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Effects of a 6-month lifestyle modification intervention on the cardiometabolic risk factors and health-related qualities of life in women with metabolic syndrome

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Abstract

Although therapeutic lifestyle modification (TLM) has been recommended as a cornerstone treatment of metabolic syndrome (MetS), little is known about the biobehavioral effects of a TLM program for patients in a community. The purpose of this study was to examine the effects of a 6-month TLM program on MetS risk factors and health-related qualities of life (HRQOL) among middle-aged and older women in a community in Korea. Fifty-two women (mean age, 62.7 ± 9.0 years) with MetS were recruited from 3 community health centers and were randomly assigned to the intervention (n = 31) or control (n = 21) groups. The patients in the intervention group participated in supervised TLM sessions for 6 months. The TLM program included health monitoring, counseling, health education, exercise, and dieting. Metabolic risk factors and HRQOL were measured at baseline, during the study (month 3), at completion (month 6), and postcompletion (month 12) of the TLM program. Compared with the control group, the TLM group showed significantly greater reductions in body weight ($P < .001$) and waist circumference ($P < .001$); these effects were sustained for 6 months after intervention. With regard to HRQOL, the TLM group showed greater improvements in physical function ($P = .017$), general health ($P < .001$), vitality ($P = .008$), and mental health ($P = .027$). These improvements, however, were not sustained after the intervention. The results indicate that a nurse-led systematic TLM program may be an effective strategy for managing middle-aged and older women with MetS at a community level.

1. Introduction

Metabolic syndrome (MetS) is a clinical entity characterized by a constellation of metabolically related abnormalities and cardiovascular risk factors, including obesity, insulin resistance/glucose intolerance, dyslipidemia, and hypertension [1]. People with MetS have an increased risk of cardiovascular disease–related morbidity and mortality, even in the absence of clinically evident cardiovascular disease and/or diabetes mellitus [2,3].

In Korea, significant socioeconomic and demographic changes have increased the incidence of MetS. The prevalence in the general Korean population increased from 23.6% in 1998 to 28.0% in 2001 [4]. In addition, previous studies reported an increased prevalence of MetS in older women and in rural populations [5-7]. The 2001 Korea National Health and Nutrition Survey data showed a higher prevalence for MetS in rural areas (29.3%) than in urban areas (22.3%) [8]; therefore, management of MetS among older women living in rural areas needs to be addressed.

Therapeutic lifestyle modification (TLM) has been recommended as a cornerstone therapy for managing patients with MetS [3,9]. Therapeutic lifestyle modification is a comprehensive approach based on exercise, diet, education, and/or pharmacotherapy. Furthermore, the third

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report of the National Cholesterol Education Program Adult Treatment Panel (NCEP-ATP III) emphasizes the role of health care providers in initiating and maintaining a TLM program for better compliance and cost-effectiveness. Previous studies have reported the positive effects of TLM. However, few studies have applied a comprehensive multicomponent approach to TLM in patients with MetS. In most intervention research with MetS patients, a single component of TLM, such as exercise alone [10,11], diet alone [12,13], drug therapy alone [14,15], or a combination of 2 components, was used [16-21] in clinical patients. In addition, little is known about the long-term effects of TLM in people with MetS; and the outcomes of TLM are mostly apparent on the physiologic markers of MetS components. Although it is generally believed that health-related quality of life (HRQOL) improves after lifestyle modification, little is known about whether TLM programs offer better HRQOL for MetS patients. Moreover, information or research on the effectiveness of TLM programs in community populations is limited. Because translational research is increasingly considered important for maximizing health benefits and health care delivery, this may allow for the combination of effective and culturally sensitive interventions with supporting environmental changes and may also encourage continuous improvement in evidence-based public policies. This study will also influence the development of strategies and policies for the management of MetS.

The purpose of this study was to examine, on a community level, the effects of a 6-month TLM program on MetS risk factors and HRQOL in middle-aged and older women with MetS. Specifically, this study primarily examined the effects of TLM on changes in body weight and other cardiometabolic factors and secondly assessed TLM's effects on HRQOL variables.

2. Methods

2.1. Study design and setting

This study was a 6-month, randomized, controlled trial conducted at the community level including middle-aged and older women with MetS. We conducted our study at 3 rural community health care centers located in one province of South Korea. The 3 centers were similar in terms of population size, patient characteristics, and number of health care providers. The number of patients who visited the centers numbered 10 to 15 on average, and most of them were farmers. A community nurse practitioner managed each center; these nurses usually collaborated with general physicians at the superior public health center. A detailed description of the trial design was published previously [22].

2.2. Study participants and ethical considerations

Potential participants for this study were screened from a review of medical records from the 3 public health centers. Among women 40 years or older (n = 790), 302 women had a diagnosis of hypertension, diabetes, or obesity (body mass index [BMI] >25 kg/m^2). Participants were eligible for this study if they had at least 3 of the 5 risk factors for MetS according to the NCEP-ATP III (the criterion of waist circumference that was applied, however, was created by the World Health Organization–Asia Pacific) and consented to participate in the study. Among patients at risk for MetS (n = 302), 65 women from the 3 centers were deemed eligible (21.5%). Thirteen women were excluded because they had underlying diseases that prevented them from exercising (uncontrolled congestive heart failure, angina or recent myocardial infarction, or breathing difficulties requiring oxygen therapy) or they had difficulty participating in the program because of employment obligations. Finally, 52 women were enrolled and were randomly assigned to either the TLM intervention group (n = 31) or the control group (n = 21) in a 3:2 ratio to compensate for the possible attrition rate in the intervention group. The randomization procedure was performed by community health practitioners using a random numbers table. Consecutive numbers on the table were used, with even- and odd-numbered participants being assigned to the intervention and control groups, respectively. Post hoc analysis of the power calculation for the sample size yielded 90% with a Cohen d of −5.4 (effect size r = −0.93) and a P value of .05. Group 1 consisted of 31 participants, and group 2 included 21. At the completion of the study, 48 women were retained throughout the study period (9.2% dropout rate). Reasons for attrition included hospitalization (n = 2), surgery unrelated to MetS (n = 1), and personal travel (n = 1). A detailed flow of participants through the study is presented in Fig. 1.

The study was approved by the local Institutional Review Board for ethical consideration of human participants, and written informed consent was obtained from each participant before the study began.

2.3. TLM intervention

A 6-month TLM intervention with 60 sessions was provided, with sessions occurring 3 times per week during the first 3 months followed by a maintenance period of 2 times per week during the next 3 months. Each 90-minute session was delivered by the community nurse practitioner at each participating health care center. The intervention consisted of comprehensive multicomponents: (1) health monitoring, (2) counseling, (3) health education, (4) exercise, and (5) diet. The first was health monitoring (ie, blood pressure, body weight) and brief individual counseling. Afterward, the practitioner checked the exercise diary and food diary, gave brief feedback (<3 minutes per person for this first session), and began a group session (ie, exercise and health education). To standardize the TLM protocol, community nurses were trained by research teams both in workshops and in educational seminars. The feasibility and effectiveness of the intervention and the usefulness of the

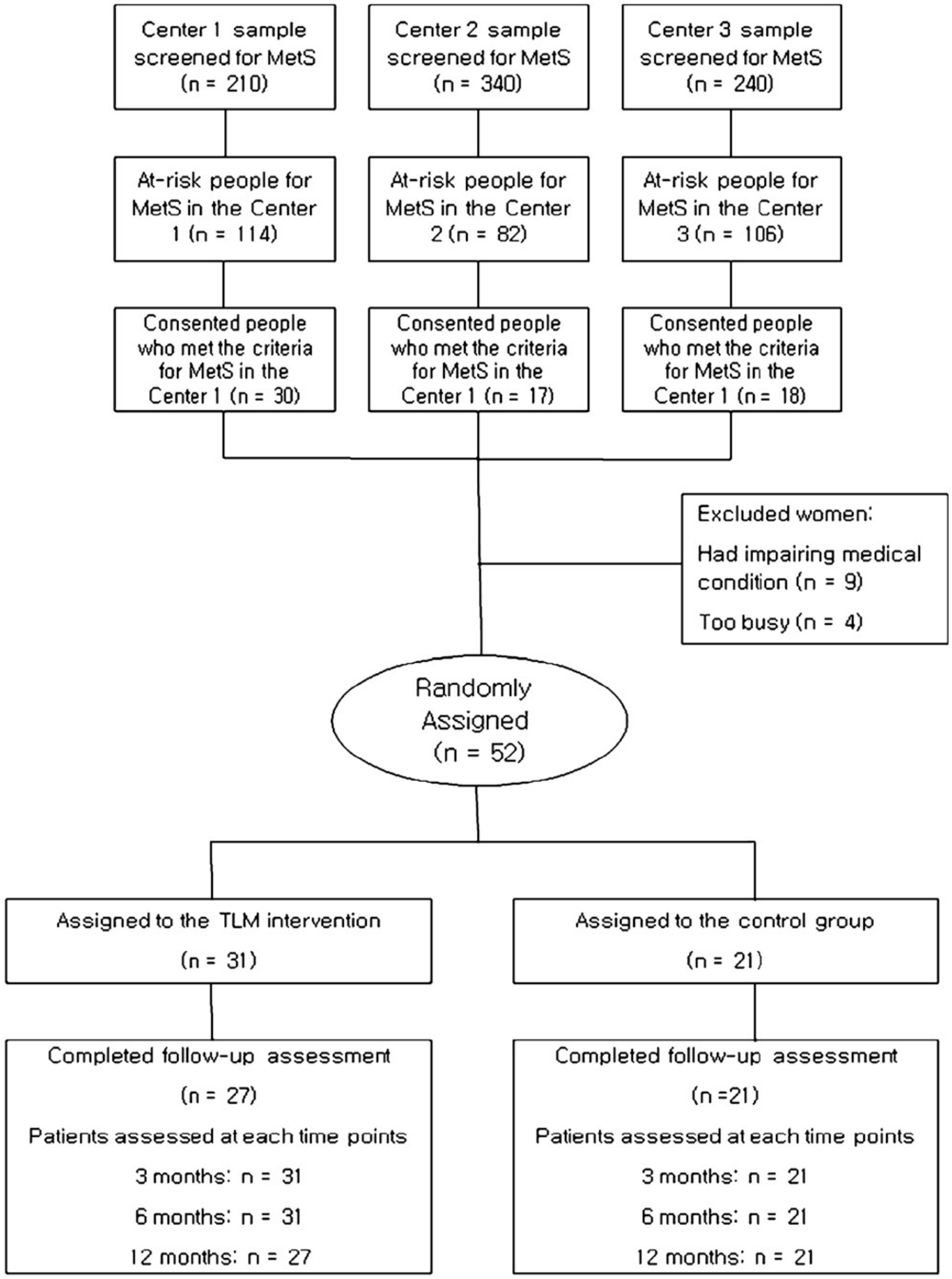

Fig. 1. Detailed flow of participants through the study. “At-risk people” indicates women having a diagnosis of hypertension, diabetes, or obesity (BMI >25 kg/m^2).

educational materials were confirmed in our pilot study [22]. The control group received only an educational booklet. Detailed contents regarding health education, exercise, and diet were as follows:

2.3.1. Health education

Participants in the intervention group received 20 minutes of health education from the researchers, including a summary of the defining characteristics of MetS and advice on lifestyle modifications such as exercise, diet, and self-care. An educational booklet, poster, and pamphlet were developed by the researchers and were given to the participants.

2.3.2. Exercise

Participants at each center attended 3 supervised exercise sessions per week for the first 3 months and 2 sessions per week for the next 3 months. The supervised group exercise intervention consisted of yoga stretching, rhythmic aerobic dance (Tae-Bo), and warm-up and cooldown exercises for a total of 40 minutes per session. To maintain a standardized exercise protocol, participants exercised along with a recorded video. Our exercise physiologist measured heart rate, ventilation (liters per minute), V_{O_2} (liters per minute), V_{CO_2} (liters per minute), V_{O_2} per kilogram (milliliters per minute per kilogram), respiratory exchange ratio, ventilation to V_{O_2} ratio, and ventilation to V_{CO_2} ratio using Metamax 3B (Cortex, Leipzig, Germany) to calculate energy expenditure during 40 minutes of Tae-Bo exercise. The total energy expended in each exercise session was calculated as 200 kcal. Pedometers were given to participants in the intervention group to motivate them to exercise. In addition to the group sessions, participants in the intervention group were encouraged to perform home-based brisk walking on a daily basis. They also kept a daily exercise diary.

2.3.3. Diet

The participants in the intervention group were instructed to follow a low-calorie and low-carbohydrate diet based on the guidelines of NCEP-ATP III [3], previous studies [23,24], and the results of our pilot study [22]. The traditional Korean diet is rice- and plant-based, and participants in our pilot study showed a high carbohydrate intake (≥70%). Therefore, participants were monitored individually to maintain less than 1500 kcal/d and to limit their carbohydrates to 55% to 60% of their caloric intake. The diet instructions focused on decreasing caloric intake by reducing high-glycemic foods (eg, rice, noodles). The nurse practitioners also encouraged participants to keep a daily food diary.

2.4. Measurements

2.4.1. Cardiometabolic risk factors

Body weight was measured with a high-precision scale (InBody 220; Biospace, Seoul, Korea). Weights were taken at the same time each session while the participants wore T-shirts and shorts. Waist circumference was measured midway between the lowest rib and the iliac crest. Blood pressure was measured with an automatic digital sphygmomanometer (OMROM T4, Kyoto, Japan). The average of 2 measurements taken at 2- or 3-minute intervals with the women in a seated position after resting for at least 15 minutes was used. Blood samples were obtained from the antecubital vein with the women in a seated position after an overnight fast. Serum levels of fasting glucose, high-density lipoprotein cholesterol (HDL-C), and triglycerides were assayed using an ADVIA 1650 Chemistry System (Bayer, Tarrytown, NY). The degree of insulin resistance was determined using the homeostasis model assessment (HOMA) and calculated according to the following formula: [fasting glucose (in milligrams per deciliter)/18 × insulin (in microunits per milliliter)]/22.5. To minimize the influence of any incidental acute phase reaction, participants were forbidden physical activity for 24 hours before blood sampling.

2.4.2. Health-related quality of life

Health-related quality of life was measured with the Medical Outcome Study Short Form-36 (MOS SF-36), version 2, which is a generic measure designed to evaluate self-reported health status, functioning, and well-being [25]. This self-report contains 8 subscales, including physical function, physical role limitations, bodily pain, general health perception, vitality, social function, emotional role limitations, and mental health. These subscales were scored from 0 to 100, with higher scores indicating a better health status. The validity and reliability of the MOS SF-36 have been confirmed by many studies. The Cronbach α coefficient for the subscales of the SF-36 ranged from 0.68 to 0.93 in general [26] and from 0.76 to 0.90 in this study.

2.5. Statistical analysis

Descriptive analyses were conducted for all sociodemographic and disease-related characteristics. The χ^2 test, Fisher exact test, and independent t test were used to determine the homogeneity of the general characteristics between the TLM intervention and the control groups. After controlling for baseline values, generalized estimating equation (GEE) analysis was used to compare the differences between the 2 groups with respect to changes over time. Time points in the analyses included baseline, during intervention (month 3), at the termination of intervention (month 6), and 6-month follow-up (month 12). All analyses of treatment differences were performed based on intention-to-treat principles. Available data for participants with missing data were included under the missing-at-random assumption of the GEE analysis. A 2-tailed $P < .05$ indicated statistical significance. Data were analyzed using the Statistical Package for the Social Sciences version 15.0 (SPSS, Chicago, IL).

3. Results

3.1. Baseline characteristics of the participants

The general characteristics of the participants are presented in Table 1. The mean age of the patients (n = 52) was 62.7 years (SD = 9.0; range, 49-90 years), and most were married (80.8%). Educational status and monthly income were relatively low. The mean BMI was 26.0 kg/m^2 (SD = 3.1). There were no significant differences between the 2 groups in baseline characteristics except for age; women in the control group were older than those in the intervention group ($P = .001$) (Table 1). Therefore, the age variable was adjusted as a covariate in all analyses. In addition, the adherence rate was calculated with the number of sessions attended. On average, participants attended 49 of the total 60 sessions (82.2%).

3.2. Effects of the TLM on cardiometabolic risk factors

We found significant differences between the changes in each group over the duration of the program for the following factors: body weight (−5, −4.3 kg), BMI (−2.0, −1.4), and waist circumference (−10.4, −9.4 cm) at month 6

Table 1
Baseline characteristics of the study participants

Characteristic	Intervention (n = 31)		Control (n = 21)		P value
	n	%	n	%	
Age (y)					.004.
Mean (SD)	59.8 (7.9)		66.9 (9.0)		
Range	49-70		50-90		
Marital status					.091
Married	26	89.7	15	71.4	
Unmarried or widowed	3	10.3	6	28.6	
Education					
None	10	32.3	12	57.1	.309
Elementary school	14	45.2	6	28.6	
≥Middle school	7	22.6	3	14.3	
Monthly income					
<US $1000	22	75.9	16	76.2	.265
≥US $1000	7	24.1	6	23.8	
Employment					.139
Yes	14	48.3	5	23.8	
No	15	51.7	16	76.2	
Weight (kg)					.373
Mean (SD)	62.4 (9.7)		59.9 (10.2)		
BMI (kg/m^2)					.890
Mean (SD)	26.3 (3.7)		26.2 (3.7)		
Health behaviors					
Smoking, yes	0	0	2	8.7	.177
Drinking, yes	5	16.1	5	21.7	.380
Regular exercise, yes	16	51.6	7	30.4	.120
Comorbidities					
Hypertension	22	71.0	14	66.7	.768
Diabetes	7	22.6	5	23.8	.999
Cardiovascular disease	4	12.9	2	9.5	.999
Gastrointestinal disease	4	13.3	6	27.6	.283
Medication, yes					
Antihypertensive drugs	21	67.7	14	66.7	.935
Hypoglycemic agents	5	16.1	7	33.3	.149

and month 12, respectively (all *P*s < .001, Table 2). The GEE analysis provided more specific results with estimates for those outcomes at month 3, at month 6, and at month 12 (Table 3). In the experimental group, body weight decreased continuously, with changes as high as 8.1% for the 6-month intervention period; and these changes were maintained for 6 months after the intervention.

Although the changes over time for each group did not yield statistically significant changes in blood pressure, fasting glucose, or HDL-C at 12 months, the patterns of change in these outcomes demonstrated clinically meaningful results. Women in the intervention group showed positive changes in systolic blood pressure (−15.0, −6.1 mm Hg), diastolic blood pressure (−8.5, −5.0 mm Hg), fasting glucose (−12.4, −7.2 mg/dL), HDL-C (+0.5, +4.6 mg/dL) at month 6 and month 12, respectively. In the control group, the same parameters did not change (Table 2). As for HOMA and triglyceride levels, there were no significant effects over time and no clinically meaningful results. Both groups' triglycerides decreased at month 3, but levels increased at the later time points.

3.3. Effects of the TLM on prevalence of MetS and medication use

Table 4 summarizes the prevalence of MetS between the 2 groups over time. Although statistical significance was not achieved (P = .058), the TLM group showed a greater decrease in percentage of MetS over time compared with that of the control group; 20 women (67.1%) in the intervention group ceased to meet MetS criteria at month 12, whereas only 6 women (30.0%) in the control group were no longer considered to have MetS (odds ratio = 0.256, 95% confidence interval = 0.065-1.005) (Table 4). There were

Table 2
Changes in cardiometabolic risk factors over time between the 2 groups

Variable		Mean (SE)				$P_{group \times time}$
		Baseline	Month 3	Month 6	Month 12	
Body weight (kg)	TLM group	61.4 (0.2)	57.4 (0.9)	56.4 (0.6)	57.1 (1.2)	<.001
	Control	61.2 (0.3)	61.2 (0.4)	59.0 (0.4)	60.3 (0.5)	
BMI (kg/m^2)	TLM group	26.1 (0.1)	24.7 (0.2)	24.1 (0.2)	24.7 (0.2)	<.001
	Control	26.0 (0.1)	25.9 (0.2)	25.4 (0.2)	25.9 (0.3)	
SBP (mm Hg)	TLM group	135.8 (1.4)	124.6 (2.0)	120.8 (2.0)	129.7 (2.4)	.477
	Control	136.8 (1.3)	131.6 (2.6)	127.1 (4.1)	133.4 (3.6)	
DBP (mm Hg)	TLM group	82.8 (1.0)	78.7 (1.9)	74.3 (1.6)	77.8 (1.7)	.841
	Control	84.6 (0.9)	77.6 (2.1)	73.6 (2.8)	77.7 (1.9)	
Waist circumference (cm)	TLM group	93.2 (0.2)	84.7 (0.7)	82.8 (0.8)	83.8 (0.9)	<.001
	Control	93.4 (0.4)	91.6 (1.0)	91.3 (1.2)	92.8 (1.2)	
Fasting blood glucose (mg/dL)	TLM group	106.6 (1.4)	103.0 (4.9)	94.2 (2.0)	99.4 (3.0)	.106
	Control	103.6 (1.4)	114.8 (4.7)	95.9 (2.7)	113.2 (9.9)	
HOMA	TLM group	2.1 (0.1)	2.2 (0.4)	2.1 (0.4)	2.9 (0.6)	.491
	Control	1.8 (0.2)	1.8 (0.4)	1.4 (0.4)	3.1 (0.8)	
HDL-C (mg/dL)	TLM group	46.0 (0.4)	48.7 (1.4)	46.5 (1.6)	50.6 (1.3)	.577
	Control	46.1 (0.7)	48.8 (1.9)	43.5 (1.3)	48.9 (1.5)	
Triglycerides (mg/dL)	TLM group	156.1 (5.3)	125.4 (12.4)	179.2 (11.0)	160.7 (12.7)	.979
	Control	165.6 (7.9)	127.6 (15.4)	189.5 (30.4)	168.5 (15.1)	

SBP indicates systolic blood pressure; DBP, diastolic blood pressure.

Table 3
GEE results of the effects of TLM on cardiometabolic risk factors

Variable	Comparison	Estimate	95% CI		*P* value
			Low	High	
Body weight (kg)	Group (TLM) * month 3	−4.027	−6.099	−1.956	<.001
	Group (TLM) * month 6	−2.885	−4.339	−1.432	<.001
	Group (TLM) * month 12	−3.414	−6.043	−0.784	.011
BMI (kg/m^2)	Group (TLM) * month 3	−1.315	0.3314	−1.965	<.001
	Group (TLM) * month 6	−1.396	0.3902	−1.965	<.001
	Group (TLM) * month 12	−1.233	0.4218	−2.059	.003
SBP (mm Hg)	Group (TLM) * month 3	−5.921	−13.475	1.633	.124
	Group (TLM) * month 6	−5.227	−15.185	4.731	.304
	Group (TLM) * month 12	−2.630	−12.004	6.743	.582
DBP (mm Hg)	Group (TLM) * month 3	2.858	−3.454	9.170	.375
	Group (TLM) * month 6	2.497	−4.531	9.525	.486
	Group (TLM) * month 12	1.941	−3.970	7.852	.520
Waist circumference (cm)	Group (TLM) * month 3	−6.630	−8.674	−4.586	<.001
	Group (TLM) * month 6	−8.260	−10.863	−5.658	<.001
	Group (TLM) * month 12	−8.791	−11.572	−6.010	<.001
Fasting blood glucose (mg/dL)	Group (TLM) * month 3	−14.859	−29.071	−0.647	.040
	Group (TLM) * month 6	−4.679	−12.900	3.542	.265
	Group (TLM) * month 12	−16.777	−38.009	4.455	.121
HOMA	Group (TLM) * month 3	0.124	−0.883	1.131	.809
	Group (TLM) * month 6	0.318	−0.814	1.449	.582
	Group (TLM) * month 12	−0.578	−2.837	1.680	.616
HDL-C (mg/dL)	Group (TLM) * month 3	−0.128	−5.151	4.896	.960
	Group (TLM) * month 6	3.043	−1.660	7.745	.205
	Group (TLM) * month 12	1.701	−2.577	5.980	.436
Triglycerides (mg/dL)	Group (TLM) * month 3	9.881	−37.822	57.585	.685
	Group (TLM) * month 6	−0.748	−69.621	68.126	.983
	Group (TLM) * month 12	2.350	−43.562	48.261	.920

also positive effects of the TLM on medication use. Five participants in the intervention group (16.1%) were not prescribed antihypertensive medication at month 6 or month 12, whereas 1 woman in the control group was newly prescribed an antihypertensive (*P* = .010). Hypoglycemic medication use decreased in the TLM group; however, it increased in the control group, although there was no statistical significance (*P* = .363) (Table 4).

3.4. Effects of the TLM on HRQOL

There were significant interactions between groups over time for physical functions (+9.4, +2.5), general health (+25.4, +14.8), vitality (+14.8, +9.0), and mental health (+15.0, +12.4) at month 6 and month 12, respectively (Table 5). Significant interactions were found between groups over time in general health and vitality both at month 3 and at month 6 and in physical function and mental health at month 6 (Table 6).

The patterns of change in the 4 subscales showed that those patients in the TLM group improved from baseline to month 6, whereas markers either became less favorable or remained constant through month 6 for the control group. The improvement in QOL outcomes in the TLM group, however, was not sustained to month 12.

Although there was no statistical significance, the mean score of bodily pain in the TLM group increased from baseline to month 6, compared with a decrease in the control group. In addition, role function and social function improved in both groups from baseline to month 6; this change was greater in the TLM group than in the control group (Table 5).

4. Discussion

To our knowledge, this is the first report to assess the effects of a lifestyle intervention in middle-aged and older women with MetS at a community level. By inducing a modest reduction in body weight and waist circumference, our comprehensive TLM intervention substantially decreased the prevalence of MetS. Moreover, our program had a positive effect on HRQOL outcomes. Our study indicated that a nurse-led TLM program could be an effective community-level strategy to manage cardiometabolic risk factors and HRQOL in MetS patients.

The beneficial effects of lifestyle intervention on body weight and waist circumference were consistent with those of previous studies [20,27-32]. The observed weight loss might be mediated by preferential reductions in visceral fat [33], as suggested by the relatively higher waist circumference reduction (ie, 8.5-10.4 cm) in our participants than for those in previous studies [27,29]. Body weight in the TLM group was reduced by 6.5% (4 kg) at month 3 and by 8% at

Table 4
Effect of the TLM on the prevalence of MetS

Variable		Baseline		Month 3		Month 6		Month 12		$P_{group \times time}$
		n	%	n	%	n	%	n	%	
Prevalence of MetS	TLM group	31	100	23	74.2	17	54.8	11	39.3	.058
	Control	21	100	15	71.4	12	57.1	14	70.0	
Medication use										
Antihypertensive drugs	TLM group	21	67.7	21	67.7	16	51.5	16	51.5	.010
	Control	14	66.7	14	66.7	15	71.4	15	71.4	
Hypoglycemic agents	TLM group	24	77.4	24	77.4	19	61.3	19	61.3	.353
	Control	17	81.0	17	81.0	18	85.7	18	85.7	

the completion of the TLM program, and weight loss was sustained at 7% at 6 months posttreatment. The therapeutic benefits of modest weight loss on MetS abnormalities have already been discussed [34]. These factors might contribute to the reduced prevalence of MetS in our participants at the end of our study.

Our TLM intervention, however, did not show statistically significant effects on other components of MetS, such as systolic and diastolic blood pressure, fasting glucose, HDL-C, and triglycerides. These results were not consistent with those of other studies [20,27-29,32]. One major reason for this discrepancy might be the small sample size of this study. Although there was no statistical significance, women in the TLM group did show clinically meaningful findings: systolic blood pressure (−6.1 to −15.0 mm Hg), diastolic blood pressure (−5.0 to −8.5 mm Hg), fasting glucose (−7.2 to −12.4 mg/dL), and HDL-C (+0.5 to +4.6 mg/dL) levels decreased during treatment, whereas those in the control group did not experience these decreases. A larger sample size may be needed to produce statistically significant differences. Secondly, we considered the contamination problem of the intervention. Because of the relatively small geographical distances separating participants and the strong cohesiveness of close social networks/relationships in the community, the women in the control group who were only given the educational booklets might also have had interactions with women in the intervention group that then increased their awareness and prompted them to try self-initiated lifestyle changes. Another explanation might be the possibility of a seasonal effect. Most participants were farmers, and the period during which our TLM intervention was given was the busy season for farming. Therefore, both the intervention and control groups were involved in physically labor-intensive farming tasks during the time of the study. The increase in physical activity might have caused an attenuation of the effects of the intervention between the 2 groups.

The lack of a positive effect on triglyceride levels in the intervention group was unexpected. Triglyceride levels decreased only at month 3, but increased from month 6 to month 12. Women in the control group also showed a similar pattern of change in triglyceride levels. This unexpected finding might result from the higher-carbohydrate diet of the control participants. Although our diet intervention focused on lowering calories by reducing carbohydrates, most Koreans eat rice on a daily basis; and most participants consumed rice or white noodles at least once a day. Previous research has found a hypertriglyceridemic effect of higher-carbohydrate diets in patients with comorbidities [35,36].

Our TLM intervention was successful in reducing the prevalence of MetS. The 61.7% reduction in our study was

Table 5
Changes in HRQOL over time between the 2 groups

Variables		Mean (SE)				$P_{group \times time}$
		Baseline	Month 3	Month 6	Month 12	
Physical function	TLM group	63.8 (1.7)	72.6 (5.1)	73.2 (4.4)	66.3 (4.0)	.006
	Control	64.5 (2.1)	60.7 (3.6)	50.9 (4.2)	56.0 (5.0)	
Physical roles	TLM group	47.3 (4.3)	70.6 (8.3)	73.2 (7.7)	59.0 (7.7)	.242
	Control	36.8 (4.5)	38.0 (6.5)	52.7 (8.9)	50.5 (8.6)	
Bodily pain	TLM group	56.9 (2.5)	62.9 (5.8)	65.1 (5.5)	67.7 (5.1)	.233
	Control	51.8 (2.9)	48.6 (4.6)	46.3 (3.9)	59.8 (6.1)	
General health	TLM group	36.6 (1.8)	57.1 (4.5)	62.0 (4.8)	51.4 (3.3)	<.001
	Control	35.1 (1.7)	38.1 (3.2)	36.7 (3.8)	47.6 (3.9)	
Vitality	TLM group	48.0 (1.9)	56.2 (5.1)	62.8 (4.6)	57.0 (3.7)	.008
	Control	45.7 (1.8)	33.8 (3.2)	38.0 (4.2)	49.0 (4.6)	
Social function	TLM group	73.5 (2.7)	88.9 (4.1)	89.1 (3.3)	81.4 (4.5)	.587
	Control	71.5 (3.5)	77.8 (5.4)	74.7 (7.2)	74.9 (6.4)	
Emotional roles	TLM group	57.9 (5.8)	79.7 (7.2)	85.5 (5.9)	70.1 (7.9)	.414
	Control	44.6 (6.8)	58.2 (8.1)	52.2 (10.4)	57.3 (9.4)	
Mental health	TLM group	57.3 (2.3)	70.5 (4.2)	72.3 (4.0)	69.7 (3.9)	.027
	Control	54.9 (2.6)	54.9 (4.4)	47.8 (4.4)	57.2 (5.7)	

Table 6
GEE results of effects of the TLM on HRQOL

Variables	Comparison	Estimate	95% CI		*P* value
			Low	High	
Physical function	Group (TLM) * month 3	12.647	−0.641	25.934	.062
	Group (TLM) * month 6	22.986	10.095	35.878	<.001
	Group (TLM) * month 12	10.959	−2.825	24.743	.119
Physical roles	Group (TLM) * month 3	22.078	−4.064	48.220	.098
	Group (TLM) * month 6	9.984	−18.385	38.353	.490
	Group (TLM) * month 12	−2.089	−27.191	23.013	.870
Bodily pain	Group (TLM) * month 3	9.153	−6.825	25.130	.262
	Group (TLM) * month 6	13.670	−0.791	28.131	.064
	Group (TLM) * month 12	2.695	−16.341	21.731	.781
General health	Group (TLM) * month 3	18.455	6.440	30.469	.003
	Group (TLM) * month 6	24.729	11.333	38.124	<.001
	Group (TLM) * month 12	3.288	−8.418	14.994	.582
Vitality	Group (TLM) * month 3	20.066	6.761	33.371	.003
	Group (TLM) * month 6	22.514	8.601	36.426	.002
	Group (TLM) * month 12	5.714	−7.164	18.592	.385
Social function	Group (TLM) * month 3	9.121	−7.047	25.289	.269
	Group (TLM) * month 6	12.423	−8.592	32.324	.221
	Group (TLM) * month 12	4.448	−17.336	24.268	.660
Emotional roles	Group (TLM) * month 3	8.203	−21.064	37.470	.583
	Group (TLM) * month 6	20.010	−14.216	54.236	.252
	Group (TLM) * month 12	−0.494	−35.000	34.011	.978
Mental health	Group (TLM) * month 3	13.205	−0.661	27.070	.062
	Group (TLM) * month 6	22.103	7.275	39.932	.003
	Group (TLM) * month 12	10.040	−7.186	27.265	.253

greater than that achieved in previous studies (from 11.2% to 59%) [19,28,31]. However, although the reduction in the percentage of MetS at 12 months in the control group was 30.0%, the true difference was smaller. Therefore, we should interpret this result with caution.

Another major finding of our trial was that the TLM intervention also had a beneficial effect on HRQOL, specifically on physical functioning, general health, vitality, and mental health. These positive results were consistent with the results of Levinger et al [37], which reported significant effects from resistance training on HRQOL in individuals with metabolic risk factors. Although the lack of published data precludes a clear interpretation in this population, these findings provide preliminary data that lifestyle interventions can be effective for the improvement of HRQOL in populations with MetS. We did not observe significant effects from the TLM intervention on the subscales of role function, bodily pain, or social function, although these subscale scores did improve. Study tool issues could possibly explain this improvement. In particular, items dealing with role limitation and social function in SF-36 may not be sensitive to our population. Because most participants were housewives or were involved in farming, we did not expect a significant change in their role function or social function during our study. This issue highlights the need for careful selection of research tools to ensure that attributes are appropriately targeted to a rural population. The effects of TLM interventions on HRQOL were maintained during the intervention. They were not, however, sustained at the 6-month follow-up. Therefore, strategies such as follow-up calls or sporadic meetings that motivate and encourage the continuation of lifestyle modifications may be needed to maintain long-term effects.

The major limitation of this study was the small number of participants. We were unable to declare the differences in some outcomes as statistically significant because of our small sample size. Further research with a larger sample size is needed. Second, this study was performed in geographically limited, rural areas in Korea; so we cannot generalize the results from this study to other areas. In addition, the measurements (including anthropometric measures) were all performed by the nurses who counseled the intervention group and who could, therefore, not be blinded to the intervention. The SF-36 may not be sufficiently sensitive to detect important changes in some functional domains for women in a rural community. Therefore, our study results should be interpreted with care.

Despite these limitations, our study demonstrated the efficacy of a comprehensive community-level TLM intervention on some MetS risk factors and HRQOL for middle-aged and older women with MetS. Our findings suggest a potential role for nurse counseling in managing metabolic and cardiovascular diseases. In addition, further studies are required to assess the cost-effectiveness of these effects.

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