

# Design and implementation of a combined observational and interventional study: Trends of prevalence, awareness, treatment and control hypertension and the effect of expanded chronic care model on control, treatment and self-care

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## Original Article

### Abstract

**BACKGROUND:** Lack of information about hypertension leads to failure in detection, treatment and reduced estimation of this disease effects. So, a comprehensive study, named trends of prevalence, awareness, treatment and control hypertension among the adults in Isfahan, Iran (2001-2016) and evaluation of the effect of expanded chronic care model (ECCM) on control, treatment and self-care, has been designed. This study explains the aspects of design and methods of its implementation.

**METHODS:** This study was conducted in four stages in 2014-2016. In the 1<sup>st</sup> stage, valid questionnaires were made to assess knowledge, attitude and practice, and self-care. In the 2<sup>nd</sup> stage, the status of prevalence, awareness, treatment and control and hypertension risk factors was assessed. In the 3<sup>rd</sup> stage, a two-group clinical trial was conducted to evaluate the effectiveness of ECCM on hypertensive patients and their families. In the 4<sup>th</sup> stage, the results of hypertension prevalence and its risk factors in adults in 2016 were compared with two other studies undertaken in 2001 and 2007.

**RESULTS:** To develop the questionnaire, face and content validity, internal and external reliability, and construct validity were examined. Prevalence, awareness, treatment and control of hypertension and risk factors among 2107 adult individuals were determined in Isfahan. In a clinical trial, 216 hypertensive patients were randomly assigned into intervention and control groups. Finally, a sample size of 8073 people was used to determine and compare the 15-year-old trend of hypertension and its affecting factors.

**CONCLUSION:** It is obvious that the final findings of this study will play a key role in health and research policy and provide a suitable model for implementing appropriate interventional measures at the provincial and national levels.

**Keywords:** Hypertension, Blood Pressure, Risk Factors, Self-Care, Educational Models, Iran

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### Introduction

Declaration of the United Nations general assembly has emphasized on the prevention and control of non-communicable diseases (NCD) and its destructive impact on health, socio-economic development and poverty alleviation.<sup>1</sup> Hypertension (HTN) is one of the risk factors of cardiovascular diseases (CVD) and has important health and economic consequences throughout the world. It is predicted that the number of people suffering from HTN reaches approximately 1.56 billion in 2025.<sup>2</sup>

In the last decade, rapid social and economic changes in Eastern Mediterranean and Middle East countries have increased the prevalence of many risk factors for CVD such as HTN. In the Middle East, on average, its prevalence is 21.7%,<sup>3</sup> in some other studies 10 to 17%,<sup>4</sup> and in Iran it is 26.6%.<sup>5</sup>

Accurate description of Epidemiology HTN in the community to identify the causes and deal with them is considered the main strategy for increasing longevity and promoting public health. Moreover, it is the basis for prevention of NCD, and

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identification, prevention and control of its risk factors.<sup>1</sup> In the treatment of HTN, important risk factors such as obesity, diabetes, dyslipidemia, and smoking should be controlled along with controlling blood pressure numerical values. These factors enhance the effect of each other and increase the overall risk of CVD in these patients synergistically, more than the sum of individual risk factors.<sup>6</sup>

Despite the importance of health policies, recent studies have shown that in most parts of the world, governments do not have policies for preventing or managing NCD.<sup>7</sup> Lack of information and data on the prevalence of HTN has led to a failure to diagnose and treat the disease and reduce the estimates of the effects of the disease.<sup>8</sup> Moreover, there are still many problems about how to treat and cure patients and how to deal with their performance in Iran, including the province of Isfahan. In general, the speed of the prevention, control and treatment of HTN is slower as compared to the speed of its spread; therefore, broader and more comprehensive policies need to be implemented.

This article explains the aspects of the design and implementation methods of a doctoral dissertation. This dissertation is a part of a national study entitled “the impact of self-care management and adopted Iranian guidelines for hypertension treatment on improving the control rate of hypertension”, with Isfahan cardiovascular research institute research code 91004751.

This work aims to explain the aspects of the design, implementation, and sampling methods of a large study about 15-year-old process of prevalence, awareness, treatment and control of HTN in the adult population of Isfahan and evaluating the impact of a caring model on control, treatment and self-care and knowledge, attitude and practice (KAP) of community about this disease.

### Materials and Methods

The implementation process of the present study was conducted in four stages. In the 1<sup>st</sup> stage, a validated questionnaire was developed about KAP of the people about HTN and complications resulting from its increase, the risk factors of HTN in the society, prevalence, awareness, control and treatment of HTN, self-care, self-efficacy and adherence to medication in HTN patients. In the 2<sup>nd</sup> stage, a cross-sectional study was carried out to assess the current status of HTN and some risk factors in Isfahan, Iran in 2015-2016. In the 3<sup>rd</sup> stage, a two-group clinical trial was performed to

evaluate the effectiveness of expanded chronic care model (ECCM) on patients undergoing treatment for HTN and their families. In the 4<sup>th</sup> stage, the factors affecting the trend of HTN in the city of Isfahan, Iran were separately determined in a total population of both healthy adult men/women and HTN patients. To do this, data from cross-sectional study of 2015-2016 were compared with data from the study of Isfahan healthy heart program (IHHP), 2001-2007.<sup>9,10</sup>

**Procedure of the 1<sup>st</sup> stage of the project: designing valid questionnaires:** This 13-month stage was aimed to design a valid questionnaire for this study. According to the objectives, hypotheses and research questions, first, a number of the questions from the World Health Organization (WHO) stepwise approach<sup>11</sup> and a number of the questions from IHHP<sup>10</sup> were used to prepare the questionnaire of the project. Moreover, the initially arranged questionnaires were further organized and developed by referring to valuable books and articles, and also after examining the most recent national clinical guidelines for the prevention, assessment and treatment of HTN, scientific resources and other similar questionnaires which had been designed to assess patients HTN self-care and self-efficacy, KAP of the HTN patients and complications resulted from its increase. Then the face validity of the questionnaire was determined by the expert panel. In these meetings, according to the individuals' suggestions, the questions were modified and consequently, the items became simpler, more appropriate, more understandable and restricted.

Then, the content validity was evaluated using two criteria of content validity index (CVI) and content validity ratio (CVR). Polit et al.<sup>12</sup> and Ayre and Scally<sup>13</sup> have explained how to calculate CVI and CVR. To calculate the CVR, 25 specialists and experts were asked to give their opinions about each item in the form of a three-part range (it is necessary, it is important but not necessary, it is not necessary). In addition, to calculate CVI, viewpoints of 17 experts and specialists were used to determine the relevance, simplicity and clarity of the options of the questionnaire by giving a score from 1 to 4.<sup>14</sup> Moreover, the reliability of the questionnaires was calculated using two types of reliability, i.e. internal and external reliability. To do so, the designed questionnaire was given to 12 individuals who were representative of the target population and internal consistency was calculated using Cronbach's alpha and a value of higher than 0.70 was confirmed.

Then, to determine the reliability, the questionnaire was given to the same people, for the second time, after 14 days. Intraclass correlation coefficient (ICC) was calculated and the values more than 0.9 were confirmed.<sup>15,16</sup>

Finally for KAP and self-care and self-efficacy questionnaires, construct validity was determined using exploratory factor analysis. Furthermore, confirmatory factor analysis was performed on KAP questionnaire. Exploratory factor analysis (for each variable, 10 samples) was used to measure construct validity. It was also determined whether questions which have been designed to evaluate an index or particular trait had a common factor loading and these factors were significant. The questionnaire of self-care, self-efficacy and adherence to medication was conducted on 203 patients with HTN and KAP questionnaire was conducted on 220 individuals. According to Lawshe table, the items with  $CVR \geq 0.5$  and  $CVI \geq 0.61$  were selected.<sup>13</sup> Confirmatory factor analysis of KAP questionnaire was also conducted on 440 people.

**The variables evaluated in the final questionnaire:** Generally there were multi-part questionnaires, in which, their first part included demographic characteristics such as age, sex, marital status, education level, occupation or their spouse's occupations, socioeconomic status, number of children, the number of people with HTN in the family, HTN risk factors (diet, tea and coffee consumption, cigarettes and tobacco consumption, alcohol, exercise, stress), current diseases and medication, hospitalization history, questions about HTN during pregnancy and contraception methods, and information about the blood pressure measurement.

The second part included the questions about knowledge (20 questions, with answers of true, false, I do not know), attitude with 18 questions based on 5-point Likert scale (strongly agree to strongly disagree), practice on blood pressure with 17 questions based on 5-point Likert scale (always to never), the complications raised from HTN increase, and HTN risk factors.

Part three contained a special form of physical examination including measurements of height (cm), weight (kg), waist, abdominal, hip and neck circumferences (cm), arm length and circumference (cm), pulse rate (per min) and regularity or irregularity of the pulse, systolic and diastolic blood pressure (mmHg) of right and left arms at three times.

Part four of questionnaire was related to individuals known to have HTN and the questions

were about how to control and measure blood pressure, reasons for not visiting a doctor for pressure control, who told them the first time that they have high blood pressure, HTN treatment and medication, family history of diseases, presence of HTN complications, adherence to medications (7 questions with 5-point Likert scale (always to never), self-efficacy with 8 questions based on 5-point Likert scale (I am not sure to quite sure) and self-care with 16 questions based on 5-point Likert scale (strongly agree to Strongly disagree).

**Procedure of the 2<sup>nd</sup> stage of the project: an examination of the current status of HTN prevalence, awareness, control and treatment, and some risk factors in Isfahan, Iran:** A new cross-sectional study was conducted to determine HTN prevalence, awareness, control and treatment and some risk factors on the adult population of Isfahan, Iran within 7 months (August 2015-March 2016). Inclusion criteria were the samples with 18 years or older and the residents of Isfahan, Iran. Exclusion criteria were any limitations on measuring blood pressure from the arm such as arm casting, existence of a shunt or fistula in the hands, fasting or any special diet for obesity or for weight loss at the time of sampling for the patients or their families, suffering from Cushing and pheochromocytoma, undergoing treatment with peritoneal dialysis or hemodialysis, suffering from mental illnesses and cancer, and pregnancy.

If the subjects were not willing to continue to participate in the study, the reasons for not-participating were presented in a report.

**Sample size and sampling methods of the 2<sup>nd</sup> stage:** In this study, considering the prevalence of HTN, 18.9%,<sup>17</sup> type I error ( $\alpha = 0.05$ ), the margin of error ( $d = 0.018$ ), 1818 people were selected using the following formula. Z value for a confidence level of 0.95 from normal distribution table was 1.96.

$$n = \frac{Z^2 P(1-P)}{d^2}$$

The number of individuals in each age group (18-29), (30-39), (40-49), (50-59), (60-69) and (over 70) was determined based on relative distribution and sex distribution of population by age groups in the community.<sup>18</sup> According to the objectives of this study, multistage random cluster sampling was conducted, families were selected randomly and based on the proportion

of the population covered by the concerned health centers.

The city of Isfahan, Iran has two health centers, i.e. No. 1 (21 centers) and No. 2 (26 centers), and they were considered as clusters of Isfahan. Based on the evidence provided by the health department of the province, in terms of socioeconomic status, the health centers of Isfahan are divided into three categories of good, fair and poor. Moreover, in the proportion of the population covered by health centers and using the lottery method, 18 centers were selected.

In the health centers, a list of files was presented and the samples were selected via systematic random sampling. After finding the addresses and referring to their homes, an eligible person over 18 who has met inclusion criteria was randomly selected from each family. Since all of the families in the city of Isfahan do not have a file at their health centers, sampling continued up to the next ten households from the right hand of this household. These people were given a reference card to health centers in their neighborhoods so that they could refer to the center with their medications and health insurance card to measure blood pressure and fill in the questionnaire. Sampling continued until the determined sample size was obtained. This sample size was according to age groups and sex distribution (equal numbers of women and men) in that center.

In the health center, attendees were initially asked to sign a written consent form. While the person was sitting, the questionnaires were completed by interviewing with full accuracy. Initially, the first and second parts of the questionnaire about demographic information and KAP were filled, and then the individuals were resting for 5 minutes in a quiet environment. The WHO standard conditions were observed when measuring the blood pressure.<sup>19</sup> This means that the people were sitting on backed chairs and did not get their legs crossed. Their soles of the feet were on the floor, the hands were at the heart level and the palms were upward. Systolic and diastolic blood pressure was measured three times (with a standard protocol) from both right and left arms, using a digital calibrated brachial sphygmomanometer. There was a one-minute interval between each measurement and all three times were recorded.

Then a brief physical exam including height and weight measurement, waist, neck and abdominal circumferences were performed, and the

measurements were recorded on a special physical examination form. At the end, there was a brief reception to thank them. Moreover, individuals with a previous history of HTN completed the questionnaire of self-care, self-efficacy and adherence to medication.

At the end of the same day, the completed questionnaire was sent to Isfahan HTN Research Center so that the data entry unit imputed the information into the Epi Info software (CDC, The United States). Then the questionnaires were archived in a safe place. The data entered into the computer at various stages were checked for errors using the interim analyses, and then these errors were fixed.

***Validity and reliability of the data collection instrument:*** Ten interviewers with previous experience and with no history of physical or mental disabilities attended the HTN Research Center to receive training for two months. Adequate explanations on how to complete the questionnaires were presented to them by the researcher. In addition, they obtained the expertise required to measure blood pressure, and body dimensions including height, weight, waist circumference, etc. After being approved by the executor, official letters were issued to them from Isfahan Cardiovascular Research Institute, Isfahan, Iran.

The tool used in this research includes a digital brachial sphygmomanometer, Microlife WatchBP Office ABI (Microlife WatchBP AG, Widnau, Switzerland), which was compared with a mercury sphygmomanometer. This device was verified several times in a row on 1-3 individuals. In addition, other tools including meters (plastic meters calibrated using a metal meter), digital scale (calibrated with a five kg weight every day) and valid questionnaires from the 1<sup>st</sup> stage of the study.

***Procedure of the 3<sup>rd</sup> stage of the project: implementation of a two-group clinical trial with before and after design (intervention and control groups):*** This stage aimed to investigate the effect of ECCM on control, treatment and self-care of HTN. This stage was conducted on identified individuals suffering from HTN who was under treatment from the 2<sup>nd</sup> stage, within 10 months. Since one of the main strategies to prevent and control chronic diseases is educating through patient- and family-centered intervention, which is based on ECCM<sup>20,21</sup> and the latest guide clinical, self-care was taught to patients with HTN and one of their family members involved in taking care of the patient in the intervention group. Then, the results were reviewed and analyzed regarding the

control and treatment of the disease, self-care, adherence to medication and KAP of patients.

**The sample size in the 3<sup>rd</sup> stage of the project:**

A total of 252 of individuals (138 women and 114 men) had been diagnosed with HTN from the previous study, and 216 of them were randomly selected. Permuted-block stratified randomization (based on age, gender and education) was used to assign the subjects to either intervention (n = 108) or control (n = 108) groups.

The required sample size in each group was estimated at 90 (using the following formula), given a significance level of 0.05, a statistical power of 80% and the normalized effect size of  $\Delta = 0.3$  to  $\Delta = 0.9$ , pertaining to the pre- and post-intervention score difference reported in the reference articles.<sup>22-24</sup> To achieve a higher precision and considering the 20% chance of attrition, the sample size was increased to 108 per group, i.e. the number of samples at this stage in intervention and control groups was 216 people. Figure 1 presents

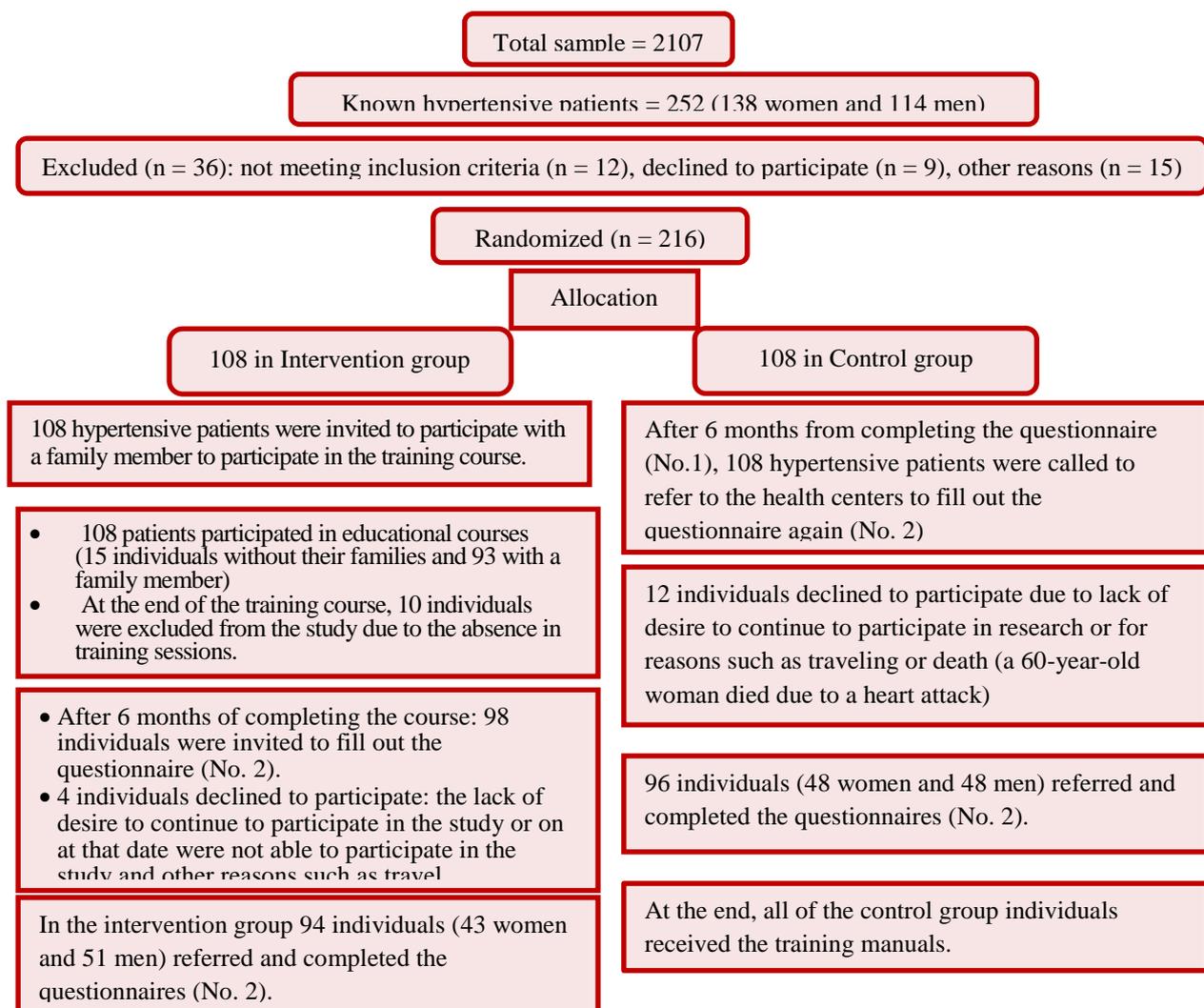
consolidated standards of reporting trials (CONSORT) flow diagram of the participants in the 3<sup>rd</sup> stage of the project.

$$n = \left( \frac{1 + \phi}{\phi} \right) \frac{(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2} + \frac{z_{1-\alpha/2}^2}{2(1 + \phi)}$$

$$Z_{1-\alpha/2} = 1.96; Z_{1-\beta/2} = 0.84; \phi = 1$$

**The procedure of the 3<sup>rd</sup> stage of the project:**

The content of the instructional booklet was prepared, printed and copied for the patients and their families. The booklet contained training on HTN and the importance of its control, the side effects of uncontrolled HTN, the available non-pharmacological treatments and healthy lifestyle choices, such as proper physical activity, stress management, restrictions on smoking, the importance of a healthy diet, especially the level of salt intake and dietary approaches to stop HTN (DASH).



**Figure 1.** Consolidated standards of reporting trials flow diagram of the participants of the 3<sup>rd</sup> stage of the project

Then, the team members who were supposed to teach the patients and families were appointed by the head of HTN Research Center and executor of the plan. Six 2-hour training sessions were held for the team to improve the capacity and coordination, to integrate educational content, and to achieve full control on HTN guidelines. The team members included general practitioners (two), PhD by research student with a Master of Nursing (one), and nutritionists (two).

In intervention group patients with HTN were given invitation and reference cards so that they could refer to the health center in their neighborhoods with their family members on specified days. Then, the training program was conducted to change the behavior of them and promote patient and family engagement in their own care. Moreover, it intended to improve their participation in the treatment process. The training program was carried out in health centers for 8 hours (two hours per week) in groups of 10 to 15 individuals. The teaching methods included lectures, booklets, PowerPoint, pictures and discussions followed by questions and answers.

There were followed up calls once a month, lasted for 6 months, to see if they were following self-care behaviors. In addition, the previously learned points were emphasized and questions were answered during these phone calls. In the intervention group, an absence in more than two training sessions was an exclusion criterion from the study. Six months after finishing the educational course, the interviews were used to complete the questionnaires again for the intervention group. Blood pressure and weight measurements were also taken by standard methods. Moreover, before and six months after the intervention, the KAP questionnaires were filled by questioning the families.

In the control group, the treatment programs continued as same as before wherein six months later the questionnaires were filled out again and blood pressure and weight measurements were taken by standard methods. Educational contents in the form of educational manuals were also given to the control group at the end of the study.

***Procedure of the 4<sup>th</sup> stage of the project: assessing the trends of HTN and its risk factors:***

At this stage, the data from three repeated cross-sectional studies with independent samples in 2001, 2007 and 2016 were used to determine the 15-year-old process of factors affecting prevalence, awareness, treatment and control of HTN in the

adult population of Isfahan.

***The number of samples in the 4<sup>th</sup> stage of the project:*** A total of 8627 individuals participated in these three studies. After the integration of data related to these three studies, management and processing of data were performed. Then, errors and data inconsistencies were eliminated, and the final file was prepared for data analysis. Finally, the data obtained from 8073 individuals were used to determine trends and also to compare the factors affecting the prevalence, awareness, treatment and control of HTN.

In IHHP 2001 and 2007, 3703 and 2660 adult residents of Isfahan, Iran were interviewed respectively. But, only 3427 and 2539 individuals who had completed data about blood pressure, age, and gender were included for data analysis. In 2016 study, 2107 adults were interviewed, and were included for analysis.

The sampling method in IHHP<sup>10,25</sup> was random cluster sampling. In 2001, the health center No. 2 was selected as a cluster. In 2007 and 2016, health centers No.1 and 2 were selected as clusters in Isfahan. The information of these individuals was available on biostatistics department of cardiovascular research institute. These data were utilized to determine the 15-year-old trend of prevalence, awareness, treatment and control of HTN in the adult population of Isfahan, Iran. Sample size, gender and age distribution, methods and places of sampling, inclusion and exclusion criteria, the start and end of each sampling are presented in table 1.

In this study, descriptive and inferential statistical methods were used. In order to achieve the research results, the collected data were coded and were analyzed using SPSS software (version 18.0, SPSS Inc., Chicago, IL, USA). Statistical methods including parametric tests such as Student's independent t-test, paired t-test, and non-parametric tests such as Mann-Whitney and Wilcoxon tests were used. Moreover, chi-square test and other statistical methods such as correlation analysis, linear regression, logistic regression, analysis of variance (ANOVA) and analysis of covariance (ANCOVA) were used in accordance with the assumptions.

The ethical code of this research project is IR.MUI.REC.2016.3.790. Presence in research environments was done by obtaining and presenting an introduction letter from the cardiovascular research institute of Isfahan, Iran and HTN Research Centre.

**Table 1.** Distribution of the reviewed sample size and sex in adult group of the 4<sup>th</sup> Stage

Phases	First phase sample size 2001			Second phase sample size 2007			Third phase sample size 2016			
	Women [n (%)]	Men [n (%)]	Total [n (%)]	Women [n (%)]	Men [n (%)]	Total [n (%)]	Women [n (%)]	Men [n (%)]	Total [n (%)]	
Age groups	18-29 year	590 (17.2)	603 (17.6)	1193 (34.8)	444 (17.5)	482 (19.0)	926 (36.5)	349 (16.6)	369 (17.5)	718 (34.1)
	30-39 year	383 (11.2)	430 (12.5)	813 (23.7)	305 (12.0)	302 (11.9)	607 (23.9)	233 (11.1)	253 (12.0)	486 (23.1)
	40-49 year	267 (7.8)	313 (9.1)	580 (16.9)	205 (8.1)	211 (8.3)	416 (16.4)	171 (8.1)	176 (8.4)	347 (16.5)
	50-59 year	192 (5.6)	178 (5.2)	370 (10.8)	141 (5.6)	134 (5.3)	275 (10.8)	135 (6.4)	145 (6.9)	280 (13.3)
	60-69 year	151 (4.4)	152 (4.4)	303 (8.8)	90 (3.5)	90 (3.5)	180 (7.1)	73 (3.5)	82 (3.9)	155 (7.4)
	≥70 year	72 (2.1)	96 (2.8)	168 (4.9)	67 (2.6)	68 (2.7)	135 (5.3)	56 (2.7)	65 (3.1)	121 (5.7)
	Total	1655 (48.3)	1772 (51.7)	3427 (100.0)	1252 (49.3)	1287 (50.7)	2539 (100.0)	1017 (48.3)	1090 (51.7)	2107 (100.0)
Total sample size = 8073			3427			2539			2107	
Sampling method		-Sampling based on age and sex distribution in the Isfahan urban population -Multi-stage include: quota, stratified, clustering, random, proportional to size, systematic simple random			-Sampling based on age and sex distribution in the Isfahan urban population -Multi-stage include: quota, stratified, clustering, random, proportional to size, systematic simple random			-Sampling based on age and sex distribution in the Isfahan urban population -Multi-stage include: quota, stratified, clustering, random, proportional to size, systematic simple random		
Sampling locations		15 health centers			15 health centers			18 health centers		
Inclusion criteria		residents of Isfahan city and aged 19 or above			residents of Isfahan city and aged 19 or above			residents of Isfahan city and aged 18 or above		
Start time and end of sampling		2000-2001			2006-2007			2015-2016		

The aim of this study was explained for each unit of study and authorities of the research environment and informed consent was obtained from individuals to participate in the research. In addition, the data collected in this study remained confidential. At the end, an educational manual was given to all HTN individuals participating in the study.

## Results

The results of this study focus on developing the questionnaire. In addition, face and content validity, internal and external reliability, and construct validity of instruments were examined. Likewise, prevalence, awareness, treatment and control of hypertension and risk factors among 2107 individual adults in Isfahan, Iran were determined. In a clinical trial, 216 hypertensive patients were randomly assigned into intervention and control groups. Finally, a sample size of 8073 individuals was used to determine and compare the 15-year-old

trend of hypertension and its affecting factors.

## Discussion

CVD and their risk factors are considered to be among the most important health problems in many countries including Iran. HTN has certainly been known as a factor causing CVD in the world.<sup>26</sup> Failure to recognize risk factors and lack of access to adequate health services could lead to a situation in which patients are not receiving effective treatments. Therefore, screening and monitoring patients with HTN are the primary objectives of preventing cardiovascular disease and considerable efforts have been made in this area.

In Italy, a descriptive study was conducted on trends in prevalence, awareness, treatment, and control of blood pressure, recorded from 2004 to 2014 during world HTN day. This study included 10051 individuals from the general adult population and was carried out in three periods from 2004 to

2010 (3115 individuals), 2011 to 2012 (3795 individuals) and 2013 to 2014 (3141 individuals). Within the overall sample of the population, prevalence and treatment did not change significantly, although HTN awareness and control increased from 65.8% to 67.4% ( $P < 0.001$  for trend). At the same time, blood pressure control in diagnosed and treated hypertensive patients increased from 50.0% to 55.5% and finally increased to 57.6% ( $P < 0.001$  for trend).<sup>27</sup> Likewise, the prevalence, knowledge, treatment, and control of HTN has been determined in our study.

A large-scale study in Northern California was conducted to compare rates of HTN control on 652763 subjects from 2001 to 2009 in the health system HTN registry (record) and treatment team members used guidelines which were updated every 2 years. Guidelines were disseminated through emails, pocket cards, videoconferences, and lectures. Follow-up measurements were also performed by the medical team. The subjects were examined 2 to 4 weeks after taking medication. Implementation of this program had a significant increase in HTN control.<sup>28</sup> Similarly, the members of treatment team have trained patients based on the guidelines in our study.

The results of the National Health and Nutrition Examination Surveys (NHANES) in 2011 and 2012, on 13431 individuals from 30 different study locations in the United States showed that 82.8% of adult patients with HTN were aware of their diseases and 51.9% had their blood pressure controlled to less than 140/90 mmHg. The rate of treatment and control of HTN in women has been more than men. Moreover, awareness, treatment and control of HTN among young adults (18-39 years) were lower as compared to older individuals. The healthy people 2020 program aim is to treat 69.5% of all adults with HTN. However, based on the NHANES, 75.7% were currently taking medication to lower their blood pressure and this amount has been above and beyond the expectations. Although the control of HTN has neither met the goal of the healthy people 2020 program (61.2% by 2020) nor the million hearts initiative program (65% by 2017), these results provide evidence for continued efforts to improve HTN control and achieve these goals.<sup>29</sup>

Another study used regression models to evaluate the trends in prevalence, awareness, management and control of HTN from 1999 to 2010 among 28995 men and women adults in the United States. In 2009 to 2010, among 5764 participants in NHANES, the prevalence of HTN

was 30.5% for men and 28.5% for women. The HTN awareness rate was 69.7% among men and 80.7% among women. The HTN control rate was 40.3% for men and 56.3% for women. From 1999 to 2010, the prevalence of HTN remained constant. Although HTN awareness, management, and control improved, the overall rates remained low and unsatisfactory (74.0% for awareness, 71.6% for management, 46.5% for control, and 64.4% for control in management). Worst of all, there was no improvement from 2007 to 2010.<sup>30</sup>

According to the past three decades reports, early diagnosis and treatment of HTN and its risk factors, as well as public health policies to reduce behavioral risk factors, have led the gradual decline in the rate of mortality from heart disease and stroke in high-income countries.<sup>31,32</sup> Moreover, due to chronic and debilitating nature of HTN and lack of control and appropriate treatment for it, it seems sensible and essential to apply a model which is proportionate and compatible with the conditions of these patients. Self-care should be emphasized, so it can help patient accept sustained health behaviors. Moreover, it will result in improving and maintaining health and in order to institutionalize it, in each country researches on practical methods should be done in accordance with the local cultures of that region.

## Conclusion

This study in an adult population of Isfahan is considered as one of the major studies in Iran and intends to examine the epidemiology of HTN and its influencing factors. In addition, by implementing a caring model and using the latest clinical guide of localization, it evaluates the impact of this model on the control and treatment of HTN using the patient and the family strength in self-care activities. This model has a lot in common with studies of HTN throughout the world. Some characteristic features of this study include regular planning and appropriate organization of administrative procedures, having a strong executive team, preparation and use of questionnaires and valid tools, having a significant sample size, observing the age and sex ratios of the population in urban areas. Obviously, the final findings of this study will play a key role in health and research policy and provide a suitable model for implementing appropriate interventional measures at the provincial and national levels.

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### Conflict of Interests

Authors have no conflict of interests.

### References

- World Health Organization. Noncommunicable diseases and mental health: Global Action Plan for the Prevention and Control of NCDs 2013-2020 [Online]. [cited 2013]; Available from: URL: [http://www.who.int/nmh/events/ncd\\_action\\_plan/en](http://www.who.int/nmh/events/ncd_action_plan/en).
- Kearney PM, Whelton M, Reynolds K, Muntner P, Whelton PK, He J. Global burden of hypertension: Analysis of worldwide data. *Lancet* 2005; 365(9455): 217-23.
- Motlagh B, O'Donnell M, Yusuf S. Prevalence of cardiovascular risk factors in the Middle East: A systematic review. *Eur J Cardiovasc Prev Rehabil* 2009; 16(3): 268-80.
- Kamran A, Sadeghieh Ahari S, Biriya M, Malepour A, Heydari H. Determinants of patient's adherence to hypertension medications: Application of health belief model among rural patients. *Ann Med Health Sci Res* 2014; 4(6): 922-7.
- Esteghamati A, Meysamie A, Khalilzadeh O, Rashidi A, Haghazali M, Asgari F, et al. Third national surveillance of risk factors of non-communicable diseases (SuRFNCD-2007) in Iran: methods and results on prevalence of diabetes, hypertension, obesity, central obesity, and dyslipidemia. *BMC Public Health* 2009; 9: 167.
- Go AS, Bauman MA, Coleman King SM, Fonarow GC, Lawrence W, Williams KA, et al. An effective approach to high blood pressure control. *Hypertension* 2014; 63: 878-85.
- Mohan V, Seedat YK, Pradeepa R. The rising burden of diabetes and hypertension in southeast asian and african regions: Need for effective strategies for prevention and control in primary health care settings. *Int J Hypertens* 2013; 2013: 409083.
- Chockalingam A. Impact of world hypertension day. *Can J Cardiol* 2007; 23(7): 517-9.
- Sarrafzadegan N, Talaei M, Sadeghi M, Kelishadi R, Oveisgharan S, Mohammadifard N, et al. The Isfahan cohort study: Rationale, methods and main findings. *J Hum Hypertens* 2011; 25(9): 545-53.
- Sarrafzadegan N, Baghaei A, Sadri G, Kelishadi R, Malekafzali H, Boshtam M, et al. Isfahan healthy heart program: Evaluation of comprehensive, community-based interventions for non-communicable disease prevention. *Prevention and Control* 2006; 2(2): 73-84.
- World Health Organization. WHO steps instrument question-by-question guide (Core and Expanded). Geneva, Switzerland: World Health Organization; 2008.
- Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Res Nurs Health* 2007; 30(4): 459-67.
- Ayre C, Scally AJ. Critical values for Lawshe's content validity ratio revisiting the original methods of calculation. *Meas Eval Couns Dev* 2013; 47(1): 79-86.
- Gilbert GE, Prion S. Making sense of methods and measurement: Lawshe's Content Validity Index. *Clin Simul Nurs* 2016; 12(12): 530-1.
- Santos JR. Cronbach's alpha: A tool for assessing the reliability of scales. *J Ext* 1999; 37(2): 1-5.
- Zamanzadeh V, Rassouli M, Abbaszadeh A, Alavi Majd H, Nikanfar A, Ghahramanian A. Details of content validity and objectifying it in instrument development. *Nursing Practice Today* 2014; 1(3): 163-71.
- Gharipour M, Khosravi A, Sadeghi M, Roohafza H, Hashemi M, Sarrafzadegan N. Socioeconomic characteristics and controlled hypertension: Evidence from Isfahan Healthy Heart Program. *ARYA Atheroscler* 2013; 9(1): 77-81.
- Statistical Center of Iran. Selection of the results of general census of population and housing in 2011 [Online]. [cited 2011]; Available from: URL: [https://www.amar.org.ir/Portals/0/sarshomari90/n\\_s\\_arshomari90\\_2.pdf](https://www.amar.org.ir/Portals/0/sarshomari90/n_s_arshomari90_2.pdf). [In Persian].
- Hackam DG, Quinn RR, Ravani P, Rabi DM, Dasgupta K, Daskalopoulou SS, et al. The 2013 Canadian hypertension education program recommendations for blood pressure measurement, diagnosis, assessment of risk, prevention, and treatment of hypertension. *Can J Cardiol* 2013; 29(5): 528-42.
- Nolte E, McKee M. Caring for people with chronic conditions: A health system perspective: A health system perspective. New York, NY: McGraw-Hill Education; 2008.
- Masterson MP, Hurley KE, Zaider T, Kissane DW. Toward a model of continuous care: A necessity for caregiving partners. *Palliat Support Care* 2015; 13(5): 1459-67.
- Shahrbabaki PM, Farokhzadian J, Hasanabadi Z. Effect of self-care education on patient's knowledge

- and performance with heart failure. *Procedia Soc Behav Sci* 2012; 31(Supplement C): 918-22.
23. Sadeghi R, Mohseni M, Khanjani N. The effect of an educational intervention according to hygienic belief model in improving care and controlling among patients with hypertension. *J Rafsanjan Univ Med Sci* 2014; 13(4): 383-94.
  24. Izadirad H, Masoudi Gr, Zareban I, shahrakipour m, haghshenas d. Effectiveness of an educational program based on Basnef model on blood pressure in hypertension. *Journal of the Iranian in Statute for Health Sciences Research* 2014; 13: 487-95.
  25. Khosravi A, Mehr GK, Kelishadi R, Shirani S, Gharipour M, Tavassoli A, et al. The impact of a 6-year comprehensive community trial on the awareness, treatment and control rates of hypertension in Iran: Experiences from the Isfahan healthy heart program. *BMC Cardiovasc Disord* 2010; 10: 61.
  26. Perkovic V, Huxley R, Wu Y, Prabhakaran D, MacMahon S. The burden of blood pressure-related disease: a neglected priority for global health. *Hypertension* 2007; 50(6): 991-7.
  27. Tocci G, Muiesan ML, Parati G, Agabiti RE, Ferri C, Virdis A, et al. Trends in prevalence, awareness, treatment, and control of blood pressure recorded from 2004 to 2014 during world hypertension day in Italy. *J Clin Hypertens (Greenwich)* 2016; 18(6): 551-6.
  28. Jaffe MG, Lee GA, Young JD, Sidney S, Go AS. Improved blood pressure control associated with a large-scale hypertension program. *JAMA* 2013; 310(7): 699-705.
  29. Nwankwo T, Yoon SS, Burt V, Gu Q. Hypertension among adults in the United States: National health and nutrition examination survey, 2011-2012. *NCHS Data Brief* 2013; (133): 1-8.
  30. Guo F, He D, Zhang W, Walton RG. Trends in prevalence, awareness, management, and control of hypertension among United States adults, 1999 to 2010. *J Am Coll Cardiol* 2012; 60(7): 599-606.
  31. Banach M, Bromfield S, Howard G, Howard VJ, Zanchetti A, Aronow WS, et al. Association of systolic blood pressure levels with cardiovascular events and all-cause mortality among older adults taking antihypertensive medication. *Int J Cardiol* 2014; 176(1): 219-26.
  32. World Health Organization. Cardiovascular disease, A global brief on hypertension [Online]. [cited 2013]; Available from: URL: [http://www.who.int/cardiovascular\\_diseases/publications/global\\_brief\\_hypertension/en](http://www.who.int/cardiovascular_diseases/publications/global_brief_hypertension/en).

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