Diabetes, Metabolic Syndrome and Obesity

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ORIGINAL RESEARCH

Health Provider's Feedback on Physical Activity Surveillance Using Wearable Device-Smartphone Application for Adults with Metabolic Syndrome; a 12-Week Randomized Control Study

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Purpose: Research on whether wearable device interventions can effectively prevent metabolic syndrome remains insufficient. This study aimed to evaluate the effect of feedback on clinical indicators in patients with metabolic syndrome on activities measured using wearable devices, such as smartphone apps.

Methods: Patients with metabolic syndrome were recruited and prescribed to live for 12 weeks using a wrist-wearable device (B. BAND, B Life Inc., Korea). A block randomization method was used to distribute participants between the intervention (n=35) and control groups (n=32). In the intervention group, an experienced study coordinator provided feedback on physical activity to individuals through telephonic counseling every other week.

Results: The mean number of steps in the control group was 8892.86 (4473.53), and those in the intervention group was 10,129.31 (4224.11). After 12 weeks, metabolic syndrome was resolved. Notably, there were statistically significant differences in the metabolic composition among the participants who completed the intervention. The mean number of metabolic disorder components per person remained at 3 in the control group, and decreased from 4 to 3 in the intervention group. Additionally, waist circumference, systolic and diastolic blood pressure, and triglyceride levels were significantly reduced, while HDL-cholesterol levels were significantly increased in the intervention group.

Conclusion: Overall, 12 weeks of telephonic counseling intervention using wearable device-based physical activity confirmation improved the damaged metabolic components of patients with metabolic syndrome. Telephonic intervention can help increase physical activity and reduce waist circumference, which is a typical clinical indicator of metabolic syndrome.

Keywords: metabolic syndrome, physical activity, wearable device, waist circumference

Introduction

Metabolic syndrome is characterized by the co-existence of several major risk factors for cardiovascular disease, high blood pressure, hyperglycemia, and dyslipidemia (reduced high-density lipoprotein cholesterol [HDL-C] or raised triglycerides).[1] Therefore, appropriate prevention and intervention are required in all related fields.[2] This syndrome occurs most frequently in populations characterized by excessive caloric intake and reduced physical activity;[3] however, underlying metabolism and genetic sensitivity are also important factors.[4]

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Mobile health technology using apps and wearable devices is becoming increasingly popular, as it allows patients to monitor their health status.[5] The advantages of wearable device technology include a possible increase in the awareness of personal healthcare and disease prevention. Recent surveys of worldwide fitness trends have shown that wearable technology is the top fitness trend.[6] Additionally, wearable devices have been shown to be an effective strategy for increasing physical activity.[7] However, it is unclear how they can be applied to continuous-wear devices and reduce metabolic syndrome risk factors. These improvements on pedometers suggest the possibility that wearable electronic monitors and their companion mobile apps still lack several important behavior-change techniques.

Recent studies have shown that telephonic counseling interventions are effective in promoting healthy behavior and improving the health-related quality of life.[8–11] While the study of telephonic interventions is known to be effective and beneficial, additional research is needed to better understand how or why they work and what factors can mitigate the effects in other populations.[12] Therefore, the purpose of this study was to evaluate the effect of telephonic feedback on the activities measured using a wearable device-smartphone app in outpatients with metabolic syndrome.

Methods

This study included 67 men and women aged 58.2±10.7 years. Patients diagnosed with metabolic syndrome were recruited for the study at Pusan National University Hospital (Busan, South Korea). Inclusion criteria were as follows: (1) diagnosed with metabolic syndrome by a doctor, a person who has three or more of the five diagnostic criteria for Korean metabolic syndrome based on the NCEP-ATP III diagnostic criteria (Abdominal obesity: waist circumference in men > 90 cm and in women > 85cm, High blood pressure: ≥ 130 / 85 mmHg or taking high blood pressure medication, Hypertriglyceridemia: ≥ 150 mg/dL or taking medication for dyslipidemia, Low HDL cholesterol: < 40 mg/dL in men and ≤ 50 mg/dL or taking medication for dyslipidemia, High fasting glucose: ≥ 100 mg/dL or taking medication for diabetes),[3] (2) aged over 19 years, (3) possession of a smartphone and a daily mobile phone user for the past 3 months and expected to use for more than 3 months, (4) a person who agrees to provide the data on the amount of physical activity measured and collected by a wearable device, and (5) a person who has no limitations on physical activity due to hip joint disease or surgery. The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Pusan National University Hospital (IRB number: 1904–022-078). All participants consented to the study protocols and the subsequent publication of their respective findings. Participants were randomized using the Research Randomizer program (randomizer.org) set to randomize at a 1:1 ratio. After participants completed screening, we allocated groups to participants using a randomization list. Researcher and participants were unblinded to group allocation. We conducted a randomized controlled 1–1 clinical trial (registry number NCT05630456 www.ClinicalTrial.gov) in 67 adults. The CONSORT flowchart of recruitment and participant retention is seen in Figure 1.[13]

Research Procedure

All participants provided information on demographics, occupation (usually for estimating physical activity intensity), frequency and duration of physical activity, history (diagnosis or drug treatment for hypertension, diabetes, or dyslipidemia), health-related habits (smoking, alcohol drinking), and medications taken, through the survey. Participants were defined as non-smokers, past smokers, current smokers, and non-smokers (0 to 98 g/week) or alcohol drinkers who drank an average of seven cups (men) or five or more cups (women), twice per person.[14]

Participants also had height, weight, waist circumference, body mass index, body composition measurements and six-hour fasting blood tests at baseline and 12th week visits. The blood pressure was measured in a sitting position after resting using a BP-203 RVII (Colin Corp., Aichi, Japan). Waist circumference was evaluated by a trained examiner (after normal exhalation) to the nearest millimeter from the midpoint between the lower edge of the rib and iliac ridge. The body weight and height were measured using a digital scale and stadiometer (BSM370, Biospace Co. Ltd., Seoul), respectively, while the study participants were dressed in light clothing without shoes. The body composition was measured using bioelectrical impedance analysis (InBody 720; Biospace Co. Ltd., Seoul). Blood samples were collected from the Jeonju vein after fasting for 6 h and were analyzed in our hospital's laboratory. The lipid profile was tested using an automated analyzer (Hitachi 747, Hitachi Corp., Japan) and an enzyme colorimetric method. Fasting plasma glucose

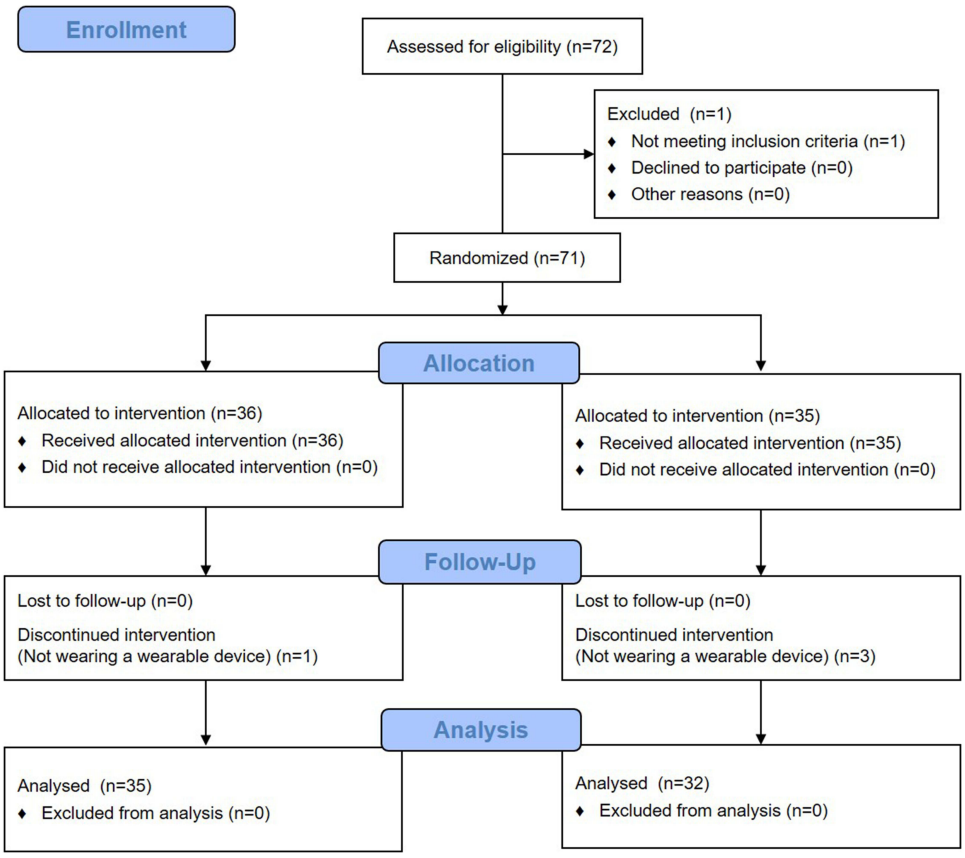

Figure 1 CONSORT flow diagram.
Notes: Schulz KF, Altman DG, Moher D, CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials. *PLoS Med.* 2010;7(3): e1000251. Creative Commons Attribution License.[13]

(FPG) levels were evaluated using the glucose oxidase method and the Synchron LX 20 (Beckman Coulter, Fullerton, CA, USA).

All participants were provided brochures containing information on dietary control as part of the treatment for metabolic syndrome.[15–17] They were also provided with a wrist-wearable device (B.BAND, B Life Inc., Korea),[18–20] which allowed them to wear and monitor for 12 weeks. Subsequently, a compatible app was installed on the participants' mobile phones and connected to the wearable device. The screen of the compatible app allowed the participants to check the number of steps and calories consumed every day. The participants regularly sent records to researchers, and researchers who had been granted access can check and track their steps, calorie consumption, and moderate-to-vigorous intensity physical activity (MVPA) on a daily basis through a web page. In addition, drugs taken over the past three months were maintained without dose changes during the study period.

Intervention Design

In the intervention group, the researcher provided feedback on the participants' exercise amount through telephone contact every two weeks during the 12-week study period. It includes recommendations for continuing exercise therapy based on the recommendations for physical activity. Through phone counseling, we answered exercise-related questions or discussed problems and recommended them to continue exercising. We informed them about how many steps they had taken and how many calories they had burned through exercise in the past two weeks. We also encouraged them to participate in more physical activities. We answered questions related to wearable devices and apps, discussed any issues, and encouraged continuous data transmission. In the control group, physical activity was monitored through wearable devices and smartphone apps without telephone counseling.

Statistical Analysis

The sample size for the study was calculated based on the results of a randomized controlled study of overweight and obese subjects with an intervention including physical activity feedback for 12 weeks that showed an effect size of 0.75.[21] The sample size was 60 for two-sided tests of significance at alpha=0.05 and power 1−beta=81%. To account for attrition, we attempted to recruit approximately 72 participants in total.

The data are expressed as mean ± standard deviation for continuous variables and as proportions for categorical variables. The general characteristics of the participants were analyzed using an independent *t*-test for continuous variables and the chi-square test for categorical variables. The Pearson's correlation coefficient was used to evaluate the degree of correlation between variables. An independent *t*-test was used to assess the physical activity. A paired *t*-test was used to compare the body composition and metabolic composition at baseline and follow-up. Two-way repeated-measures analysis of variance was used to determine the mean difference between groups. Statistical analysis was performed using SPSS 21.0 (IBM Corp., Armonk, NY, USA); a P-value <0.05 was considered significant.

Results

Demographic characteristics of the study population at the baseline are shown in Table 1. The study consisted of 67 participants (35 in the intervention group and 32 in the control group). The mean age of the intervention group was 61 ± 9 years and consisted of 10 men, and the mean age of the control group was 56 ± 12 years and consisted of six men. The mean height was 160.07 ± 7.72 cm and 162.78 ± 8.38 cm, the mean weight was 69.76 ± 9.78 kg and 73.28 ± 12.49 kg, and the mean body mass index was 27.27 ± 3.11 kg/m2 and 27.70 ± 6.42 kg/m2 for the intervention and control groups, respectively. When asked whether they currently smoked, four (88.6%) participants in the intervention group and four (87.5%) in the control group answered "yes". When asked whether they were currently drinking alcohol, 20 (57.1%) participants in the intervention group and 13 (40.6%) participants in the control group answered "yes". There were no significant differences in the parameters between the intervention and control groups at the baseline.

Table 2 shows the participants' physical activity collected through the wearable device. The number of steps was 10,129.31 ± 4224.11 steps/day in the intervention group and 8876.26 ± 4404.11 steps/day in the control group. The amount of calories burned was 323.96 ± 146.48 kcal/day in the intervention group and 265.53 ± 131.39 kcal/day in the control group. The MVPA time was 73.21 ± 31.32 time/week in the intervention group and 60.40 ± 29.65 time/week in the control group. There were no significant differences in these parameters between the intervention and control groups. However, the intervention group showed higher values for all physical activities.

Table 3 shows a comparison of the body composition between the baseline and post-intervention for the telephone counseling intervention and control groups. The difference in the body composition among participants who completed the intervention was not statistically significant.

Table 4 summarizes the changes in the metabolic disorder components from baseline to follow-up at 12 weeks in the intervention and control groups. After 12 weeks, metabolic syndrome was resolved. In particular, there were statistically

Table 1 Demographics of the Study Population at Baseline

	Intervention Group (n=35)	Control Group (n=32)	*P*
Male, n (%)	10 (28.6)	6 (18.8)	0.346
Age (years)	61 ± 9	56 ± 12	0.057
Height (cm)	160.07 ± 7.72	162.78 ± 8.38	0.173
Weight (kg)	69.76 ± 9.78	73.28 ± 12.49	0.202
BMI (kg/m^2)	27.27 ± 3.11	27.70 ± 6.42	0.609
Smoking, n (%)	4 (88.6)	4 (87.5)	1.000
Alcohol drinking, n (%)	20 (57.1)	13 (40.6)	0.177

Abbreviation: BMI, body mass index.

Table 2 Participants' Physical Activity Data Collected Through Wearable Devices

	Intervention Group (n=35)	Control Group (n=32)	*P*
Physical Activity			
Steps (step/day)	10,129.31 ± 4224.11	8876.26 ± 4404.11	0.235
Calories burned (kcal/daily)	323.96 ± 146.48	265.53 ± 131.39	0.089
MVPA (time/week)	73.21 ± 31.32	60.40 ± 29.65	0.088

Abbreviation: MVPA, moderate-to vigorous intensity physical activity.

Table 3 Comparison of Body Composition Between Baseline and Post Intervention in the Telephone Counseling Interventions and the Control Groups

	Baseline	Follow-Up	*P*	Group x Time Interaction
Body composition				
Weight (kg)				
Intervention	69.76 ± 9.78	69.46 ± 9.31	0.214	0.312
Control	73.28 ± 12.49	73.40 ± 12.64	0.733	
Skeletal muscle mass (kg)				
Intervention	24.34 ± 4.64	25.69 ± 11.86	0.389	0.984
Control	25.45 ± 4.97	26.75 ± 9.98	0.430	
Body fat mass (kg)				
Intervention	25.21 ± 6.32	25.50 ± 6.42	0.385	0.865
Control	27.03 ± 9.30	27.21 ± 8.20	0.768	
Percent body fat (%)				
Intervention	35.95 ± 6.80	36.10 ± 6.96	0.647	0.856
Control	36.20 ± 9.31	36.53 ± 8.12	0.727	
BMI (kg/m2)				
Intervention	27.27 ± 3.11	27.13 ± 2.99	0.150	0.567
Control	27.70 ± 3.76	27.65 ± 3.70	0.708	

Abbreviation: BMI, body mass index.

significant differences in the metabolic composition among the participants who completed the intervention. The mean number of metabolic disorders components per person remained at 3 in the control group, and decreased from 4 to 3 in the intervention group. In addition, in the intervention group, waist circumference (P=0.031), systolic and diastolic blood pressure (P=0.028), and triglyceride levels (P=0.025) were significantly reduced, while HDL-C levels (P=0.046) were significantly increased.

Among the five metabolic syndrome factors of the participants', changes in the number of factors were compared between baseline and post intervention. After 12 weeks, metabolic syndrome was resolved. The mean number of metabolic disorder components per person remained at 3 in the control group, and decreased from 4 to 3 in the intervention group (Figure 2).

Table 4 The Comparison of Metabolic Composition Between Baseline and Post Intervention in the Telephone Counseling Interventions and the Control Groups

	Baseline	Follow-Up	*P*	Group x Time Interaction
Metabolic composition (number)				
Intervention	4 ± 1	3 ± 1	<0.001*	0.901
Control	3 ± 1	3 ± 1	0.058	
Waist circumference (cm)				
Intervention	89.69 ± 5.83	89.03 ± 5.77	0.031*	0.154
Control	91.97 ± 9.45	91.94 ± 9.91	0.923	
Systolic blood pressure (mmHg)				
Intervention	132.03 ± 18.55	125.06 ± 13.13	0.028*	0.966
Control	133.69 ± 13.04	126.53 ± 12.04	0.026*	
Diastolic blood pressure (mmHg)				
Intervention	81.37 ± 10.92	77.20 ± 9.28	0.023*	0.410
Control	83.31 ± 10.27	76.88 ± 13.58	0.005*	
Glucose (mg/dL)				
Intervention	108.57 ± 27.13	102.06 ± 32.72	0.334	0.674
Control	109.66 ± 28.39	107.19 ± 36.50	0.723	
Triglyceride (mg/dL)				
Intervention	108.57 ± 27.13	140.26 ± 69.15	0.025*	0.535
Control	109.66 ± 28.39	149.06 ± 107.56	0.046*	
LDL-cholesterol (mg/dL)				
Intervention	114.82 ± 39.61	119.06 ± 44.69	0.393	0.414
Control	119.04 ± 31.40	128.69 ± 33.83	0.033*	
HDL-cholesterol (mg/dL)				
Intervention	55.43 ± 14.37	59.23 ± 17.76	0.046*	0.311
Control	55.50 ± 15.83	56.84 ± 14.32	0.381	

Note: *$p<0.05$.
Abbreviations: LDL-cholesterol, low density lipoprotein cholesterol; HDL-cholesterol, high density lipoprotein cholesterol.

Discussion

This study aimed to investigate the applicability of wearable devices to care for outpatients with metabolic syndrome in clinical settings and the impact of phone feedback on the physical activity measured using a wearable device-smartphone app. We found that a 12-week intervention based on wearable device wear improved the impaired metabolic components in patients with metabolic syndrome. In addition, it was found that damaged metabolic components further improved when telephonic feedback on the physical activity of experts was added.

The main result of this study was that the mean number of metabolic disorder components per capita remained at 3 in the control group, while it decreased from 4 to 3 in the intervention group. Notably, the results of this study showed that after wearing a wearable device, the five factors of metabolic syndrome showed improvements in all groups; in particular,

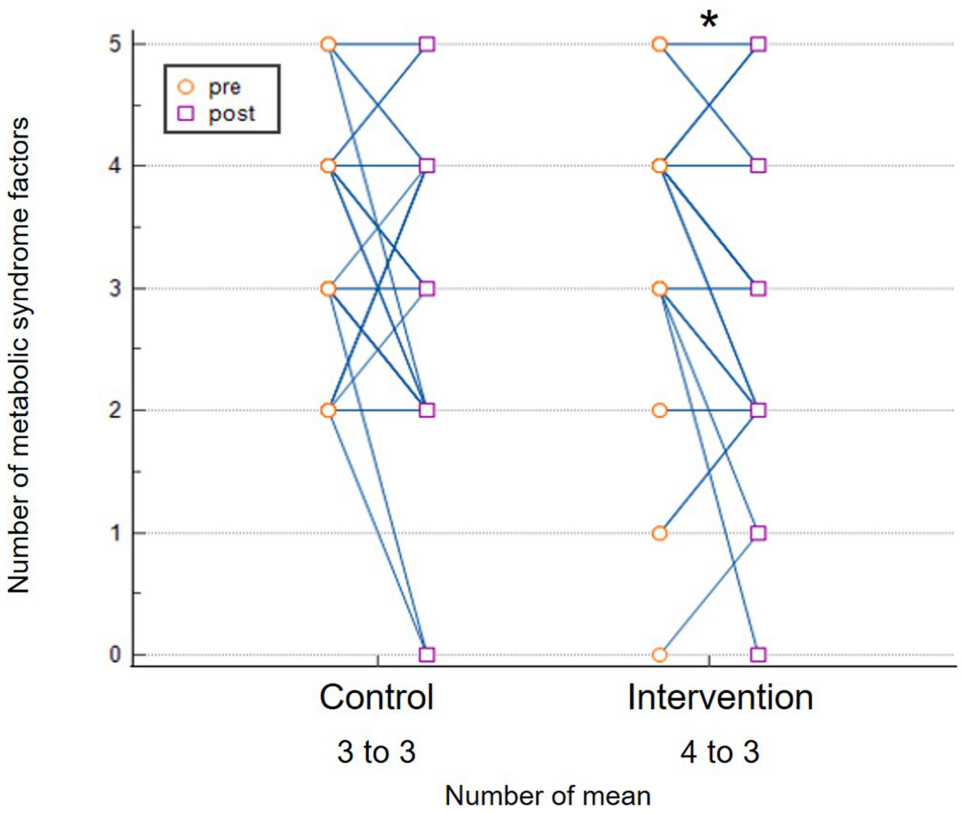

Figure 2 Comparison of the number of five factors of metabolic syndrome before and after intervention in participants. The intervention group showed a change in metabolic syndrome risk factors averaging from four to three. *$p<0.05$.

decreased waist circumference and increased HDL-C were significant only in the intervention group. Abdominal obesity, evaluated based on the waist circumference, plays an important role in evaluating the risk of metabolic syndrome. According to the 2005 IDF standards revised in 2009, abdominal obesity decreases the levels of HDL-C fractions and increases the levels of triglycerides.[22] According to previous studies, changes in the waist circumference can independently predict changes in metabolic syndrome factors; additionally, changes in the waist circumference are highly correlated with the likelihood and severity of metabolic syndrome regardless of the reference level.[23] Therefore, the results of the intervention in this study suggest that a reduction in the waist circumference is particularly effective in preventing metabolic syndrome.

The mean number of steps in the control group was 8892.86 (4473.53), while those in the intervention group was 10,129.31 (4224.11). Although there was no statistically significant difference, the number of steps taken in the intervention group was higher. Checking the daily step count is a simple way to estimate the amount of physical activity performed and a practical way to monitor the physical activity.[24] Previous studies have proposed the following classifications for daily steps: <5000 steps/day = sedentary, 5000–7499 steps / day = low active, 7500–9999 steps / day = somewhat active, 10,000–12,499 steps/day = active, and ≥12,500 steps = highly active.[25] An inverse correlation was found between the risk of metabolic syndrome and an increased step count.[26] Newton et al showed a correlation between an increase in the number of daily steps and a decrease in the prevalence of metabolic syndrome.[27] In addition, according to previous studies, walking is reported to be advantageous for improving metabolic syndrome factors, such as systolic blood pressure, fasting plasma glucose, waist circumference, and HDL-C.[28] Previous studies have suggested that public health goals should aim for more than 10,000 steps per day, and some countries have adopted the 10,000-step target as a national public health goal.[29,30] In this study, walking more than 10,000 steps was considered helpful in reducing the waist circumference and metabolic syndrome. Therefore, walking at least 10,000 steps per day is recommended.

The peculiarity of the intervention method in this study was to conduct telephonic counseling to encourage to keep wearing the wearable devices and promote physical activity. Several previous studies have reported that exercise interventions are effective for metabolic syndrome; however, current alternatives are difficult to implement due to the lack of time and cost problems.[31] Lack of time is a major barrier to face-to-face counseling;[32] additionally, demands regarding transportation and time are factors that make face-to-face counseling difficult for adults.[33] Therefore, it is very important to consider non-face-to-face intervention methods, such as mobile app-based interventions and phone consultations, that are suitable for modern individuals when cost and time constraints occur frequently or face-to-face contact is not allowed.[31] Phone-based counseling can be a feasible and cost-effective way to improve the quality of care and the patient risk profiles and associated outcomes.[34] In addition, feedback on physical activity monitoring can lead to successful increases in physical activity levels and be beneficial for managing target diseases.[34] This can be an attractive approach for both patients and practitioners seeking a convenient approach rather than providing professional support.[35] Previous studies have demonstrated an increasing demand for telephonic counseling interventions.[36] Moreover, telephonic counseling interventions have been shown to be effective as a booster strategy and provide continuous support to promote habitual behavioral changes.[37,38] According to previous studies, phone counseling can be effective in providing advice and education to patients with metabolic syndrome who need continuous improvement in health behaviors.[39] However, there is still a lack of research on telephonic counseling for patients with metabolic syndrome. Future research should investigate how telephonic counseling can complement other aspects of health promotion and disease management in the long term.[35]

This study has a few limitations. First, the sample size was small and only those individuals diagnosed with metabolic syndrome in Korea were recruited in this study. Therefore, our findings cannot be generalized to other ethnicities or geographic regions. Second, we did not know if there were other confounders affecting the predictive factors of weight loss and metabolic syndrome, such as a diet control program, evaluation of diets and participation in an individual exercise program during participation in the study. In addition, through various wearable devices and cutting-edge mobile apps, it will be necessary to study the predictive factors of metabolic syndrome, lifestyle, and clinical indicator trends of the patient group, and convergence intervention studies on appropriate diet and physical activity to prevent metabolic syndrome are needed.

Conclusion

In conclusion, our findings suggest that a 12-week telephonic counseling intervention utilizing wearable device-based monitoring can improve metabolic parameters in patients with metabolic syndrome. Telephonic intervention can help increase physical activity and reduce the waist circumference, which is a typical clinical indicator of metabolic syndrome.

Data Sharing Statement

All data generated or analyzed during this study are not publicly available to maintain the privacy of individuals. The datasets used or analyzed in this study are available from the corresponding author on reasonable request.

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Disclosure

The authors report no conflicts of interest in this work.

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