Original Article

Lifestyle interventions for hypertension treatment among Iranian women in primary health-care settings: Results of a randomized controlled trial

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Background: Lifestyle factors such as weight, salt intake, and physical activity have shown to be important in treating hypertension. The object of this study was to describe feasibility and to assess the effectiveness of a multicomponent lifestyle intervention on high blood pressure (BP) of Iranian women. **Materials and Methods:** This randomized controlled trial was conducted in four health centers by recruiting 161 women aged 35-65 years with high BP and randomizing them to a 4-week lifestyle modification (n = 80) or control group (n = 81). BP level and other health behavioral factors were assessed before and after the 4-week intervention and also after 6 months. **Results:** The mean systolic BP changed from 158.8 (±8.1) mmHg to 153.2 (±6.4) mmHg during 4-week and to 145.5 (±4.6)) mmHg after 6 months in the intervention group ($P < 0.001$). There was a significant difference between two groups of study after 4-week mean = 5.6 (confidence interval [CI] = 5.1-6.6) and 6 months follow mean (CI = 12.3-14.6).($P < 0.001$) A significant correlation was detected between systolic BP (SBP) and diastolic BP (DBP) with weight, body mass index, waist circumference, salt intake, and physical activity level ($P < 0.001$). Stepwise regression analyses indicated that the weight, dietary salt intake, and physical activity level were significant predictors of SBP and DBP. **Conclusion:** The results of this study suggest that lifestyle modification program is associated with improvements in BP level in Iranian women.

Key words: Blood pressure, multicomponent lifestyle, primary health-care centers, physical activity

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INTRODUCTION

An annual consensus conference reviewing the world literature including the cochrane collaboration databases and JNC 7 program recommends lifestyle modification as a key strategy for prevention and treatment of hypertension (HTN).[1] Over 20% of Iranian adults are hypertensive. Recent studies suggest that approximately 23% of individuals aged 35-65 years in Isfahan have a high blood pressure (BP).[2,3] The risk of cardiac accidents and stroke mortality rise with increasing levels of BP. Preventing and controlling HTN was known as the one of the most cost-effective strategies for reducing the global burden of premature cardiovascular disease and death.[4] The goal of prevention and management of HTN is to reduce morbidity and mortality. This goal may be achieved by lifestyle modification, alone or with pharmacological therapy.[1] Reducing just 3 mmHg of systolic BP (SBP) in the general population has the potential to decrease stroke mortality by 8% and coronary artery disease mortality by 5%.[5] Studies have demonstrated a relation between high BP and lifestyle factors such as overweight, high salt intake, physical inactivity, and maladaptive coping with stress.[6,7] For as long as anyone can remember, lifestyle modification has been recommended in order to reduce BP.[8] In fact, if people decreased their sodium intake, exercised more, and kept their weight at an optimal level, HTN would have been less prevalent.[9] Countries differ in their ability to manage HTN and implement these interventions. According to World Health Organization (WHO), the most vital barriers for lifestyle modification programs in developing countries are low literacy levels and low income. WHO encourages countries to develop prevention programs based on their own resource and patients' education levels.[10] Iran conducted every 3 years Screening program for HTN in patients over 30 years in primary health-care setting. Sohrabi and Heydarnia (HM) in a study to evaluate national screening program reported follow-up activities for the known cases was low and unsatisfactory.[11] In Iran the Isfahan Healthy Heart Program (IHHP) showed after the comprehensive, integrated community-based lifestyle intervention program, beneficial changes were

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noted in diet and physical activity.[12] In fact, IHHP was targeting the general population and the environment. Jahromy *et al*. in a noncontrolled trial study reported lifestyle education, improve healthy lifestyle performance in hypertensive patients.[13] Science, the organizational structure, and human resources of health centers can be considered as an opportunity for lifestyle modification interventions. On the other hand, women are the major attendants to primary health centers and the myth that heart disease is a "man's disease" has been debunked. Hence, we designed a lifestyle intervention package including diet, physical activity, and stress management components in order to change the women's behavioral health with high BP attending the health-care centers in Isfahan, Iran. Present paper reported the effectiveness of a multicomponent lifestyle guidance on lowering BP in health center settings.

MATERIALS AND METHODS

Our study design and intervention methods have been completely described previously.[14] The study design, protocols, and informed consent procedure have been approved by the Medical Ethics Committee of Isfahan University of Medical Sciences (Ethical Number: 391298).

The lifestyle modification trial is a multi-center, randomized, controlled trial, designed to assess the effectiveness of a 4-week educational lifestyle intervention program on the improvement of dietary status, physical activity level, and control of daily stress in order to reduce BP levels in short- and long-term follow-up. The trial was endeavoring in four health-care centers in Isfahan, Iran.

Study population

According to the inclusion and exclusion criteria, a total number of 160 participants (80/group) was enrolled in the study. Eligibility criteria included hypertensive patients (taking anti-hypertensive drugs or having a SBP of 140-179 mmHg or a diastolic BP (DBP) of 90-109 mmHg), based on the average of two screening visits. Major exclusion criteria were any condition, which might have had a negative effect on the compliance of the participants, including a prior cardiovascular event, congestive heart failure, angina pectoris, cancer diagnosis or treatment in the past 2 years, diabetes, history of leisure-time exercise in the past 6 months, pregnancy, planned pregnancy, or lactation and being absent in two consecutive sessions of the classes.

Randomization

We selected intervention and control group from separate health centers in order to prevent contamination. According to the Isfahan province health center report, HTN screening program was conducted in only six of eleven health centers of Isfahan. Furthermore, two of the six health centers did not have enough hypertensive patients for our study (15 and 17). So, we selected the four remaining health centers and randomly assigned two centers to intervention and two centers to control group. The centers are located in different zones of the city, and we will try to control the socioeconomic state as a confounder in the statistical analysis.

Sample size and power

The power calculations were based on 5.32 mmHg[8] standard deviation (SD) of the change in the major primary outcome SBP between the intervention and control groups with $\alpha = 0.05$ and $\beta = 20\%$. The calculations yielded 160 subjects for the study (80 subjects/group).

Blinding

All physical examinations were assessed by nurses unaware of group allocation. We could not blind participants to the intervention, but we asked them not to reveal the information about their intervention to the nurses.

Baseline assessment

In order to reduce possible observer bias, all physical examinations were performed by a trained nurse, who rotated between the health-care centers. The average of the two values was considered as the baseline for BP. The anthropometric measurement and demographic data were administered by a trained nurse. All measurements and also filling the questionnaires were repeated right after intervention and 6 months after the intervention.

Instruments

To assess the physical activity level, we used the long forms of the Persian version of the International Physical Activity Questionnaire (IPAQ). The questionnaire, which has been developed by WHO, is composed of 28 questions about physical activity in a typical week and assesses the physical activity in four domains, namely, work (7 items), transportation (6 items), household/gardening (6 items), and leisure-time activities (6 items). IPAQ also includes two questions about the time spent on sitting as an indicator of sedentary behavior. In order to measure energy expenditure, the concept of metabolic equivalents (MET) was used. MET is the ratio of a person's working metabolic rate relative to the resting metabolic rate.[15] Reliability and validity for the Persian version of the long form IPAQ were acceptable.[16]

The stress level of the participants was assessed by a Persian translation of the 14 Likert-type items Cohen perceived stress scale (PSS; Cohen *et al*. 1983)[17] in the past month. Items are rated on a 5-point Likert scale ranging from 0 (never) to 4 (very often). Total scores (0-56) are generated by summing individual items, with higher scores indicative of greater perceived stress. A group of Iranian scholars and experts approved the content and face validity of the translated scales. The Cronbach's alpha was 0.78-0.81.[18]

To measure dietary intake, all participants completed a self-report 3 days food record questionnaire. The questionnaire was completed over 2-week days and 1-week end day. Daily nutrients obtained from the N4 software, a software for analyzing food that is compatible for Iranian food) (Nutritionist: version 4.0; Tinuviel Software, Warrington, United Kingdom were fats and oils, protein, complex carbohydrates, simple carbohydrates, cholesterol, sugar, salt, and water.[19]

Content of the intervention program

The intervention was provided over the course of four sessions weekly. Each session had a theme incorporating the specific domains of a lifestyle modification program concluded with a 15 to 20-min guided relaxation. Participants received written manual and a CD-ROM containing PowerPoint slides (Microsoft office 2007) in movie format covered in each of the four sessions for their review and relaxation music for home practice. Nurses working in these health centers were trained about lifestyle modification package by the researcher. They handled the classes.

All recommendations were based on The seventh report of the joint national committee on prevention, detection, evaluation, and treatment of high BP (JNC 7).[1] Dietary guidelines are based on dietary approaches to stop hypertension (DASH) dietary plan with a little modification for Iranian patients.[20] The physical activity instructions were in accordance with The American Heart Association guideline for adults.[21] For stress management, we followed the Breathing awareness meditation and progressive muscle relaxation method.[22,23] The structure and content of the educational package have been approved by a group of experts.

- Session 1: Defining the course and introduction; the nature and etiology of HTN, its epidemiology and the potential for prevention, and reversal of HTN and its complications through better lifestyle behaviors in the areas of smoking, sedentary living, diet, and stress management were described. Teaching relaxation and meditation by a qualified mentor were implemented. The patients were encouraged to practice this technique individually at home twice a day and were given a video-CD for guidance. Patients were requested to watch videos with their family once a week and present their ideas in the class every week. Furthermore, subjects were prescribed to write their experiences about healthy cooking for the next session.
- Session 2: This session focused on the food pyramid and optimal diet based on DASH, Also information about the role of different dietary components and also weight control on HTN were provided. Patients discussed about their practice in healthy cooking. The relaxation technique session was repeated.
- Session 3: In this session, the effects of physical activity on the cardiovascular system were explained, and aerobic exercises and several techniques for decreasing knee and back pain were taught. Patients talked about their barriers to achieve optimal physical activity levels and discussed the ways to overcome them.
- Session 4: On this session, identifying the symptoms of stress and the ways to cope with it was the main discussion. Furthermore, the effects of stress on BP were explained. We asked the participants to explore their negative and positive feelings when they encountered problems or in stressful situations. At the end of the session, the relaxation practice was repeated.

Health text messages

All intervention participants were requested to deliver their mobile phone number or their family member's to facilitate communication. The intervention group received a text message (short message service) weekly to remind and motivate them about the topics discussed in the previous sessions throughout the follow-up periods.

Follow-up protocol

For both intervention and control group, all physical examinations and other assessments were repeated after the intervention as well as 6 months after the baseline.

Usual program for control group

In primary health-care settings, all people over 30 years of age are screened for HTN every 3 years. Patients with high BP are visited by a physician working in rural primary care settings every 3 months but in urban primary care settings (health-care centers), patient treatment and management are passive. In fact, to the best our knowledge, there is no defined intervention strategy for the hypertensive patients in these settings.[11,24]

Analysis

Analyses were performed to estimate the effect of the intervention on four domains: Mean change of BP level after intervention and follow-up period, physical activity levels, diet composition, perceived stress levels. Intention-to-treat method was used for statistical analysis. The scale scores of the IPAQ and perceive stress were computed based on the scoring manuals.[15,25]

Two-sample *t*-tests were used for the comparison of continuous variables. BP, physical activity level, dietary composition, and stress scale in each group before and after study were compared using Paired *t*-test and for 6 months follow-up by repeated measure ANOVA. We used mixed-model ANOVA for comparison between intervention and control group. All comparisons were carried out on a two-tailed basis.

The Pearson correlation analyses were used to study the bivariate relationships between lifestyle modification components and change in SBP and DBP. To determine the effective components of the intervention, we performed stepwise regression analyses.

We tried to control the effect of drugs and different teachers on BP using the analysis of covariance model.

RESULTS

Of the 187 possible participants, 179 patients acquired the inclusion criteria and were enrolled in the study. Eleven patients were excluded due to diabetes ($n = 6$), recent unstable angina ($n = 1$), foot fracture ($n = 1$), and low back pain ($n = 3$). Seven patients refused to participate because of their lack of interest in the research participation ($n = 2$), being responsible for their grandchild care ($n = 3$) and a long travel distance to the education center ($n = 2$). Overall, 161 patients (80 in the intervention and 81 in the control group) attended four educational sessions and completed before and after data sets.

A summary of behavior and health variables at baseline is presented in Table 1. The mean age was 55 ± 4.8 years for the intervention and 54 ± 4.9 for the control group. Almost all of them were married (98%) and housewives (96%). Most intervention patients took various anti-hypertensive drugs (96.5%), and the rest of the patients (3.5%) had been previously prescribed anti-hypertensive drug but they did not take the medicine. The mean level of BP was significantly different in those who took a different type of medications. None of them were smokers, but 30% were passive smokers. There was no significant difference in distribution of demographic and clinical characteristics between intervention and control groups. There were no statistically significant differences in demographic variables between the women who excluded and those who refused to participate ($P > 0.05$).

The mean changes of SBP and DBP from baseline to after the intervention and 6 months follow-up are presented in Table 2. After the 4-week program and 6 months follow-up, participants had significant changes in their behavior and health factors levels [Table 3]. The reductions in systolic and DBP, weight, waist circumference, body mass index (BMI), energy, NaCl, and PSS were significant ($P < 0.001$). After 4-week, the mean physical activity level increased from 405 (MET) min/week (SD = ±30.8) to 667 MET (SD = ±77.9), after 6 months reached 708 MET (SD = 60) in the intervention group ($P < 0.001$). The mean changes of systolic and DBP based on a different kind of antihypertensive drugs showed the same statistical result. The mean changes of health and behavior factors were not significantly different between the two health centers that were in the intervention group.

There was a significant difference between two groups of study at the end of the intervention as well as 6 months ($P < 0.001$). There was no statistically significant improvement in all health and behavioral factors after 4-week and follow-up period in the control group.

Repeated measures analysis of variance indicated a significant time effect ($P < 0.001$) and mixed model of

Table 1: Demographic and clinical characteristics of the study[a]

Variables	Intervention group ($n = 80$)	Control group ($n = 81$)	*P*
Age (year)	55.2 (4.8)	54.1 (4.9)	0.612
Education (year completed)	8.2 (2.4)	8.5 (2.9)	0.437
Pharmacological treatment %	96.5	95	0.212
SBP (mmHg)	158.8 (8.1)	157.3 (7.7)	0.521
DBP (mmHg)	100 (4.2)	100 (4.7)	0.512
Weight (kg)	87.7 (13.2)	87.5 (14.2)	0.921
BMI (kg/m^2)	31.4 (4.1)	30.2 (3.5)	0.743
Circumference of waist (cm)	100 (8.1)	100 (9)	0.845
Physical activity<half an hour/day %	100	100	0.837
Dietary salt intake (g)	10 (0.6)	10 (0.2)	0.561
Smoking %	9.2	8.9	0.737
Perceived stress scale	26.5 (2.3)	26.1 (2.1)	0.836
Energy (kcal)	2200 (303)	2180 (317)	0.461

[a]Data are presented as mean (SD) or percentage; SD = Standard deviation; SBP = Systolic blood pressure; DBP = Diastolic blood pressure

Table 2: BP (mmHg) changes in the intervention and control groups during the follow-up of 4-week and 6 months

Variables	4-week	6 month	4-week	6 months
	Mean change (SD)	Mean change (SD)	Mean change between intervention and control (CI)	
SBP				
Intervention	5.6 (2.9)***	13.2 (4.9)***	5.8 (5.1-6.6)***	13.4 (12.3-14.6)***
Control	0.2 (1.5)	0.2 (1.5)		
DBP				
Intervention	4.07 (2.1)***	9.8 (3.1)***	4.1 (3.6-4.6)***	9.8 (9.1-10.5)***
Control	0.05 (0.2)	0.02 (0.3)		

****P* < 0.001; CI = Confidence interval; BP = Blood pressure; SD = Standard deviation; SBP = Systolic blood pressure; DBP = Diastolic blood pressure repeated measures analysis showed the time effect for SBP and DBP were significantly influenced by intervention status ($P < 0.001$). Analysis of covariance showed that the time effect of SBP and DBP was not significantly associated with age, exposure to tobacco, and different type of antihypertensive medication [Figure 1].

Bivariate correlation was determined between the outcome measures. There was a significant positive correlation between SBP and DBP with weight ($r = 0.58$, $P = 0.000$), waist ($r = 0.47$, $P = 0.000$), BMI ($r = 0.5$, $P = 0.001$) right after intervention. Similarly, a positive correlation between SBP and DBP with weight ($r = 0.55$, $P = 0.001$, waist circumference ($r = 0.53$, $P = 0.001$), BMI and NaCl ($r = 0.5$, $P = 0.001$) intake were observed within 6 months. We detect a negative correlation between SBP and DBP with physical activity level ($r = -0.6$, $P = 0.001$). Furthermore, there was no significant correlation between study outcome with perceived stress level.

Stepwise regression was used with change in SBP through 4-week as the dependent variable and intervention status

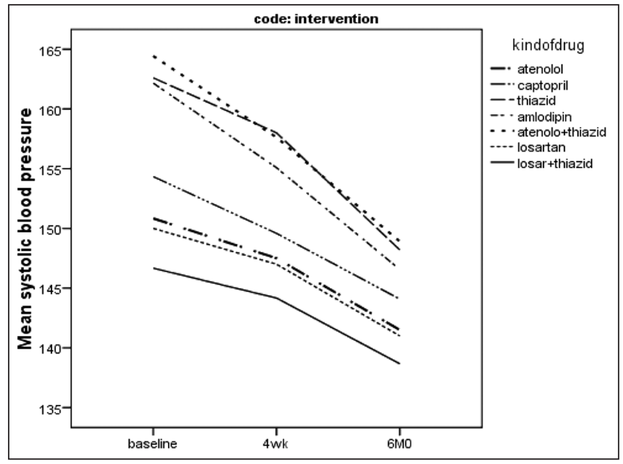

Figure 1: Mean baseline and after 4-week and 6 months follow-up by different kind of drug

Table 3: Changes in cardiovascular risk factors during the follow-up of 1-month and 6 months

Variables	1-month	6 months	1-month	6 months
	Mean change (SD)	Mean change (SD), *P*	Mean change between intervention and control (CI), *P*	
Weight (kg)				
Intervention	2.5 (0.9)***	6.4 (2.3)***	2.5 (2.3-2.8)***	6.5 (5.9-7)***
Control	0.03 (0.7)	0.03 (0.7)		
BMI (kg/m²)				
Intervention	0.9 (0.3)***	2.3 (0.7)***	0.9 (0.8-0.1)***	2.3 (2.1-2.5)***
Control	0.01 (0.2)	0.01 (0.2)		
Circumference of waist (cm)				
Intervention	5.5 (4.7)***	7.3 (4.7)***	5 (4-6)***	7.3 (6.3-8.4)***
Control	0.02 (0.7)	0.03 (0.2)		
Physical activity				
Intervention	262 (87)***	303 (65)***	260 (242-277)***	299 (284-314)***
Control	2.1 (9)	3.3 (16)		
Perceived stress scale				
Intervention	4.5 (1.3)***	1.2 (1.9)	4.3 (4.3-5.1)***	1.1 (0.6-1)
Control	0.2 (1)	0.07 (0.5)		
Energy				
Intervention	438 (198)***	683 (270)***	464 (418-510)***	610 (529-690)***
Control	152 (46)	73 (24)		
Salt				
Intervention	1.3 (0.9)***	2.5 (1)***	1.3 (1.1-1.5)***	2.5 (2.2-2.7)***
Control	0.01 (0.2)	0.03 (0.2)		

***$P < 0.001$; SD = Standard deviation; BMI = Body mass index; CI = Confidence interval

Table 4: Significant predictor of SBP and DBP during the follow-up of 1-month and 6 months*

Month	Dependent variable	Model	Standardized beta	*P*	Standard error of the estimate	R^2 %
>1-month	SBP	Weight	0.5	<0.001	0.03	40
		Physical activity	−0.2	<0.001	0.003	
	DBP	Weight	0.5	<0.001	0.02	51
		Physical activity	−0.46	<0.001	0.002	
>6 months	SBP	Weight	0.8	<0.001	0.03	34
		NaCl	1.2	<0.001	0.01	
	DBP	Weight	1.1	<0.001	0.02	39
		NaCl	0.8	<0.001	0.003	

*Stepwise regression; SBP = Systolic blood pressure; DBP = Diastolic blood pressure and change scores through 4-week in BMI, waist, physical activity, PSS, salt, as the independent variables [Table 4]. The best fitting model indicated that 42% of the variation in change in SBP was explained by change in weight (b = 0.5, P = 0.001) and physical activity (b = −0.2, P = 0.001) and 41% of the variation in change in DBP was explained by change in weight (b = 0.5, P = 0.001) and physical activity (b = −0.46, P = 0.001). Using stepwise regression with the same variables, but reflecting change scores through 6 months, 34% of the variation in change in SBP was explained by the change in salt (b = 1.2, P = 0.001) and weight (b = 0.8, P = 0.001) and 39% of the variation in change in DBP was explained by change in weight (b = 1.1, P = 0.001) and salt (b = 0.8, P = 0.001).

DISCUSSION

The primary aim of this study was to evaluate the effectiveness and feasibility of the lifestyle modification at lowering BP in Iranian women in health center settings. The lifestyle intervention based on group sessions achieved a positive effect on BP in hypertensive women similar to several other intense multimodality lifestyle programs.[26] Descriptive results of this study indicated that the studied population had high BP in spite of using medication. Evidence showed that drug therapy effectively controls BP in only about 50% of those treated as also it has been confirmed that the patient's compliance are usually <90%.[27,28]

In our study after 4-week of intervention prominent changes in SBP and DBP as well as changes in all behavior factor influencing BP was detected, and this difference was statistically significant between the intervention and control group. Participants in the intervention group had weight loss, reduced dietary sodium intake, and also increased physical activity level during the 6 months follow-up. According to evidence it has been previously mentioned that lifestyle intervention programs have successfully lowered BP level through weight loss, decreasing salt intake and increasing physical activity.[5,23] In fact, programs that combine lifestyle intervention with medical therapy are shown to be successful. Englert *et al*. in a community-based risk reduction program (CHIP) reported significant improvement in total cholesterol, low-density lipoprotein (LDL), triglycerides (TG), blood glucose, BP, and weight loss.[29]

According to our results approximately weight reduction of 6.5 kg was observed from baseline to 6 months follow-up in the intervention group Similarly, modest reductions in dietary salt intake were achieved from relatively high baseline levels of 10.8 g to 8,7 g through 4-week and 7.5 g through 6 months. Premier collaborative research group in a comprehensive lifestyle modification program reported over 18 months, persons with pre-HTN and stage 1 HTN can decrease body weight, salt intake.[8]

At baseline, almost all of studied population reported low levels (<600 m) of physical activity. 86% of the participants in the intervention group made good progress toward moderate (600-1500 m) physical activity within 30 days and similarly 94% of interventions achieved moderate physical activity through 6 months.

Our study reported a significant reduction in perceived stress level (26.5-21) in interventions after 4-week (P < 0.001) but failed to show a significant decrease during 6 months.

This result can suggest the necessity of implementing group based relaxation practice. Several trial demonstrated the feasibility and short-term efficacy of using selected stress-reduction approaches on reducing perceived stress but further research is essential to determine whether the observed treatment effect can be sustained over a longer period.[30,31] Another explanation is the benefits of social interaction, positive reinforcement, and positive peer group effect were helpful on stress changes during 4-week. Furthermore, a systematic review suggested stress, anxiety, and depression were most commonly barriers that delayed adoption of a healthier lifestyle.[32]

Repeated measures analysis showed that the intervention significantly lowered SBP and DBP through 4-week and 6 months of follow-up. In addition, the intervention significantly improved physical activity level, BMI, perceived stress level, and dietary sodium intake within 4-week and 6 months of follow-up. Previous researches have found that multiple lifestyle modifications could improve the control of BP and reduce the risk for chronic diseases.[4,8]

The mean level of SBP and DBP at baseline was significantly different in various groups of BP-lowering medications. After adjusting for this confounder, repeated measure of analysis indicated that the mean change in BP was not significantly different between various groups medications.

Systolic blood pressure and DBP were moderately correlated with all lifestyle factors such as weight and waist circumference, physical activity level, NaCl intake. Although BP and lifestyle factor were significantly correlated, the stepwise regression analysis showed that change in weight and physical activity level can predict the change in SBP level within 4-week and similarly, dietary salt intake, and weight loss were the best predictor factors for SBP level after 6 months.

The result of the stepwise regression showed that, SBP was decreased by 0.5 mmHg for 1 kg decrease in weight and 0.2 mmHg for every unit increase in physical activity level through 4-week. SBP can be predicted by 1.2 mmHg for 1 g decrease in dietary salt intake and 0.8 mmHg for 1 kg decrease in body weight. Based on a long experience, there is empirical evidence for the moderate relationship between BP with lifestyle changes, like weight reduction if appropriate, sodium restriction and exercise.[9,27,33] According to the seventh report of the joint national committee on prevention, detection, evaluation, and treatment of high BP (JNC 7),[1] each 10 kg weight loss resulted 5-20 mmHg, Engage in at least 30 min/day, most days of the week showed 4-9 mmHg decrease, and reduce dietary sodium intake to 6 g NaCl due to 2-8 mmHg.

As we mentioned before, we conducted intervention by two different educators (members of the health centers) at two health center, we detected the same result for both centers. So, we can say implementing such programs at these settings could be feasible.

Another characteristic of our study was the usage mobile phone text messages in order to increase the patients' adherence to weekly sessions and also lifestyle changes. BJ Fogg, PhD, Director of the Stanford Persuasive Technology Laboratory (Stanford, CA), that sponsored a conference called mobile persuasion suggested the use of mobile technology in order to change patient's attitudes and behaviors.[34]

We tried to present educational content by picture, graph, and flowchart in order to being suitable for lower literacy and elderly patients. Our educational materials were full of simple and cheap ways for changing diet and practical recommendation for doing regular exercise at home. Remo Ostini and Kairuz suggested "a possible U-shaped relationship between nonadherence and health literacy where people with low health literacy are more often nonadherent, largely unintentionally."[35,36]

Our study, also implicated some limitations that should be considered. This study had a small sample size, which reduced the statistical power. Another limitation of this study was self-reported food record questionnaires. For this reason, participants were interested in reporting less dietary intake especially salt and oil intake. To better estimate measuring blood sample for fasting blood sugar, TG, LDL, and urinary Na suggested.

CONCLUSION

However as few studies have addressed the effectiveness of lifestyle modification program on BP control in Iranian women in primary health setting. The results of this randomized controlled trial study show that multimodality lifestyle modification can improve BP control in primary care settings in a developing country like Iran. Decreased body weight and sodium intake and also increased physical activity level over the study period was directly associated with a decrease in BP level. Hence, targeted interventions and incorporate lifestyle modifications in addition to pharmacological treatment should be considered in the care of women with high BP in primary care settings in developing countries.

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AUTHOR'S CONTRIBUTION

TH was the main investigator, who analyzed the data and wrote the paper. ZDS contributed to the study design, data analysis, and writing of the paper. ZF helped in designing the study, contributed to the analysis, and helped in writing the final paper. ZP contributed to the dietary plan and dietary data analysis. FR helped in data analyzing and writing the paper. All authors read and approved the final version of the paper.

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