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Original article

Effect of the Oral Consumption of Lavender Extract (Lavandula) on Prehypertension in the Retirees of Retirement Centers: A Randomized Clinical Trial

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SUMMARY

Introduction/Aim: Hypertension is a common disorder of old age, which could be prevented by medicinal herbs. The present study aimed to evaluate the effect of lavender extract on prehypertension in the retired population.

Methods: This triple-blind clinical trial was conducted on 60 retired men and women who were divided into two groups of lavender extract and placebo using the permuted block technique. Lavender extract (originating from flower part) and placebo were used twice a day (3 grams is equivalent to 3 cc each time) for two weeks. Blood pressure was measured before use, in the first and second week after use, and one week after the discontinuation of the medication to evaluate the stability of the drug effects. Data analysis was performed in STATA software version 14 at the significance level of $p < 0.05$.

Results: Before the intervention, the mean systolic blood pressure in the lavender extract and placebo groups was 133.9 ± 9.3 mmHg and 127.3 ± 6.3 mmHg, respectively. After a one-week intervention, the mean blood pressure of the groups was 123.1 ± 12.6 mmHg and 125.8± 7.2 mmHg, respectively, while it was 120.8 ± 10.7 mmHg and 127.9 ± 2 mmHg after two weeks. One week after drug discontinuation, these levels were estimated at 123.7 ± 10.7 mmHg and 129.2 ± 10.10 mmHg, respectively. The results of repeated measures ANOVA indicated that lavender extract had significant effects on systolic and diastolic blood pressure in the intervention group ($p < 0.05$).

Conclusion: According to the results, lavender extract was effective in prehypertension control in the retired subjects.

Keywords: **lavender, prehypertension, retirees, flower, medicinal plant**

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INTRODUCTION

Retirement is mandatory in every country, and old age is the beginning of this period (1). The ageing population is growing in the world and in Iran, where this population is expected to reach 10% in 2021 and 19.4% in 2041 (2). Non-communicable diseases are the leading cause of death in this age group. Among these diseases, hypertension is a risky, yet modifiable factor, contributing to cardiovascular diseases (3). Statistics suggest that one in three individuals aged 60 - 70 years and one in two individuals aged more than 80 years have hypertension (4). It is also estimated that 59% of individuals with prehypertension develop high blood pressure after eight years (5). Several studies have investigated prehypertension, reporting the global prevalence rate of 30 - 48.9%. In Iran, the prevalence rate of hypertension is estimated at 44.2 -59.6% in men and 35.5 - 44.5% in women (6).

According to research published by The Eighth Joint National Committee (JNC 8), the start of drug therapy for patients with hypertension in people younger than 60 years from 140/90 mmHg and in people over 60 years is 150/90 mmHg. In addition, the American Blood Pressure Association recommends starting medication in those aged less than 80 years with the blood pressure of 140/90 and 150/90 in those aged more than 80 years. Notably, the rate could change with lifestyle modifications (7).

Previous studies have suggested strategies to control blood pressure, which mainly involve lifestyle changes, regular exercise, and nutrition to prevent hypertension. According to the literature, 87% of the elderly have at least one obstacle to abstain from physical exercise, such as a lack of motivation and companionship, fear of falling, disinterest in exercise, and fatigue (8). A study conducted in Neishabour (Iran) indicated that 84.7% of the elderly had a mediocre lifestyle, 14.7% had an unfavorable lifestyle, and only one subject had a healthy lifestyle (9). Furthermore, the elderly cannot follow dietary plans due to dental problems (10). In alternative medicine, effective approaches have been proposed for the control and reduction of blood pressure, including dietary modification, physical exercise, stress management, and herbal medication (11).

Herbal medicines stand for an effective therapeutic approach, which have been used increasingly in recent decades mainly because they are cost-efficient and free of chemical agents (12). In the mentioned study in Neishabour, 33% of the subjects used medicinal plants personally given the absence of side-effects, and 32% used herbal medication since they were aware of the therapeutic properties of these plants (12).

Lavender (*Lavandula angustifolia L.*) belongs to the Lamiaceaeis family and is a medicinal plant frequently consumed in Iran, which may be effective in lowering the blood pressure (11, 13). Lavender has neurological, cardiovascular, and respiratory effects and could be used for the treatment of fungal diseases (13). This plant also has more than 40 active ingredients, and the main components include linalool, linalyl acetate, cineole, terpene, and camphor (11). Lavender is primarily used as an antispasmodic, analgesic, and sedative. Studies have confirmed the effects of lavender on blood pressure through enhancing the parasympathetic nerve activity (14, 15), stimulation of nitric oxide production (11) as a vasodilator, inhibition of angiotensin, enzyme conversion by flavonoids, inhibition of calcium channels with a similar effect to verapamil (16), and antioxidant activity, which is essential to the control of hypertension (11). Lavender is a perennial plant that uses flowers and flowering tops that produce valuable essential oils and has been widely used as a dry or essential oil in aromatherapy, pesticides and as an antimicrobial. Lavender essential oil has antifungal and antibacterial activity and is used for neurological disorders and infections. Flower oil mainly contains linalool, linalyl acetate, camphor and 1, 8-cineole, while the oil coming from the leaves mainly borneol, camphor and 1, 8 cineole (13).

Moreover, lavender has been reported to exert tranquilizing effects and lower the blood pressure by increasing the alpha waves in the brain (14).

Several studies have been focused on aromatherapy mostly in young or middle-aged populations (17 - 20). Notably, chemical drugs are not used for the treatment of prehypertension, and emphasis is mainly placed on lifestyle modification, nutrition, and improvement of physical activity (11). In addition, herbal medicines have not been commonly used in patients with prehypertension.

The present study aimed to investigate the effect of lavender on the retirees with prehypertension.

METHODS

This triple-blind clinical trial was conducted

on the retirees of the retirement centers in Neishabour, Iran during February - March 2016. The study protocol was approved by the Ethics Committee of Sabzevar University of Medical Sciences (ethics code: IR.MEDSAB.REC1398.081). The study has been registered in the Iranian Registry of Clinical Trials (No. IRCT20200111046077N1). The sample size was calculated based on the study by Maisi et al. (2017) (18) at 95% confidence level and test power of 0.95 considering the effect size of 0.375 and four replications. The final sample size was 60, with 30 subjects assigned to each group (Figure 1).

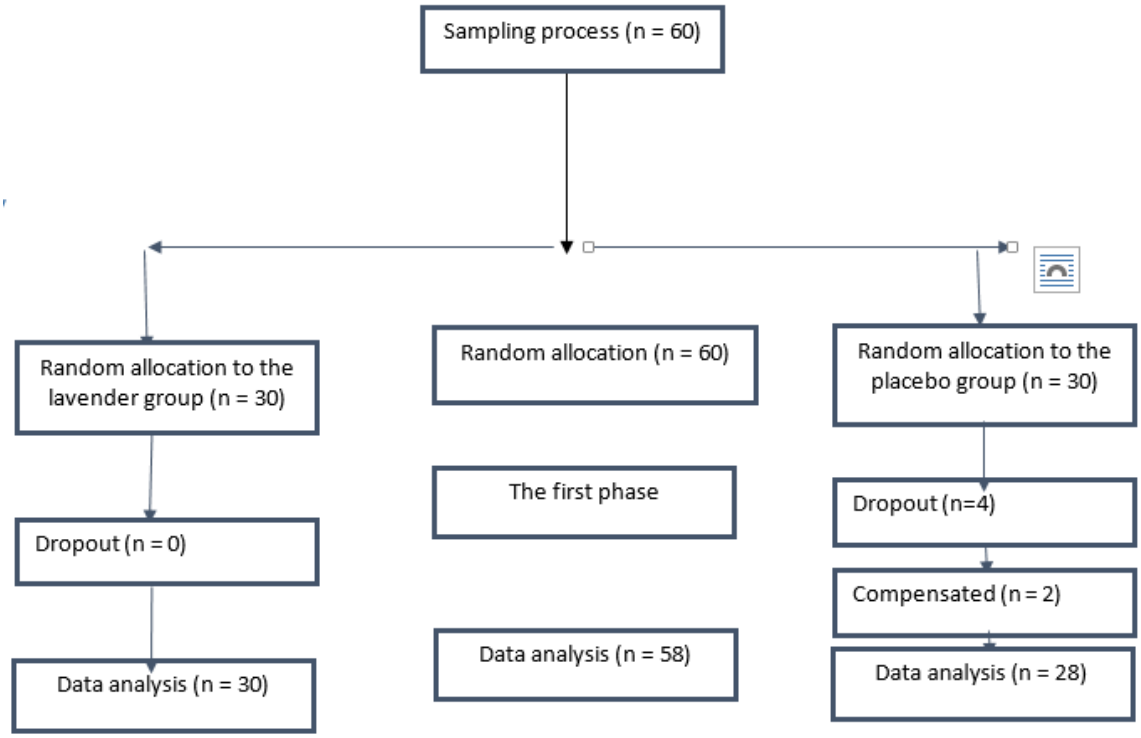

Figure 1. *Flowchart of the design, group, and participants in the study*

Two subjects were excluded from the placebo group due to lack of cooperation, and two others were excluded from the placebo group due to the side-effects of placebo and were replaced. Data were collected from 58 retired subjects. The inclusion criteria of the study were retirement and blood pressure of 120/80 - 139/89 mmHg. The exclusion criteria were as follows: 1) lavender allergies; 2) opium addiction; 3) diabetes and chronic kidney disease; 4) using antihypertensive drugs; 5) using herbal medicines to lower blood pressure, and 6) severe liver failure. The withdrawal criteria during the study period were not using the medications for two days, allergies to lavender appearing with consumption, and possible side-effects of lavender.

For sampling, we prepared a list of medical science, teachers, and workers retirees in Neishabour within the past six years. Subjects were selected via convenience sampling according to inclusion criteria. After explaining the objectives of the study, the subjects who met the inclusion criteria and provided informed consent were enrolled in the study using the permuted block technique. The selected subjects were randomly divided into two groups of lavender extract and placebo, with the intervention group marked A and the placebo group marked B. The size of each block was determined to include four subjects, and a sequence of 15 blocks was selected.

The subjects in the intervention group received a lavender extract *(Lavandula*), and the other group received placebo. To prepare the product, the flower part of the plant was used and 1 kg of extract was extracted from every 5 kg of the plant. This extract is dark brown in color and has a pH of 6.5 and is prepared by hydroalcoholic method. The amount of ethanol used in this product was 70% and the extraction temperature was 60 degrees Celsius. Lavender extract (*Lavandula*) and placebo were used

twice a day (3 grams is equivalent to 3 cc each time) for two weeks. For data collection, the blood pressure of the subjects was measured before the study, one week after the intervention, two weeks after the intervention, and one week after drug discontinuation at a certain time of day (5 – 6 p.m.) to assess the stability of the effects. Placebo was an ineffective substance composed of distilled water and some eatable color prepared by Dr. Zarghani Pearl Farm Company, which is similar to the main medicine in terms of shape, color and container, but has not been matched in terms of taste and smell.

After selecting the subjects, they were contacted to provide their home address and invited to the research setting. Data were collected using a demographic questionnaire, a checklist of possible complications, and a checklist of blood pressure. Blood pressure was measured by the researcher before the intervention, on days seven and 14 after the intervention, and one week after the cessation of the intervention using a aneroid sphygmomanometer and a medical stethoscope (model: BRISK, made in Germany), which is approved by the European Union. To calibrate the aneroid sphygmomanometer, mercury sphygmomanometer was used on the first person and every ten people.

The demographic questionnaire consisted of data on the age, gender, height, weight, and body mass index (BMI) of the subjects. The checklist of possible complications was also completed daily after asking relevant questions. The lavender extract used in the present study was purchased from Dasht-e-Jovein Pearl Farm Company (license number: 31/10192; Dr. Zarghani brand). Three grams equivalent to 3 cc of the extract was administered to the subjects. For accurate measurements, all the subjects were administered with the extract using a 5-cc syringe, and their daily consumption was explained.

The subjects were selected after obtaining informed consent based on the inclusion/exclusion criteria. They were assured of confidentiality terms regarding their information and the fact that they would be provided with the results of the study upon request. Furthermore, the subjects would be asked to discontinue participation if they were taking other herbal medicines. To avoid possible bias, the triple-blind method was used for data collection so that the researcher, subjects, and statistical consultant would be blinded to the procedures, and only one trusted individual was informed on the assigned codes. In addition, the researcher and statistical consultant were unaware of the allocation of the patients to the study groups. For this random allocation, two glasses were labeled A and B, with glass A showing the lavender extract group and glass B showing the placebo group. The researcher explained to the subjects that they would be given the lavender extract or placebo randomly. At the next stage, the amount and method of consumption were explained to the subjects in a written and oral manner, and the correct method of use was asked every other day. The participants were asked to contact the researcher in case of complications or questions. In addition, they could report possible allergies, such as redness, itching, burning, urticaria, blisters, nausea and vomiting, jaundice, stomach bleeding, and melena, daily through the allergy checklists.

During the study, two subjects in the placebo group developed complications. One showed sign and symptom of urticaria and pruritus, and the other one had a sore throat after the second day of the intervention. One hour after the onset of these symptoms, they were resolved without any specificaction. Nevertheless, both subjects were excluded from the study.

Data analysis was performed in the STATA software version 14 considering the p-value of less than 0.05 as the significance level. Chi-square was used to assess the indicators of gender, marital status, place of residence, education level, occupation status, use of antihypertensive drugs, diabetes, history of allergies, addiction status, alcohol consumption, and family history. T-test was also applied to evaluate age, BMI, retirement period, work experience, mobility, and history of herbal medication. To compare the blood pressure of the subjects before, after taking the extract, and one week after stopping the intervention, repeated measures of the analysis of variance (ANOVA) were used.

RESULTS

The mean age of the subjects in the lavender extract and placebo groups was 58.46 ± 9.89 and 57.7 ± 6.79 years, respectively. The mean BMI was 27.34 ± 4.17 kg/m^2 in the lavender extract group and 26.9 ± 4.71 kg/m^2 in the placebo group. The percentage of male and female subjects in the lavender extract group was 60% and 40%, respectively, and it was 68.8% and 31.3% in the placebo group, respectively. The study groups were also compared in terms of

other demographic variables, such as marital status, place of residence, education level, diabetes, allergies, addiction history, family history of hypertension, retirement period, and work experience, and no

Table 1. *Demographic characteristics of subjects in intervention and control groups*

Variable		Group		P-value
		Intervention	Placebo	
Age (year; mean ± SD)		58.4 ± 9.8	57.7 ± 6.79	***0.71
BMI (kg/m²; mean ± SD)		27.3 ± 4.1	26.9 ± 4.7	***0.72
Gender N (%)*	Female	18 (60)	22 (68.8)	*0.47
	Male	12 (40)	10 (31.3)	
Marital status N (%)*	Married	29 (96.7)	31 (96.9)	*0.73
	Widow	0	1 (1.3)	
	Divorced	1 (3.3)	0	
Place of residence N (%)	City	27 (90)	29 (90.6)	>*0.99
	Village	3 (10)	3 (9.4)	
Education level N (%)	Illiterate	6 (20)	5 (15.6)	**0.47
	Primary	9 (30)	9 (28.1)	
	Secondary	3 (10)	0	
	Diploma	4 (13.3)	3 (9.4)	
	Associate degree	2 (6.7)	3 (9.4)	
	Bachelor	4 (13.3)	10 (31.3)	
	MA	2 (6.7)	2 (6.3)	
Diabetes N (%)	Yes	0	1 (3.1)	> *0.99
	No	30 (100)	31 (96.9)	
Allergies N (%)	Yes	4 (13.3)	8 (25)	*0.24
	No	26 (86.7)	24 (75)	
History of addiction N (%)	Yes	1 (3.3)	4 (12.5)	*0.35
	No	29 (96.7)	28 (87.5)	
Family history of hypertension N (%)	Yes	13 (43.3)	21 (65.6)	*0.07
	No	17 (56.7)	11 (34.4)	
Retirement period (mean ± SD)		4.7 ± 1.6	5.1 ± 6	***0.78
Work experience (mean ± SD)		24.8 ± 7.37	25.8 ± 6.95	***0.59

*Chi-square; **Fisher's exact test; ***t-test

significant differences were observed (Table 1).

According to the findings, diastolic blood pressure decreased from 85.7 ± 5.7 to 77.8 ± 8.87 mmHg in the lavender extract group before and one week after drug administration, while reaching 76 ± 8.03 mmHg two weeks after administration and 79.3 ± 7.5 mmHg one week after drug discontinuation. Repeated measures ANOVA indicated a statistically significant difference in this regard (Figure 2; Table 2).

The mean systolic blood pressure in the lavender extract group decreased from 133.9±9.3 before drug administration to 123.16 ± 12.3 mmHg, 120.8 ± 10.7 mmHg, and 123 ± 10.79 mmHg, one week, two weeks after drug administration and one week after drug discontinuation, respectively. Repeated measures ANOVA showed a significant difference in this regard ($p < 0.001$) (Figure 3).

Mean systolic blood pressure in the placebo group was 127.3 ± 6.30 and 125.89 ± 7.72 mmHg before and one week after drug administration, respectively, reaching 129.2 ± 10.06 mmHg one week after drug discontinuation. However, repeated measures

Figure 2. *Effect of time on estimated mean diastolic blood pressure in intervention group and placebo group*

Table 2. *Comparison of mean blood pressure at four time points in intervention and placebo groups*

Blood pressure		Before intervention	One week after intervention	Two weeks after intervention	One week after drug discontinuation	Repeated measures ANOVA
Placebo	Systolic blood pressure	127.3 ± 60.30	125.89 ± 7.2	127.9 ± 8.10	129.20 ± 10.06	Group: P = 0.55 Time: P = 0.11 Mutual: P = 0.51
	Diastolic blood pressure	82.67 ± 3.72	81.42 ± 4.04	82.14 ± 4.79	83.39 ± 6.24	Group:P = 0.31 Time: P = 0.21 Mutual: P = 0.31
Intervention	Systolic blood pressure	133.9 ± 9.3	123.16 ± 12.6	120.8 ± 10.7	123 ± 10.79	Group:P < 0.001 Time:P = 0.02 Mutual: P < 0.001
	Diastolic blood pressure	85 ± 5.72	77.8 ± 8.77	76 ± 8.03	79.3 ± 7.5	Group: P = 0.03 Time: P < 0.001 Mutual: P = 0.51

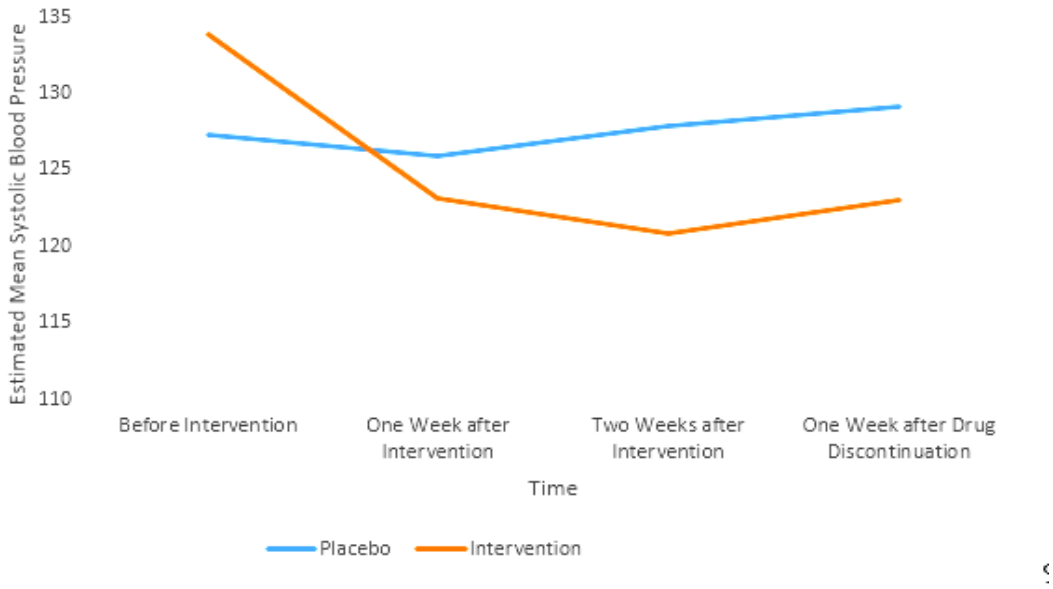

Figure 3. *Effect of time on estimated mean systolic blood pressure in intervention group and placebo group*

ANOVA showed no significant difference in this regard (Figure 3).

The results of repeated measures ANOVA indicated the significant effect of the lavender extract on the systolic and diastolic blood pressure of the patients in the intervention group ($p < 0.001$). Moreover, the time trend in the intervention group had significant effects on the systolic and diastolic blood pressure ($p < 0.001$ and $p = 0.025$, respectively). The interaction of time and group also had a significant effect on the diastolic blood pressure ($p < 0.001$) (Table 2), while no such effects were observed on the systolic blood pressure ($p = 0.51$) (Table 2).

DISCUSSION

According to the results of the present study, lavender extract could reduce systolic and diastolic blood pressure. Despite discontinuing the drug after one week, the diastolic blood pressure of the subjects did not return to the state before the consumption of lavender extract, whereas systolic blood pressure returned to the state before the administration of lavender extract.

We also used placebo in the current research, and the blood pressure of these subjects was monitored before use, one week and 14 days after use, and one week after stopping the placebo. According to the obtained results, placebo did not affect the blood pressure of the subjects. In this regard, in their study, Maisi et al. investigated the effects of lavender aromatherapy and classical music on pregnant women with hypertension, and their findings are in line with the present study (18). However, the mentioned study differed from the current research as Maisi et al. measured blood pressure on the same day before and after the intervention, and the long-term effects of the intervention could not be evaluated. In the present study, monitoring was performed one and two weeks after the intervention, and the long-term effects of lavender extract were determined. In addition, they evaluated the effects of aromatherapy with lavender on blood pressure, which is not comparable to the oral type.

In their research, Moradi et al. investigated the effects of lavender essential oil aromatherapy on the anxiety and vital signs of ischemic heart patients, and lavender scent was reported to decrease blood pressure and 'anxiety by affecting the patients' anxiety (17). In the mentioned study, aromatic lavender was compared with distilled water (odorless), and the patients with anxiety were considered, while the subjects were not assessed in non-stressful situations. Another aromatherapy study conducted by Ahmad et al. was focused on the academic stress and vital signs of pharmacy students, and aromatherapy with lavender oil was observed to reduce blood pressure by decreasing autonomic stimulation (19). Furthermore, the mentioned study was performed on young subjects without underlying diseases. The timing of the study varied depending on the time of the tests, and all the subjects were male, which im-

pairs the generalizability of the results. In addition, the blood pressure of the subjects was measured on the same day before and after the intervention, and the long-term effects of the intervention could not be evaluated. In the present study, the retirees were selected considering the possibility of underlying diseases, the duration of extract administration was well defined, and men and women were homogeneous in the two groups.

A study conducted by Salamati et al. investigated the anxiety and vital signs of patients after open heart surgery, and the obtained results indicated that lavender extract could reduce blood pressure in the subjects by decreasing sympathetic nerve activity (20). In the mentioned study, blood pressure inclusion criteria were higher than 100/60 mmHg, and the study had no control group. However, in the present study, only patients with prehypertension were evaluated in two groups of intervention and placebo (control). As can be seen, human studies have mostly used lavender scent and measured its effect on hypertension. The only similar study that used the oral type of this herbal medicine was performed by Abadi et al. aiming to assess the effects of lavender extract orally and intravenously on the blood pressure of rat species as an animal model. Consistent with our findings, they observed that lavender extract could lower blood pressure. In terms of the mechanism of hypotension, the mentioned study indicated that lavender extract could reduce blood pressure by decreasing the thickness of the media layer and cross-section of the aortic wall and increasing the thickness of elastic fibers (11).

Limitations of the study

Since the participants' blood pressure was measured in their homes and due to the relatively high incidence of covid-19 in Iran and the world, the cooperation level of the retirees was very low, and the researcher was not allowed to visit them for sampling. The researcher had to select the samples from the volunteers, but random allocation was used to place them in the groups. Another limitation of our study was subjects that were limited to retirees and might have affected the generalizations of the findings.

One of the strengths of our study was the measurement of blood pressure at the retirees' homes, which reduced the anxiety caused by relocation. Most of the studies in this regard have been focused on lavender aromatherapy, while the main consumption of herbs is oral, which was considered in our study.

CONCLUSION

According to the results, lavender extract was effective in prehypertension in the first and second week of the intervention. Despite drug discontinuation, diastolic blood pressure did not return to the state before receiving the lavender extract one week after stopping the medication. Since prehypertension control during retirement is paramount in the elderly, herbal medicines are used frequently for this purpose. Notably, lavender did not cause allergic reactions in our patients. Given the effects of lavender extract on prehypertension in this age group, it is recommended that lavender extract be used as a non-chemical option to control prehypertension. Since the placebo group in our study was not homogenized in terms of taste and smell, further investigations are recommended to assess the placebo group in terms of taste and smell. It is also suggested that the effectiveness of lavender aromatherapy be evaluated with its oral form.

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Conflict of Interest

Authors declare that there is no conflict of interest.

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Efekat oralne konzumacije ekstrakta lavande (Lavandula) na prehipertenziju kod penzionera smeštenih u gerontološkim centrima: randomizovana klinička studija

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S A Ž E T A K

Uvod/Ciljevi. Hipertenzija je čest poremećaj kod starije populacije koji se može sprečiti lekovitim biljem. Cilj ove studije bila je procena efekta ekstrakta lavande na prehipertenziju kod populacije penzionera.
Metode. Ova trostruko slepa klinička studija obuhvatila je 60 penzionera muškog i ženskog pola, koji su bili podeljeni u dve grupe, primenom tehnike permutovanog bloka: grupu koja je primala ekstrakt lavande i placebo grupu. Ekstrakt lavande (poreklom iz cveta biljke) i placebo primenjivani su dva puta dnevno (3 gr je ekvivalent 3 cc) u trajanju od dve nedelje. Krvni pritisak meren je pre primene, nedelju dana i dve nedelje nakon primene leka, kao i nedelju dana nakon prekida davanja leka, kako bi se procenila stabilnost efekata leka. Obrada podataka urađena je pomoću STATA softvera, verzija 14, a nivo značajnosti je postavljen na $p < 0,05$.
Rezultati. Pre intervencije, srednja vrednost sistolnog krvnog pritiska ispitanika iz grupe koja je primila ekstrakt lavande bila je 133,9 mmHg ± 9,3 mmHg, a iz placebo grupe 127,3 mmHg ± 6,3 mmHg. Nedelju dana nakon intervencije, srednje vrednosti krvnog pritiska ispitanika iz ovih grupa iznosile su 123,1 mmHg ± 12,6 mmHg i 125,8 mmHg ± 7,2 mmHg, a nakon dve nedelje 120,8 mmHg ± 10,7 mmHg i 127,9 mmHg ± 2 mmHg. Nedelju dana nakon prekida davanja leka, nivoi vrednosti krvnog pritiska ispitanika iz ovih grupa iznosili su 123,7 mmHg ± 10,7 mmHg i 129,2 mmHg ± 10,10 mmHg. Rezultati ponovljene ANOVA analize pokazali su da je ekstrakt lavande značajno uticao na vrednosti sistolnog i dijastolonog krvnog pritiska ispitanika iz interventne grupe ($p < 0,05$).
Zaključak. Prema dobijenim rezultatima, ekstrakt lavande bio je efikasan u kontroli prehipertenzije kod populacije penzionera.

Ključne reči: **lavanda, prehipertenzija, penzioneri, cvet, lekovita biljka**