

# Effects of multicomponent lifestyle modification on blood pressure control in health centers: Design of the study

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**Background:** Designing an intervention based on healthcare settings resources and patient acceptability is potentially important in the prevention of high blood pressure (BP) and other risk factors of cardiovascular disease. To explain a multicenter randomized controlled trial that is designed to examine the effects of the multicomponent lifestyle modification program on BP. **Materials and Methods:** The effectiveness of the lifestyle modification program versus usual care in health-care centers is evaluated in a randomized controlled trial. Patients aged 30 years or older having a systolic blood pressure (SBP) of 140-179 mmHg or a diastolic blood pressure (DBP) of 90-109 mmHg or patients taking antihypertensive medications are eligible for the study. The primary outcomes measured are SBP and DBP levels. Mediator outcomes include physical activity level, stress scale, dietary composition, and weight measurements. All measurements will be conducted after the 4 weeks of intervention and also at 6 months. **Conclusion:** Outcomes of the study will present the effects of implementing multicomponent lifestyle intervention programs to control BP in health-care centers settings.

**Key words:** Health-care center, hypertension, lifestyle modification, prevention, physical activity

## INTRODUCTION

The importance of high blood pressure (BP) as a risk factor for coronary heart disease and stroke has been established in many epidemiological studies. Adverse complications of hypertension can be prevented by detecting and treating this condition appropriately.<sup>[1-3]</sup> There are credible data about the relation between high BP and lifestyle factors such as overweight, high salt intake, and physical inactivity.<sup>[4]</sup> Studies have confirmed a decrease in BP when sodium intake is reduced.<sup>[5]</sup> Physical activity has produced positive long-term effects on BP.<sup>[6,7]</sup> Many clinical trials showed that weight loss caused BP reduction and improved antihypertensive effects of medication.<sup>[4]</sup> Studies demonstrated that stress has been related to greater cardiovascular risk, and stress management is a recommended intervention for patients with high BP. Stress management through relaxation techniques has been shown to have an effect on human physiology, including lowering BP.<sup>[8,9]</sup>

The epidemic of sedentary lifestyle and poor eating behavior, with associated high BP and cardiovascular disease, has challenged researchers to develop new strategies aimed at preventing these health problems.<sup>[10-12]</sup> However, the implementation of lifestyle intervention in real-world settings has proven to be a challenge in communities with limited resources. Countries differ

widely in their ability to manage hypertension and world-wide the majority of diagnosed hypertensive patients are poorly controlled.<sup>[3,12,13]</sup> Carefully, planned community based demonstration programs form an important effort in order to solve this problem.<sup>[14]</sup>

According to the health ministry report, the prevalence of hypertension is more than 20% in Iranian adults and in Isfahan approximately 23% of adults (35-65 years old) are affected with a high BP.<sup>[15,16]</sup> BP screening program has been conducted every 3 years for adults 30 years and older in primary health-care setting in Iran. However, the evaluation of the follow-up activities for the known cases was low and unsatisfactory.<sup>[17]</sup>

World health organization (WHO) suggested that the most important barriers for lifestyle modification programs in developing countries are low literacy levels and low income. WHO recommends that these interventions should be community based and appropriate to the culture, income and literacy level.<sup>[4]</sup> Providing suitable environments for changing behavior and involving the family members and also empowering individuals to select healthy behaviors are key issues in designing health programs.<sup>[18-20]</sup>

We designed a lifestyle training package including diet, physical activity and stress management

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components to target the patients with high BP attending the health-care centers of Isfahan. The present paper reports the methodological design of the lifestyle modification study as well as the content of the intervention program.

## MATERIALS AND METHODS

### Study design

The lifestyle modification trial is a multi-center, double-blind, randomized, controlled trial, designed to evaluate the effectiveness of a 4 week lifestyle intervention program on improvement of dietary status, physical activity level and control of daily stress in order to reduce BP levels in short- and long-term follows-up. The Medical Ethics Committee of Isfahan University of Medical Sciences has approved the study design, protocols and informed consent procedure (Ethical Number: 391298).

This trial will be carried out in four health-care centers in Isfahan, Iran. A total of 160 participants (80/group) will be enrolled in the study after being selected according to inclusion and exclusion criteria. Written consent will be obtained from all of the participants. The health centers will be assigned randomly to two intervention and control groups. For baseline measurements, all participants will undergo the first screening program for modifiable risk factors, such as BP, weight, body mass index (BMI), waist and hip circumference stress level, dietary, exercise status and also smoking. Lifestyle intervention program with main focus on diet, physical activity, and stress management will be held on 4 weekly sessions for intervention groups by trained nurses. Participants in the intervention group will receive one text message per week for the 5 months follow-up period. The second screening will be conducted right after the completion of the 4 week intervention program. Measurements will be repeated after 6 months post-baseline for long-term follow-up. The control group will be screened the same way.

### Study population

Subjects participating in the study are recruited by nurses who are working in the health centers. From the available list of hypertensive patients who were screened in the national screening program, nurses ask patients to participate in the program by telephone call. They describe the study for the patients. After having agreed to participate, patients are informed about the date and place of the sessions. Subsequently nurses again call the interested patients to remind them of the date of the introduction session. During the session, subjects are selected based on the inclusion/exclusion criteria. Individuals aged 30 years or over will be eligible for enrollment in the study, if their screening systolic blood pressure (SBP) is 140-179 mmHg or if their diastolic blood pressure (DBP) is 90-109 mmHg or

if they are taking antihypertensive medications. Exclusion criteria are any diagnosed disease or condition, which might have a negative influence on the well-being of the individuals or their compliance during the intervention and follow-up, including a prior cardiovascular event in the past years, congestive heart failure, angina, 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.<sup>[1,21]</sup>

### Randomization

We selected intervention and control group from separate health centers in order to prevent contamination. According to the Isfahan province health center report, hypertension screening program was conducted in only six of eleven health centers of Isfahan. Furthermore, two of the six health centers didn't 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 sample size of the trial was based on the primary outcome, namely, systolic BP at 6 months. We estimated that the standard deviation of the change in SBP would be 5.32 mm Hg<sup>[3]</sup> providing 80% power with  $\alpha = 0.05$  for a sample size of 140 participants (70/group) to detect pairwise between-group differences in SBP 2.5 mm Hg in the entire sample. To increase the power of the study, we considered 10% attrition rate. The final sample size was estimated 160 participants (80/group).

### Blinding

All anthropometric measurements will be assessed by examiners unaware of group allocation. Participants cannot be blinded to the intervention, but are asked not to reveal the information about their intervention to the examiners. The key of coding concerning group assignment is only known by the programmer of the database that is used during the study.

### Baseline assessment

The assessments are performed by a specially trained nurse, who rotates between the health-care centers in order to eliminate possible observer bias.

BP measurements are performed by standard mercury sphygmomanometer. BP is measured twice from the right arm with appropriate-sized cuff in the sitting position after 5 min of rest. The average of these two values is used as the base BP.

Weight, height and BMI: Subjects are weighed without shoes and heavy clothing. Height is measured without shoes. BMI is calculated from the measured weight and height as  $\text{kg}/\text{m}^2$ . Waist and hip circumference will be measured with a metric tape. The waist circumference is measured from the midway between the inferior margin of the last rib and the crest of Ilium. The hip circumference is measured from the maximum extension of the buttocks.

### Questionnaires

The participants will fill out several questionnaires. This includes (1) international physical activity questionnaire (IPAQ) (2) 3 days food record (3) perceived stress. A personal interview helps to collect reasonably good data on the levels of stress, physical activity, and diet. The nurses will ask subjects about medical history and medications used (participants have to present their medicines).

Physical activity level is assessed using long forms of the IPAQ with physical activity level categorized as low, moderate, and vigorous levels on the basis of the IPAQ guidelines for data processing and analysis. This 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). The questionnaire also includes two questions about the time spent on sitting as an indicator of sedentary behavior. It also determines the intensity of activity (i.e., vigorous or moderate) in each domain as well as the time spent on sedentary behaviors such as watching TV. Sedentary behavior was defined as activities such as sitting at a desk, traveling in car/bus/train, and reading, working with computer, and watching television. In order to measure energy expenditure, the concept of metabolic equivalents (MET) is used. MET is the ratio of a person's working metabolic rate relative to the resting metabolic rate. One MET is defined as the energy cost of sitting quietly, and is equivalent to a calorie consumption of 1 kcal/kg/h. The IPAQ collects separate frequency and duration data for walking, vigorous-and moderate-intensity physical activities. Weighted MET minutes per week (MET min per week) are calculated as duration  $\times$  frequency/week  $\times$  MET intensity for each activity type (four METs for moderate activity and walking and eight METs for vigorous activity). MET min/week data from each activity category will then be summed up to produce an overall estimate of total physical activity.<sup>[22]</sup> The Persian version of the long form IPAQ has an acceptable reliability and validity.<sup>[23]</sup> In the first session, all questions will be completely explained to the participants and then the patients will be asked to complete the IPAQ form according to their physical activity levels in a typical week.

### 3-day food diary

To measure, dietary intake all participants complete a self report questionnaire before participating in the program (baseline) and at the end of 4 week intervention as well as after 6 months post-baseline. Respondents will be requested to complete the diary over 2 weekdays and 1 weekend day. Daily nutrients from food, obtained from the N4 software are fats and oils, protein, complex carbohydrates, simple carbohydrates, cholesterol, sugar, salt, and water.<sup>[24]</sup>

### Perceived stress questionnaire

Perceived stress will be assessed with a Persian translation of the Cohen perceived stress scale. The scale measures perceived stress over a 4-week period and consists of 14 Likert-type items, scored on a 5-point scale, ranging from never (0) to very often (4) a group of Iranian scholars and experts assessed content and face validity of the translated scales to detect any unclear, confusing, or highly sensitive questions. In several studies, internal consistency of the translated and revised scales is assessed. The Cronbach's alpha is 0.78-0.81.<sup>[25,26]</sup>

### Content of the intervention program

Our lifestyle intervention is based on group sessions in health-care center settings. The intervention curriculum includes the following topics: epidemiology and complications of hypertension, atherosclerosis, coronary risk factors, smoking, exercise, dietary fiber, fat and cholesterol, the optimal diet, overweight, hypertension, hyperlipidemia, lifestyle and health, behavioral change, and stress management. We developed two separate guidebooks for patients and educators. In addition to written material, we converted our power point presentation into a video CD format so that the patients could watch the educational movie with their families.

All recommendations are based on The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7).<sup>[27]</sup> Dietary guidelines are based on Dietary Approaches to Stop Hypertension (DASH) dietary plan with a little modification for Iranian patients.<sup>[28]</sup> The physical activity instructions are in accordance with the American College of Sports Medicine and The American Heart Association guideline for adults, An European Framework to Promote Physical Activity for Health and Be Active Program (Australian guideline).<sup>[29,30]</sup> For stress management, we followed the Breathing awareness meditation and Progressive Muscle Relaxation method.<sup>[31-33]</sup>

The structure and content of the educational package have been approved by a cardiologist, a dietitian, a physiotherapist, a psychologist, and a community medicine

specialist. The intervention program consists of 4 weekly sessions (2 h). Nurses who work in these health centers are trained about lifestyle modification package by the researcher. They will handle the classes. All participants will receive guided booklet with a video CD with main focus on diet, exercise and stress management for patients with high BP and one relaxation music CD.

The first session is about developing an intelligent self-care in patients involving a clearer understanding of the nature and etiology of hypertension, its epidemiology and the potential for prevention, and reversal of hypertension and its complications through better lifestyle choices in the areas of smoking, sedentary living, diet, and stress management. At the end of the first session, the relaxation technique will be implemented. All subjects will be asked to practice the relaxation technique once a day for 15 min while sitting comfortably with eyes closed. For the next session, intervention subjects should write their experiences about healthy cooking. Patients will be requested to watch educational videos with their family once a week and present their ideas in the class every week.

Second session: The trained nurses' talk about the food pyramid and optimal diet based on DASH diet. Information about the role of different dietary components such as salt, fat, and fiber and also weight control on hypertension will be provided. The consumption of grains, legumes, vegetables, fresh fruits, complex carbohydrates will be encouraged. Participants discuss about healthy cooking and the relaxation technique will be repeated.

Third session: Information about the effects of physical activity on cardiovascular system and also recommendations for enhancement of cardiovascular fitness are provided. The nurses train the participants with a variety of aerobic exercises. Participants speak about their barriers to achieve recommended physical activity levels and discuss the ways to overcome these barriers. Several techniques for decreasing knee and back pain will be taught. Teaching relaxation techniques follow exercise sessions.

Fourth session: In the last session, trained nurses talk about identifying the symptoms of stress and the ways to cope with it. They also discuss the effect of stress on BP. The relaxation technique involves having the individuals sitting upright in a comfortable position with eyes closed. Then, they are instructed to focus on the movements of their diaphragm while breathing in a slow, deep, and relaxed manner.

#### Health text messages

During the follow-up periods, the subjects receive one text message per week to remind and motivate them about the topics discussed during the course.

#### Follow-up protocol

The follow-up assessment is taking place right after the intervention as well as 6 months after baseline and includes the same measurements as those performed at baseline. The follow-up protocol for control group is the same.

#### Usual care for control group

In the national screening program for diabetes and hypertension, all people aged 30 or older are screened for hypertension every 3 years. Patients with high BP are visited by physician in rural primary care settings every 3 months but in urban primary care settings (health-care centers) there is no defined intervention strategy for these detected patients. In fact, the health service delivery systems in health-care centers is passive.<sup>[17,34]</sup>

#### Statistical analyses

Analyses will be performed to estimate the effect of the intervention on four domains (1) mean change of BP level after intervention and follow-up period, (2) physical activity levels, (3) diet composition (4) perceived stress levels.

Primary analysis will be performed according to the intent-to-treat method. Statistical comparison of continuous variables (BP, physical activity level, dietary composition, and stress scale) in each group will be carried out by using paired *t*-test for before and after intervention and for follow-up period by repeated measure ANOVA. Statistical analysis between intervention and control group will be performed by mixed model ANOVA.

The linear regression model will be employed to assess the effects of a lifestyle modification program on change in SBP and DBP from baseline to 6 months post-randomization. To examine, which factor of lifestyle intervention (exercise, diet, stress management, and message) may have contributed to the improvements in BP, hierarchical regression analyses will be performed. We control the effects of drugs on BP with analysis of covariance model. As the interventions are conducted in two separate health centers by different teachers, we also compare two sets of results by *t*-test analysis. All analyses are performed using SPSS version 20.

## DISCUSSION

The lifestyle modification intervention program is designed to fill the gaps that currently exist for primary health-care settings in order to provide appropriate guidance for health workers and high BP patients. As we mentioned above, according to the WHO report, designing programs appropriate for lower literacy and income levels is a critical factor. Because of its simplicity and its graph and pictures, the lifestyle modification package is expected to be a useful tool.<sup>[9,35]</sup> We also will present helpful, simple and cheap

ways for changing diet. Furthermore, our package contains practical recommendations for exercise at home.

Furthermore, the educational sessions in our study are provided by members of the primary health-care setting and hence conducting lifestyle modification programs in the national level will be feasible. Short-term training programs makes it possible for the patients to attend all the of sessions.<sup>[35]</sup>

Furthermore, we will try to test the effect of mobile phone text messages on the patients' adherence to lifestyle changes. As the intervention will be conducted in two centers with different educators; we can examine the effect of different teachers on the desirable outcome. The results of the current study will improve the insight to some of the determinants of the BP control (type of diet, salt reduction, high vegetable diet, weight loss, physical activity, stress level) and in the effectiveness of this type of intervention program. In brief, the results from this intervention trial will provide the scientific rationale for implementing multicomponent lifestyle intervention programs designed to manage BP and ultimately prevent BP-related cardiovascular disease in the primary health-care setting.

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