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# Routine Screening and Consultation Facilitate Improvement of Metabolic Syndrome

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This randomized controlled trial study aimed to investigate the effects of a lifestyle intervention on metabolic syndrome (MetS) among middle-aged Koreans. A total of 243 middle-aged Koreans with MetS were randomly assigned to either of 2 types of lifestyle intervention for MetS and followed for 12 months. Health examinations and interventions were implemented at 16 regional branch facilities of a Korean medical institution from 2010, following the NCEP-ATP III criteria and recommendations. Lifestyle intervention (LI) group (n = 137) participated in a 12-week multi-component intervention including individual counseling, group sessions, and self-help materials. Basic usual intervention (BI) aroup (n = 106) was provided with one-page health information sheet on MetS and MetS management at baseline. Prevalence of MetS and each of MetS components, except for low HDL-cholesterol, in both groups were significantly reduced and maintained after the intervention. Notably, prevalence of hypertension and abdominal obesity continued to improve during the follow-up period. Between-group differences in results were not found. Both interventions were effective when they were accompanied with repeated check-ups and notification of MetS status. It is recommended to design clear guidelines for the notification of MetS after MetS screening and to encourage checking MetS status periodically for effective MetS management (KCT 0000446).

Keywords: Metabolic Syndrome; Lifestyle Intervention; Randomized Controlled Trial; Middle-aged Adults

# **INTRODUCTION**

Metabolic syndrome (MetS) is a cluster of risk factors for diabetes (1), cardiovascular disease, and all-cause mortality (2). The prevalence of MetS has been increasing globally with widely varying pace by demographic factors such as age, sex, and ethnicity. The significant increase of MetS in western countries during the last decades has been a very serious public health concern (3, 4). The increase of MetS is responsible for high socioeconomic cost due to higher prevalence of comorbidities (5).

The epidemic of MetS has been considered as an important public health problem in most Asian countries as well with prevalence higher than 20% (6, 7). Asians are likely to carry more body fat at a lower body weight or smaller waist circumference than Caucasians (8, 9). The prevalence of MetS has been increasing in Korea, especially in middle-aged adults. The age-adjusted prevalence of MetS increased significantly from 24.9% in 1998 to 31.3% in 2007 (10). The National Health Insurance Service (NHIS) Korea reports that about 30% of Koreans aged 30 yr and older have MetS (11). About 3 quarters (73.7%) of Korean adults have at least one of five parameters composing the MetS at an abnormal level. From 1998 to 2007, the prevalence of low HDL-cholesterol increased the most (+ 13.8%) among Koreans, followed by abdominal obesity (+ 8.7%) and hypertriglyceridemia (+ 4.9%).

With an increased concern, control of MetS has been one of the main targets of public health interventions in Asian countries (12). For example, Japanese government introduced a national strategy to prevent the obesity and MetS which is called as 'Metabo-Law'. The Metabo-Law requires waist circumferences of all Japanese adults aged 40-74 to be measured at annual health check-ups performed via local governments and employers. According to the Metabo-Law, those with abdominal obesity (waist circumference > 85 cm for male and > 90 cm for female) are referred to counseling sessions with phone calls and e-mail correspondence, and motivational support (13). In Korea, the metropolitan government of Seoul has launched the "5-Rock" MetS control and prevention program since 2011 (http: //www.5check.or.kr/). Citizens of Seoul can participate in the program via local public health centers in all 25 districts in Seoul. Those diagnosed with MetS receive counseling services in this program on a regular basis to reduce the MetS risks through lifestyle changes.

Most interventions on MetS prevention and management consist of lifestyle modification strategies. The U.S. National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) emphasized lifestyle modification as an essential strategy for the risk management for cardiovascular diseases (14). The Korean Academy of Family Medicine also endorses lifestyle changes, dietary therapies, and physical activity as non-pharmaceutical strategies for prevention and control of MetS (15). The positive impact of lifestyle modification interventions on MetS management including dietary changes and physical activity have been reported by several empirical studies (16-18).

MetS intervention studies in Korea so far (19, 20) have been implemented to limited target population, few of which have evaluated long-term effects of the interventions. In the 5-Rock project, for example, the group with 6-month intervention resulted in significant improvements in four of five components of MetS except for the HDL-cholesterol (19). However, the evaluation was limited as there was not a control group in the study, the intervention programs were not standardized across the public health centers, and the program participation was on a voluntary basis.

The present study was an attempt to investigate the effects of lifestyle interventions on MetS in Korean middle-aged adults in a randomized controlled trial with multiple follow-up assessments. A theory-based nationwide intervention program conducted by the Korea Association of Health Promotion (KAHP) was followed multiple times for 12 months to identify long-term effects of the intervention on MetS in comparison with conventional basic care for MetS at KAHP.

# **MATERIALS AND METHODS**

#### Study design and participants

Effective lifestyle interventions for MetS are recommended to combine guidance for nutrition and exercise with behavioral and cognitive strategies (21). This study employed an 'alternative-treatments design with pretest' (22) in order to determine the effectiveness of a 12-week multi-component lifestyle intervention versus a one-time, single-component usual care for MetS. This design was particularly useful because it allowed us: 1) to compare the effectiveness of an alternative intervention to that of a usual care; and 2) to stay ethical to provide care for all

Risk factors	Components	Defining level
Hypertension	Blood pressure	Systolic BP $\ge$ 130 mmHg or Diastolic BP $\ge$ 85 mmHg
Abdominal obesity	Waist circumference	Male $> 90$ cm or Female $> 80$ cm
Hyperglycemia	Fasting glucose	≥ 100 mg/dL
Hypertriglyceridemia	Triglycerides	≥ 150 mg/dL
Low HDL-cholesterol	HDL-cholesterol	$\label{eq:Male} Male < 40 \ \text{mg/dL} \ \text{or} \ \text{Female} < 50 \ \text{mg/dL}$

BP, blood pressure; HDL-cholesterol, high-density lipoprotein cholesterol.

participants in this study.

A total of 457 Korean men and women aged 40-60 yr were recruited nationwide after having been identified with MetS at one of 16 regional branch health facilities of the KAHP in 2010. MetS was defined by the NCEP -ATP III criteria for MetS and the Asia-Pacific standard for abdominal obesity (23). That is, middle-aged Koreans who have 3 or more of the five conditions described in Table 1 are classified as having MetS.

Primary outcome of this study was the prevalence of MetS. We assumed improvement rates of 65% for intensive intervention and 44% for basic usual intervention based on our previous studies on lifestyle interventions for MetS (24, 25) for sample size calculation. Similarly, 30% attrition was considered. With 80% power and 5% level of significance, the sample size required per group was 111.

Of these 457 participants with MetS, 125 people were excluded: who were in treatment or on medication for MetS-related health conditions such as hypertension, dyslipidemia, and diabetes; who provided incomplete information to core study questions in the survey; and who had not signed consent for participation in the study (Fig. 1). Using a random number table, the 332 eligible people who agreed to participate were randomly assigned either to a 12-week intensive lifestyle intervention (LI) group or to a basic usual intervention (BI) group. Both participants and researchers were blinded to be unaware of intervention allocations. During the intervention, 38 participants in LI group and 51 participants in BI group discontinued participating. Thereby, 137 participants in LI group and 106 participants in BI group were included in post-intervention health examination and survey, and followed for multiple post assessments for 12 months. There were no significant differences in socio-demographic and MetS characteristics between the intervention

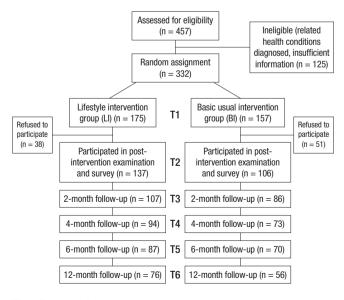


Fig. 1. Flow chart of participants.

participants and the dropouts at baseline (data not shown). This study is registered in the Clinical Research Information Service by Korea Centers for Diseases Control and Prevention, Republic of Korea (#KCT 0000446).

#### Intervention program

The LI group received a theory-based 12-week multi-component intervention after having been diagnosed of MetS (Table 2). The multi-component intervention program included individual health counseling, health education classes - group sessions, and a booklet and newsletters for self-management. Oneon-one health counseling was provided every week by health counselors, most of whom were trained dietitians, at the KAHP health facilities where the participants had been screened for MetS. The Intervention Mapping Approach (26) was employed as a framework for the development of the intensive lifestyle intervention. A matrix of change objectives was structured for each MetS-related health behavior and appropriate theoretical methods and strategies were matched. Based on the Transtheoretical Model (27), assessments were conducted on individual participants' MetS status and related health behavior problems including stages of changes for healthy diet, physical activity, and weight control. Then the participants established behavioral objectives and strategies for dietary behaviors, physical activity, smoking, alcohol drinking, and stress management guided by health counselors. They were advised to monitor their own behaviors every day by keeping a health diary and to check with their health counselors to modify the lifestyle change strategies. In addition, the LI group was invited to two health education classes on prevention and management of hypertension, diabetes, and MetS. A handbook and monthly newsletters on healthy lifestyle were sent to LI group to promote self-management.

 Table 2. 12-week intensive lifestyle intervention program contents

Week	Session topics	TTM & SCT based methods and strategies
1	<ul> <li>Overview of the program</li> <li>MetS and its relation to CVDs &amp; diabetes</li> <li>Managing MetS through lifestyle change</li> </ul>	<ul> <li>Consciousness raising</li> <li>Outcome expectation</li> <li>Self-liberation</li> </ul>
2-7	<ul> <li>Weight control</li> <li>Balanced diet and fruits/vegetable intake</li> <li>Reduction of total caloric intake and low fat diet</li> <li>Special diet for risk factor management</li> <li>Physical activity guideline to manage MetS</li> <li>Physically active lifestyle</li> </ul>	<ul> <li>Knowledge acquisition</li> <li>Skill building</li> <li>Decisional balance</li> <li>Goal setting</li> <li>Self monitoring</li> <li>Self efficacy</li> </ul>
8-9	<ul><li>Moderate alcohol drinking and smoking cessation</li><li>Managing stress and depressive mood</li></ul>	<ul> <li>Counterconditioning</li> <li>Stimulus control</li> </ul>
10	- Regular health check-ups	
11-12	- Maintaining healthy lifestyle	<ul><li>Feedback</li><li>Self efficacy</li><li>Reinforcement management</li></ul>

MetS, metabolic syndrome; CVD, cardiovascular diseases; TTM, transtheoretical model; SCT, social cognitive theory. The aforementioned strategies were applied to enhance the participants' self-efficacy and motivation based on the Social Cognitive Theory (28).

The BI group, on the other hand, was informed about their MetS status once diagnosed and provided with a one-page health information sheet about MetS and self-management guidelines. During one-year follow up, both groups were screened for MetS for 4 times: at 2-, 4-, 6-, and 12-month post intervention. More detailed protocol and theoretical framework of the intervention is described elsewhere (25).

Before the onset of study, all intervention implementers attended a training session on study procedure based on a standardized protocol across intervention sites. Plus, 'intervention site' was included in the analysis as a variable for adjustment.

For participants in both groups, five clinical and anthropometric outcomes related to MetS were measured at baseline, post intervention (12 weeks from the baseline) and at 2-, 4-, 6-, and 12-month follow-ups post intervention. Trained research assistants performed clinical and anthropometric measurements with a standardized protocol. Blood pressure was measured with an automatic digital sphygmomanometer (TM-2655P, A&D, Tokyo, Japan). Measurements were made after participants being seated quietly for at least 5 min in a chair with feet on the floor. Determination of blood pressure is based upon the mean of two measurements separated by at least 2 min. Waist circumference was measured with a tape spring-tension measure at a level midway between the lowest rib and the iliac crest. Fasting blood samples were drawn and analyzed at KAHP laboratories. Fasting glucose, triglycerides and HDL-cholesterol were measured using HITACHI 7600-110 (HITACHI, Tokyo, Japan). Socio-demographic characteristics of the participants including age, sex, education level, marital status, employment status, and monthly income were surveyed at baseline by trained research assistants.

#### Statistical analysis

Baseline socio-demographic and MetS characteristics were reported and compared between the LI and BI groups with chisquare tests for discrete variables and t-tests for continuous variables. Binary outcome measures consisted of prevalence of the MetS and abnormality of each of five MetS parameters. Continuous outcome measures consisted of measured values of each MetS component, the number of MetS risks of each participant, that is, the number of MetS components at abnormal levels, and z-MetS score. The z-MetS score was calculated as below where SD<sub>SBP</sub>, SD<sub>DBP</sub>, SD<sub>WC</sub>, SD<sub>FG</sub>, SD<sub>TG</sub>, and SD<sub>HDL-C</sub> are genderspecific standard deviations for systolic blood pressure, diastolic blood pressure, waist circumference, fasting glucose, triglyceride, and HDL-cholesterol, respectively, from all participants at baseline (29). Z-MetS score can detect continuous changes in each MetS component even though the changes does not influence the binary MetS status.

- $\label{eq:score} \begin{array}{l} z\text{-MetS score for male} = (Systolic Blood Pressure-130)/SD_{SBP} \\ + (Diastolic Blood Pressure-85)/SD_{DBP} + (Waist Circumference-90)/SD_{WC} + (Fasting Glucose-100)/SD_{FG} + (Triglyceride-150)/SD_{TG} + (40\text{-HDL-Cholesterol})/SD_{HDL-C} \end{array}$
- $\label{eq:score} \begin{array}{l} z\text{-MetS score for female} = (Systolic Blood Pressure-130)/SD_{SBP} \\ + (Diastolic Blood Pressure-85)/SD_{DBP} + (Waist Circumference-80)/SD_{WC} + (Fasting Glucose-100)/SD_{FG} + (Triglyceride-150)/SD_{TG} + (50\text{-HDL-Cholesterol})/SD_{HDL-C} \end{array}$

Means and standard deviations (SDs) of the measures at each measured time point were calculated. Changes occurred in outcomes between baseline and post intervention were examined with McNemar's tests for discrete variables and paired t-tests for continuous variables. Effect size statistics with standardized mean differences for the continuous variables and odds-ratios for the binary variables were calculated to characterize the magnitude of the intervention program effect (29).

Post intervention follow-up measurements were taken multiple times up to the 12-month post intervention point to exam-

#### Table 3. Baseline (T1) characteristics according to the LI and the BI group

ine between-group and between-time differences in outcomes, respectively. Follow-up results were analyzed with the Generalized Estimating Equations (GEE) models for discrete variables and the mixed effects model for continuous variables. The long-term effects of interventions were analyzed comparing the out-come values of the intervention groups at post intervention (T2) with those at 6-month follow-up (T5) and at 12-month follow-up (T6). Intervention group by measured time point interaction was included in the analysis to determine whether the changes between both intervention groups were different. Missing values were imputed with the multiple imputation procedure, and analysis was performed according to the 'intention-to-treat' approach. All statistical analyses were performed using the SAS 9.3 statistical software package (SAS Institute, Cary, NC, USA).

# **Ethics statement**

The study protocol was approved by the institutional review board of the KAHP (IRB No. 10-B-01). Informed consent was confirmed by the board and obtained from all study participants.

Characteristics			No. (%) of participants		Duoluo*
Characteristics		LI group (n = 137)	BI group (n = 106)	All (n = 243)	— P value*
Socio-demographic c	characteristics				
Age in years	Mean (SD)	51.4 (5.5)	51.6 (5.6)	51.5 (5.5)	0.730
Sex	Male	52 (38.0)	40 (37.7)	92 (37.9)	0.972
	Female	85 (62.0)	66 (62.3)	151 (62.1)	
Education	Middle school	35 (25.7)	34 (32.4)	69 (28.6)	0.306
	High school	53 (39.0)	43 (41.0)	96 (39.8)	
	College	48 (35.3)	28 (26.7)	76 (31.5)	
Marital status	Live with spouse	116 (85.3)	87 (82.9)	203 (84.2)	0.607
	Live without spouse	20 (14.7)	18 (17.1)	38 (15.8)	
Employment	Employed	81 (60.0)	55 (54.5)	136 (57.6)	0.630
	Housewives	39 (28.9)	35 (34.7)	74 (31.4)	
	Others	15 (11.1)	11 (10.9)	26 (11.0)	
Monthly income	1,000 USD >	12 (9.3)	14 (13.9)	26 (11.3)	0.120
	1,000-3,000 USD	50 (38.8)	48 (47.5)	98 (42.6)	
	≥ 3,000 USD	67 (51.9)	39 (38.6)	106 (46.1)	
Metabolic syndrome	characteristics, mean (SD)				
No. of risks meetin	g MetS	3.3 (0.5)	3.4 (0.6)	3.3 (0.5)	0.154
z-MetS score		0.6 (2.2)	1.2 (2.5)	0.9 (2.3)	0.087
Hypertension (No.,	%)	101 (73.7)	74 (69.8)	175 (72.0)	0.501
Systolic BP (mmł	Hg)	130.1 (12.3)	130.2 (14.0)	130.2 (13.0)	0.933
Diastolic BP (mm	Hg)	81.9 (8.8)	83.5 (9.5)	82.6 (9.1)	0.179
Abdominal obesity	(No., %)	117 (85.4)	95 (89.6)	212 (87.2)	0.328
Waist circumfere	nce (cm)	88.8 (7.4)	89.6 (8.2)	89.1 (7.7)	0.425
Hyperglycemia (No	., %)	91 (66.4)	71 (67.0)	162 (66.7)	0.927
Fasting glucose (	mg/dL)	112.1 (36.2)	110.1 (23.7)	111.2 (31.3)	0.615
Hypertriglyceridem	ia (No., %)	96 (70.1)	72 (67.9)	168 (69.1)	0.719
Triglycerides (mg	/dL)	198.0 (92.4)	202.1 (100.7)	199.8 (95.9)	0.740
Low HDL-cholester	ol (No., %)	43 (31.4)	48 (45.3)	91 (37.4)	0.026
HDL-cholesterol	(mg/dL)	52.2 (9.3)	50.3 (9.4)	51.4 (9.4)	0.123

\**P* value, based on a *t*-test for continuous variables and the chi-square test for categorical variables (Education and marital status include 2 missing values; employment includes 7 missing values; monthly income includes 13 missing values). L1, intensive lifestyle intervention; B1, basic usual intervention; SD, standard deviation; MetS, metabolic syndrome; BP, blood pressure; HDL-cholesterol, high-density lipoprotein cholesterol.

# RESULTS

# **Participant characteristics**

Table 3 presents baseline (T1) characteristics of the participants per intervention group. At baseline, participants in this study had 3.3 risks of MetS on average. Baseline prevalence of each of four MetS components except for low HDL-cholesterol (37.4%) was higher than 60%. Both LI and BI groups were similar in all reported characteristics except for the prevalence of low HDLcholesterol, which was higher in BI group (P = 0.026).

#### Effects of intervention on MetS

Table 4 shows the prevalence of MetS and measured values of the MetS components at baseline and post intervention. Prevalence of MetS and each of its components in both groups was significantly reduced after the interventions except for the prevalence of low HDL-cholesterol in the LI group. More than 40% of participants (48.2% of LI and 40.6% of BI) no longer had MetS post intervention (P < 0.001). The average number of MetS risks per person was significantly decreased from 3.3 to 2.6 in the LI group and from 3.4 to 2.8 in the BI group after the intervention (P < 0.001). Z-MetS scores were also reduced significantly in both groups after the intervention: from 0.6 to -0.4 in the LI group (P < 0.001) and from 1.2 to 0.3 in the BI group (P = 0.003). For the effect size of this study, the odds of being free of abdominal obesity for the LI group were 1.95 times greater than those for the BI group. Based on the standardized mean difference effect size (29), the LI group improved the number of MetS risk components by +0.19 standard deviation relative to the BI group.

While the prevalence of MetS was reduced significantly, some of the average measured values of MetS components were improved. Systolic and diastolic blood pressure levels were reduced significantly in both LI and BI groups. Triglycerides level was significantly decreased only in the LI group (P = 0.003), whereas fasting glucose level was significantly decreased only in the BI group (P = 0.033). Average waist circumference and HDLcholesterol level did not change in either group. In addition, there were no significant differences in all of the measured values by sex except for average waist circumference. The average waist circumference of men in the LI group became significantly smaller (P = 0.034) from 93.6 cm at baseline to 92.6 cm at post intervention, while such a change was not observed in women (data not shown).

Fig. 2 shows the changes in prevalence of MetS and each MetS component during the follow-up period after adjusting for age, sex, education level, marital status, intervention site, frequency of visits, and the baseline values. Once the prevalence of MetS was reduced at post intervention (T2), the reduced prevalence of most MetS components was maintained during the 12-month follow-up period. The prevalence of hypertension and abdominal obesity, in particular, continued to decline after the interventions: from 51.1% at T2 to 34.1% at T5 (P = 0.003) and to 29.7% at T6 (P = 0.001) for hypertension: and from 71.5% to 63.6% at T5 (P = 0.026) for abdominal obesity. Furthermore, the LI group participants were less likely to be obese in abdomen than the BI group participants after adjusting for the other variables (P =0.045 at T5 and P = 0.048 at T6). There were no differences between intervention groups in all measures except for abdominal obesity throughout the 12-month follow-up period. No effects were found for intervention group by time point interaction.

Table 5 presents the long-term effects of interventions on each component of the MetS, the number of MetS risks, and z-MetS score, which were adjusted for age, sex, education level, marital status, intervention site, frequency of visits, and the baseline values. The mean values of both systolic blood pressure (P < 0.001 at both T5 and T6) and diastolic blood pressure (P = 0.001 at

Table 4. Changes of metabolic syndrome components at baseline and post intervention

Componente	Ll group (	n = 137)	<ul> <li>– P value*</li> </ul>	BI group	(n = 106)	- P value*	Effect size <sup>+</sup> (95% CI)
Components	Baseline (T1)	Post (T2)	- r value	Baseline (T1)	Post (T2)	- r value	Ellect Sizer (95% CI)
Prevalence of the MetS, No. (%)	137 (100)	71 (51.8)	< 0.001	106 (100.0)	63 (59.4)	< 0.001	1.36 (0.85, 1.87)
Hypertension	101 (73.7)	70 (51.1)	< 0.001	74 (69.8)	54 (50.9)	0.001	0.99 (0.48, 4.50)
Abdominal obesity	117 (85.4)	98 (71.5)	< 0.001	95 (89.6)	88 (83.0)	0.035	1.95 (1.32, 2.58)
Hyperglycemia	91 (66.4)	72 (52.6)	< 0.001	71 (67.0)	57 (53.8)	0.003	1.05 (0.54, 1.56)
Hypertriglyceridemia	96 (70.1)	70 (51.1)	< 0.001	72 (67.9)	58 (54.7)	0.003	1.14 (0.63, 1.65)
Low HDL-cholesterol	43 (31.4)	44 (32.1)	0.853	48 (45.3)	36 (34.0)	0.014	1.09 (0.55, 1.63)
MetS components, mean (SD)							
Systolic BP (mmHg)	130.1 (12.3)	124.9 (12.5)	< 0.001	130.2 (14.0)	127.0 (13.2)	0.016	0.16 (-2.35, 2.26)
Diastolic BP (mmHg)	81.9 (8.8)	79.6 (9.1)	0.002	83.5 (9.5)	81.0 (11.3)	0.016	0.14 (-2.01, 1.66)
Waist circumference (cm)	88.8 (7.4)	88.3 (8.0)	0.139	89.6 (8.2)	89.6 (8.2)	0.826	0.16 (-1.40, 1.50)
Fasting glucose (mg/dL)	112.1 (36.2)	109.2 (35.8)	0.092	110.1 (23.7)	106.6 (20.5)	0.033	-0.09 (-3.99, 5.91)
Triglycerides (mg/dL)	198.0 (92.4)	172.6 (90.5)	0.003	202.1 (100.7)	189.1 (111.2)	0.184	0.17 (-21.00, 15.32)
HDL-cholesterol (mg/dL)	52.2 (9.3)	51.4 (9.8)	0.283	50.3 (9.4)	50.7 (9.0)	0.627	-0.07 (-1.79, 1.57)
No. of risks meeting MetS	3.3 (0.5)	2.6 (1.1)	< 0.001	3.4 (0.6)	2.8 (1.0)	< 0.001	0.19 (0.00, 0.37)
z-MetS score	0.6 (2.2)	-0.4 (3.0)	< 0.001	1.2 (2.5)	0.3 (3.2)	0.003	0.23 (-0.38, 0.73)

\**P* value, based on a paired *t*-test for continuous variables and the McNemar test for categorical variables; <sup>†</sup>Cohen's d (standardized mean difference) for continuous variables and odds ratios for categorical variables. LI, intensive lifestyle intervention; BI, basic usual intervention; CI, confidence interval; SD, standard deviation; MetS, metabolic syndrome; BP, blood pressure; HDL-cholesterol, high-density lipoprotein cholesterol.

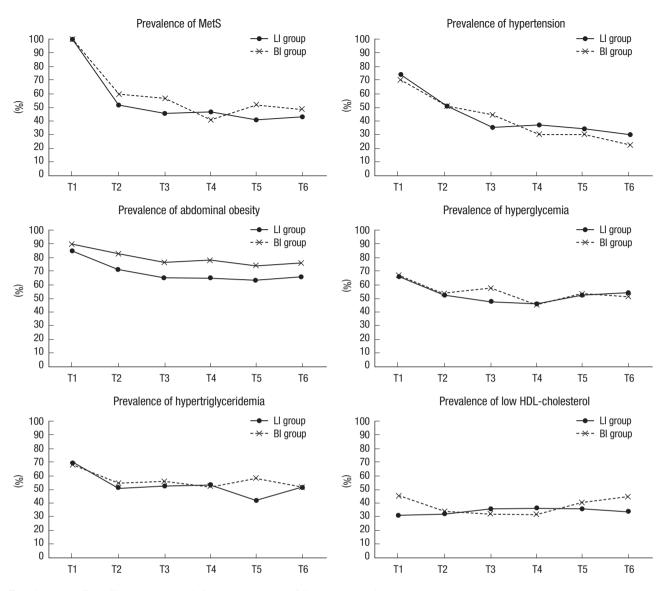


Fig. 2. Long-term effects of intervention on metabolic syndrome prevalence followed-up 12 months.

both T5 and T6) continuously decreased during the follow-up period. The decreased mean values of triglycerides in the LI group and fasting glucose in the BI group at T2 were maintained throughout the follow-up period. Waist circumference of the LI group decreased from T2 to T5 (P = 0.001), but the change was not sustained until T6. The fact that the number of MetS risks and z-MetS score had consistently improved one year after the intervention may infer a potential of long-term MetS control or even health improvement.

# DISCUSSION

We examined the effects of lifestyle interventions on MetS management among middle-aged Koreans. A 12-week theory-based intensive lifestyle intervention program was conducted nationwide, and compared with basic usual one-time intervention for 12 months. The overall prevalence of MetS was significantly reduced after the interventions, along with the improvements in individual MetS components except for the HDL-cholesterol. Reduced prevalence of MetS and improvements in the levels of fasting glucose and triglycerides were maintained throughout the follow-up period, and the prevalence of hypertension and abdominal obesity continued to decrease. Between intervention group differences were, however, not observed.

Several previous intervention studies also reported no significant differences between the intervention group and the control group (30, 31). It should be noted though that the BI group in this study was not a 'non-treatment' control group, but a group with basic usual intervention. At baseline, the participants in both groups were informed that they had a condition called 'Metabolic Syndrome (MetS)' and explained what MetS was. Such notification made the participants pay attention to 'MetS',

	Post interv	Post intervention (T2)		6 months	6 months after the intervention (T5)	ention (T5)			12 months	12 months after the intervention (T6)	ention (TG)	
Components/risks	Ll group $(n = 137)$	BI group $(n = 106)$	Ll group (n = 88)	Bl group (n = 69)	Time effect	Group effect	Time × group effect	Ll group $(n = 74)$	BI group (n = 58)	Time effect	Group effect	Time × group effect
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		Estimates <sup>§</sup>		Mean (SD)	Mean (SD)		Estimates	
MetS components												
Systolic BP (mmHg)	124.9 (12.5)	124.9 (12.5) 127.0 (13.2)	122.5 (12.2)	118.8 (10.6)	-7.7100 <sup>‡</sup>	-1.6260	$5.6649^{\dagger}$	118.6 (12.2)	117.7 (12.0)	-8.6307 <sup>‡</sup>	-1.9257	2.6634
Diastolic BP (mmHg)	79.6 (9.1)	81.0 (11.3)	78.3 (8.2)	76.7 (8.5)	-3.6190†	-0.5251	2.3390	77.7 (8.6)	75.7 (7.8)	-4.2309 <sup>†</sup>	-0.5529	2.4910
Waist circumference (cm)	88.3 (8.0)	89.6 (8.2)	86.9 (7.9)	87.4 (7.7)	-1.4704 <sup>†</sup>	-0.4044	0.2701	87.1 (7.8)	88.6 (7.4)	-0.1910	-0.2532	-0.7514
Fasting glucose (mg/dL)	109.2 (35.8)	106.6 (20.5)	103.2 (16.6)	105.4 (19.1)	0.3068	1.7020	-1.4848	105.2 (16.1)	102.7 (13.9)	-0.7830	1.4474	-1.0324
Triglycerides (mg/dL)	172.6 (90.5)	189.1 (111.2)	152.0 (72.3)	184.6 (116.5)	-3.4847	-16.3580	-10.7127	169.9 (90.1)	202.8 (138.3)	14.2499	-12.5951	-12.9605
HDL-cholesterol (mg/dL)	51.4 (9.8)	50.7 (9.0)	49.6 (9.1)	49.5 (7.4)	0.1896	-0.0419	-0.8878	50.1 (8.7)	49.6 (12.3)	-0.4291	-0.3818	-0.0323
No. of risks meeting MetS	2.6 (1.1)	2.8 (1.0)	2.3 (1.1)	2.6 (1.1)	-0.2415*	-0.0940	-0.1059	2.4 (1.1)	2.5 (1.0)	-0.3084*	-0.0564	-0.0026
z-MetS score	-0.4 (3.0)	0.3 (3.2)	-1.2 (2.7)	-1.0 (2.8)	-1.2696 <sup>‡</sup>	-0.2606	0.5896	-1.2 (2.7)	-1.0 (2.7)	-0.9612 <sup>†</sup>	-0.2039	0.1437
*P < 0.05; <sup>1</sup> P < 0.01; <sup>#</sup> P < 0.001; <sup>#</sup> Coefficients obtained by comparing differences in the variables between post intervention (T2) and 6 months after the intervention (T5) based on Mixed Effects Models for adjusted for age, sex, education level, income, marriage status, intervention site, frequency of visits and the baseline values; "Coefficients obtained by comparing differences in the variables between post intervention (T2) and 12 months after the intervention (T2) and 12 months after the intervention (T6) hased on Mixed Effects Models for adjusted for age, sex, education level, income, marriage status, intervention site, frequency of visits and the baseline values; "Coefficients obtained by comparing differences in the variables between post intervention (T2) and 12 months after the intervention (T6) hased on Mixed Effects Models for an evention (T2) and 12 months after the intervention (T6) hased on Mixed Effects Models for an evention (T8) has evention of the haseline values (T8) has evention (	001; <sup>§</sup> Coefficients status, interventi Aodele for adiuste	s obtained by comp on site, frequency	aring differences of visits and the t	in the variables b paseline values; "(	etween post ir Soefficients ob	itervention (T2)	and 6 months after aring differences in	the intervention ( the variables be	T5) based on Mixt tween post interve	ed Effects Mod Intion (T2) and	els for adjusted 12 months afte	for age, sex, edu- r the intervention

syndrome; BP, blood pressure; HDL-cholesterol, high-density lipoprotein cholesterol

standard deviation: MetS. metabolic

the health condition that was unfamiliar to many of the participants. An in-depth interview with Korean adults with MetS addressed that those diagnosed with the unfamiliar term 'MetS' took their health issues more seriously and had greater motivation to cope with MetS (32). Diagnosis and notification of the exact health status can raise awareness and motivation which facilitate self-management of MetS.

The BI group participants attended regular checkups as part of this study and were informed about their MetS status in the same frequency as the LI group. Participants in both intervention groups in this study might have been strongly motivated with elevated awareness and knowledge about their MetS status that they had not known before. Furthermore, repeated examinations for MetS in this study might have impacted both LI and BI group participants to be more conscious of their health status and management. Research participation or consequent awareness of being observed is likely to influence participants' behavior to demonstrate better performances that can be confounded with the outcomes being studied (33). It might have resulted in improvements of MetS status in all participants in the study and non-significant differences between groups. Further research is called for in order to examine intervention effects on MetS by intervention intensity, particularly from the standpoint of process evaluation.

Nearly half of the participants in this study no longer had MetS after the interventions. As the MetS is defined with the number of risk factors, small changes in the clinical values of MetS parameters near cut-off points could have affected the reduction in prevalence of MetS (34). In this study, 70% of participants had three MetS risks at baseline, thus improvement in one of the 3 risks that was slightly abnormal might have helped them being out of MetS. The GEE models and the mixed effects models in this study included baseline values to analyze adjusted long-term effects of interventions. The baseline values of all components affected the MetS status significantly (P < 0.001, data now shown), which means that the participants who were with more severe MetS at baseline were less likely to demonstrate improvements in their MetS status, although overall intervention effects were observed in the study. Nevertheless, a consistent decrease in z-MetS score in this study may infer that improvements may be observed further.

In a recent systematic review and meta-analysis with eleven intervention studies with follow-up periods of 6 months or longer in eight randomized controlled trials from 1966 to 2011 (17), lifestyle modification interventions were concluded to be effective in reducing MetS and improving the levels of MetS components. However, lifestyle intervention effects on low HDL-cholesterol were non-significant. Indeed, lifestyle intervention effects on HDL-cholesterol have been reported as less effective (35, 36). Results of this study on HDL-cholesterol corroborate such previous findings. It is possible that most lifestyle inter-

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vention programs employ fat reduction strategies in diet, which may affect adversely to raise the HDL-cholesterol level decided by ratio of polyunsaturated to saturated fats (37).

National Health Insurance Service (NHIS) Korea funds biannual health check-ups which includes all clinical tests for MetS for adults. Over 70% of NHIS beneficiaries participate in the national health screening program annually, and the screening rate has grown gradually (11). The examinees who are diagnosed with MetS by the national NHIS screening program are highly recommended to participate in the NHIS MetS management program. The NHIS MetS management program provides health consultation and MetS-related health information materials online. However, all such processes depend on voluntary participation and are limited to online services. Therefore, clients, especially elderly, could be challenged to sustain their efforts for self-management of MetS via the program. As we found in this study, regular check-ups and notification of MetS status motivated participants to manage and promote their health. Therefore, more concrete guidelines for MetS screening and lifestyle modifications and practicing the guidelines are required to achieve effective prevention and sustained management of MetS within the screening system.

There are some limitations in this study. First, although randomly selected, participation in this study was on a voluntary basis. Study participants might have been more health conscious and willing to modify their health behaviors than non-participants. Significant reduction of MetS prevalence observed in the BI group implies that relatively moderate efforts for promoting MetS management can give more motivation for a lifestyle change of the participants than expected. It is required to take more caution to develop universally effective strategies for a lifestyle modification intervention. Second, during the 1-yr follow-up period, 45.7% of participants dropped out of the study, and more than 20% of which occurred at T6. In previous intervention studies in Korea and Japan, about 80% of participants refused or gave up their participation during the follow-up period (20, 31). Participants in this study had some difficulties with frequent visits to interventions which required fasting. Approximately 60% of the participants were employed, and half a day off from the work was needed for each visit to the intervention program. Reminder calls and personalized text messages were attempted in this study to keep the participants in the program. There were no significantly different characteristics between retained participants and dropouts in this study. Still, more effective strategies to lowering the dropout rates are needed in the future research. This study also leaves a room for further research to identify effects of behavior changes on MetS management, to determine effects of MetS intervention by its level of intensity, and to implement the interventions in younger people with MetS.

Despite some limitations, this study is still meaningful for evaluating the lifestyle intervention effects on MetS over one year. Lifestyle modification intervention was effective to reduce MetS risks among the participants, and continuous progress was also observed during the follow-up period. Regular checkups and appropriate notifications of their own MetS status and progress is helpful for MetS risk groups to manage and promote their health. The overall results of such research will be helpful for establishing evidence for more concrete MetS prevention and management strategies in Korea.

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#### DISCLOSURE

The authors declare that there are no conflicts of interest.

#### **AUTHOR CONTRIBUTION**

Conception and coordination of the study: Yoo S. Design of ethical issues: Yoo S, Kim H. Acquisition of data: Kim H, Han Y. Data review: Yoon N, Han Y, Kim H. Statistical analysis: Yoon N, Han Y, Yoo S. Manuscript preparation: Yoon N, Yoo S, Han Y. Manuscript approval: all authors

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