Development, Implementation, and Evaluation of an Educational Package to Control the Biomedical Profile of Metabolic Syndrome

Abstract

Background: Unhealthy lifestyle behaviors are a major concern in the development of metabolic syndrome (MetS). This study aimed to develop, implement, and evaluate a lifestyle education package as a strategy to control the biomedical components of MetS. **Methods:** A total of 72 women and men (aged 18–68 y) with MetS were selected through randomized sampling. They were classified into 2 groups: an intervention group that received a lifestyle educational package with close follow-ups and a control group that received only usual care. Anthropometric indices, blood pressure, lipid profiles, and fasting blood sugar were assessed at baseline and after 3 months. **Results:** The lifestyle-modification program was associated with a modest weight loss (2 ± 0.4 kg; $P < 0.001$), a significant reduction in waist circumference (2.3 ± 0.9 cm; $P < 0.001$) and the hip circumference (1 ± 0.3 cm; $P < 0.001$), and a sharp decrease in diastolic blood pressure (5.3 ± 1.4 mm Hg; $P < 0.001$), compared with the baseline values in the intervention group. Additionally, according to the one-way MANOVA analysis, 33.8% of the changes in MetS components were attributable to the educational intervention ($P < 0.001$, F = 5.27). **Conclusions:** Improvement in lipid profile and anthropometric measures suggest that a lifestyle package based on multivariable health education is an acceptable method.

Keywords: *Health education, life style, lipids, metabolic syndrome, obesity, triglycerides*

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Introduction

Metabolic syndrome (MetS), also called "syndrome X", is a constellation of metabolic risk factors that directly feed into the prevalence of atherosclerotic cardiovascular disease and diabetes mellitus type II.[1,2] MetS has a worldwide prevalence rate ranging from <10% to >84%, depending on the definition method.[3] As reported the prevalence of MetS in the Iranian adult population was 26% and the incidence was 97.96 per 1000. The prevalence of MetS was higher in women and those living in urban areas.[4] The results of a comprehensive study (from 2001 to 2013) indicated a 6.9% increase in the prevalence of MetS in Iran.[5,6] It is worth noting that the observed rates have been higher than the predicted rates around the world by 20–25%.[7]

Unhealthy lifestyle behaviors increase the possibility of developing MetS. Making an optimal behavioral change is a continuing challenge that needs innovative solutions. According to the PREDIMED study,

conducted in Spain, the Mediterranean diet, together with increased physical activity (PA) levels, contributed to the motivational enhancement of MetS management. Intentional adherence to physical activity levels and the Mediterranean diet conferred the ability to lower the Mets prevalence and cardiovascular clinical events.[8,9] Studies have also demonstrated that education is a priority in the management and prevention of MetS, especially at lower levels of knowledge. Education also leads to an increase in populations' adherence to medical recommendations and adaptation to healthy habits.[8,9] Concomitant verbal and nonverbal education augments the efficacy of the method in that it not only does it facilitate the comprehension of the target population but also it improves attitudes and adaptation to social and cultural contexts and engagement in active education.[10] In general, there is limited evidence of specific educational strategies as a lifestyle education method in controlling MetS biomedical components. On the other hand, most studies have suggested multivariable educational methods to increase the persuasion and adherence of populations.[11] Accordingly,

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in the present study, we propose a package of self-training lifestyle modification that consists of close follow-ups and face-to-face counseling, in conjunction with educational pamphlets, videos, and messages. The objective of our study was to evaluate the effect of the lifestyle-modification package on the biomedical profile of MetS to provide meaningful information for the management of MetS in the at-risk population.

Methods

The present quasi-experimental study was conducted on 72 participants (age = 18–68 y) with MetS in 2019 in Tehran, Iran. In a simple random sampling, two centers were selected from the southern region of Tehran with cultural/economic similarities as intervention and control groups. Then, 72 participants aged 18–68 years of both sexes (36 participants in each group) with MetS (at least 3 components) were recruited from the electronic health record of District 17 (intervention group) and District 19 (non-intervention group). It should be noted that the participants of each center consisted of respondents and inhabitants of the same districts. So these people were not in touch with each other.

The sample size (*n*) was calculated using the following formula [Eq. 1]:

$$n = \frac{\left(Z_1 - \frac{\alpha}{2} + Z_1 - \beta\right)^2 \left(\sigma_1^2 + \sigma_2^2\right)}{\left(\mu_1 - \mu_2\right)^2} \quad (1)$$

Where the test power and confidence intervals were (α = 5%) and (β = 20%), respectively. The standard deviation of the intervention group was 8.7, while the standard deviation of the non-intervention group was 7.7. Besides, the mean score of the studied variable in the intervention group & non-intervention group was 99.8 and 94.1, respectively. Assuming a failure to consent rate of 10% (not eligible as well as declining to participate) and a dropout rate of 10%, 36 participants in each group was needed.[12]

According to the International Diabetes Federation (IDF) definition,[3] and classification for MetS, patients ≥18 years old and ≥3/5 elements of MetS were selected. The elements of MetS comprised the following: (1) central obesity (men: ≥94 cm and women: ≥80 cm waist circumference); (2) hypertension (systolic ≥130 mm Hg, diastolic ≥85 mm Hg, and/or antihypertensive treatment); (3) impaired fasting glucose (fasting blood sugar [FBS] ≥100 mg/dL and/or antidiabetic treatment); (4) elevated triglycerides (TGs) ≥150 mg/dL; and (5) low high-density lipoprotein (HDL) (men: <40 mg/dL and women: <50 mg/dL) and/or cholesterol-lowering treatment (3). The exclusion criteria were comprised of hepatic diseases, hematologic diseases, renal failure (glomerular filtration rate <30), hypothyroidism, taking oral contraceptives, severe psychological illness, physical disability, cancer, type 1 diabetes, dementia, a level

of education less than fifth grade, immigration to another city, and changes in medications during the study period.

Intervention

In the development phase, the educational content was extracted from the guidelines and discussed by 5 experts: 2 cardiologists, 1 family medicine specialist, 1 health education specialist, and 1 media expert. The media and text messages were pretested by interviewing 10 participants using a researcher-made checklist. In the implementation phase, the research objectives were explained to eligible participants, and informed consent was obtained. The intervention group received close follow-ups, with an educational package based on a 3-month schedule. In the first month, face-to-face individualized consultations were done, and an approved pamphlet was given to the participants. As a virtual education, 14 text messages were sent to the cell phones of the participants during the second month, and they watched an educational film in the third month. Commitment to a healthy diet and an increase in physical activities were the central points in the study design. Diet recommendations were personalized in keeping with Iranian lifestyle habits [Appendices A and B]. The control group received usual care by a family physician in each follow-up [Figure 1]. The family physician managed any required change in the type or dose of the medications.

Anthropometric measurements

All the participants were weighed in the fasting state without shoes and with light clothing on a Seca scale (Seca,
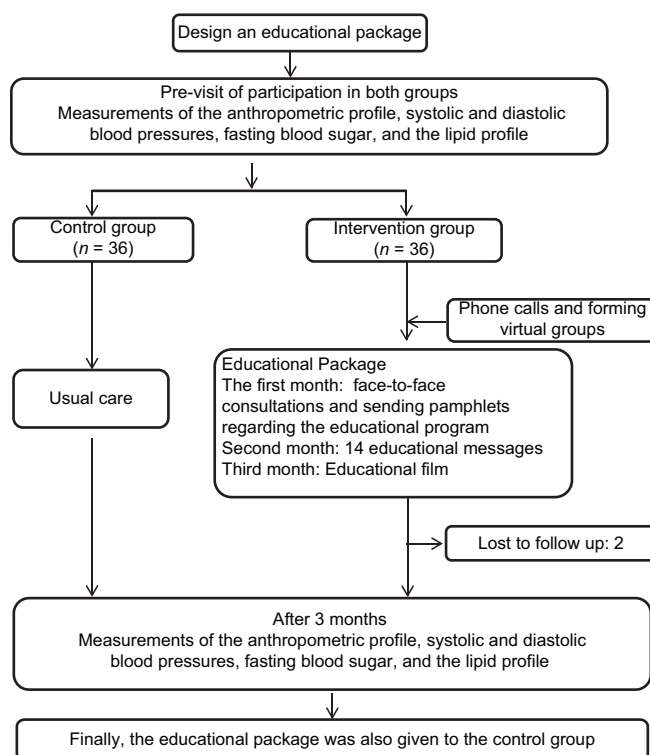

Figure 1: Study design chart

Hamburg, Germany). Waist circumference was assessed with the participants standing, at the level midway between the lower rib margin and the iliac crest.

Blood pressure measurement

Blood pressure was measured 3 times, each time after a 15-minute rest, using a digital sphygmomanometer (Omron, Japan). The participants were asked to breathe out gently and relax during the measurements.

Biochemical analysis

Blood samples were collected from the antecubital vein in the sitting position after 12-hour fasting. FBS was assessed via the glucose oxidase mechanism. Additionally, total cholesterol (TC) and HDL cholesterol levels were specified via the Trinder CHOD/POD End Point method. TGs were determined via the GPO/POD method, and low-density lipoprotein (LDL) cholesterol was measured via the Friedewald formula.[13] Cutoff points were taken as follows: TG ≥150 mg/dL; TC ≥200 mg/dL; HDL cholesterol <40 mg/dL in men and <50 mg/dL in women; and LDL cholesterol ≥70 mg/dL.[3,14]

Statistical analysis

The statistical analyses were performed using SPSS, version 22.0, (SPSS, Chicago, IL). The variables were presented as the mean ± the standard deviation (SD). The Independent-samples t-test was used for comparison of the means between groups on the age, and Chi-square for comparison of sex, education, smoking, drug abuse, hypertension, Diabetes Mellitus and hyperlipidemia history, and ACEI/ARB consumption between the two groups. One-way multivariate analysis of variance (MANOVA) and one-way multivariate analysis of covariance (MANCOVA) were used to determine whether there are any differences between groups of Mets components and covariate interaction, respectively. Two-way MANOVA was done to adjustment of gender and education. A comparison of the mean anthropometric and metabolic profile at baseline and 3 months was calculated using the paired *t*-tests. The results were considered statistically significant at a *P*-value < 0.05.

Results

A total of 72 participants (29.2% were male and 70.8% were female) were recruited in this study. The participants were 43.6 ± 9.9 years old, 98.6% were married, and 72.2% had a high school diploma. All the diabetic patients were on oral antihyperglycemic agents. According to the results of the Chi-square test analysis, the baseline characteristics of the study participants are compared in Table 1. The anthropometric and metabolic profile changes over the 3 months are listed in Table 2. According to the results of the one-way MANOVA analysis, changes in the components of MetS were highly dependent on the educational intervention (F = 5.27, P < 0.001, partial η2 = 0.338). The educational intervention accounted for 33.8% of the changes in MetS biomedical components. Moreover, among these components, changes in waist circumference and diastolic blood pressure were significant [Table 3]. There was not a statistically significant interaction effect between the educational level of participants and intervention on the diff of MetS components, $F_{(6, 60)} = 1.081$, $p = 0.384$; Wilks' Λ = .902. Also, there was not a statistically significant interaction effect between gender and intervention on the diff of MetS components, $F_{(6, 60)} = 0.373$, $p = 0.894$; Wilks' Λ = .964. In one-way MANCOVA, there was a statistically significant difference between the two groups on the combined Mets components after controlling for baseline FBS, $F_{(6, 61)} = 5.44$, $p < .001$, Wilks' Λ = .651.

Discussion

We planned a 3-month lifestyle intervention to make behavioral changes toward healthy habits through close physician follow-ups and an educational package consisting of face-to-face consultations, pamphlets, messages, and videos. We observed significant improvements in terms of weight, waist circumference, waist-hip ratio, TGs, HDL, and diastolic blood pressure. However, systolic blood

Table 1: Baseline characteristics of study participants			
Variable	**Intervention Group (*n*=34)**	**Control Group (*n*=36)**	*P*
Age (mean±SD)	43.6±9.9	47.9±7.5	0.044
Sex (% male)	9 (25.0%)	12 (33.3%)	0.437
Married (%)	35 (97.2%)	36 (100%)	0.5
Education:			0.021
<high school diploma (%)	21 (58.3%)	31 (86.1%)	
≥ high school diploma (%)	15 (41.7%)	5 (13.9%)	
Smoking (% yes)	1 (2.8%)	0.0%	0.5
Drug abuse (% yes)	1 (2.8%)	0.0%	0.5
Hypertension history *n* (% yes)	11 (32.3%)	12 (33.3%)	0.800
Diabetes mellitus history *n* (% yes)	10 (29.4%)	11 (30.5%)	0.017
Hyperlipidemia history *n* (% yes)	8 (23.5%)	6 (16.6%)	0.780
ACEI/ARB consumption *n* (% yes)	8 (23.5%)	10 (27.7%)	0.800

ACEI: Angiotensin-converting-enzyme inhibitor; ARB: Angiotensin II receptor blocker

Table 2: Comparison of the mean anthropometric and metabolic profile at baseline and 3 months after the intervention in both groups

Variable	Intervention Group (*n*=34)			Control Group (*n*=36)		
	Baseline	3 months	*P*	Baseline	3 months	*P*
Weight (kg)	82.3±13.6	80.3±14	<0.001	80.7±11.5	80.8±11.9	0.671
Waist circumference (cm)	102±8.8	99.7±7.9	<0.001	102.4±6	103±6.3	0.061
Hip circumference (cm)	111.5±10.2	110.1±10.5	<0.001	108.8±7.7	109±8.3	0.513
Waist-hip ratio	0.92±0.06	0.90±0.06	0.042	0.94±0.06	0.95±0.05	0.237
SBP (mm Hg)	118.7±18.3	114.7±16	0.06	121.8±20.4	118.8±17.6	0.166
DBP (mm Hg)	78.4±10.6	73.1±9.2	<0.001	77.2±9.9	76.4±7.9	0.433
MAP	91.8±12.3	86.9±11.1	<0.001	92.1±12.6	90.5±10.5	0.206
FBS (mg/dL)	103.3±15.1	104.1±10.5	0.746	125.2±44.2	125.7±46.5	0.872
Cholesterol (mg/dL)	186.4±33	178.6±32.7	0.168	191.1±33.2	179.5±31.7	0.102
Triglycerides (mg/dL)	172.1±76.7	138.5±56.8	0.002	216.2±116.1	177.9±72.3	0.043
HDL (mg/dL)	40.2±6.8	43.5±8.1	0.012	40.6±6.8	42.6±6.7	0.048
LDL (mg/dL)	114.2±27.1	106.8±28.9	0.132	104.3±30.6	101.8±27.9	0.697

Data are presented as the mean±the standard devation (SD). SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HDL: High-density lipoprotein; LDL: Low-density lipoprotein; MAP: Mean arterial pressure; FBS: Fasting blood sugar

Table 3: Prediction the effect of the intervention on metabolic syndrome components in MANOVA analysis

Variable	F	Partial Eta Squared	Sig*
Diff waist circumference	23.27	0.258	<0001
Diff SBP	0.08	0.001	0.773
Diff DBP	8.29	0.11	0.005
Diff FBS	0.06	0.001	0.810
Diff TG	0.01	0	0.931
Diff HDL	0.63	0.009	0.429

*$P<0.05$. SBP: Systolic blood pressure; DBP: Diastolic blood pressure; FBS: Fasting blood sugar; TG: Triglyceride; HDL: High-density lipoprotein

pressure and FBS were not considerably enhanced at the 3-month follow-up. Moreover, changes in the components of MetS were highly dependent on the lifestyle modification intervention (F = 5.27, $P < 0.001$, partial η2 = 0.338).

The obtained results were consistent with Amiri studies, which showed that healthy lifestyle intervention reduced MetS in both genders in the short term.[15] Similarly, Chaiyasoot *et al.* in Thailand showed that a 3-month lifestyle educational intervention in adults with obesity and MetS resulted in a dramatic reduction in weight, waist circumference, blood pressure, and lipid profile.[16]

The findings of the present study indicated that our lifestyle intervention offered modest efficacy in reducing weight, which led to considerable improvements in the clinical abnormalities of MetS such as blood pressure/FBS and the lipid profile. Even a mild-to-moderate weight loss (2–7%) in 3 months may improve the metabolic profile, despite a high body mass index. However, as the loss in the body mass index is escalated, the metabolic improvements are further boosted.[17,18]

The results of the present study demonstrated the potential benefits of using social media to improve weight loss

and anthropometric indices. Consistent with other studies, our educational intervention was effective in decreasing waist circumference and waist-hip ratio (P < 0.001).[15,16,19] Contrary to the obtained results, the DHIAAN study demonstrated no significant change in waist circumference.[20,21] Nonetheless, the reported differences between the groups could be considered clinically substantial (discrepancy of 8 inches; P = 0.39), showing that the study may not be powered enough.[22] Whereas systolic blood pressure did not change significantly, the mean arterial pressure and diastolic blood pressure decreased considerably (P < 0.001), which is consistent with the results of some previous investigations.[20,23,24] The drop in diastolic blood pressure may contribute to weight loss and improvements in lipid profiles; it could, thus, be suggested that long-term interventions need to control systolic blood pressure.[25,26] according to Shuai study, motivating and encouraging people to do moderate to high intensity exercise 3 to 5 days a week and creating awareness of people about healthy eating have been shown to improve abdominal obesity and lipid profile. It can be claimed that high-intensity exercise for 6 months is needed to lower blood pressure and blood sugar, which could explain no change in blood pressure and blood glucose.[27] according to a cross-sectional study on adults in Korea, no association detected between lipid profile and educational level of patients which is inconsistent with our results.[28]

In the current investigation, FBS was almost unchanged in both groups. This finding underscores the need for ongoing support and long-term educational interventions to lower the FBS level. Similar to our results, Sareban Hassanabadi study demonstrated that baseline FBS was not associated with the risk of Mets persistence. The study reported participants with higher BMI and WC are more at the risk of MetS persistence rather than FBS. Therefore, decreasing obesity is more important to decrease the risk

of MetS persistence.[29] According to previous studies, although technology (film and educational messages) was found to be a valuable tool to make lifestyle changes, it was ineffective compared with individual education methods.[30-32] A systematic review reported that educational packages, including face-to-face consultations, pamphlets, videos, and messages, were the most useful method for lifestyle modifications in Mets. Furthermore, the results indicated that although knowledge of Mets and its prevention was necessary, it was not enough.[22] Our study results suggested that for lifestyle modification, the provision of sufficient information on the adherence to healthy habits in participants was not adequate per se, but individual beliefs and social norms should be considered as well. On the other hand, most of the care was provided at home. The current short duration of intervention was likely insufficient for effecting metabolic benefits; accordingly, more intense follow-ups and long-term interventions might be needed to overcome this limitation.

Study limitations

This study provides a multidisciplinary educational method for controlling the biomedical components of MetS; nevertheless, its short duration of intervention and follow-up is one of its limitations. The imbalance between the male-to-female ratio in the 2 groups may also have impacted the results. Another salient weakness is the non-measurement of adherence to the proposed medications and behaviors using a checklist, which precluded us from establishing a causal relationship between biomedical components and adherence to healthy behaviors.

Conclusions

Our lifestyle educational package had a significant effect on waist and hip circumferences and diastolic blood pressure within 3 months. Improvement in lipid profile and anthropometric measures suggest that a lifestyle package based on multivariable health education is an acceptable method. Preliminary findings on MetS risk indicators suggest that a long-term intervention requires exploring the effects of educational Package on other components such as blood glucose and systolic blood pressure.

Ethical approval and consent to participate

The present study is part of a thesis to receive the Ph.D. certificate of family physicians. All the participants signed written informed consent forms, and the trial was approved by the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE. REC.1396.3071).

Conflicts of interest

There are no conflicts of interest.

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Supplementary materials

Appendix A: Educational package

Duration	First Month	Second Month	Third Month
Educational Method	Face-to-face education and pamphlets	Virtual education	Educational videos
Intervention Description	Face-to-face consultations were offered to focus on metabolic syndrome, the prevalence and importance of its risk factors, and its therapeutic and preventive recommendations. Moreover, the participants were encouraged to lose weight, have appropriate physical activities, and avoid smoking. The duration of the first phase of education was about 15 minutes. The sessions were held in the physician's office. Pamphlets were used to cover the lifestyle modification issues that were taught during the face-to-face education program.	Fourteen educational messages were sent to the subjects in the intervention group in the first 5 days of each week based on knowledge, attitude, and performance in preventing the components of metabolic syndrome.	Educational videos (15 minutes) were shown in the comprehensive health center classroom.
Intervention Goals	Improving knowledge, attitude, and behaviors regarding healthy dietary habits, appropriate physical activities, and avoiding smoking • Motivating the subjects to modify their unhealthy behaviors • Creating a supportive environment to encourage healthy behaviors among the participants • Reducing the rate of non-communicable diseases	The text messages aimed to increase health literacy and increase motivation among the participants. The messages also tried to make recommendations on having a healthy lifestyle and provide metabolic syndrome educational programs. The transmission of these messages to a wide range of people in the community can prevent cardiovascular disease and diabetes to a large extent.	The objective was to promote and encourage the individuals, increase their amount of memorization of materials, and transfer their shared experiences regarding metabolic syndrome components, related diseases, methods of diagnosis, and control and prevention by lifestyle modification.

Appendix B: Practical recommendations regarding lifestyle modification[14]

Dietary recommendations

Overweight and obese individuals should be encouraged to lose weight by 5-10% and adopt healthy eating habits by increasing the consumption of fresh fruits and vegetables by more than 2 to 3 units per day, whole grains and seeds, beans, white meat, and fish, nuts, and low-fat dairy products. Moreover, the participants should be advised not to use unsaturated fats such as solid and animal oils and butter and replace them with liquid vegetable oils. Further, the participants should be motivated to reduce the consumption of fried food, fast food, and instead consume a diet with a restricted amount of sugar, sweetmeat, starch, and red meat products. This study emphasizes the significance of the consumption of salt up to 2 teaspoons per day; individuals should be encouraged not to use the saltshaker in setting the table to control blood pressure based on the 2016 European Guideline on Cardiovascular Diseases Primary Prevention. Additionally, individuals aged above 18 years are recommended to schedule yearly regular checkups and do the required tests at the physician's discretion.

Physical exercise recommendations

Participants should be encouraged to do moderate-to-severe physical activity for at least 30 minutes, 3 to 5 times a week.