

Original Article



The Effect of Continuous Care Model on Blood Pressure and Quality of Life in Patients with Hypertension: A Randomized Clinical Trial

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Abstract**Introduction:** Hypertension is one of the most common diseases in all populations. Since people with hypertension have a lower quality of life (QoL) compared to healthy people, it is necessary to follow up these patients according to their conditions. This study aimed to investigate the impact of a continuous care model on blood pressure and QoL in hypertensive patients.**Methods:** Using a random sampling method, this randomized clinical trial (RCT) included 66 patients with hypertension referring to the clinic of Shahid Madani hospital in Tabriz, Iran in 2019. Data collection tools in this research were demographic information questionnaire, sphygmomanometer control device and stethoscope and Quality of Life questionnaire (The Short Form Health Survey-12, SF-12). The patients were randomly assigned into two groups of control and experimental. After the pre-test, the patients' needs in the experimental group were assessed and the problems were resolved. Then, the post-test was performed one month and two months after the intervention. Data analysis was performed using SPSS software version 13.**Results:** After the intervention, there was a significant difference in the QoL score and blood pressure in the experimental group. However, this difference was not significant in the control group.**Conclusion:** Results indicated that using a follow-up care model had a positive effect on the blood pressure and QoL of patients with hypertension. It is recommended that further studies examine the impact of the integrated care model on QoL in other chronic diseases.**Introduction**

Secondary non-communicable chronic diseases have become widespread due to changing lifestyles and people's tendency to inappropriate habits, leading to poor prognosis and hospitalization.¹ Chronic illness affects not only the lives of those who suffer from it, but also the family members who care for them.² Hypertension is a major risk factor for the development of cardiovascular disease.³ The amount of force the blood exerts on the vessel wall is called blood pressure.⁴ A systolic blood pressure greater than 140 mm Hg and diastolic blood pressure greater than 90 mm Hg is defined as high blood pressure.⁵ Hypertension is caused by such complications as peripheral artery function and homeostasis. The function of peripheral arteries itself is largely dependent on endothelial function.⁶ Hypertension is positively associated with risk of stroke and coronary heart disease. Apart from coronary heart disease and stroke, the complications of hypertension can include heart failure, peripheral vascular disease, kidney failure, retinal bleeding, and visual impairment.⁷

The disease affects more than one billion people worldwide and it is estimated that by 2025, the prevalence

of hypertension will increase by 60% to 1.5 billion.⁸ According to the Iranian Ministry of Health and Medical Education, out of 100 Iranian adults, 20 people have a high blood pressure, of whom only ten know about their disease and only five seek for treatment. In other words, 75% of Iranian patients with hypertension receive no treatment.⁹ Hypertension, like most chronic diseases, is closely linked to lifestyle, mental health, and quality of life (QoL), and failure to manage it in a timely and appropriate manner can lead to various diseases, disability, reduced productivity, and ultimately lower QoL.¹⁰ If a high blood pressure is controlled well, it can prevent clinical complications and increase QoL.¹¹

Health-related QoL is a multidimensional concept that refers to the patient's mental understanding of the impact of the disease and their treatment on the physical, psychological, and social aspects of daily life.¹² Essential components of health-related QoL assessment are physical health, mental health, social functioning, illness status, and overall health understanding.¹³ Various studies have shown that people with hypertension have a poor QoL compared to healthy people. A study by Xu et

al found that middle-aged hypertensive adults had lower QoL scores. According to previous reported studies in this field, high blood pressure significantly affects the QoL related to the health of patients.¹⁴

Recently, the nursing profession has sought to base nursing care delivery on the results of evidence-based research. Given that theories and models of nursing focus on clinical practice, education, and research in this field, the use of nursing models is one of the essential steps in achieving this goal.¹⁵ According to the results of Borji et al¹⁶ after using continuous care model, there was a significant difference between the mean scores of QoL between the two groups.¹⁶

Ahmadi proposed the “continuous care model” for patients with chronic coronary artery disease to create a dynamic, flexible, and continuous communication and caregiver relationship between the nurse and the patient to improve patients’ lifestyles.¹⁷ Zheng et al,¹⁸ age over 80 years, having less education or higher income and the presence of concurrent diseases were associated with lower QoL, and on the other hand, regular physical activity and medical examination had a positive effect on QoL.¹⁸ Alshammari et al¹⁹ several factors such as gender, education, occupation and income status can affect the QoL of hypertensive patients.

Therefore, proper management of hypertension can lead to improved QoL. Nonetheless, the impact of a continuous care model on blood pressure and QoL in patients with hypertension has not been addressed yet. Therefore, this study aimed to investigate the impact of the continuous care model on hypertension and QoL in hypertensive patients. It is hoped that at the end of this project, a suitable framework to improve the QoL and solve the problems of hypertensive patients be provided. In continuous care model, the nurse is the educator and caregiver and the patient is the continuous care agent. Therefore, it is necessary for specialized people such as nurses to control and moderate the complications of the disease by training and providing continuous follow-up care programs. As far as the researchers investigated, no research has been performed on the effect of implementing a continuous care model on blood pressure and QoL in patients with hypertension.

With the increase in the number of patients with high blood pressure and the lack of controlling this disease, problematic complications for individual life occur, and as a result, a huge financial burden is imposed on the family and country due to the maintenance of patients with hypertensive complications.

Nursing models can provide care models and performance guides for nurses, and lack of controlling hypertension can cause irreversible complications such as cardiovascular disease, kidney disease, etc., which requires careful care. The results of this study can help nurses to provide better services in various areas including education, research, and health promotion of

hypertensive patients.

Materials and Methods

Using a random sampling method, this single blind randomized clinical trial (RCT) included 66 patients with hypertension referring to the clinic of Shahid Madani hospital in Tabriz, Iran in 2019. The patients were randomly assigned into two groups of control and experimental.

Sampling was done by random allocation method. The duration of sampling was one month. After completion of the questionnaires, they were randomly numbered; the odd numbers were considered for the control group and even numbers for the experimental group. Due to differences in the treating physician and different referral days, the two groups had no relationship with each other. The inclusion criteria were no history of depression, other chronic mental illnesses, and cancers that may cause skipping the training sessions; insulin-dependent diabetes based on clinical record and questionnaire information; ability to read and write; age between 35-65 years; hypertension according to the physician’s diagnosis; lack of physical and mental disability; and willingness to participate in the research. All incomplete questionnaires were excluded from the study.

Data collection tools in this research were demographic information questionnaire, Quality of Life questionnaire (The Short Form Health Survey-12, SF-12) and sphygmomanometer control device. Demographic information questionnaire consisted of personal characteristics, disease features, nutritional information, and history of participation in blood pressure training classes. For the validity of the demographic information tool, the content validity method was used and this questionnaire was reviewed by 10 professors from different universities and their opinions were taken into consideration and it was finally validated and the retest method was used to confirm the reliability of the tool correlation test was used ($r = 0.86$). Quality of Life questionnaire (SF-12) assesses QoL based on general perception of health, physical function, physical health, emotional problems, physical pain, social functioning, and mental health. The answers to the questions were measured with a Likert multiple-choice scale and based on the total score, they are classified into three categories: good, medium and poor, so a high score indicates good quality. In the studies by Saeidimehr et al²⁰ and Habibi et al²¹ the validity of the instrument was determined by the content validity method and its reliability was determined by the test-retest method.

Blood pressure control in this research was measured by a single person with an assumed KJ206C blood pressure monitor in compliance with the standards of blood pressure measurement. Also, to check the reliability of the tool and prevent errors, a second person was also used to control blood pressure simultaneously with the

first person in the first session.

After completing the questionnaires and controlling patients' blood pressure, the continuous care model was administered to the patients in the experimental group in four stages. The first step was identifying the disease and its related problems. The researcher conducted a 45-minute telephone conversation with the test group, attended by one patient's family member, emphasizing the continuous care model as a contributing role to the person's care. Encouraging the patient, identifying each other's expectations, and emphasizing the need for continued collaboration, and discontinuation of the caregiver relationship were performed until the final stage. At this stage, the questionnaire was completed and the way of communication between the parties was determined.

The sensitization phase was a follow-up for the patient and her family to participate in the implementation of the continuous care model. In this regard, the intervention program included introducing and understanding hypertension, highlights of the issue of hypertension control, expressing the symptoms and discussing this issue with patients, teaching blood pressure measurement to a family member correctly using a blood pressure monitor, and presentation based on nutritional problems according to the patients themselves and the expression of proper nutrition.

The measures taken for the experimental group at this stage included counseling sessions and group discussions in the clinic of Shahid Madani hospital. After performing these steps, the control and follow-up phase was performed, because the most appropriate programs without control and follow-up were forgotten over time. And lose their desired effect, so given that the pattern used is a follow-up care model, the rest of the time remaining after the intervention was related to follow-up. This stage was performed with regular physical presence and continuation of follow-up care consultations on a weekly basis and telephone call twice a week and attending the clinic in accordance with the care needs and completing frequent checklists. At the end of the training sessions, the clients were given a training package containing the information provided, and this training package was not the same for all samples.

The evaluation stage was the fourth and final step of the model and this stage was considered in all stages from the beginning and dynamically. One month after the intervention and two months after the intervention, the QoL questionnaire was completed again and patients' blood pressure was controlled. Figure 1 shows the CONSORT diagram of the study, which is presented in a step-by-step study.

The data were analyzed before and after the intervention, one and two months after the intervention using SPSS software version 13 (SPSS Inc., Chicago, IL, USA). The level of significance was considered less than 0.05. Mann-Whitney, independent *t* test, Fisher exact test, chi-square,

non-parametric Friedman test, and generalized estimating equations (GEE) method was used for data analysis.

It should be noted that all interventions for patients were performed by the researcher himself and all ethical considerations were based on the ethical guidelines of Tarbiat Modares University, including obtaining a letter from the university to submit to Tabriz Shahid Madani hospital, obtaining consent from the department and management of Shahid Madani hospital, and obtaining a written consent. Written consent was obtained from the patient to knowingly participate in this study and the code of ethics was obtained from the university. In order to follow the ethical criteria at the end of the present study, the control group was provided with educational booklets.

Results

In this study, 66 patients (age range: 35-65 years) were divided into two equal groups of experimental and control ($n=33$). The demographic information of both control and experimental groups has been presented in Table 1.

Table 1 shows the demographic information of the intervention and control groups obtained from the study questionnaires.

After collecting the data, the normality of systolic and diastolic blood pressure and QoL were checked by using the Kolmogorov-Smirnov test, in two groups in the experimental and control groups based on the time before the intervention, one month after and two months after the intervention. Based on normality and abnormality, independent *t* test and Mann-Whitney tests were used. In each control and experimental group, since the normality assumption was not satisfied, non-parametric Friedman's test was used.

Table 2 shows the controlled blood pressures at three measurement times in the control and experimental groups.

The blood pressure in each group was measured three times (before the intervention, one month after the intervention and two months after the intervention) and the results show that there was no significant difference between the control and experimental groups in the blood pressure before the intervention in the two groups. And two months after the intervention, there is a significant difference between systolic and diastolic blood pressure in the test group and the control group (Table 2).

In the study of systolic blood pressure in the control group, there is no significant difference between the data of one month later and two months later, and the significance is the result of the data before the intervention and one month after the intervention (The difference is less than 1.5 units) (Table 2).

Table 3 shows the QoL at three measurement times in the control and intervention groups.

According to the results of the data, there is a significant difference in the QoL between the two groups before the intervention, and the control group had a higher average

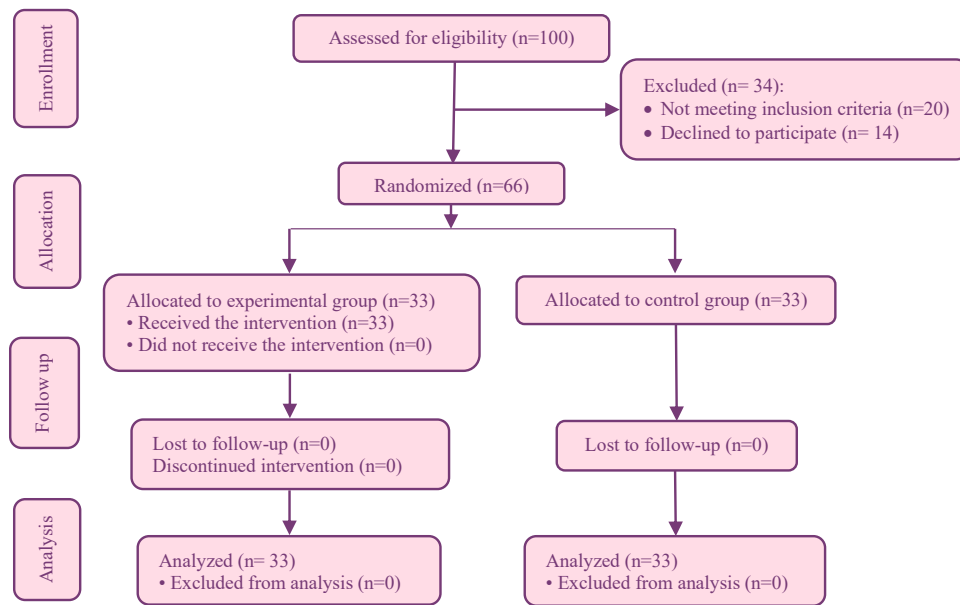


Figure 1. Flow chart of the study

Table 1. Demographic information in the experimental and control groups

| Variable | Experimental group (n= 33) | Control group (n= 33) | P value ^a |
|-------------------------------|-------------------------------|--------------------------|----------------------|
| | No. (%) | No. (%) | |
| Gender | | | |
| Female | 19 (57.6) | 18 (54.5) | 0.80 |
| Male | 14 (42.4) | 15 (45.5) | |
| Marital status | | | |
| Single | 3 (9.1) | 4 (12.1) | 0.68 |
| Married | 30 (90.9) | 29 (87.9) | |
| Duration of illness | | | |
| Less than a year | 7 (21.2) | 7 (21.2) | 0.99 |
| 1-2 years | 6 (18.2) | 6 (18.2) | |
| Over 2 years | 20 (60.6) | 20 (60.6) | |
| Education | | | |
| Diploma and lower | 31 (93.9) | 30 (90.9) | 0.98 |
| College | 2 (6.1) | 3 (9.1) | |
| Other diseases | | | |
| Yes | 3 (9.1) | 7 (21.2) | 0.17 |
| No | 30 (90.9) | 26 (78.8) | |
| Blood pressure control | | | |
| Yes | 16 (48.5) | 10 (30.3) | 0.13 |
| No | 17 (51.5) | 23 (69.7) | |
| Blood pressure control status | | | |
| Good | 11 (33.3) | 9 (27.3) | 0.27 |
| Medium | 7 (21.2) | 13 (39.4) | |
| Unsuitable | 15 (45.5) | 11 (33.3) | |
| Job | | | |
| Farmer | 1 (3) | 1 (3) | 0.96 |
| Housewife | 17 (51.5) | 17 (51.5) | |
| Others | 15 (45.5) | 15 (45.5) | |

Table 1. Continued

| Variable | Experimental group (n= 33) | Control group (n= 33) | P value ^a |
|-----------|-------------------------------|--------------------------|----------------------|
| | No. (%) | No. (%) | |
| Insurance | | | |
| Yes | 31 (93.9) | 31 (93.9) | 1.00 ^b |
| No | 2 (6.1) | 2 (6.1) | |
| Smoking | | | |
| Yes | 3 (9.1) | 5 (15.2) | 0.70 ^b |
| No | 30 (90.9) | 28 (84.8) | |

^a Chi square test was used; ^b Fisher exact test was used.

than the experimental group. Although the control group had a higher average before the intervention, but the experimental group had a higher average one month later and two months later, and this difference was significant. In other words, the intervention was able to significantly increase the average in the test group (Tables 3).

Univariate analysis was then performed and the variables that had significant relationship with response variable (systolic blood pressure, diastolic blood pressure, and QoL) were entered into GEE multivariate model (with probability value close to 0.10 or less) (Tables 4-6).

Table 4 shows the results of the GEE model analysis to examine the relationship between demographic variables and systolic blood pressure.

Table 5 shows the results of the GEE model analysis to examine the relationship between demographic variables and diastolic blood pressure.

Table 6 shows the results of the GEE model analysis to examine the relationship between demographic variables and QoL.

Discussion

The aim of this study was to determine the effect of

Table 2. Comparison of blood pressure in three measurement times in the control and experimental groups

| Variables | Experimental group | | | Control group | | | P value ^a |
|-----------------------------------|---------------------|-----|-----|---------------------|-----|-----|----------------------|
| | Mean (SD) | Max | Min | Mean (SD) | Max | Min | |
| Systolic blood pressure | | | | | | | |
| Before the intervention | 147.88 (20.54) | 210 | 115 | 147.85 (21.43) | 200 | 110 | 0.95 |
| One month after the intervention | 140.15 (19.53) | 180 | 115 | 146.36 (14.65) | 200 | 110 | 0.13 ^b |
| Two months after the intervention | 134.39 (19.84) | 160 | 110 | 145.76 (10.66) | 200 | 110 | 0.006 ^c |
| P value ^c | <0.001 [*] | | | <0.001 [*] | | | - |
| Diastolic blood pressure | | | | | | | |
| Before the intervention | 86.67 (12) | 120 | 60 | 86.36 (12.66) | 115 | 60 | 0.92 |
| One month after the intervention | 82.27 (11.57) | 100 | 60 | 85.61 (9.60) | 115 | 60 | 0.22 ^b |
| Two months after the intervention | 79.85 (10.70) | 90 | 60 | 85.45 (8.24) | 110 | 60 | 0.02 ^{b*} |
| P value ^c | <0.001 [*] | | | 0.23 | | | - |

^aIndependent t test; ^bMann-Whitney test; ^cNonparametric Friedman test; ^{*}Statistically significant.

Table 3. Comparison of quality of life variable in three measurement times in the control and experimental groups

| Variable | Experimental group | | | Control group | | | P value ^a |
|-----------------------------------|---------------------|-----|-----|---------------|-----|-----|----------------------|
| | Mean (SD) | Max | Min | Mean (SD) | Max | Min | |
| Quality of Life | | | | | | | |
| Before the intervention | 25.76 (6.43) | 43 | 12 | 29.45 (5.61) | 41 | 19 | 0.01 [*] |
| One month after the intervention | 35.8 (3.59) | 44 | 27 | 29.67 (5.35) | 42 | 18 | <0.001 [*] |
| Two months after the intervention | 38.8 (2.28) | 45 | 32 | 29.5 (5.41) | 42 | 18 | <0.001 ^{b*} |
| P value ^c | <0.001 [*] | | | 0.86 | | | - |

^aIndependent t test; ^bMann-Whitney test; ^cNonparametric Friedman test; ^{*}Statistically significant.

Table 4. The results of GEE Model to investigate the relationship between demographic variables and systolic

| Variable | B | Standard error | P value |
|----------------|-------|----------------|---------|
| Insurance | | | |
| Yes | 9.87 | 6.38 | 0.12 |
| No | ▲ | - | - |
| Smoking | | | |
| Yes | 12.6 | 9.01 | 0.15 |
| No | ▲ | - | - |
| Other diseases | | | |
| Yes | -8.02 | 5.45 | 0.14 |
| No | ▲ | - | - |
| BMI | | | |
| Normal | 4.66 | 4.61 | 0.31 |
| Obese | ▲ | - | - |

▲Indicates the reference level.

continuous care model on blood pressure and QoL of patients with hypertension. Our results showed that continuous care model had a significant effect on blood pressure and QoL of patients with hypertension.

QoL is an important indicator for evaluating the therapeutic results of high blood pressure. A systematic review of 20 studies showed that patients with high blood pressure had a lower QoL than those with low blood pressure. Also, the results of Ha et al²² showed that the

Table 5. The results of GEE Model to investigate the relationship between demographic variables and diastolic blood pressure

| Variable | B | Standard error | P value |
|-------------------|-------|----------------|---------|
| BMI | | | |
| Normal | 2.46 | 2.66 | 0.35 |
| Obese | ▲ | - | - |
| Education | | | |
| Diploma and lower | 8.26 | 5.64 | 0.14 |
| College | ▲ | - | - |
| Insurance | | | |
| Yes | 4.31 | 2.44 | 0.07 |
| No | ▲ | - | - |
| Other diseases | | | |
| Yes | -5.77 | 3.32 | 0.83 |
| No | ▲ | - | - |
| Smoking | | | |
| Yes | 3.76 | 4.90 | 0.44 |
| No | ▲ | - | - |

▲Indicates the reference level.

QoL is relatively low among hypertensive patients living in a rural area in the southern part of Vietnam.

The results of this study showed that in the experimental group, the average total QoL and the average score in different dimensions of QoL before and after the intervention were significantly different. This means

Table 6. The results of GEE Model to investigate the relationship between quality of life and demographic variables

| Variable | B | Standard error | P value |
|------------------------|-------|----------------|---------|
| Gender | | | |
| Female | -2.32 | 1.24 | 0.06 |
| Male | ▲ | - | - |
| Other diseases | | | |
| Yes | 3.39 | 1.89 | 0.07 |
| No | ▲ | - | - |
| Blood pressure control | | | |
| Good | 4.42 | 1.46 | 0.003* |
| Medium | -0.60 | 1.50 | 0.69 |
| Unsuitable | ▲ | - | - |

▲Indicates the reference level; *Statistically significant.

that the follow-up care model improved the QoL of these patients, while in the control group, the average score of total QoL and the average score in different dimensions of QoL before and after the intervention did not change.

The study groups were significantly different in terms of average score of QoL after the intervention, so that the continuous care model improved the QoL of patients with hypertension. In their study, Lawrence et al²³ showed that the reasons for the decrease in QoL in people with high blood pressure compared to healthy people were repeated visits to medical centers, stress, and non-specific symptoms of high blood pressure.

Also, in this study, the mean blood pressure of the patients examined in the experimental group decreased significantly after the intervention, and there was a stability during the intervention. In this regard, patients should be taught the need for regular blood pressure control.

Based on the findings of a study by Molazem et al²⁴ using follow-up care model, patients in the intervention group showed a significant improvement in lifestyle and the lifestyle score of the intervention group after three months was significantly higher than the control group.

The results of a study by de Carvalho et al showed that people with high blood pressure had a lower QoL compared to people with normal blood pressure.²⁵ Hypertension is one of the most chronic diseases in the world that requires self-care and disease control. This study looked at a suitable and low-cost way to lower blood pressure and increase QoL in patients with high blood pressure.

One of the limitations of this study is the individual differences of the research units in terms of answering the questions of the questionnaires and the possibility of impairment in the full representation of the checklists.

Conclusion

According to results of current study, among patients who followed the continuous care model, the QoL score increased and the blood pressure level decreased

compared to the control group. The effect of continuous care model on blood pressure and QoL of patients with hypertension in other centers, clinics, and different areas should be assessed at the community level. The results showed that the more appropriate the blood pressure control, the higher the QoL. It is also recommended to evaluate the effect of the continuous care model on QoL in other chronic diseases, as well as in other health centers and regions.

Considering the effect of the continuous care model on QoL and blood pressure in patients with hypertension, future studies might investigate the following issues: the role of the family as a helper in the treatment and control of patients with hypertension; the role of self-care in controlling hypertension; and the effect of continuous care model based on nutrition and lifestyle on the level of blood pressure in patients.

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Authors' Contributions

NS, FA: Contributed to the conception and design, acquisition of data; NS, FA, AR: Analysis, and interpretation of data, drafting of the article, review of the article, and final approval.

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Data Accessibility

The datasets are available from the corresponding author on reasonable request.

Ethical Issues

This study was approved by the ethics committee of Tarbiat Modares University of Medical Sciences (ethical code: IR.MODARES.REC.1397.173). Also, this study was registered with the code IRCT20200718048130N1 on the website of the Iranian Registry of Clinical Trials. Written informed consent was obtained from all participants.

Conflict of Interests

The authors declared no conflict of interest.

Research Highlights

What is the current knowledge?

Exist knowledge in most texts indicates that hypertension can affect patients' QoL.

What is new here?

Implementation of the continuous care model as a comprehensive, simple, and native model in hypertensive patients has a good effect on blood pressure control and improves their QoL.

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