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## Effect of Continuous Care model on lifestyle modification in patients with hypertension: Randomized clinical trial study

Afsane Shahrani<sup>1</sup>, Reza Daryabeigi<sup>2\*</sup>, Mohsen Shahriari<sup>3</sup> and Alireza Khosravi<sup>4</sup>

<sup>1</sup>MSc Student, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>2</sup>Ulcer Repair Research Center, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>3</sup>Nursing and Midwifery Care Research Center, Health Adult Nursing Department, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>4</sup>Hypertension Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

Correspondence E-mail: [daryabeigi@nm.mui.ac.ir](mailto:daryabeigi@nm.mui.ac.ir)

### ABSTRACT

Hypertension is the most important modifiable cardiovascular disease. One of the main factors affecting the risk of hypertension is people's lifestyle, for which appropriate changes in lifestyle-related factors creating cardiovascular risks need to be developed through new and effective approaches in long-term. Follow-up is an important tool for active participation in treatment and behavior changes; therefore, the present study aimed to evaluate the effect of continuous care model on the lifestyle of patients with hypertension. In this two-stage clinical trial, two groups of 64 patients with hypertension at the Isfahan Hypertension Center were selected through simple sampling, who hold the study criteria. The samples were randomly divided into two groups of 32 people as the experimental and control groups. The continuous care in the test group was carried out in the form of a four-stage program including orientation, sensitization, control and evaluation for 3 months. The control patients received usual care. Two questionnaires were employed to collect demographic data and lifestyle inventory data for hypertension used in two stages of pre- and post-intervention. Data were analyzed using descriptive statistics and statistical tests such as chi-square, Mann-Whitney, independent and paired t-test and analysis of covariance by SPSS version 20. Statistical tests showed no significant differences between the mean scores of two groups in life style dimensions before the intervention. After the intervention, however, the mean scores of lifestyle and its dimensions were significantly higher in the test group than those in the control group ( $p < 0.001$ ). According to the results, it can be concluded that applying continuous care model has significantly been effective in lifestyle modification of patients with high blood pressure. Training the patients and strengthening by repetition, monitoring and management of nurses can be important factors in promoting behavioral and lifestyle changes in these patients. Therefore, the use of this model can be useful.

**Key words:** Hypertension, lifestyle, continuous care model

## INTRODUCTION

Hypertension is the most important modifiable cardiovascular disease [1] and one of the risk factors responsible for 20 to 50 percent of mortalities in the world [2]. High prevalence of hypertension associated with serious complications on the bodily organs have turned this disease into a major health problem worldwide [3]. It is a silent disease with no symptoms and easily identifiable and controllable, while, if untreated, can cause fatal complications such as cardiovascular disease, cerebrovascular events [4], hepatic insufficiency [5], visual disturbances, kidney failure, and premature death [6]. The World Health Organization estimates that approximately one billion people worldwide are suffering from hypertension [7], 4.9 million of which lose their lives annually as a result of developing this disease and its complications [8], and it is expected to spread to 1.56 billion by 2025 [7]. In Iran, about 25-35% of adults are suffering from high blood pressure [9] and the prevalence of the disease in people over 20 years has been reported to be around 18% in Isfahan [10].

An objective of the public health project in 2010 in the field of hypertension was to reduce its incidence and increase the success rate of treatment and control of this disease, the achievement of which requires the use of a multi-purpose approach [11]. It is possible to control the disease with medication, changing the lifestyle, and a knowledge of disease management [2]. Although pharmacotherapy is important in the treatment and control of hypertension in these patients [12], a large body of evidence indicates the relationship between life style of people and cardiovascular disease, hence, it is obviously quite justifiable to emphasize the necessity of lifestyle modification as an important factor in determining prognosis and disease complications [13].

Today, a significant proportion of patients do not achieve treatment goals, because the modification of lifestyle is difficult [14]. The habits have formed over time under the influence of beliefs, attitudes, and life experiences, and are established as part of one's identity [15]. In addition, there are not academic and professional resources in the society to help these patients, and their lifestyles are not sufficiently examined by a doctor. While lifestyle could well be modified under the supervision of a trained nurse [16], and though patients are provided with necessary information at hospitals and health centers, the patients gradually forget them; therefore, it is essential to strengthen the information provided to the patients. Follow-up account for an appropriate measure for these patients and with renewal of educational notes, health behaviors trained will become more established [17]; patients who are followed up are more likely to change their improper and inappropriate behaviors [18]. Patients as the main beneficiaries should be involved in the healing process because they should be take the responsibility of doing day-to-day preventive behaviors, detailed progress reports and discussions on health-related problems; thence, an effective participation requires motivation, comprehensive training, and counseling [19], which, if accomplished along with family members by engaging them in the patient care, would improve the motivation and ability of individuals to establish and maintain lifestyle changes [1]. Accordingly, an effective care is plausible when the relationship between the nurse, patient, and family is continuous, all with similar and common aims and understanding of cases [20].

So, it seems that in order to modify the behaviors of patients, a plan managed by a nurse (nurse- leader) along with follow-up can be a successful and applied model.

Given that nursing theories and Models steer clinical activities, training, and research in this field, the use of nursing models is one of the critical steps to achieve this target [16]. Continuous care model (CCM) is one of the first models designed by Ahmadi for cardiovascular patients [21] and then employed by other researchers in patients with coronary disease [22], myocardial infarction [14], multiple sclerosis [23], schizophrenia [20], hemodialysis [24], etc. CCM is a regular and sequential process for the establishment of effective, interactive, and follow-up relationships between the client as the cause of continuous care and the one who offers health-care services (the nurse) in order to identify the needs and problems of clients to motivate them in adopting and doing continued health behaviors and to help them maintain their wellness and health improvement [20]. The main goal of CCM is to design and codify a program that can brought about the adoption and increased suitable insight for an effective continuous care thereby to efficiently control disease, possible complications [25], and improved lifestyles of patients [16].

Regarding interventions affecting lifestyle, such approaches as individual- and family-oriented training [1], paradigms such as motivational interviewing [27], the Precede-Proceed Model [27], family-oriented empowerment [28], etc. have been used, which have resulted in no impacts in some studies [29].

Since CCM has been designed through a qualitative research in the Iranian community based on the public cultural and socioeconomic characteristics of the country, it can be prioritized to be applied in the society compared to other similar methods and models presented. Continued cares and follow-up of patients in our community is diminished, and additionally, the cares taken do not fit a special scientific framework, whereas use of nursing models helps organize the cares and facilitate access to the training goals. In order to perform their professional duties, nurses in turn need to know patients' needs and abilities and understand the nature of their communications and social context, the recognition of which according to an interactive CCM pattern can be as a convenient and practical guide to promote health-related behaviors and maintain lifestyle changes in patients with hypertension.

Although the impacts of the program have been proven to be positive in diseases such as coronary [22], heart failure [30], schizophrenia [20], multiple sclerosis [24], diabetes [31], and so on, some studies show no effects in some aspects [16, 32].

Considering the contradictory studies conducted and due to the paucity of research concerning the effectiveness of interventions on the lifestyle of patient with hypertension as well as the lack of relevant research on the impacts of CCM on the lifestyles of these patients in our country, this study aimed to examine the effect of continuous care (follow-up) on the lifestyles of hypertensive patients referred to the Isfahan Hypertension Center.

## MATERIALS AND METHODS

This study is a clinical, two-stage, and double-group clinical carried out at the Isfahan Hypertension Center in 2015. The patients with high blood pressures were sampled based on the following conditions: diagnosis of hypertension confirmed by medical professionals, being older than 18 years, literacy and fluency in Farsi, not being with severe stress, no other chronic medical records, and the ability to control and access to the samples. Exclusion criteria were: lack of desire to continue participating in the study, and more than one session absence in the training sessions.

The number of samples was calculated using the sample size formula with a confidence level of 95% and at power of test to be 80% for each group of 32 individuals, which was set as a final size of 35 individuals in each group by counting the loss of samples. Data were collected from the patients who were given enough confidence about anonymity, confidentiality, and privacy by explaining them the purpose of research and obtaining their informed consent of the study subjects to participate in the research. Then the questionnaires were collected containing information from both groups. A simple sampling method was conducted in this study and the samples were placed in each of the control and experimental groups by random allocation using numbered cards. The control group received the usual care routinely, and the CCM was implemented for the test groups.

Continuous care model has four stages namely orientation, sensitization, control, and evaluation [21].

**1.Orientation:** The first step in CCM is to provide and orientate both the sensitivity and the background for creating necessary sensitivities aiming at proper understanding of problem, motivation, and a feeling of the need for follow-up process in the clients. This step was held during a session of 20-40 minutes with the patients and their entourages to become familiar interactively (patient, family, and caregiver), explaining the model stages and motivating the patients, the expectations of each other, the agreements in telephone and instant appointments, and the need for a continued care-treatment relationship between the parties until the end of arranged time [21].

**2.Sensitization:** The sensitization process was meant to engage patients and families in the implementation of the CCM approach. The measures performed for the studied samples during the model implementation stage were accomplished in the form of consulting sessions as counseling, group discussions, speeches, and questions and answers sessions in three subgroups of 10 to 13 individuals depending on the nature and type of needs, and problems of patients and their families. The most important issues and topics of consultation included an explanation about the disease and the resultant complications (existing and potential), the basic needs of diet, drugs, and physical activity, the importance of maintaining and adjusting weight, stress management, the need to quit inappropriate habits such as smoking, and the importance of continued care and health behaviors in maintaining health and control of complications. The numbers of sessions were dependent upon the knowledge, frequency, and severity of problems similar among the samples, which was held as many as 6-8 sessions on average with the patients in each group and their families. Each single session lasted one to two hours depending on the level tolerated by patients and their

families. In cases where a problem was beyond the expertise and scope of the study, both the clients and families were referred to a specialist. The orientation and sensitization stages were performed during the first three weeks of the three-month period intended to implement the model. At the end of the sensitization stage, the patients were provided with the Benson's relaxation CD, a brochure, self-control checklist, and contact information of the researcher.

**3.Control:** The rest of the remaining 12 weeks (9weeks) was devoted to the control and follow-up with the aim of establishment and continuation of good treatment practices to promote health status. Continued consultations on follow-up care were implemented weekly as ongoing in person visits and by phone depending on the care needs with the following aims: the process and quality of cares, indirect assessment of acquired skills, evaluation of the sustainability of health behaviors (observation, query, and reviewing the self-control checklists), presenting positive feedback to the measures taken and reinforcement of health behaviors, consideration of recent problems and re-sensitization to solve the problems, exchanging ideas about success and failure of measures and explaining the proposed solution with the help of patients and families. In this study, the issues were followed up on a weekly basis and sometimes during each patient's visit to the center as well as within group meetings. Following making sure that the previous problems were still running or resolved, any new problem was monitored and relevant counseling and care measures were taken on that particular problem.

**4.Evaluation:** This was proposed as the fourth and final step of the model but it is important in all stages with ongoing attention. The purpose of this stage was to monitor the process of care (successes and failures), the impact of trainings presented, control of health behaviors, and measurement and comparison of the control indices of patients [21]. Ultimately, the questionnaires were completed for both groups in identical conditions at the end of Week 12.

**Tools:** In this study, data were collected using a two-sectional tool composed of: A first part including questions about demographic information and data on the disease; the second part containing a "Hypertension Lifestyle Inventory" designed by Refahi *et al.* (2012). It has four main dimensions including 68 questions (nutritional status, stress, smoking, and physical activity each with 36, 13, 9, 10 questions, respectively). Each of the options was scored from 0 to 100 by changing the suitable variable. When the selected sample was closer to the health behaviors it scored higher, and if the choice was farther from health behaviors it scored lower. The validity and reliability were measured by Refahi *et al.*, and the reliability of the tool was estimated based on the re-test model ( $r = 0.83$ ); the content validity method verified the scientific validity of this tool [34].

In order to apply content validity method used in this study to determine the validity of questionnaires, necessary changes were applied in the questionnaire using books, scientific journals, and comments of five esteemed professors from the Isfahan Faculty of Nursing and Midwifery, as well as remarks of five respected professors from the Department of Nutrition, Isfahan Faculty of Nutrition Science. Afterward, the questionnaire was offered to ten hypertensive patients who had the inclusion criteria, for which the Cronbach's alpha was 0.84; these patients were then excluded.

Data were statistically analyzed using descriptive statistics and the use of tests such as Chi-square, Mann-Whitney, independent and paired t-test, and covariance analysis by SPSS software version 20.

#### *Ethical considerations*

This study was approved by the Research Department of Isfahan University of Medical Sciences, Number code 394897. The researcher described the research purposes to all patients participating in the center, and all the participants completed the written consent form before participating in the study. The samples were assured of the confidentiality of information. They had the option to withdraw or continue working at any point. It should be noted that this study provided the control group with an educational pamphlet after completion of the intervention in the test group.

## RESULTS

This research employed independent t-test ( $P = 0.84$ ) to investigate the homogeneity of the two groups in age levels, chi-square test ( $P = 0.18, P = 0.40, P = 0.40, P = 0.71$ ) in terms of gender, marital status, occupation, and history of hospitalization, and Mann-Whitney test ( $P = 0.91, P = 0.68$ ) in terms of education level and duration time of diagnosis, all of which resulted in no significant differences between the two groups.

Before the intervention, the mean scores of lifestyle (P = 0.81), nutritional habits (P = 0.86), stress management (P = 0.24), physical activity and exercise (P = 0.56), and smoking (P = 0.68) were not significantly different between the two groups. After the intervention, however, the mean scores of life style, nutritional habits, stress management, physical activity and exercise (P < 0.001), and smoking (P = 0.002) were significantly greater in the test patients than the control group. According to the increased mean values, it can be stated that the lifestyle and its aspects have been improved in the intervention group resulting from the implementation of the caring model (Table 1).

**Table 1: Mean total scores of lifestyle and its dimensions in both groups before and after intervention**

Time Group Dimensions	Before running the model						After running the model					
	Groups		Control		Independent-test		Groups		Control		Independent tests	
	Average	Standard deviation	Average	Standard deviation	t	P	Average	Standard deviation	Average	Standard deviation	t	p
Total score of lifestyle	43.4	11.9	42.7	10.7	0.24	0.81	70.1	10.1	41.3	10.5	14.98	<0.001
Nutritional habits	51.7	7.2	51.9	6.4	0.17	0.86	92.5	3.03	51.3	5.9	35.44	<0.001
Stress management	31.1	7.7	33.2	6.8	1.18	0.24	78.7	6.4	31.9	7.1	28.21	<0.001
Physical activity and exercise	17.9	9.6	16.5	10.3	0.58	0.56	54.3	15.9	15.7	10.5	11.72	<0.001
Smoking	72.7	35.5	69.1	34.8	0.42	0.68	90.9	26.4	66.2	34.2	3.31	0.002

As seen in Table 2, the mean scores of lifestyle and nutritional habits, stress management, physical activity and exercise (P < 0.001), and smoking (P = 0.002) were significantly higher after the intervention than before this action in the experimental group. In the control group, the mean scores of lifestyle (P = 0.13), nutritional habits (P = 0.09), stress management (P = 0.14), physical activities and exercise (P = 0.162), and smoking (P = 0.16) were not significantly different after and before the intervention.

**Table 2: Mean total scores of lifestyle and its dimensions in both groups before and after intervention**

Dimension	Intervention						Control					
	Before		After		Pairedt-test		Before		After		Pairedt-test	
	Average	Standard deviation	Average	Standard deviation	t	p	Average	Standard deviation	Average	Standard deviation	t	p
Total score of lifestyle	42.7	10.7	41.3	10.5	1.63	0.13	43.4	11.9	70.1	10.1	20.43	<0.001
Nutritional habits	51.9	6.4	51.3	5.9	1.76	0.09	51.7	7.2	92.5	3.03	37.85	<0.001
Stress management	33.2	6.8	31.9	7.1	1.61	0.14	31.1	7.7	78.7	6.4	36.89	<0.001
Physical activity and exercise	16.5	10.3	15.7	10.5	1.43	0.162	17.9	9.6	54.3	15.9	17.01	<0.001
Smoking	69.1	34.8	66.2	34.2	1.44	0.16	72.7	35.5	90.9	26.4	3.46	0.002

Independent t-tests also showed that the mean score changes of lifestyle and all its dimensions were significantly higher in the test groups than the control group after the intervention (P < 0.001) (Table 3).

**Table 3: Mean scores of lifestyle changes and its dimensions in both groups after the intervention in comparison with before intervention**

Dimension	Test group		Control		Independent t-test	
	Average	Standard deviation	Average	Standard deviation	t	p
Total score of lifestyle	35.7	10.04	-1.4	0.5	20.56	<0.001
Nutritional habits	40.8	6.2	-0.6	0.3	36.90	<0.001
Coping with stress	47.5	7.4	-1.3	0.5	35.72	<0.001
Physical activity and exercise	36.4	12.3	-0.8	0.5	5.17	<0.001
Smoking	18.2	5.2	-2.9	2.04	3.80	<0.001

This study aimed to investigate the effect of follow-up care on the lifestyle modification of hypertensive patients at the Isfahan Hypertension Center. The results of this study showed that implementation of CCM has impacted the lifestyle of hypertensioned patients. Because this model focused on all affecting factors (physical activity, diet, medication regimes, stress management, the need to eliminate harmful habits like smoking, etc., determining a skill

pattern and changes in lifestyle, an explanation and an emphasis on the effects of early and late complications), a continued sensitization process, and the involvement of families in the follow-up and training as a principle, it can be stated that following implementation of the caring model, the lifestyle scores and its dimensions increased in the intervention group indicating that this model has been effective in improving their lifestyles. These results are in agreement with those of Hang [35], Hanbin [26], Zhang [36], and Zhu *et al.* [37] conducted on the effects of interventions on the lifestyles of hypertensioned patients.

Molazem *et al.* (2013) studied the effect of CCM on the lifestyles of patients with myocardial infarction and showed that mean total scores of different lifestyle dimensions were significantly higher in the intervention group than the control group after 3 months ( $P < 0.0001$ ; 16). Furthermore, Akbari *et al.* (2014) examined the effects of applying CCM on the self-efficacy in patients with myocardial infarction and concluded that the use of this model influenced the promotion self-efficacy in the patients; there were no significant differences between the two groups ( $P = 0.83$ ) before the intervention. After the intervention, however, the self-efficacy scores were significantly higher in the intervention group than the control individuals ( $P < 0.001$ ) (14). Various studies also reported the impacts of CCM on factors such as quality of life [24, 23, 31, 32], re-hospitalization and chest pain [22], weight and body mass index [38].

Unlike the present study, Weber (2011) showed that although follow-up by phone had a positive impact on improving risk factors, it had no significant effects on promoting adherence to lifestyle modification (30). The difference between the above and present investigations might have arisen from cultural and social differences of samples, the type and duration of follow-ups, and training offered. Ghavami *et al.* also showed that follow-up care had no influences on the reduction of systolic blood pressure in diabetic patients. This difference may be due to the motives, interests, and cultural backgrounds of samples or the normal range of baseline blood pressure in patients with diabetes or as a result of focus on their blood sugar control [25].

The results of this study also showed that the overall mean score of lifestyle and its dimensions were significantly different ( $p < 0.001$ ) in the test group before and after intervention, while the difference was not statistically significant in the control group; such marked differences between the means of samples before and after intervention have been driven by CCM implementation leading to significant differences. Accordingly, it can be concluded that the individual, group and family instructions to the patients and the continued sensitization process have been effective on the adoption and accomplishment of continuous health behaviors and their conditions.

Rahimi *et al.* (2006) in a study on the impacts of CCM on stress, anxiety, and depression in hemodialysis patients showed that the mean scores of stress, anxiety, and depression in the research samples were significantly different before and after the intervention ( $P < 0.0001$ ) (39). Salari *et al.* (2009) in their study on the effects of CCM upon the quality of life in chemical warfare victims with bronchiolitis obliterans reported significant differences between mean scores in quality of life reaches and total score of life quality in the test group before and after the intervention ( $p < 0.05$ ) while the control group remained unchanged [40].

Contrary to the results of this study, a research by Rahimi *et al.* (2006) through repeated measurements and analyzing data by statistical tests and ANOVA revealed that application of follow-up care on the weight control and blood pressure in hemodialysis patients rendered significant differences ( $P < 0.05$ ) in mean systolic and diastolic blood pressure levels following six measurements before and after the intervention; even so, no significant differences were found in the repeated measurements between different times of weight estimations. It could probably be reasoned that the discrepancies between the results of this study and those of other studies might have caused by cultural, social, environmental, and seasonal differences as well as lack of support and care from families and literacy in the samples of present research [33].

It is noteworthy here that a major key principle in this model is the follow-up after training classes, hence, it can be concluded that the main reason for the increases in the scores of lifestyle and its dimensions in the test group after the intervention are probably due to the continuous pursuit and a two-way dynamism and interaction, which account for the strengths of this model. According to Chiu and Wong (2010), nursing advice and follow-up influence blood pressure control of patients and their commitment to comply with a healthy lifestyle, and a subsequent follow-up by phone is complementary to the impact of nursing advice [41]. Integration of regular follow-up programs and a systematic approach [1] makes the health behaviors trained about the disease and its control become established among the patients and improve the commitment of patients and their families about adherence to lifestyle

modification. This, in turn, results in reduced frequency of hospitalization, decreased economic costs, increased longevity, and diminished mortality [18].

Among the limitations and difficulties of such studies are knowledge, previous experiences, interests of clients in model adaptation, and the impacts of emotional and psychological characteristics as well as cultural backgrounds of the patients and their families on their learning levels, which were, in some cases, beyond the control of the researcher.

### CONCLUSION

The results of this study showed that implementation of continuous care model is correlated to the lifestyle modifications in patients with hypertension meaning that the model can improve the lifestyles of these patients. Patient education and its empowerment through repeating, monitoring, and management by nurses can be important factors in making behavioral changes and improving the lifestyles of patients. Therefore, it is suggested that favorable environments should be provided for the implementation of effective caring models such as continuous care model.

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