ORIGINAL ARTICLE

Impact of lifestyle interventions on reducing dietary sodium intake and blood pressure in patients with hypertension: A randomized controlled trial

Hipertansif hastalarda uygulanan yaşam tarzı müdahalesinin diyetsel sodyum alımı ve kan basıncı düşürülmesi üzerine etkisi: Randomize kontrollü bir çalışma

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ABSTRACT

Objective: The objective of this study is to determine the impact of applying lifestyle intervention in the form of a continuous care model (CCM) on reducing dietary sodium intake and blood pressure (BP) in patients with hypertension.

Methods: This randomized controlled trial was conducted in a 2-group design on a total of 50 patients who were hypertensive (experimental and control) as a pre-post test study. A healthy lifestyle (emphasizing physical activity and heart-healthy diet) in the form of CCM, which considers the patient as an active agent in the health process, was conducted in the experimental group over a period of 4 months. The mean BP value and dietary sodium intake in both groups were measured at the beginning and the end of the study.

Results: The mean sodium intake, the mean systolic BP, and the mean diastolic BP decreased to 2.42±0.73 mm Hg (from 3.12±0.79), 128.4±13.04 mm Hg (from 144.20±13.12), and 79.4±8.93 mm Hg (from 89±9.12), respectively, after the intervention in the experimental group (p=0.021, p<0.001, and p=0.011, respectively).

Conclusion: Applying lifestyle intervention in the form of CCM may be recommended to reduce dietary sodium intake and mean systolic and diastolic BP in patients who are hypertensive. Considering the fact that lifestyle modifications are quite important regardless of the use of antihypertensive drugs, lifestyle intervention in the form of CCM is recommended to improve patient's adherence to dietary restrictions and consequently, treatment outcomes in patients who are hypertensive.

ÖZET

Amaç: Bu araştırmanın amacı, hipertansif hastalarda Sürekli Bakım Modeli-SBM şeklinde uygulanan yaşam tarzı müdahalesinin diyetsel sodyum alımı ve kan basıncı düşürülmesi üzerine etkisini belirlemektir.

Yöntemler: Bu randomize kontrollü çalışma, ön test ve son test olarak iki grup tasarımında (müdahale ve kontrol) toplam 50 hipertansif hasta üzerinde gerçekleştirildi. Fiziksel aktivite ve kalp için sağlıklı beslenmeyi vurgulayan, sağlıklı yaşam tarzı (hastayı sağlık sürecinde aktif bir ajan olarak gören) SBM şeklinde, müdahale grubunda 4 aylık bir süre boyunca uygulandı. Her iki gruptaki hastalarda kan basıncı ortalaması ve diyetsel sodyum alım miktarı çalışma sonunda tekrar ölçüldü.

Bulgular: Deney grubunda girişim sonrası ortalama sodyum alımı 2.42±0.73 mm Hg'ye (3.12±0.79'dan) düştü (p=0.021), ve sistolik kan basıncı ortalaması 128.4±13.04 mm Hg'ye (144.20±13.12'den) düştü (p<0.001). Diyastolik kan basıncı ortalaması deney grubunda 79.4±8.93 mm Hg'ye (89±9.12'den) düştü (p=0.011).

Sonuç: Yaşam tarzı müdahalesinin SBM şeklinde uygulanması, hipertansif hastalarda diyetsel sodyum alım miktarını sistolik ve diyastolik kan basıncını azaltabilir. Antihipertansif ilaçların kullanılmasına bakılmaksızın yaşam tarzı değişikliklerinin oldukça önemli olduğunu göz önüne alındığında hipertansif hastalarda hastanın diyet kısıtlamalarına bağlılığını ve dolayısıyla tedavi sonuçlarını iyileştirmek için SBM şeklinde uygulanan yaşam tarzı müdahalesi önerilmektedir.

Cardiovascular diseases (CVDs) are a common cause of death in people aged >65 years.[1] Raised blood pressure (BP) and hypertension are major risk factors for CVD because they are underlying contributing factors in 62% of all stroke events and 49% of all coronary heart disease cases.[2] Hypertension is a major cause of strokes (such as cerebral infarction, cerebral hemorrhage, and subarachnoid hemor-

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rhage), heart diseases (such as coronary artery disease [CAD], cardiac hypertrophy, and heart failure), kidney diseases, and macrovascular diseases.[3]

Lifestyle is a way that one may adopt for his/her life and is a very important factor for physical and mental health, especially for patients with chronic diseases.[4] In addition, physical activity (PA), healthy dietary habits, and a history of no smoking are associated with reduced cardiovascular morbidity and mortality.[5] Conclusions from the eighth Joint National Committee guidelines, which is based on evidence from randomized controlled trials, suggest that healthy eating, weight management, and appropriate PA are essential for the management of high BP in adults because these lifestyle managements have the potential to improve BP control and even reduce the need for medication.[6] Lifestyle modifications are quite important regardless of the use of antihypertensive drugs. Among the lifestyle modifications, salt reduction is most important, especially among East Asian people who still consume a significant amount of salt. Because the awareness of salt reduction may not necessarily lead to actual salt reduction, the assessment of individual salt intake is essential when members of the medical staff provide practical guidance regarding salt reduction.[7] The World Health Organization (WHO) recommended <5 g per day intake of salt.[8] In addition to the reduction of sodium intake, a variety of dietary modifications are known to be beneficial in the treatment of hypertension, including moderation of alcohol intake; weight loss in individuals who are overweight or obese; and a diet rich in fruits, vegetables, legumes, and low-fat dairy products and also low in snacks, sweets, meat, and saturated fat. Individual dietary factors may also be helpful in lowering BP.[9]

The increasing prevalence of chronic diseases as a result of an aging population and concomitant unhealthy lifestyle habits necessitates new approaches in healthcare systems, particularly in terms of patient self-monitoring and management of lifestyle interventions.[10] In this regard, the continuous care model (CCM) is a supportive intervention that was designed and implemented by Ahmadi[11] for managing patients with chronic CAD in Iran.

Considering the international guidelines on CVD prevention that include lifestyle counseling to improve unhealthy lifestyle habits with the aim of reducing cardiovascular risk, [7] this randomized controlled trial was designed to evaluate the impact of lifestyle intervention in the form of CCM on reducing dietary sodium intake and BP in patients with hypertension. We hypothesized that lifestyle intervention in the form of CCM would decrease the mean of dietary sodium intake and BP in the experimental group of the study.

Abbreviations:

ACE	*Angiotensin-converting-enzyme*
BP	*Blood pressure*
CAD	*Coronary artery disease*
CCB	*Calcium channel blocker*
CCM	*Continuous care model*
CVD	*Cardiovascular disease*
PA	*Physical activity*
WHO	*World Health Organization*

METHODS

Ethical approval and study population

The study protocol was approved by the Research Ethics Committee of Urmia University of Medical Sciences, Iran (Reference Number IR.UMSU.REC.1397.363). The study was conducted in accordance with the principles of the Declaration of Helsinki. A written informed consent was obtained from each participant.

This single-center, randomized controlled study with a pre-post test design included a total of 50 patients. Inclusion criteria were as follows: male or female patients aged ≥40 and ≤70 years, previously physician-diagnosed hypertension (we considered a BP >130/80 mm Hg after repeated examination as hypertension),[12] willingness to participate in the study, willingness to give a written informed consent, patients who were not taking diuretics, and patients who did not follow a specific diet. Exclusion criteria were as follows: a history of comorbidities, such as another CVD or diabetes, pregnancy, participation in another interventional study within the last 6 months, patients with a physical/psychiatric disorder that could seriously impair their physical mobility, currently smoking, and missing of >1 session of training classes for participants in the experimental group. As seen in the CONSORT flow diagram (Fig. 1), no missing in the training classes of >1 session occurred.

Details of power calculations and sample size

Because there was no other study on the impact of lifestyle interventions in the form of CCM on reducing dietary sodium intake and BP in a population of patients with hypertension, no appropriate informa-

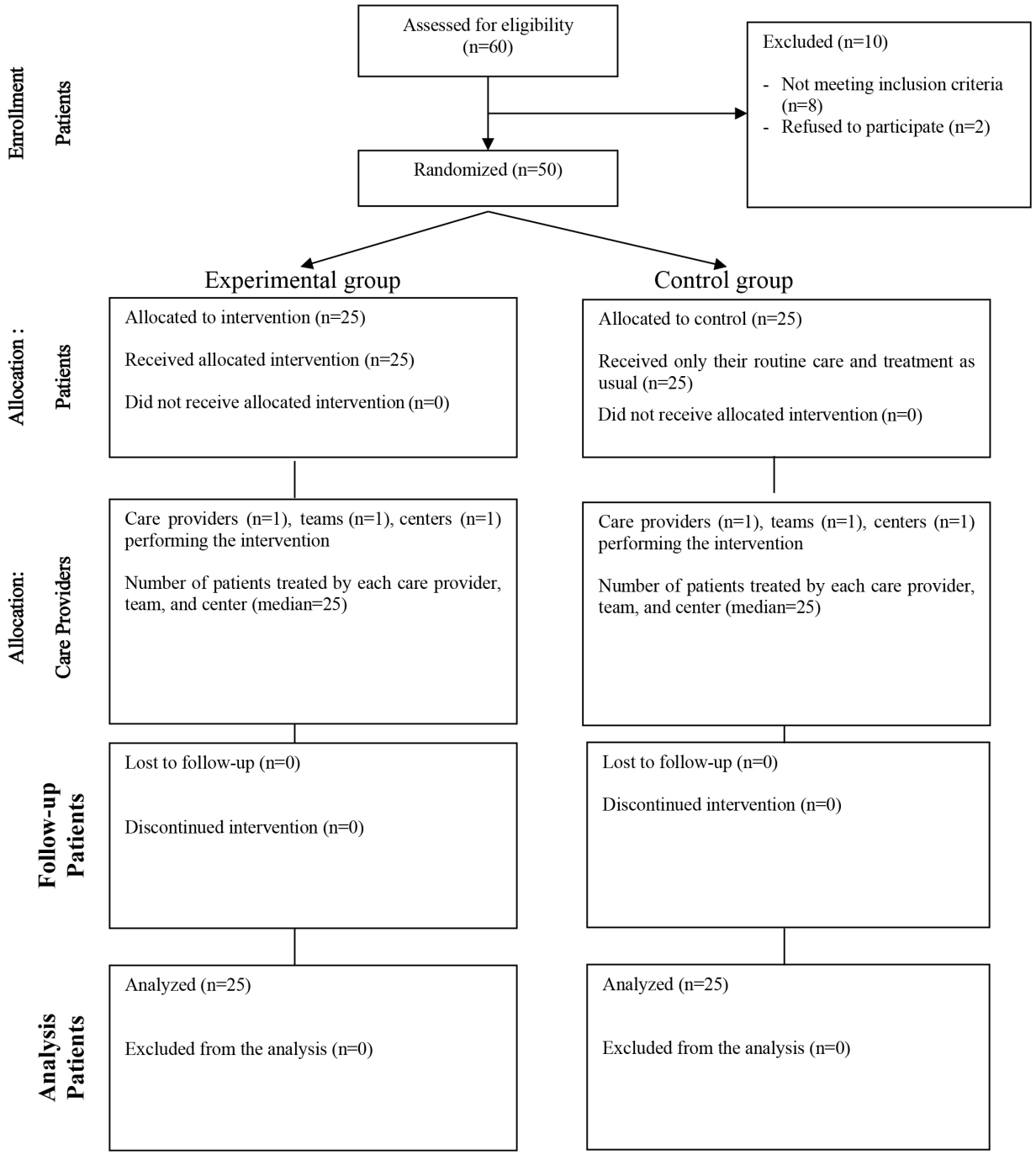

Figure 1. CONSORT flow diagram.

tion was available to calculate the sample size for this study. On the basis of the study conducted by Rezaie et al.,[13] which is related to our study and in which the mean and standard deviation of BP in control and experimental groups were reported as 86.88±8.00 and 76.64±9.63, respectively, the sample size for our study was calculated by the following formula:

$$n = \frac{(s_1^2 + s_2^2)^2 (z_{\frac{\alpha}{2}} + z_{\beta})^2}{(\bar{x}_1 - \bar{x}_2)^2}$$

$$n = \frac{(1/96+1.64)^2 (9.36^2+8^2)}{(76/64-86/88)^2} \approx 19$$

Where we considered the following: X_1=76.64, X_2=86.88, S_1=9.36, S_2=8, Zα/2=1.96, and Zβ=1.64.

We concluded that recruitment of 25 patients for each group could give us a 90% power to detect a difference in the mean amount of dietary sodium intake and BP at α level of 0.05. So, we registered 50 patients (25 for each group).

Data collection and measures

Data were obtained from demographic information form, from the laboratory test results of urinary sodium-to-potassium ratio measurement that represent the amount of dietary sodium intake (all samples were sent to the same laboratory), and from BP measurements (a master's student in nursing measured the BP of both groups of study according to the standard protocol with an electronic sphygmomanometer in the morning hours after the patients were instructed to sit for 10 minutes in a quiet room at the heart clinic. The sphygmomanometer (Omron, Kyoto, Japan) that was used in this study was made in Vietnam. Its calibration was checked before the study.

For randomization in this study, an independent investigator made random allocation cards using computer-generated random numbers. The allocator kept the original random allocation sequences in an inaccessible third place and worked with a copy. She used the Codes E and C (E for the experimental group and C for the control group). Then, she continued randomization until 25 samples were allocated to the experimental group and 25 to the control group.

Intervention method

Interventions for the experimental group

For the first part of the intervention (healthy lifestyle education), a master's student in nursing at the Division of Medical Surgical Nursing took the experimental group on healthy lifestyle courses. She also passed her patient education course during her master's program before this research.

The CCM was implemented on the experimental group for 4 months. A total of 25 persons received continuous care that was implemented according to the following 4 steps:

1. Orientation. The goal of this step is to introduce the patient and nurse to each other, explain the stages of the model, create motivation about the necessity of continuing their participation, explain the goals and manner of implementing CCM, and explain the time and place of the next meetings. This step was carried out in 1 session that lasted about 20-40 minutes. The session was held for both the experimental and control groups, but it differed in terms of time and type of expectations and plans. At this stage, demographic information was collected for all participants. In addition, BP and dietary sodium intake were measured in both groups of the study.

2. Sensitization. The goal of this stage is to give information about hypertension and a healthy lifestyle in the form of educational courses. The educational courses were held for each 12-13 patients twice a week. Each session lasted for 60 minutes, and a total of 8 sessions (including 3 sessions on hypertension, its consequences, and CVD risk factors; 3 sessions on healthy nutrition emphasizing necessary diet changes; and 2 sessions on PA) were hold.

The healthy nutrition courses aimed to increase the use of fruits and vegetables, nuts, and legumes and encourage diets rich in mono and polyunsaturated fats, lean protein, and low and nonfat dairy; to encourage the replacement of refined grains with whole grains; and to decrease the overall intake of calories, desserts, processed foods, sugar-sweetened beverages, saturated fats, and sodium chloride (<5 g/day) or sodium (<2 g/day).[14]

The PA courses aimed to promote PA by educating patients and one of their family members; participants were encouraged to perform PAs, including progressive, moderate-intensity aerobic exercise (typically for 20–30 minutes), such as walking and Pilates Exercises.

3. Control. This step was performed in 12 consultation sessions (for 40 minutes) that were conducted weekly for each patient. The goal of this stage was to encourage the continuity of a healthy lifestyle and adherence to treatment; the patients were monitored for the acquired knowledge during the sensitization

stage. The process of continuity of the healthy lifestyle was monitored by reviewing eating and PA checklists at this stage.

4. Evaluation. At this stage, BP and dietary sodium intake were measured again in both groups of the study.

Interventions for the control group

The control group had their routine/traditional care and received their treatment as usual. They did not receive any lifestyle intervention or counseling.

Data analysis

Statistical Package for the Social Sciences software, version 22, (IBM Corp.; Armonk, NY, USA) was used for statistical analysis. Data regarding the characteristics of the participants are presented as a percentage and mean±standard deviation. Shapiro–Wilk test, chi-square test, independent sample *t*-test, and paired sample *t*-test were used for statistical analysis. Results were accepted at the confidence level of 95% and the statistical significance level of $p<0.05$. Shapiro–Wilk test was used to check the normality of data distribution. According to the results of this test, the significance value was greater than 0.05 in all of the variables, which indicated that the distribution of data between the 2 groups of the study was normal.

RESULTS

Demographic characteristics of participants at baseline

The participants included in the study were comparable with each other regarding variables that might affect the results of the study, such as sex, educational level, employment status, years of hypertension diagnosis, and age. No baseline differences existed between the 2 groups of the study regarding these demographic characteristics, and the groups were similar to each other (Table 1).

In the experimental group, 36% of the patients were on angiotensin-converting-enzyme (ACE) inhibitors, 16% were on beta-blockers, 8% were on calcium channel blockers (CCBs), and 40% were on diuretic combinations. In the control group, 40% of the patients were on ACE inhibitors, 12% were on beta-blockers, 4% were on CCB, and 36% were on diuretic combinations, and only 8% of the patients were on a low salt diet without any antihypertensive drug. With regard to antihypertensive drugs, the 2 groups of the study were similar to each other (p=0.341).

Table 1. Demographic characteristics of participants at the baseline

Variable	Experimental group, n (%)	Control group, n (%)	*p*
Gender			
Male	14 (56)	15 (60)	0.770
Female	11 (44)	10 (40)	
Education level			
Primary school	11 (44)	13 (52)	0.210
High school	9 (36)	11 (44)	
Above high school	5 (20)	1 (4)	
Employment status			
Unemployed	13 (52)	13 (52)	0.500
Employee	7 (28)	6 (24)	
Self-employment	3 (12)	1 (4)	
Retired	2 (8)	5 (20)	
Hypertension diagnosis time			
<1 year	5 (20)	2 (8)	0.460
1-5 years	12 (48)	13 (52)	
>5 years	8 (32)	10 (40)	
Quantitative variable	Experimental group Mean±SD	Control group Mean±SD	p=0.22
Age	58.28±7.16	55.60±8.04	

SD: standard deviation.

Intervention impact measurement

The mean amounts of dietary sodium intake were 3.12±0.79 and 3.23±0.97 in the intervention and control groups, respectively, before the intervention. The results of the independent *t*-test showed that the 2 groups of the study had no statistically significant differences in the mean amount of dietary sodium intake before the intervention (p=0.43). Therefore, they were homogenous (Table 2).

On the other hand, the mean sodium intake after intervention decreased to 2.42±0.73 (from 3.12±0.79) in the experimental group, whereas in the control group, it decreased to 3.04±0.92 (from 3.23±0.97) after the intervention; independent *t*-test showed a statistically significant difference in the mean amount

Table 2. Comparison of the mean sodium intake and blood pressure between the two groups of the study before and after intervention (on the basis of independent *t*-test)

Amount of sodium intake or blood pressure, before or after intervention		Control group	Experimental group	*t*-test statistic	*p*
Amount of sodium intake	Before intervention	3.12±0.79	3.23±0.97	0.79	0.430
	After intervention	3.04 ±0.92	2.42±0.73	0.20	0.021
Systolic blood pressure	Before intervention	142.20±13.39	144.20±13.12	0.53	0.590
	After intervention	141.60±12.96	128.40±13.04	-3.58	0.001
Diastolic blood pressure	Before intervention	87.80±9.58	89.00±9.12	0.45	0.650
	After intervention	86.40±9.73	79.40±8.93	-2.64	0.011

Table 3. Comparison of the mean sodium intake and blood pressure in the two groups of the study before and after intervention (on the basis of paired *t*-test)

Amount of sodium intake	Before intervention	After intervention	*t*	*p*
Experimental group	3.12±0.79	2.42±0.73	0.62	0.010
Control group	3.23±0.97	3.04±0.92	-0.82	0.420
Systolic BP	Before intervention	After intervention	*t*	*p*
Experimental group	144.20±13.12	128.40±13.04	7.47	<0.001
Control group	142.20±13.39	141.60±12.96	0.38	0.700
Diastolic BP	Before intervention	After intervention	*t*	*p*
Experimental group	89±9.12	79.40±8.93	5.40	<0.001
Control group	87.80±9.58	86.40±9.73	0.79	0.430

BP: blood pressure.

of dietary sodium intake between the 2 groups of the study after the intervention (p=0.021) (Table 2).

Furthermore, the paired sample *t*-test showed a statistically significant difference in the mean amount of dietary sodium intake in the experimental group of study after the intervention (p=0.01) (Table 3).

The mean systolic BP values were 144.20±13.12 and 142.20±13.39 in the intervention and control groups, respectively, before the intervention. The mean diastolic BP values were 89±9.12 and 87.80±9.58 in the intervention and control groups, respectively, before the intervention (Tables 2, 3).

The results of the independent *t*-test showed that the 2 groups of the study had no statistically significant differences in the mean systolic (p=0.59) and diastolic (p=0.65) BP before the intervention. Therefore, they were homogenous (Table 2).

On the other hand, the independent *t*-test showed a statistically significant difference in the mean systolic (p=0.001) and diastolic (p=0.011) BP between the 2 groups of the study after the intervention (Table 2).

Furthermore, the paired sample *t*-test showed a statistically significant difference in the mean systolic (p<0.001) and diastolic (p<0.001) BP in the experimental group of the study after the intervention (Table 3).

DISCUSSION

This randomized controlled study was designed to evaluate the impact of lifestyle intervention in the form of CCM on the mean dietary sodium intake and BP in hypertensive patients. Our study findings support our hypothesis that lifestyle intervention in the form of CCM would decrease the mean dietary sodium intake and BP in the experimental group of the study.

Recommendations were made by the WHO to limit sodium intake to approximately 2.0 g per day (equivalent to approximately 5.0 g salt per day) in the general population, and a particular effort in reducing salt intake should be made in the hypertensive population, which counts more than a billion patients globally.[15] In our study, the mean daily so-

dium intake in the experimental group decreased to 2.42±0.73 (from the baseline value of 3.12±0.79), suggesting that applying lifestyle intervention in the form of CCM may reduce dietary sodium intake in patients with hypertension.

Lifestyle measures plus antihypertensive drug therapy should be used to treat adults with hypertension. Adults with clinical CVD (coronary heart disease, heart failure, and stroke) should have their BP reduced below 130/80 mm Hg for secondary prevention of recurrent CVD events.[16] In our study, mean systolic BP decreased to 128.4±13.04 (from 144.20±13.12) in the experimental group ($p<0.001$), and the mean diastolic BP decreased to 79.4±8.93 (from 89±9.12) in the experimental group ($p=0.011$), suggesting that applying lifestyle intervention in the form of CCM may reduce the mean systolic and diastolic BP in patients with hypertension.

The findings of our study are consistent with those of the study by Lönnberg et al.[5] on the lifestyle habits in patients with high cardiovascular risk, which showed that after a 1-year intervention, including 5 counseling sessions that focused on lifestyle habits, significant changes were observed for PA, dietary habits, smoking, and stress over 1 year. Their results support the utility of a multifactorial, structured approach to change unhealthy lifestyle habits for cardiovascular risk prevention in a primary care setting.[5]

An online survey by Nishigaki et al.[17] titled "Physician and patient perspectives on hypertension management and factors associated with lifestyle modifications in Japan" showed that in addition to effective regular follow-up regarding lifestyle modifications, patient motivation by physicians is an important factor for improving lifestyle modifications and achieving effective hypertension management in Japan,[17] and we applied CCM for effective regular follow-up regarding lifestyle modifications on CVD in our study.

In addition, our finding is consistent with that of Huang et al.'s[18] study titled "The positive effect of an intervention program on the hypertension knowledge and lifestyles of rural residents in China," which showed that implementation of a community intervention program involving hypertension education and lifestyle modifications for rural residents is a powerful approach to reducing hypertension prevalence and improving long-term health outcomes.[18]

Our finding is also in line with that of Ghavami et al.[19] whose study was on improving health status in patients with diabetic neuropathy; breast cancer survivors [20,21]; and patients with postcoronary artery bypass grafting[22] as chronic diseases, after the application of lifestyle intervention programs.

Similar to the results of our research, a study by Molazem et al.[23] indicated that applying CCM had positive effects on lifestyle in patients with myocardial infarction.

Despite the overwhelming evidence that lifestyle factors affect CVD, a distinct minority of individuals are following these practices. The American Heart Association estimates that only 5% of individuals follow all of these lifestyle factors as components of a strategy to achieve ideal cardiovascular health.[24] On the basis of these findings, it is necessary to consider the role of healthcare providers in enhancing patients' adherence to healthy lifestyle programs in the form of CCM. Whereas the results of our study showed that CCM is effective for patients who are hypertensive, an implementation research is crucial to improve the understanding of the challenges that healthcare providers face in confronting the real life by broadening and deepening the understanding of these real-world factors and how they impact on implementations, such as caring models.

Limitations

Our study has some limitations. One of the limitations of the study is that it is not a blinded study. In addition, the participants in our study were recruited only from 1 hospital. In addition, the duration of intervention in our study was relatively short. Therefore, we recommend a multicenter study with a longer intervention period to confirm our findings.

Conclusion

Our study showed that applying lifestyle intervention in the form of CCM may reduce dietary sodium intake and the mean systolic and diastolic BP in patients who are hypertensive. Considering the fact that lifestyle modifications are quite important regardless of the use of antihypertensive drugs, lifestyle intervention in the form of CCM is recommended to improve patient's adherence to dietary restrictions and consequently, treatment outcomes in patients who are hypertensive.

Ethics Committee Approval: Ethics committee approval was received for this study from the Research Ethics Committee of Urmia University of Medical Sciences (Approval Date: May 29, 2018; Approval Number: IR.UMSU.REC.1397.363).

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Keywords: Diet, hypertension, lifestyle, physical activity, sodium

Anahtar Kelimeler: Diyet, hipertansiyon, yaşam tarzı, fiziksel aktivite, sodyum