



Original Research / Özgün Araştırma

## Effects of Salt Restriction Counseling on Primary Hypertension Patients Already Receiving Pharmacotherapy; A Randomized Controlled Trial

Tedavi Altındaki Primer Hipertansiyon Hastalarında Tuz Kısıtlaması Danışmanlığının Kan Basıncı Kontrolüne Etkisi; Randomize Kontrollü Çalışma

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### ABSTRACT

**Background and aim:** Providing a healthy lifestyle is the first stage of controlling hypertension, which is an important public health problem. However, lifestyle modification targets can only be achieved among limited patients. As a result, expected benefits from those modifications remain limited. In this research, we aimed to verify the additional gains from salt restriction counseling on blood pressure control among primary hypertensive patients already receiving pharmacotherapy. **Materials and methods:** Primary hypertension patients under a stable medical treatment were randomly assigned to a salt restriction group and a control group. All participants completed a questionnaire of demographic data, medical history, and diet. Twenty-four-hours ambulatory blood pressure measurements were recorded at the beginning and at the end of 3 months. Personalized education and counseling were performed only to the salt restriction group. Patients were followed up with phone calls. Effects of salt restriction were evaluated with sodium excretion on 24-hour urine. **Results:** Total 172 patients enrolled in the study; 86 patients were in salt restriction group and 86 patients were in control group. The patients' 71,5% (123) were women, 28,5% (49) were men. The mean age of participants was 56,8±5,9 years. Urinary sodium excretion increased 1.8±5.2 g/day in the control group (Z=3,120; p=0,002) but decreased 1,0±4,9 g/day in the study group (Z=1,983; p=0,047). Ambulatory systolic and diastolic blood pressures increased 3,2±9,3/2,3±6,9 mm Hg in the control group (Z=3,165; p=0,002/Z=2,956; p=0,003), whereas they decreased 6,1±9,4/4,7±7,8 mm Hg in the salt restriction group (Z=5,137; p<0,001/Z=4,993; p<0,001). **Conclusion:** Our study indicates that salt restriction counseling significantly contributed to blood pressure control also in primary hypertension patients already receiving pharmacotherapy. Lifestyle modification proves to be an effective treatment in patients who receive regular medical treatment.

**Keywords:** Ambulatory blood pressure measurements, hypertension, primary care settings, lifestyle change, salt restriction, randomized controlled study

### ÖZET

**Amaç:** Önemli bir toplum sağlığı sorunu olan hipertansiyonun kontrolünde birinci aşama, hastalarda sağlıklı yaşam tarzının sağlanmasıdır. Uygulamada tedavi hedeflerine kısıtlı bir hasta grubunda ulaşılabilen, yaşam tarzı değişiklikleri ve bunlardan beklenen yarar eksik kalmaktadır. Bu çalışmada tıbbi tedavi altındaki primer hipertansiyon hastalarında mevcut tedavilerine eklenecek tuz kısıtlaması danışmanlığı ile elde edilecek ek yararları belirlemek amaçlanmıştır. **Gereç-yöntem:** Randomize, kontrollü desende çalışmaya sabit tedavi altındaki primer hipertansiyon hastaları dâhil edildiler. Hastalar tuz kısıtlaması ve kontrol gruplarına ayrıldılar. Tüm katılımcılara demografik bilgileri, tıbbi öykü ayrıntıları, beslenme alışkanlıklarını sorgulayan bir anket uygulandı. Çalışma başlangıcında ve 3 aylık çalışma süresi sonunda Holter ile 24 saatlik ambulatuvar kan basıncı ölçümü yapıldı. Tuz kısıtlaması konusunda bireyselleştirilmiş danışmanlık görüşmesi yapıldı. Kontrol grubuna görüşme planı verildi. Çalışma grubu hastalarının önerilere uyumu telefon görüşmeleri ile izlendi. Tuz kısıtlaması danışmanlığının etkisi 24 saatlik idrarda hesaplanan sodyum atılımı ile izlendi. **Bulgular:** Araştırmaya dahil olan toplam 172 katılımcının %71,5'i (123) kadın, %28,5'i (49) erkek, yaş ortalamaları 56,8±5,9 yıl idi. Çalışma, tuz kısıtlaması grubunda 86 ve kontrol grubunda 86 hipertansiyon hastası ile sonuçlandırıldı. Çalışmamızın sonuçlarına göre üriner sodyum atılımı kontrol grubunda 1,8±5,2 gr/gün artarken (Z=3,120; p=0,002), tuz kısıtlaması grubunda 1,0±4,9 gr/gün azaldı (Z=1,983; p=0,047). Ambulatuvar sistolik ve diastolik kan basıncı ölçümleri kontrol grubunda 3,2±9,3 mm Hg (Z=3,165; p=0,002) /2,3±6,9 mm Hg artarken (Z=2,956; p=0,003), tuz kısıtlaması grubunda 6,1±9,4 mm Hg (Z=5,137; p<0,001) /4,7±7,8 mm Hg düştü (Z=4,993; p<0,001). **Sonuçlar:** Çalışma sonuçlarımız, halen tedavi altında olan hipertansiyon hastalarında da tuz kısıtlaması danışmanlığı verilmesinin daha iyi kan basıncı kontrolü sağlanmasına katkı yapmakta olduğunu gösterdi. Yaşam tarzı değişiklikleri hipertansiyon hastalarının sabit ilaç tedavisi protokollerine geçildikten sonra da etkin tedavi özelliğini sürdürmektedir. **Anahtar kelimeler:** Ambulatuvar kan basıncı ölçümü, hipertansiyon, yaşam tarzı değişikliği, tuz kısıtlaması, randomize kontrollü çalışma

Received / Geliş tarihi: 14.02.2019, Accepted / Kabul tarihi:07.08.2019

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Ağaoğlu H, Şahin EM, Aydın GS, Akay A. Effects of Salt Restriction Counseling on Primary Hypertension Patients Already Receiving Pharmacotherapy; A Randomized Controlled Trial. TJFMPC, 2019;13(4): 514-522.

DOI: 10.21763/tjfm.527288

## 1. INTRODUCTION

Hypertension (HT) is an important healthcare problem which globally affected 31.1% (1.39 billion people) of adult population.<sup>1</sup> Uncontrolled HT is associated with both all-cause and cardiovascular mortality as an important risk factor.<sup>2</sup> Although treatments which are effective in lowering blood pressure (BP) have been available, awareness, treatment, and control rates of HT are low.

All guidelines recommended healthy lifestyle changes primarily in the treatment of hypertensive patients. These changes may slow disease progression and may decrease or delay the requirement for pharmacotherapy. In most of the patients with HT, two or more drugs are needed to achieve effective BP control.<sup>3</sup> Adequate BP control may not be achieved even with appropriate antihypertensive drugs or drug combinations until proper lifestyle changes are performed.<sup>4</sup> Regular physical exercise, reducing salt intake, healthy diet, smoking cessation and restricting alcohol intake are defined as effective lifestyle changes in controlling BP.<sup>5</sup> Daily salt consumption can contribute to increase in BP and the development of essential hypertension with advancing age.<sup>6</sup> Studies showed a relationship between the average dietary sodium intake and the prevalence of HT in population.<sup>7</sup> The mean decrease in systolic BP was found to be about 6.7 mmHg between the groups with strict and small salt restrictions.<sup>8</sup> World Health Organisation (WHO) and HT guidelines recommend that adults should limit their daily dietary salt intake by 5-6 grams at most.<sup>9,10</sup>

In practice, targets for HT treatment are achieved only in a limited group of patients. The establishment of lifestyle changes and the benefit expected from these changes usually remain incomplete. The aim of the present study is to investigate additional BP benefit of salt restriction counseling added to antihypertensive pharmacotherapy of patients with primary hypertension.

## 2. MATERIAL and METHODS

### 2.1 Design

This is a randomized, controlled, non-blinded trial of lifestyle intervention on hypertensive patients already taking a stable pharmacotherapy.

### 2.2 Setting

This study is conducted at Family Medicine Clinic of Çanakkale Onsekiz Mart University Medical School Hospital, Turkey, between June-December 2013.

Primary HT patients aged 40-65 years, had been receiving a fixed treatment protocol for at least 3 months with the systolic BP of 120-160 mm-Hg measured in polyclinic conditions with cuffed manometers, were invited to participate in the study and evaluated for inclusion/exclusion criteria (Table 1) of the study. All the patients were followed by their physicians with no treatment modification. The patients, whose treatment had been modified during the study period, were excluded.

This study included one intervention and one control groups by 1:1 ratio. Inclusion criteria (Table 1) and randomization was performed by two researchers. The intervention was carried out by one researcher, no blinding performed because of the nature of the interventions did not allow it.

### 2.3 Sample Size

In the power analysis of the study, considering that significant target systolic BP difference was 5 mmHg and standard deviation for systolic BP was 10 mmHg in the groups, it was calculated that each group has to include minimum 85 individuals when  $\alpha$  error level and the power of the test were accepted as 0.05 and 90% ( $\beta=0.10$ ).

### 2.4 Participants

Total of 193 hypertensive patients was invited to study. Twenty-one patients were excluded from study because 12 patients didn't keep their appointment, 1 patient doesn't tolerate ambulatory device, 1 patient refused the second measurement because there was an error in his first measurement, 1 patient became pregnant, 1 patient got cancer diagnosis and 5 patients' second measurements couldn't be performed because we failed to reach them. Finally, the study was completed with 172 participants. Among these, 86 patients were in salt restriction group and control group included 86 patients.

**Table 1. Inclusion and exclusion criteria of the study**

<u>Inclusion criteria of the study</u>	<u>Exclusion criteria of the study</u>
1- Age between 40-65 years 2- The diagnosis of HT made according to JNC 7 criteria 3- Receiving antihypertensive treatment with a regular treatment plan 4- The mean daily polyclinic systolic BP value between 120 – 160 mmHg	1- Alteration of treatment plan in the last 2 months 2- The mean daily systolic BP value <120 or >160 mmHg 3- Presence of a disease or disability preventing compliance to study method (being bedridden, presence of a psychiatric disorder preventing the assessment of reality, dementia) 4- Patients with Type 1 diabetes 5- Patients with secondary HT 6- Receiving steroid or any other pharmacological agents directly affecting BP 7- Patients with heart failure, arrhythmia, coronary artery disease, peripheral vascular disease, recent myocardial infarction or detection of high risk for heart disease after history and physical examination 7- Patients rejecting to follow the recommendations for life style changes 8- Pregnancy

## 2.5 Ethical considerations

The ethics committee approvals of the study were obtained from Çanakkale Onsekiz Mart University Ethics Committee; number/date 050.99-183/30.11.2012. Informed consent was signed by all patients included in the study.

## 2.6 Data collection tools

The primary outcome of the study was collected with measurements of 24-hour ambulatory BP. The effects of salt restriction counseling were evaluated with daily salt consumption calculated from Na<sup>+</sup> excretion in 24-hour urine.

A questionnaire paper prepared by the investigators including questions about demographical information, details of medical history, dietary and exercise habits, addictions, treatment status, and previous treatment protocols were applied to the participants. The anthropometric measurements were also done.

24-hour ambulatory blood pressure monitoring was performed using a Holter device (Microlife Watch-BP Analyzer O3). Average daily BP values were used as study data.

Na<sup>+</sup> measurement in 24-hour urine performed by ISE (ion-selective electrode) method after sodium concentration of the separated sample. The volume of urine collected for 24 hours was measured; daily salt (NaCl) consumption was calculated from the amount of urine sodium.

## 2.7 Intervention

In this study implemented intervention was the patient counseling interview organized in a semi-structured fashion. The interviews were carried out by the same researcher, had trained before, to all patients in the study arm.

The researcher gave information about the interview and asked the patients about the time of hypertension diagnosis, the importance of dietary compliance especially the salt restriction in the treatment of hypertension. Potential sources of salt consumption were revised. Reducing the salt consumption plan has been developed with patients. Written and visual training materials were given to the patients and the interview was terminated after the preparation of a follow-up interview plan.

The compliance of intervention groups' patients to recommendations were followed by telephone calls. The patients in the intervention group were called-up 3 times, the first was within 7-10 days, the second call was in 30-40 days and the third call was made in 60-70 days after the first meeting, in which dietary salt restriction recommendations were revised and reminded.

## 2.8 Implementation

The patients who were chosen for this study, were informed and their consent were requested. After receiving their contact information, they filled the prepared questionnaire with the researchers' help. The patients were equipped with a Holter device for ambulatory BP monitoring and they were asked to collect urine for a period of 24 hours. Later patients were given an appointment for the next day.

After receiving the collected urines and ambulatory measurements, the patients were randomly assigned to control and study groups. No blinding was performed. The patients who were assigned into the control group were given a meeting schedule for the future. The patients in the study group received individualized counseling about salt restriction and related changes in lifestyle. Later they were also given a different meeting schedule. As mentioned in detail above the patients in the intervention group received following phone calls.

All the patients were requested to maintain their current treatment regimens followed by the physicians they preferred and they were asked to inform in case of any changes.

According to the meeting schedule, after 90-110 days from the beginning of the study, patients in both groups came to the final meeting. In this final meeting, the patients

were equipped with a Holter device for ambulatory BP monitoring and they were asked to collect urine for a period of 24 hours again. They were invited for the next day in order to collect the final results; ambulatory measurements were recorded into data and urine results were sent to biochemical evaluation.

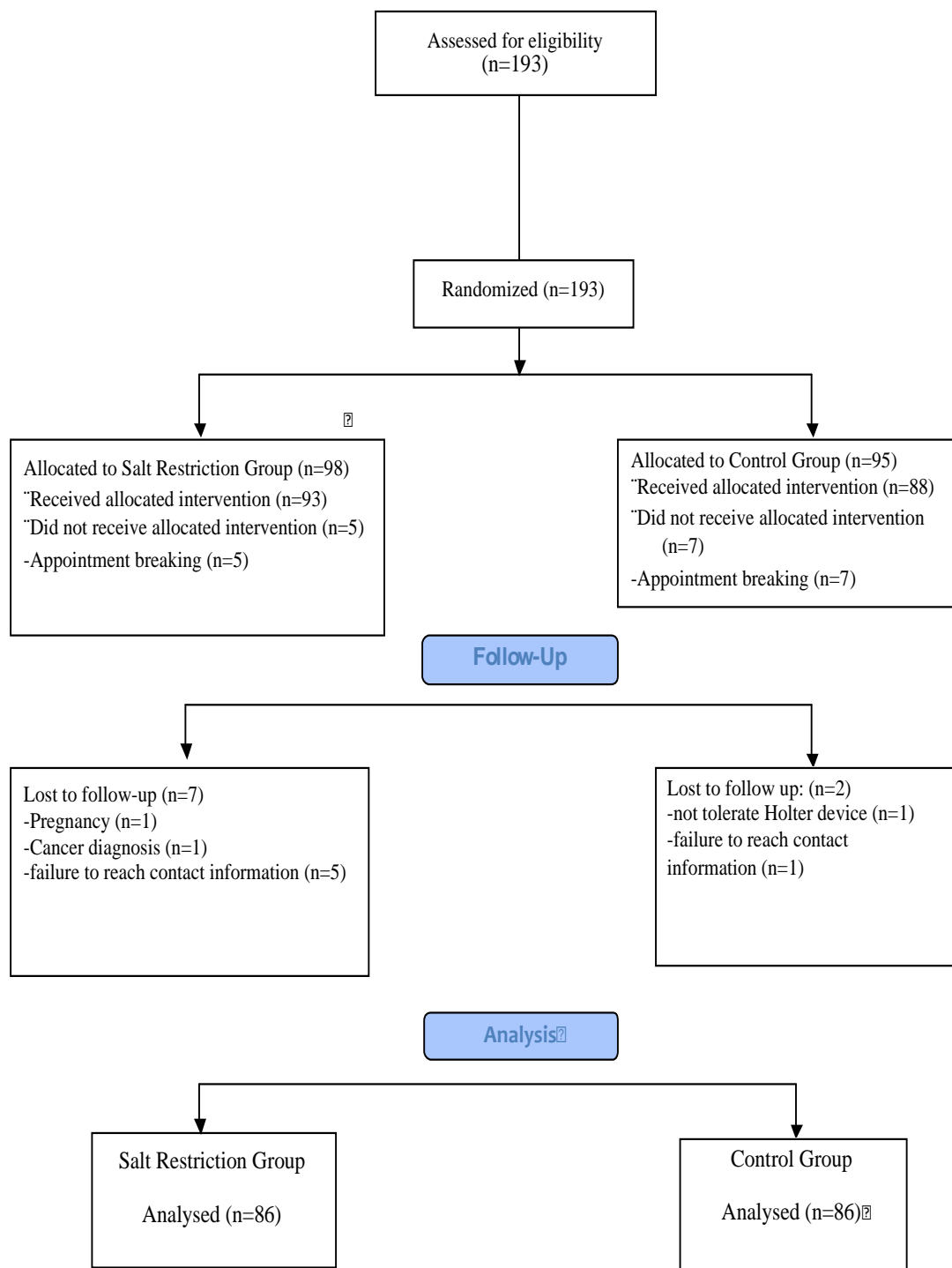
## 2.9 Statistics

The SPSS 19.0 (NY: IBM Corporation) was used for statistical evaluation. Wilcoxon test was used for the repeated measures within each of groups. Mann-Whitney U test was used for analysis between intervention and control groups and  $p < 0.05$  is accepted as the statistical significance.

## RESULTS

A flow diagram of the study participants was reported in Figure 1. Among 172 patients enrolled in the study, 123 (71.5%) were females and 49 (28.5%) were males. The mean age of the participants was  $56.8 \pm 5.9$  (41-65) years. The mean duration of antihypertensive treatment protocols of the patients was  $40.6 \pm 45.4$  (1-240) months. The most commonly used HT drugs were ARB and diuretic combination (26.1%), ACEI (11.6%), ACEI and diuretic combination (11.6%). Table 2 shows the distribution of demographical and disease history features of the participants in the groups. There was no significant difference between initial polyclinic systolic ( $U=3553.5$ ;  $p=0.657$ ) and diastolic blood pressure measurements between groups ( $U=3269.0$ ;  $p=0.187$ ).

Although initial ambulatory SBP and DBP measurements of the salt restriction group patients were higher than the control group patients' ( $U=2474,5$ ;  $p < 0.001/U=2357,5$ ;  $p < 0.001$ ), there is no significant difference between the outcome measurements ( $U=3157,5$ ;  $p=0,125/U=3233,0$ ;  $p=0,154$ ). While both SBP and DBP measurements were significantly decreasing in the salt restriction group patients ( $z= -5,137$ ;  $p < 0,001/z=4,993$ ;  $p < 0,001$ ), they were increased in the control group patients ( $z=3,165$ ,  $p=0,002$ ;  $z=2,956$ ,  $p=0,003$ ). 1 g decrease of daily salt consumption accompanied by 6.1 mmHg SBP and 4.7 mmHg DBP decrease in salt restriction group whereas 1.8 g increase of daily salt consumption accompanied by 3.2 mmHg SBP and 2.3 mmHg DBP increase in control group. The measurements of salt restriction and control group were shown in Table 3.



**Figure 1. Distribution of participants**

	<b>Salt restriction group (n=86)</b>	<b>Control group (n=86)</b>
Mean age in year	57.1±5.6	56.5±6.3
Gender (Female)	60 (69.8%)	63(73.3%)
Marital status (married)	75 (87.2%)	76 (88.4%)
Education (total successful year in school)	6.3±3.5	6.9±5.2
Active workers	20 (23.3%)	22 (25.6%)
Smoker	13 (15.1%)	15 (17.4%)
Alcohol user	15 (17.4%)	16 (18.6%)
Regular physical exercise (3 day/30 minute/week)	30 (34.9%)	26 (30.2%)
Duration of HT (years)	8.5±6.4	6.9±5.6
Duration of HT treatment protocol (months)	49.0±52.3	32.2±35.8
Total number of hypertensive drugs	1.3±0.6	1.2±0.5

HT; hypertension

	<b>Salt restriction group</b>	<b>Control Group</b>	<b>Statistical evaluation*</b>
<b>Ambulatory SBP (mmHg)</b>			
Initial measure	123.7 ±10.1	117.4 ± 10,9	<b>U=2474,5p&lt;0,001</b>
Outcome measure	117.6 ± 9.7	120.6 ± 10.6	U=3157,5p=0,125
Differencemean±SD(95%CI)	-6.1 ± 9.4(4.1-8.1)	3.2 ± 9.3(1.2-5.2)	
Statistical evaluation**	<b>z= 5,137p&lt;0,001</b>	z=3,165p=0,002	
<b>Ambulatory DBP(mmHg)</b>			
Initial measure	76.6 ± 8.3	71.4 ± 7.7	<b>U=2357,5p&lt;0,001</b>
Outcome measure	71.9 ± 7.4	73.7 ± 7.0	U=3233,0p=0,154
Difference mean±SD(95%CI)	-4.7 ± 7.8(3.0-6.4)	2.3 ± 6.9(0.8-3.8)	
Statistical evaluation**	<b>z=4,993p&lt;0,001</b>	z=2,956p=0,003	
<b>Salt (NaCl) (gr/day)</b>			
Initial measure	10.1 ± 4.4	9.5 ± 4.3	U=3385,0p=0,338
Outcome measure	9.1 ± 4.1	11.3 ± 5.1	U=2728,0p=0,003
Differencemean±SD(95%CI)	-1.0±4.9(0.04-2.07)	1.8±5.2(2.9-0.7)	
Statistical evaluation**	z=1,983p=0,047	z=3,120p=0,002	

\*Mann-Whitney U test \*\* Wilcoxon Signed Ranks test  
SD; standard deviation, CI; confidence interval

## DISCUSSION

This study showed that an additional benefit in BP control might be achieved with salt restriction counseling in hypertensive patients who already receive pharmacotherapy. Daily salt consumption decreased by salt restriction

and provided a decrease of 6.1 mmHg in SBP and 4.7 mmHg in DBP.

The salt restriction is one of the major lifestyle changes which was recommended for first-line treatment of primary HT and reducing cardiovascular risk factors in the guidelines.

Decreasing salt intake underlies prevention of primary hypertension, also.<sup>6, 10</sup>

It is proven that the blood pressure reduced with salt restriction in the literature.<sup>11, 12</sup> A significant correlation was detected between cardiovascular disease risk and sodium intake equal to or more than 2.3 g/dl.<sup>13, 14</sup> It has also been suggested in the studies that decreasing daily sodium intake below 1.5 g was very effective in preventing cardiovascular diseases and treating the diseases that already exist. SALTurk study revealed that each 6 g/day salt intake caused 8.2 mmHg and 4.9 mmHg increases in SBP and DBP values, respectively.<sup>9</sup> According to the data of DASH-sodium study, 1.8 g/day decrease in the salt content of diet in hypertensive patients lowered SBP/DBP by 5.3/2.9 mm Hg, while it was 10.5/5.7 mmHg for 2.4 g/day decrease and 15.8/8.6 mmHg for 3.6 g/day decrease.<sup>15</sup> In our study, 6.1/3.8 mmHg decrease in BP was achieved with 1 g decrease in salt intake at the end of 3 months in the patients who received salt restriction counseling. These values of BP control obtained after salt restriction counseling in hypertensive patients receiving pharmacotherapy that controlling effect of salt restriction continued as strong as at the beginning of HT treatment. Considering that the average salt consumption is higher, salt restriction counseling should be the first topic of physicians' at any time of the treatment processes of their hypertensive patients.

While the follow up of HT patients is focused on the medical treatments, the lifestyle changes which are difficult to maintain are usually ignored. There is limited evidence for the maintenance of initially recommended lifestyle changes for the HT patients who started receiving pharmacotherapy. Furthermore studies to show the effect of lifestyle changes started for HT patients who already on a regular pharmacotherapy regime is totally missing.

We think that this study proved the continuation of treating the effect of salt restriction as one of the healthy lifestyle changes, which constitute the baseline of HT treatment, in the patients who are on pharmacotherapy. This effect may show the increase in efficacy achieved by individual counseling, while it may also show that there may be some missed opportunities for behavioral changes in the follow-up of HT. Unique nature of behavioral change forces it to be constantly on the interview and an area in which physician and patient exert effort.

Physicians mostly consider reaching targeted BP values by a current antihypertensive drug, while the patient considers the recommendations on the use of the drug. However, healthy lifestyle behaviors applied in every stage of treatment increase the efficacy of antihypertensive treatment and even termination of pharmacological treatment may be possible under some clinical conditions.<sup>16</sup> It is important that patients and healthcare professionals providing health service should be careful on this subject and take advantage of every encounter.

Patient follow-up mechanisms are used to adopt lifestyle changes. Better BP values were achieved in primary care studies with personalized treatment for a hypertensive individual.<sup>17, 18</sup> But it is not clear that how physicians should make optimal behavioural interventions and provide recommendations about reducing salt intake.<sup>19</sup> Some studies reported better blood pressure control was obtained from tailored and repetitive lifestyle interventions than regular education programmes and telephone calls could be an effective counseling way.<sup>20, 21</sup>

The method of this study was evaluated with regard to applicability in primary care settings which provide service with the principle of continuity in time and individual aspects. The applicability of study method, including patient interviews, periodical telephone callings in primary care settings for individual behavioral counseling was also confirmed.

For the future studies on the topic, the possibility of replacing the pharmacotherapy with the life style changes might be tried. The effect of possible life style interventions in patients with different disease and treatment characteristics would be also another area of future research.

### **Study Limitation**

The main limitation of this study is the follow-up time. The changes beyond 3 months of follow up time would be important. The power of the interventions to decrease the blood pressures with strong and loose control options should also be checked. With further available funds for the study, a high number of participants would be possible and subgroup analysis according to antihypertensive treatment would be carried out.

In our study, clinical features of the groups are not all equal. The effects of the intervention

on various patients such as varying duration of HT, the differences in the duration of last treatment protocols, the rate of the patients who follow the suggested physical exercises couldn't be determined. The effects of such characteristics on the results can be examined in the following studies. Because the patients are chosen from the primary care patient population, it has been difficult to compare groups' similarities. Furthermore, it was prioritized to study real primary care patients instead of equal groups. In this regard, performing blinding couldn't be possible with the applied study method. Although the method of the study has theoretical limitations, the results are fully compatible with primary care settings.

### CONCLUSION

Although lifestyle changes constitute the first and main stage of primary hypertension treatment, patients are usually not successful in performing these changes permanently. Despite the fact that lifestyle changes are always kept on the interview in newly diagnosed patients, the benefit of these changes still persists even in the advanced stages of the disease and after medical treatment modalities are commenced to be used permanently. Our study showed that salt restriction significantly contributed to BP control also in hypertensive patients already receiving pharmacotherapy. Keeping healthy lifestyle changes constantly on the interview and providing help and counseling to patients during follow-up of hypertensive patients will be necessary and helpful to achieve treatment success.

### Acknowledgments

This study was supported by Çanakkale Onsekiz Mart University Scientific Research Project Coordination Unit (TTU-2013-38).

This research project won the first prize in 2013 TAHUD Association of Turkish Family Physicians, Scientific Project Contest.

### Conflict of interest

There is no conflict of interest of authors to declare.

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