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A randomized controlled trial of therapeutic lifestyle modification in rural women with metabolic syndrome: a pilot study

Eui-Geum Oh[a,*], Sa Saeng Hyun[b], Soo Hyun Kim[b], So-yeoun Bang[c], Sang Hui Chu[a], Justin Y. Jeon[d], Myung Sook Kang[b]

[a]College of Nursing, Nursing Policy and Research Institution, Yonsei University, Seoul 120-752, Korea
[b]College of Nursing, Yonsei University, Seoul 120-752, Korea
[c]HaeChun College, Yonsei University, Seoul 120-752, Korea
[d]Department of Sport and Leisure Studies, Yonsei University, Seoul 120-752, Korea

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Abstract

The aim of the study was to identify the effects of the therapeutic lifestyle modification (TLM) program on women with the metabolic syndrome in rural areas. Thirty-two women with the metabolic syndrome were randomly assigned to the intervention or control group. The women in the intervention group participated in a 4-week TLM program consisting of health screening, education, exercise, diet, and counseling. Those in the control group received a booklet with basic education for metabolic syndrome. Repeated-measures analysis of variance was used for analyzing the effects of the TLM intervention on anthropometric indicators, serologic assays, and psychosocial outcomes. The participants in the intervention group showed significant reductions in body weight (−4.6 kg vs −2.0 kg), waist circumference (−6.2 cm vs −1.7 cm), and triglyceride levels (−52.2 mg/dL vs −2.2 mg/dL) compared with those in the control group at 4 weeks ($P < .01$). In addition, the TLM intervention group showed significant positive behavior changes; almost all of the women tried to control their intake of food and their weight and to exercise 3 times per week. The TLM intervention showed no group and time interaction effect on systolic blood pressure, fasting glucose, high-density lipoprotein cholesterol, or low-density lipoprotein cholesterol levels. However, there was a positive time effect; after the program, high-density lipoprotein cholesterol levels increased and systolic blood pressure, fasting glucose, and low-density lipoprotein cholesterol decreased compared with levels before the intervention in both groups. These results indicate that a well-developed comprehensive TLM intervention can improve metabolic syndrome over a short-term period.

1. Introduction

Metabolic syndrome, also called *syndrome X*, is characterized by insulin resistance, abdominal obesity, elevated blood pressure, and lipid abnormalities [1]. The clustering of risk factors called the *metabolic syndrome* confers an increased risk of cardiovascular disease–related morbidity and mortality [2,3] and all-cause mortality, even in the absence of clinically evident cardiovascular disease and/or diabetes mellitus [3]. The *Third Report of the National Cholesterol Education Program Adult Treatment Panel* (NCEP-ATP III) has recommended appropriate measures to identify individuals with the metabolic syndrome and to manage their care before development of cardiovascular complications [4].

Difference in prevalence of metabolic syndrome has been reported in previous studies [1,5-7]. The prevalence is increased in middle- or older-aged women [5,8]. Over the past decades, South Korea has experienced rapid socioeconomic growth, resulting in lifestyle changes that promote the development of components of metabolic syndrome within the population [8]. Using the NCEP-ATP III definition of metabolic syndrome, it was found that its age-

* Corresponding author. Division of Clinical Nursing Science (Adult Health Nursing), College of Nursing, Nursing Policy and Research Institution, Yonsei University, 134 Shinchon-Dong, Seodaemun-Gu, PO Box 8044, Seoul 120-752, Korea. Tel.: +82 2 2228 3256; fax: +82 2 392 5440.
E-mail address: euigeum@yumc.yonsei.ac.kr (E.-G. Oh).

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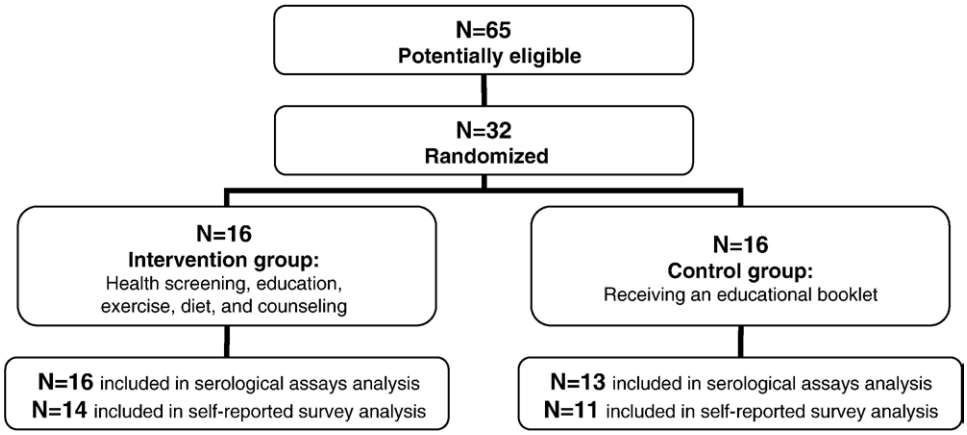

Fig. 1. Detailed flow of participants through the study.

adjusted prevalence was 14.2% in Korean men and 17.7% in Korean women, although only 2.3% of this population was *obese*, as defined by a body mass index (BMI) ≥30 kg/m^2 [5]. These results support earlier findings that central obesity and insulin resistance in Asians are associated with a high prevalence of cardiovascular risk.

In Korean men, the prevalence of metabolic syndrome reaches a plateau during the middle years of life and beyond. In Korean women, however, the prevalence of metabolic syndrome increases rapidly in women older than 50 years [8]. Menopause has been considered as a contributing factor for this epidemiologic trend. Sex differences in the prevalence of metabolic syndrome after the age of 50 years may be related to the higher prevalence of abdominal obesity and prominent weight gain associated with aging in Korean women compared with men [9]. In addition, a previous study has reported that low socioeconomic status is associated with a higher mortality rate from cardiovascular disease [8]. Therefore, older women with low socioeconomic status would be a high-risk group for metabolic syndrome in Korea.

The NCEP-ATP III suggests a therapeutic lifestyle change for managing patients with metabolic syndrome. This is a multifactorial approach based on exercise, diet, education, and/or pharmacotherapy. Furthermore, the NCEP-ATP III emphasizes the role of health care providers in initiating and maintaining a therapeutic lifestyle modification (TLM) program for better adherence and as a cost-effective way of management. Therefore, individual counseling and monitoring are recommended as important components. However, only few studies have applied a multifactorial approach in patients with metabolic syndrome [8,10]. In most intervention research with metabolic syndrome patients, a single component of TLM, such as exercise alone [11-14], diet alone [15-20], or drug therapy alone [21,22], or a combination of 2 components was used [12,23]. In addition, previous intervention studies for patients with metabolic syndrome have overlooked the health care provider role of monitoring and maintaining TLM.

The purpose of the study was to identify the effects of the 4-week TLM program on women with metabolic syndrome in rural areas.

2. Methods

2.1. Study design and participants

This study was a 4-week randomized controlled trial conducted on rural women with metabolic syndrome. *Metabolic syndrome* was defined as the presence of at least 3 out of 5 risk determinants according to the NCEP-ATP III (however, the criterion of waist circumference was applied by the World Health Organization–Asia Pacific), as follows: increased waist circumference (>90 cm in men, >80 cm in women), hypertriglyceridemia (triglyceride [TG] >150 mg/L), low high-density lipoprotein cholesterol (HDL-C; <40 mg/dL in men, <50 mg/dL in women), high blood pressure (≥130/85 mm Hg or use of antihypertensive medication), and high fasting plasma glucose (≥110 mg/dL or treatment of diabetes mellitus).

Participants were recruited from a branch of a rural public health center in Korea. The participants were screened if they (1) had a diagnosis of hypertension, diabetes, or hyperlipidemia; (2) had abdominal obesity (>90 cm in men, >80 cm in women); and (3) were at least 20 years old. Sixty-five women were recruited by these selection criteria. To select women with metabolic syndrome from the potential 65 women, a blood test was done to screen for study participants who met the metabolic syndrome diagnosis criteria. Finally, 32 women were identified as having a metabolic syndrome and included in the study. Participants were randomly assigned to the TLM intervention group (n = 16) or control group (n = 16). Three women in the control group dropped out, and 4 women (intervention group, 2; control group, 2) did not complete the survey. A detailed flow of participants through the study is presented in Fig. 1. This study was approved by the director of the Galsan branch of the public health center

Table 1
The TLM intervention program

Program contents		Duration (min)
Health status check	Blood pressure, body weight	5
Counseling	Food diary, exercise adherence, and health status	20
Education	Greeting and making a contract	30
	1 Evaluation of own health status Education of writing out food and exercise diaries	
	2 Definition of metabolic syndrome	
	3 Diet of metabolic syndrome I	
	4 Diet of metabolic syndrome II	
	5 Exercise of metabolic syndrome I	
	6 Exercise of metabolic syndrome II	
	7 Metabolic syndrome and hypertension	
	8 Metabolic syndrome and diabetes	
	9 Metabolic syndrome and obesity	
	10 Metabolic syndrome and hyperlipidemia	
	11 Metabolic syndrome and prognosis	
	12 Summary and quiz	
Exercise	Warm-up Stretching Strength training Rhythmic dance Cool-down	60
Wrap-up		5

(local ethics committee). Informed consent was obtained from each participant.

2.2. TLM intervention

The 4-week TLM intervention was provided in 12 sessions (3 times per week, 2 hours per session). The intervention consisted of 5 components: (1) health screening (blood pressure and body weight check), (2) education, (3) exercise, (4) diet, and (5) counseling. The details of the TLM intervention program are described in Table 1. The control group only received an educational booklet, and a systematic TLM program was not given.

2.2.1. Education

Participants in the intervention group received health information from the researcher, including a definition of the disease, and information on exercise, diet, risk factors, related disease (eg, hypertension, diabetes mellitus, hyperlipidemia, obesity), and self-care. Detailed information is presented Table 1. An educational booklet that included this information was also given to the participants.

2.2.2. Exercise

Participants attended 3 supervised sessions per week and were encouraged to perform home-based walking exercise daily. Pedometers were given to women in the intervention group. Supervised exercise intervention consisted of stretching, strength training, rhythmic dance, warm-up, and cool-down exercises for 60 minutes per session. These types of exercise were targeted to expend 500 kcal (supervised exercise, 200 kcal; home-based walking, 300 kcal). Exercise prescriptions were approved by an exercise physiologist.

2.2.3. Diet

The participants in the intervention group were given detailed advice on how to reduce 300 kcal from their usual daily food intake. The diet included more fruit, vegetables, and low-fat dairy products and less saturated fat, total fat, and cholesterol. It also contained more whole grains and fewer refined grains, sweets, and red meats. In addition, participants kept a daily food diary. A nurse researcher calculated total calories based on the participants' food diary.

2.2.4. Health counseling

A nurse researcher provided 20 minutes of counseling on diet based on the food diary, exercise adherence, and health status (blood pressure, body weight) at every session. Problems and concerns in carrying out the program were also discussed.

2.3. Study outcomes

2.3.1. Anthropometric indicators

Body weight was measured with a high-precision scale (GM1000; NeoGMTEC, Seoul, Korea). Weights were taken at the same time at each session, with the women in T-shirts and shorts. Participants were asked to remove their shoes. Waist circumference was measured midway between the lowest rib and the iliac crest. Blood pressure was measured with an automatic digital sphygmomanometer (Hem 432C, Omron Healthcare, Kyoto, Japan). The average of 2 measurements taken at a 2- or 3-minute interval with the women in a sitting position after resting for at least 15 minutes was used.

2.3.2. Serologic assays

Blood samples were obtained from the antecubital vein with the women in a seated position after an overnight fast. Samples were collected and analyzed at the Association of Health Management (Chung-Ju, Korea). To minimize the influence of any incidental acute phase reaction, participants were requested not to perform any major physical activity before collection of blood samples.

2.3.3. Psychosocial factors

Self-efficacy was measured with the 8-item new general self-efficacy scale (GSE) developed by Chen et al [24]. The GSE construct originated from the concept of self-efficacy generality, which is delineated in the Bandura social cognitive theory [25]. However, GSE is distinguishable from the concept of self-efficacy because, whereas self-efficacy is a relatively malleable, task-specific belief, GSE is a relatively stable, trait-like, generalized competence belief [24,26]. This scale is a 5-point Likert scale (1, strongly disagree; 5, strongly agree), with a higher score representing better self-efficacy. Internal consistency for the scale in this study was Cronbach alpha of 0.87.

Table 2
Baseline characteristics of participants (n = 29)

Characteristics		Experimental (n = 16)	Control (n = 13)	χ^2	*P*
		Valid n[a] (%)			
Marital status	With spouse	11 (68.8)	11 (94.6)	.986	.410
	Without spouse	5 (31.2)	2 (15.4)		
Educational status	Illiterate	2 (12.5)	4 (36.4)	2.290	.318
	Elementary school	11 (68.8)	6 (54.5)		
	Middle school	3 (18.8)	1 (9.1)		
Occupational status	Employed	2 (12.5)	5 (38.5)	2.286	.315
	Unemployed	14 (87.5)	8 (61.5)		
Monthly income ($US)	<1000	3 (25.0)	0 (0.0)	3.163	.217
	1000-2000	9 (75.0)	11 (100.0)		
Having a religion	Yes	8 (53.3)	4 (30.8)	1.448	.229
	No	7 (46.7)	9 (69.2)		
Comorbidities, yes	Diabetes mellitus	0 (0.0)	1 (7.7)	1.140	.478
	Hypertension	10 (62.5)	8 (61.5)	.379	.640
	Hyperlipidemia	1 (6.3)	0 (0.0)	.958	1.000
	Obesity	4 (25.0)	1 (7.7)	1.982	.317
	Cardiovascular disease	1 (6.3)	2 (15.4)	.491	.590
	Musculoskeletal disease	6 (37.5)	5 (38.5)	.048	.827
		Mean (SD)		*U*	*P*
Age (y)		64.6 (10.2)	70.1 (7.5)	71.0	.156
Blood pressure (mm Hg)	Systolic	145.8 (19.7)	142.6 (17.2)	95.5	.709
	Diastolic	86.8 (12.0)	81.5 (10.5)	71.5	.149
Body weight (kg)		63.0 (11.1)	60.8 (11.0)	83.5	.369
BMI (kg/m^2)		28.9 (2.7)	26.2 (3.4)	100.0	.880
Abdominal circumference (cm)		94.8 (5.98)	93.1 (6.2)	96.5	.742
Fasting glucose (mg/dL)		114.2 (15.6)	119.7 (22.8)	92.5	.613
HDL-C (mg/dL)		40.4 (4.5)	40.5 (5.7)	104.0	1.00
LDL-C (mg/dL)		126.6 (28.1)	136.6 (30.9)	85.0	.405
TG (mg/dL)		141.9 (64.9)	143.5 (54.9)	100.5	.878

[a] Excluded no response.

Quality of life (QOL) was measured with EQ-5D. The EQ-5D is a brief questionnaire that is commonly used to provide an estimate of overall health status in large-scale surveys, clinical research, and health economic evaluation [27]. The EQ-5D descriptive system consists of 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each dimension is assessed by one item with 3 response choices: no problems, some problems, and severe problems. These 5 ratings are used to derive the weighted EQ-5D index score, a single score representing overall health, with higher scores indicating better health status. An index score of 1 corresponds to perfect health and 0 corresponds to death, although negative scores representing health states worse than death are possible [28,29]. The reliability, validity, and responsiveness of the EQ-5D have been demonstrated in the general population samples as well as samples of patients with a wide range of medical conditions [26]. In addition, 3 items of health behavior were assessed: "Do you try to control amount of food?", "Do you try to control your body weight?", and "Do you exercise above 3 times a week with moderate to vigorous intensity?" These items were answered by dichotomous response (yes or no).

2.4. Statistical analysis

Statistical analysis was performed using SPSS 12.0 for Windows (SPSS, Chicago, IL). Descriptive analysis was used to evaluate the demographic and clinical characteristics of the women. Nonparametric statistical methods were used because of the small number in each group. To evaluate homogeneity of the 2 groups, χ^2 test, including Fisher exact test for small samples, and Mann-Whitney *U* test were done. Repeated-measures analysis of variance was calculated with the treatment period as the within-subject factor and with the TLM intervention as the between-subject factor. χ^2 test was also used to evaluate changes in health behavior. All *P* values are 2-sided, and *P* value of .05 was considered statistically significant.

3. Results

3.1. Characteristics of the participants

The characteristics of the participants in the intervention and control groups are presented in Table 2. Their mean age was 66.7 years (SD = 9.7), and most women were married (75.9%). Their educational status was relatively low, and household monthly income was also low. Their mean BMI

Table 3
Effects of TLM

Variables		Mean (SD)		$F(P)_{group}$	$F(P)_{time}$	$F(P)_{group \times time}$
		Pre	Post			
Body weight (kg)	Experimental (n = 16)	63.0 (11.1)	58.4 (10.3)	.049 (.826)	170.061 (<.001)	26.776 (<.001)
	Control (n = 13)	60.8 (11.0)	58.8 (10.8)			
BMI (kg/m^2)	Experimental (n = 16)	26.9 (2.7)	24.9 (2.4)	.011 (.918)	182.923 (<.001)	29.582 (<.001)
	Control (n = 13)	26.2 (3.4)	25.3 (3.5)			
Waist circumference (cm)	Experimental (n = 16)	94.8 (6.0)	88.6 (6.9)	.074 (.788)	54.516 (<.001)	18.505 (<.001)
	Control (n = 13)	93.2 (6.2)	91.5 (7.4)			
Systolic blood pressure (mm Hg)	Experimental (n = 16)	145.8 (19.8)	122.6 (11.2)	.539 (.469)	21.576 (<.001)	4.062 (.054)
	Control (n = 13)	142.6 (17.2)	133.5 (18.0)			
Diastolic blood pressure (mm Hg)	Experimental (n = 16)	86.8 (12.0)	75.7 (10.6)	.230 (.635)	9.937 (.004)	2.501 (.125)
	Control (n = 13)	81.5 (10.5)	77.8 (11.1)			
Fasting glucose (mg/dL)	Experimental (n = 16)	114.2 (15.6)	100.8 (9.3)	1.169 (.289)	14.185 (.001)	.775 (.387)
	Control (n = 13)	119.7 (22.8)	111.4 (33.5)			
HDL-C (mg/dL)	Experimental (n = 16)	40.4 (4.5)	46.9 (7.9)	.043 (.837)	32.437 (<.001)	.207 (.653)
	Control (n = 13)	40.5 (5.7)	46.0 (4.1)			
LDL-C (mg/dL)	Experimental (n = 16)	126.6 (28.1)	108.8 (28.5)	1.206 (.282)	15.329 (.001)	.157 (.695)
	Control (n = 13)	136.6 (30.9)	122.1 (35.4)			
TG (mg/dL)	Experimental (n = 16)	141.9 (64.9)	89.7 (25.0)	1.857 (.184)	9.781 (.004)	8.244 (.008)
	Control (n = 13)	143.5 (54.9)	141.3 (75.5)			
Self-efficacy	Experimental (n = 14)	25.2 (6.8)	26.6 (9.6)	.380 (.544)	1.017 (.324)	2.419 (.134)
	Control (n = 11)	28.1 (6.2)	21.4 (7.7)			
EQ-5D index score	Experimental (n = 14)	0.53 (0.14)	0.54 (0.12)	2.550 (.134)	0.820 (.382)	1.540 (.237)
	Control (n = 11)	0.45 (0.16)	0.33 (0.35)			

was 26.6 kg/m^2 (SD = 3.0), and 21 women (72.4%) were overweight (BMI ≥25.0 kg/m^2). There were no significant differences between the 2 groups in baseline characteristics (Table 2).

3.2. Effects of the TLM intervention

The means of outcome measures for the treatment group at baseline and 4 weeks post baseline are presented in Table 3. There were significant group and time interactions for body weight ($P < .001$), BMI ($P < .001$), waist circumference ($P < .001$), and TG ($P = .008$). These indicators showed a greater reduction in the TLM intervention group than in the control group. Systolic blood pressure showed borderline significance in group and time interactions ($P = .054$) and had a greater reduction in the TLM intervention group than in the control group. There was no significant group and time interaction for diastolic blood pressure, fasting glucose, HDL-C, or low-density lipoprotein cholesterol (LDL-C). However, these outcomes showed positive time effects: when the interaction term was removed, diastolic blood pressure ($P = .004$), fasting glucose ($P = .001$), and LDL-C ($P = .001$) decreased in both groups over time; HDL-C increased in both groups over time ($P < .001$). There was no significant difference over time between groups for the self-efficacy or QOL. However, the TLM intervention group had an increase in self-efficacy, whereas the control group had a decrease. For QOL, the EQ-5D index score was stable in the TLM intervention group, but decreased in the control group.

3.3. Changes in health behaviors after TLM intervention

Analyses of changes in health behavior (food control, weight control, exercise ≥3 times per week) are shown in Table 4. Before the 4-week TLM intervention, women in both groups showed almost no food control, weight control, or exercise with a frequency of 3 times per week. However, women in the TLM intervention group showed significant positive behavior change; almost all of the women tried to control their intake of food and their weight and to exercise 3 times per week.

4. Discussion

This pilot study of randomized controlled trial using a comprehensive TLM intervention, which consisted of health

Table 4
Changes in health behavior after TLM (n = 25)

Categories	Groups	n (%)		χ^2	P
		Pre	Post		
Food control, yes	Experimental (n = 14)	0 (0)	14 (100)	14.973	<.001
	Control (n = 11)	0 (0)	3 (27.3)		
Weight control, yes	Experimental (n = 14)	2 (14.3)	14 (100)	10.048	.002
	Control (n = 11)	0 (0)	5 (45.5)		
Exercise ≥3/wk, yes	Experimental (n = 14)	0 (0)	13 (92.9)	5.578	.018
	Control (n = 11)	0 (0)	5 (45.5)		

screening, education, exercise, diet, and counseling, had a positive effect in reducing body weight, waist circumference, TG level, and systolic blood pressure and in improving health behavior in rural women with metabolic syndrome. Although the duration of the intervention (4 weeks with 12 sessions) was relatively shorter than those of previous studies (≥12 weeks) [11,12,15,18,19,23,30], the effects of the intervention were similar.

These results suggest that a well-designed and systematic TLM program can improve metabolic syndrome even though it is only provided for a short-term period.

The effect of the intervention on body weight or BMI was found most frequently in previous studies [11,15,17,18,20,23]. Our study also showed a significant decrease in body weight (−4.6 kg). The main components of the 4-week TLM intervention in the present study were exercise and diet. Exercise or diet has been shown to be a viable option for controlling body weight. The weight changes in previous studies were various (2.3-16 kg) and were from diet interventions such as meal replacement [17]; low-fat, high-carbohydrate diet [20]; or low-calorie diet [18]. In our study, weight reduction was made possible, in part, by reducing calorie intake by more than 30% to less than 1000 kcal/d. Waist circumference and TG decreased significantly for the women in our study. These results are consistent with previous studies [12,15,19]. Weight reduction and low-carbohydrate diet might be contributing factors to these results.

The 4-week TLM intervention had no group and time interaction effect in systolic blood pressure, fasting glucose, HDL-C, or LDL-C. However, there was a positive time effect: after the program, HDL-C increased and systolic blood pressure, fasting glucose, and LDL-C decreased in both groups compared with levels before the intervention. However, the levels of these serologic markers in the intervention group returned to normal limits (mean systolic blood pressure, 145.8-122.6 mm Hg; mean fasting glucose, 114.2-100.8 mg/dL; mean HDL-C, 40.4-46.9 mg/dL; LDL-C, 126.6-108.8 mg/dL), whereas this effect was not found for the control group. Thus, large sample sizes may be needed to show statistical differences.

We did not find positive statistically significant intervention effect on psychosocial outcomes such as self-efficacy or QOL. However, the intervention group had a clinically positive trend: self-efficacy was increased in the intervention group, whereas it was decreased in the control group. For QOL, EQ-5D index scores were stable in the intervention group, but decreased in the control group. These results might be a measurement issue such as small sample size or problems with instrumentation. Especially in terms of QOL, we assume that EQ-5D may not be sensitive enough to represent effects of the TLM intervention. In addition, there could be a "history" for women in the control group who were only given the educational booklet. Because of limited geographical space, the women in the control group might also have had an increased awareness, so that they may have tried to change their lifestyle by self-learning.

A high prevalence rate of metabolic syndrome has been found: 32 women (49.2%) among the 65 high-risk participants. Community health care providers should be concerned and screen registered chronic illness patients if they are identified as having metabolic syndrome. The study results also support a conclusion that the rural community is a vulnerable region to metabolic syndrome. Previous intervention studies for participants with metabolic syndrome in Korea as well as other countries focused on either clinic-based or urban populations [8,12,14,16,18,19,22]. This study indicated that community-based research with vulnerable people with metabolic syndrome is needed.

One of the limitations of this study is the small sample size and the limited geographic region in which this study was conducted. Thus, the findings of this study must be interpreted with caution; and further study with a large sample size is needed. Second, the period of the intervention in our pilot study was short. Thus, there is a need to examine if the effects of TLM intervention would be sustained. Third, we tried to measure psychosocial outcomes such as self-efficacy and QOL in patients with metabolic syndrome. However, the EQ-5D may not be sensitive enough to detect important changes in emotional, social, or other domains.

Although there are these limitations, our study showed that a comprehensive 4-week TLM intervention had positive effects on various outcomes in rural women with metabolic syndrome. Blood pressure and blood glucose level each returned to the normal range. Although waist circumference did not return to the normal range, a statistically significant time by group interaction effect was found. These results show that waist circumference indicating abdominal obesity might return to the normal range if the program was provided for a long-term period. The TG level significantly decreased from the high border of the normal range, and HDL-C increased close to the normal range. These results suggest that a well-designed and systematic TLM program can improve metabolic syndrome even though it is only provided for a short-term period. These benefits might be mediated by improved health behaviors. Overall, these results provide evidence for the role of a comprehensive approach including health screening, education, exercise, diet, and counseling in managing metabolic syndrome.

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