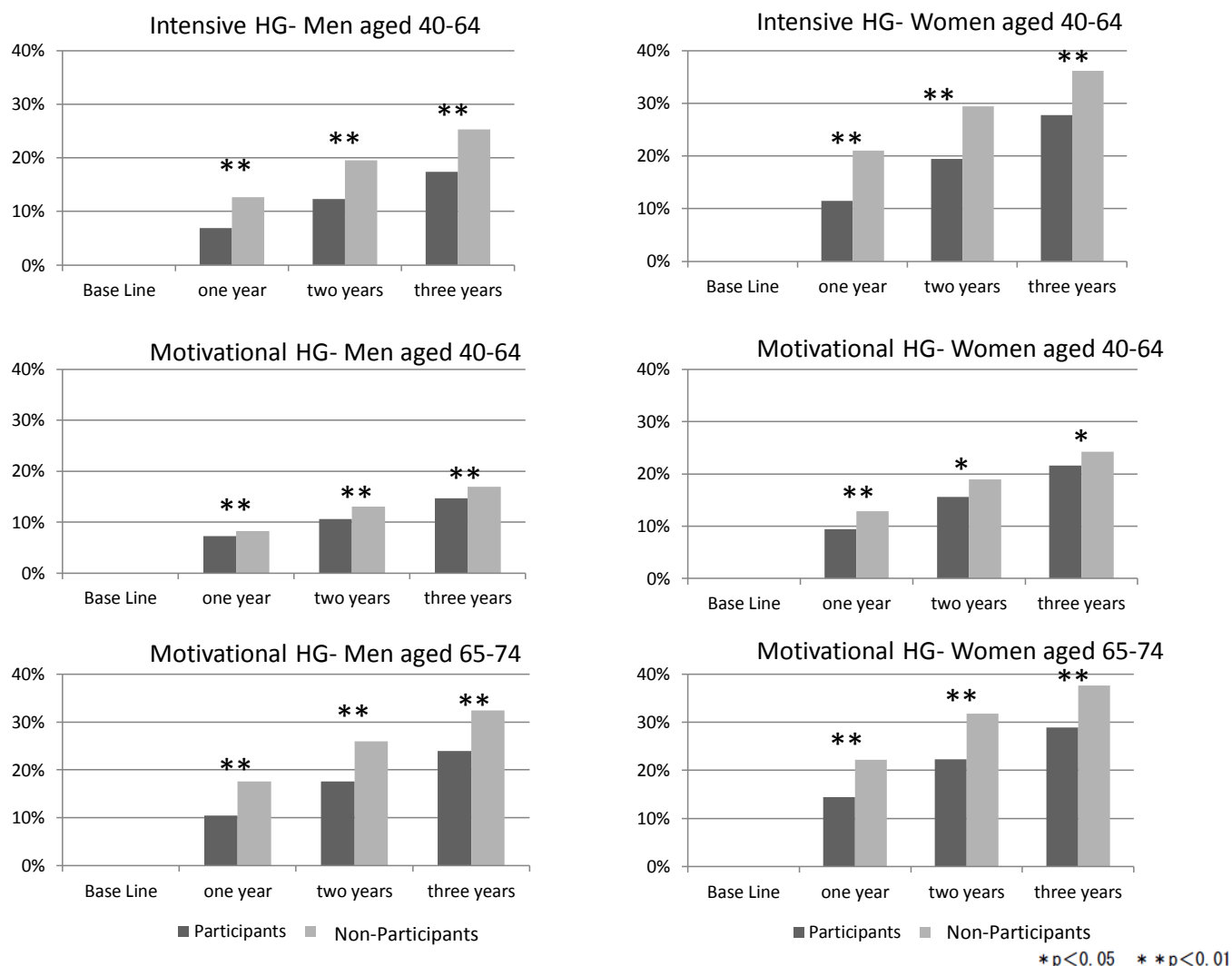


Fig. 4. Proportion of individuals who started pharmacological therapy in baseline and each follow-up year in the intensive Health Guidance (HG) and motivational HG aged 40–64 and 64–74.

* $p < 0.05$, ** $p < 0.01$: differences between participants and nonparticipants.

midterm evaluation of Health Japan 21 (the First Edition, 2000), which reported a gradual increase in prevalence of overweight, especially in adult men⁴², despite increased campaigns to promote a healthy lifestyle⁴³. The NDB analysis revealed that more than 60% of medicated men had abdominal obesity⁴⁴. Physicians had very limited options to deal with increased abdominal obesity in patients other than prescribing drugs, even though early initiation of pharmacological therapy without lifestyle modification could lead to polypharmacy. On the basis of this experience, SHC/SHG system was designed to focus on preclinical signs of NCDs, notably abdominal obesity and accompanying MetS risk factors, and provide lifestyle intervention to improve the condition before the onset of type 2 dia-

betes, stroke, and/or cardiovascular disease. We can also expect additional health benefits, as MetS is related to chronic renal disease⁴⁵ and periodontal disease⁴⁶. It is yet unclear whether the small but significant improvements in MetS risk factors achieved by SHG can bring measurable reductions in health-care costs associated with NCDs. To answer this question, analysis of the NDB's SHC/SHG data linked to medical expenditure data with a longer follow-up period is warranted.

Lastly, SHC/SHG was introduced as an innovative public health program to make Japan a model country of healthy longevity with contained medical expenditure, but relatively low participation rates pose a concern. As the United Nations General Assembly on the Prevention and Control of NCDs has pro-

claimed⁴⁷⁾, we believe that all sectors in Japan, including policy makers, insurers, health-care providers, researchers, and citizens, should recognize the importance of prevention and work together to realize the full potential of this program.

Conclusion

This study revealed that participants in SHG showed greater improvement in MetS profiles with less pharmacological treatments. Although there were limitations including selection bias, our nationwide experience supported that targeting small reductions in body weight and WC would be a potential strategy to prevent MetS and its sequelae in Japanese adults. (2,909 words)

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Supplemental Table 1. Number of participants and non-participants in the SHG (5-year age subgroups by sex)

Sex	Age	Total N	Intensive HG		Motivational HG	
			Participants N	Non-ptcpts N	Participants N	Non-ptcpts N
MEN	40-44	16,775	1,532	10,468	174	4,601
	45-49	17,246	1,673	10,986	213	4,374
	50-54	21,414	2,109	13,964	242	5,099
	55-59	26,152	2,203	17,262	402	6,285
	60-64	18,681	1,401	11,823	851	4,606
	65-69	25,782			5,099	20,683
	70-74	23,682			4,518	19,164
WOMEN	40-44	3,652	124	1,124	151	2,253
	45-49	4,727	174	1,450	204	2,899
	50-54	7,051	305	2,396	363	3,987
	55-59	10,502	520	3,705	702	5,575
	60-64	13,535	901	4,894	1,601	6,139
	65-69	17,134			3,546	13,588
	70-74	15,183			2,782	12,401
Total		221,516	10,942	78,072	20,848	111,654

Supplemental Table 2. Change in body weight from baseline (2008) to next year in participants and non-participants (5-year age subgroups by sex)

	MEN	40-44	45-49	50-54	55-59	60-64	65-69	70-74	
Intensive HG	Participants	-2.11 (0.10)	-1.92 (0.08)	-2.07 (0.07)	-1.85 (0.06)	-1.95 (0.08)			
	Non-ptcpts	-0.50 (0.03)	-0.43 (0.04)	-0.39 (0.02)	-0.40 (0.02)	-0.43 (0.03)			
	<i>p</i> value	<0.01	<0.01	<0.01	<0.01	<0.01			
	WOMEN	40-44	45-49	50-54	55-59	60-64	65-69	70-74	
	Participants	-2.10 (0.33)	-1.87 (0.31)	-2.20 (0.18)	-2.36 (0.15)	-2.29 (0.09)			
	Non-ptcpts	-0.52 (0.11)	-0.60 (0.08)	-0.55 (0.06)	-0.69 (0.05)	-0.79 (0.04)			
	<i>p</i> value	<0.01	<0.01	<0.01	<0.01	<0.01			
	Motivational HG	Participants	-1.89 (0.31)	-1.04 (0.20)	-1.15 (0.19)	-1.42 (0.13)	-1.46 (0.09)	-1.31 (0.04)	-1.27 (0.04)
		Non-ptcpts	-0.23 (0.05)	-0.28 (0.04)	-0.32 (0.06)	-0.30 (0.04)	-0.41 (0.04)	-0.45 (0.02)	-0.41 (0.02)
<i>p</i> value		<0.01	<0.01	<0.05	<0.01	<0.01	<0.01	<0.01	
WOMEN		40-44	45-49	50-54	55-59	60-64	65-69	70-74	
Participants		-1.69 (0.29)	-1.59 (0.20)	-1.65 (0.16)	-1.43 (0.09)	-1.53 (0.06)	-1.54 (0.04)	-1.46 (0.04)	
Non-ptcpts		-0.37 (0.07)	-0.27 (0.05)	-0.30 (0.04)	-0.51 (0.04)	-0.52 (0.03)	-0.64 (0.02)	-0.64 (0.02)	
<i>p</i> value		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	

Values are Mean (SE). *P* values are comparison between each group of participants and control (non-participants) group.