THE EFFECT OF NURSİNG INTERVENTİONS BASED ON CONSERVATİON MOTİVATİON THEORY ON DRUG ADHERENCE AND HEALTHY LİFESTYLE BEHAVİORS İN PATİENTS WİTH HYPERTENSİON: A RANDOMİZED CONTROLLED STUDY

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ABSTRACT

Hypertension is a major global public health problem. For success in the prevention and management of hypertension, it is necessary to ensure that patients receive timely and accurate diagnosis, acquire healthy lifestyle habits, start antihypertensive drug treatment on time, and ensure compliance with treatment. The study was conducted in a pre-test-post-test parallel group randomized controlled design in order to determine the effects of nursing interventions consisting of hypertension education and sending short messages, created by utilizing Rogers' Protective Motivation Theory (CMT), on medication compliance and healthy lifestyle behaviors for hypertensive individuals. The study was conducted at Family Health Center No. 7 in the center of Karaman province between November 2023 and May 2024. The study group included individuals between the ages of 40 and 59, who had low compliance with treatment, had no communication problems in terms of hearing, vision, and understanding, used a mobile phone to receive the short message to be sent by the researcher, and were diagnosed with primary hypertension. The study was conducted with 78 hypertensive individuals, 39 in the intervention group and 39 in the control group, calculated with 95% power. Ethics committee, institution, scale use permission and written consent of the participants were obtained before the study. Data were collected at the beginning (T_0), at the end of the third month (T_1) and at the end of the sixth month (T_2) using the Personal Information Form, Antihypertensive Drug Treatment Adherence Scale, Healthy Lifestyle Behaviors Scale, Blood Pressure Monitoring Form. Multiple nursing interventions consisting of hypertension education, brochure and short message created by using Rogers' KMT were applied by the researcher for 14 weeks. The control group was expected to continue their routine treatment for six months and no intervention was applied. Pre-test, interim and post-test measurements were collected by the researcher using the face-to-face interview method. Blindness was applied in terms of statistics expert and reporting. In the analysis of data, t test, chi-square test (Pearson chi-square/Fisher exact test) were used in independent groups, mixed order analysis of variance (ANOVA) was used in comparing variables according to follow-up times in groups, and Bonferroni correction was used in comparing main effects in the analyses. After the applied nursing interventions, a significant difference was found between the total mean scores of Antihypertensive Drug Treatment Adherence Scale, Healthy Lifestyle Behaviors Scale and systolic blood pressure and diastolic blood pressure values of the intervention and control groups ($p<0.05$). After the nursing interventions, the total mean scores of Antihypertensive Drug Treatment Adherence Scale and systolic blood pressure and diastolic blood pressure values of hypertensive

individuals in the intervention group were significantly lower compared to the control group, and the total scores of Healthy Lifestyle Behaviors Scale were significantly higher ($p<0.05$). Based on the results of this study, feasible, economical interventions combining health education and technology can be recommended as an important tool in health services to reduce the burden of hypertension in society.

Keywords: Nursing, Hypertension, Medication adherence, Protective motivation theory, Healthy lifestyle behavior.

1. MATERIALS AND METHODS

1.1. Type of Research

This study was conducted in a randomized, pre-test, post-test controlled experimental parallel design. The research was reported according to CONSORT 2022 (Junqueira et al., 2023).

1.2. Location and Characteristics of the Research

The research was conducted at Family Health Center No. 7 (ASM) affiliated with the Karaman Provincial Health Directorate. The center serves a total of 9,150 people. Three family physicians, three family health workers and one assistant staff work at this center. The ASM provides service between 08:30 and 17:30 on weekdays. The ASM has a laboratory, injection-dressing-emergency room and an examination room for patients. Polyclinic services are provided at all three polyclinics. Regarding hypertension, cardiovascular risk assessment, screening, follow-up and result procedures are performed for individuals registered in the family medicine unit for hypertension. In terms of the duties of the nurse, the nurse measures the blood pressure of hypertensive patients who apply to the center when deemed necessary and directed by the physician, and provides education and counseling services on the disease, medication use and health lifestyle behaviors. There is no planned education or telephone follow-up for patients with hypertension at the center.

1.3. Universe of the Research and Study Group

Universe: The research population consists of 407 individuals with primary hypertension between the ages of 40-59, registered in Family Health Center No. 7.

Working group: In this study, the sample size was calculated before the data collection stage at a 95% confidence level using the "G. Power-3.1.9.2" program to determine the study group. Özpancar's (2013) study, which examined the effect of education given by nurses on

treatment compliance in patients with hypertension, was used for the calculation. According to the data obtained from the study in question, the sample number required for the study was determined as 35 for each group (35 people for the control group + 35 people for the experimental group; 70 people in total) by taking the alpha value of 0.05 for the Mann Whitney U test, the effect size of 0.90, and the theoretical power as 95%. The 10% loss rate in previous studies (Zahr et al., 2019; Dağıstan Aköz, 2022) was taken into account and it was decided to include a total of 78 participants, 39 in each group.

1.4. Inclusion and Exclusion Criteria for Participants in the Study

In this study, the characteristics in Table 3.1 regarding the inclusion and exclusion criteria in the study group were taken into consideration.

Table 1. Participant inclusion and exclusion criteria

Inclusion	Exclusion
• Participants diagnosed with primary hypertension (at least one year) • Between the ages of 40 and 59 * • Those who use a mobile phone to receive the SMS to be sent by the researcher • Those who are at least literate and can speak Turkish • Those who have no communication problems in terms of hearing, seeing and understanding • Those who use antihypertensive medication and who score “8 and above” on the compliance scale, and who are defined as non-compliant with treatment, were decided to be included in the study	• Those with a second chronic disease • Those with a mental or communication problem • Those with secondary hypertension (Addison's disease, Renal artery stenosis, Hypo/hyperthyroidism, Parenchymal kidney disease, Cushing's disease) • Those who are pregnant or breastfeeding,

* It is known that hypertension increases with age (Turkish Society of Endocrinology and Metabolism, 2022). At the same time, according to the socio-demographic data obtained from the ASM where the study was planned to be conducted, the age of the hypertensive individuals who will participate in the study is similar in terms of age, 40 and above, so the lower age limit was determined as 40 in our study. In addition, according to TÜİK data, the upper age limit was determined as 59 years due to the decrease in the rate of internet and mobile phone use in people over 60 years of age in our country (TÜİK, 2022).

1.5. Exclusion Criteria from the Study

1. Wanting to leave the study
2. Moving to another city during the follow-up period
3. Death during the follow-up period
4. Having acute health problems that require hospital monitoring and treatment during the follow-up period

1.6. Randomization

The socio-demographic data (age, gender, education level and income level) of hypertensive patients from the 7th Family Health Center where the study was to be conducted were obtained as a list and found to be similar. Therefore, no stratification was applied in the study while determining the sample of the study. In the first stage of the study, the individuals registered in the 7th Family Health Center and continuing antihypertensive drug treatment were used to determine the hypertensive individuals defined as non-adherent to the treatment (scoring "8 and above") using the antihypertensive drug treatment compliance scale. This process was continued until the specified sample size (n: 78) was reached. Each individual to whom the scale was applied was given a number from one to 78 according to the application order and a list of orders was created. In the second stage, the participants were assigned to the intervention and control groups from the web page (https://www.random.org/) according to the simple randomization method based on the order in the list created. In this assignment, the assignment of the groups was made by an expert in order to ensure blindness.

The flow chart of the control and intervention groups was prepared in line with the guidelines specified in CONSORT 2022 (Figure 1) (Junqueira et al, 2023).

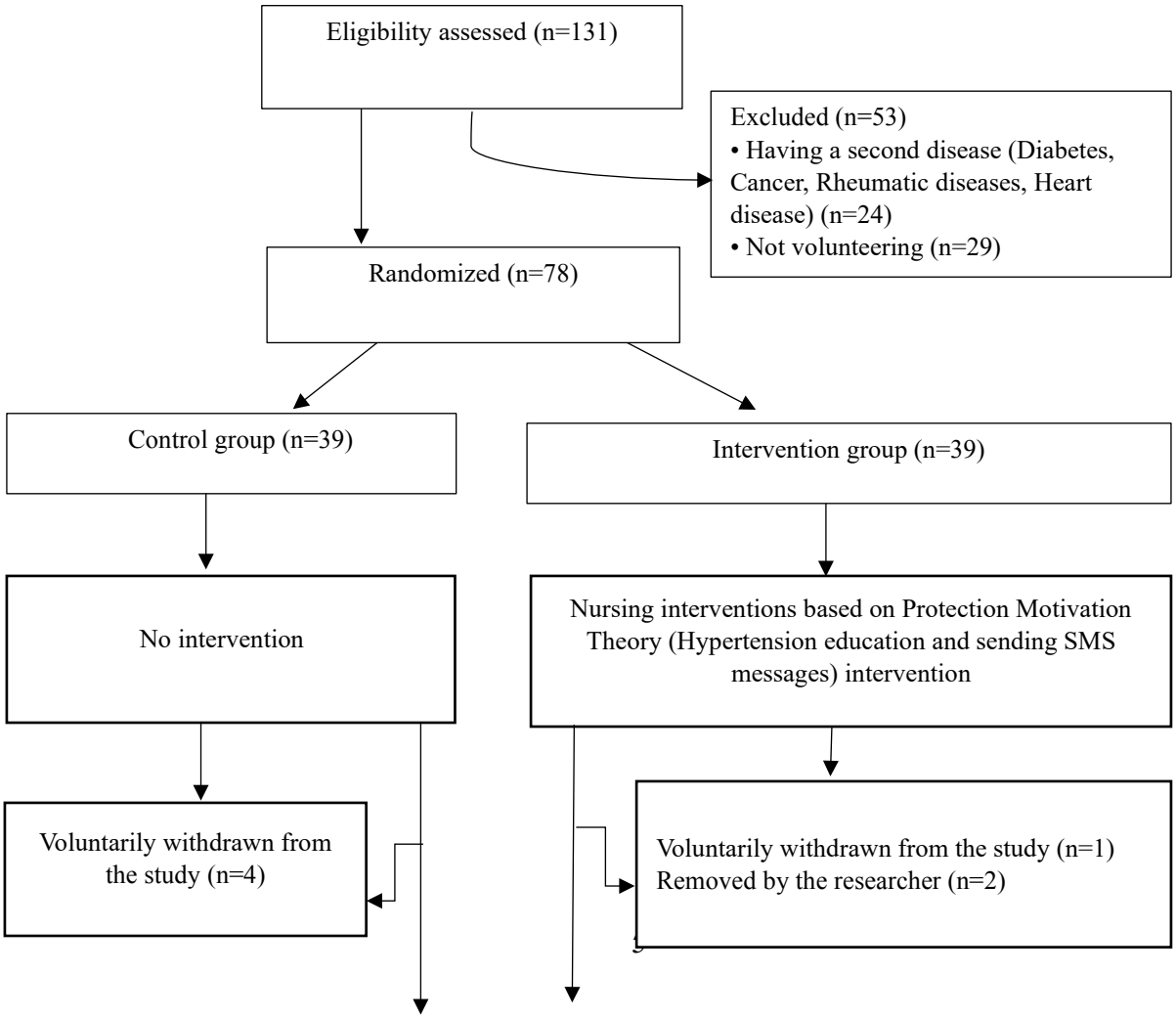


Figure 1. CONSORT (2022) Flowchart of the study.

*ITT analysis

1.7. Reasons for Leaving the Study

The study started with a total of 78 participants and ended with "three" from the intervention group and "four" from the control group. After the participants left, the study was completed with a total of 71 patients, 36 from the intervention group and 35 from the control group. The patients who left the study stated the following reasons for leaving the study: "I am very busy, I can no longer spare time for your work" (n=3), "My blood pressure is no longer high, I am better, I want to leave your intervention" (n=1), "I cannot walk or diet, I cannot lose weight, I do not want to fill out your survey" (n=1) (5 patients in total). In addition, a total of 2 patients had to be removed from the study because the phone numbers they provided could not be reached by the researcher.

1.8. Blindfold

The patients were invited to the study by the researcher involved in the study and participant registration was carried out until the targeted sample size (78 participants) was reached. During participant registration, the names and contact information of the patients were collected, and it was stated that they would be contacted and called for the process related to the study. When the targeted sample size was reached in the study, participant registration was terminated and a participant list was created. It is essential that those conducting the randomized controlled experimental study and the participants do not know who is in the intervention group and who is in the control group until the study starts (Akın and Koçoğlu, 2017). Using the participant list created for this purpose, random selection and assignment were made by someone other than the researcher in the study. Thus, selection bias was controlled in the study. After the groups were determined, the patients were not blinded since their consent would be obtained for the application to be made to them during the intervention process.

In this study, a blind technique was applied by concealing from the researcher who was in the control and intervention groups until the nursing interventions based on KMT began. However, the researcher was not blinded during the intervention period.

Since the aim of the nursing profession is to produce information related to real-world practice beyond the boundaries of the laboratory, it is stated that the action approach will more accurately reflect nursing practice, however, it is said that blinding in action (pragmatic) experiments can generally be difficult (ethical, practical, etc. reasons) and sometimes even impossible, and in this case, it can be recommended to blind only those who evaluate the outputs and perform data analysis (Akın and Koçoğlu, 2017). For this purpose, in order to prevent bias in the evaluation of the data; statistical analyses of the coded data (A and B) in the prepared database were performed by a statistician, independent of the researcher. After the statistical analyses of the study and the appropriate tables for the results were made and the research report was written, the codings made for the control and intervention groups were explained. Thus, statistician and reporting blinding was performed during the research process. Intention to treat analysis (ITT) was applied to prevent attrition bias due to missing data in the outcome/outcome measurements during the study process after randomization. In this way, selection, attrition, statistical and reporting bias were controlled.

1.9. Data Collection Tools

In collecting the data of the study; Exclusion Criteria Form, Personal Information Form, Antihypertensive Drug Treatment Adherence Scale, Healthy Lifestyle Behaviors Scale (SYBDÖ-II), Blood Pressure Monitoring Form, Telephone Monitoring Form, and Short Message Service Monitoring Schedule were used.

1.9.1. Exclusion criteria form

This form was created according to the exclusion and inclusion criteria of the study in order to determine the participants to be included in the study. The form consists of a total of 7 questions (age, education level, primary hypertension diagnosis, a second chronic disease, pregnancy or breastfeeding, mobile phone use, compliance with antihypertensive drug treatment) and 1 study inclusion criterion.

1.9.2. Personal information form

This form was created by the researchers as a result of a literature review (Hacıhasanoğlu et al., 2012; Erci et al., 2018; Deniz Akan et al., 2020; Republic of Turkey

Ministry of Health, General Directorate of Public Health, 2021). The form consists of a total of 20 questions. 9 of which determine the socio-demographic characteristics of individuals (age, weight, height, gender, marital status, education status, employment status, monthly income, lifestyle) and 11 questions related to hypertension (duration of hypertension diagnosis, number of daily anti-hypertensive drugs used, duration of anti-hypertensive drug use, regular use of hypertension drug/drugs, place where the treatment is followed, family history of hypertension, hypertension-specific diet application status, daily tea/coffee consumption status, smoking status, alcohol consumption status, regular exercise status).

1.9.3. Antihypertensive drug treatment compliance scale

The Turkish validity and reliability of the scale developed by Morisky, Green and Levine was conducted by Demirezen and Nahcivan (Demirezen and Nahcivan, 2006). The scale includes a total of 9 statements that diagnose medication-taking behavior. The first 8 questions are answered as Yes and No, and yes answers are coded as “1” and no answers are coded as “0”. The ninth question has the options “1” never/rarely, “2” occasionally, “3” sometimes, “4” usually, and “5” always, and only one option is marked. In the scoring, Yes = 0 points and No = 1 points are evaluated in questions 5 and 6, while Yes = 1 and No is evaluated as 0 in the other questions. The last question, item 9, is a Likert-type and is evaluated between 1 and 5. The Cronbach alpha coefficient of the scale was reported as 0.82 for the entire scale. In the study, the definitions of compliance and non-compliance with antihypertensive drug treatment were determined according to the 80% cut-off point. In this study, Cronbach's Alpha reliability coefficient was found to be 0.674 in the first measurement, 0.797 in the second measurement and 0.748 in the third measurement. In the evaluation of compliance with antihypertensive drug treatment, an increase in score indicates that the individual is "non-compliant". The total scale score varies between '1-13'. Accordingly, individuals who score "1-7" according to the total scale score are defined as compliant with treatment, while participants who score "8 and above" are defined as non-compliant with treatment.

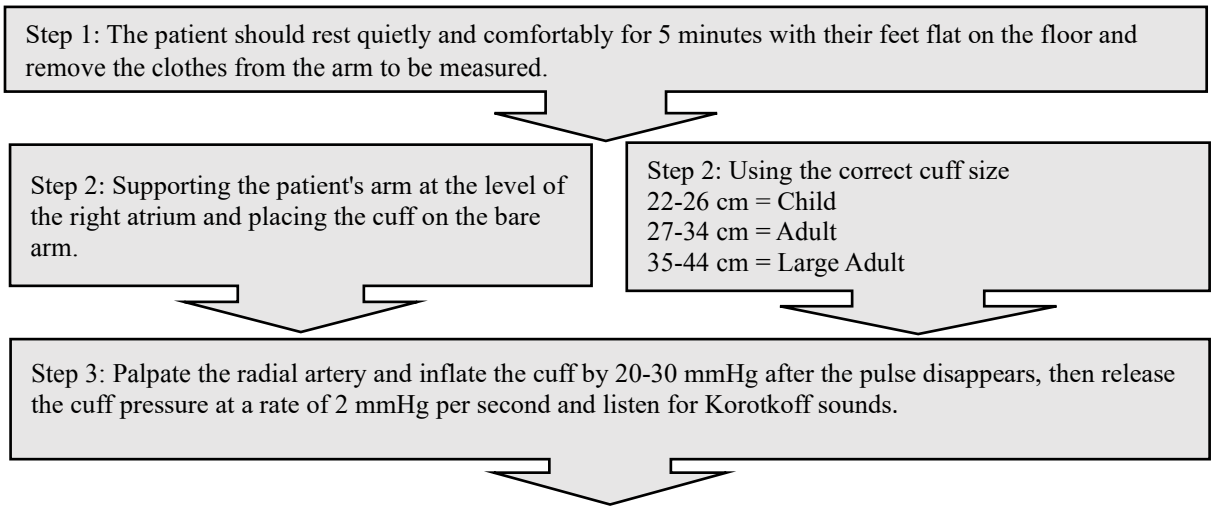
1.9.4. Healthy lifestyle behaviors scale II

Healthy behaviors were collected with the “Healthy Lifestyle Behaviors Scale (HLBS-II)”. The scale was developed by Walker et al. (1987) and revised again in 1996 (Walker and Hill-Polerecky, 1996). The scale consists of 52 items in total and has 6 subfactors. The subgroups are spiritual development, health responsibility, physical activity, nutrition,

interpersonal relations, and stress management. All items of the scale are positive. The rating is in the form of a 4-point Likert. Never (1), sometimes (2), often (3), and regularly (4) are accepted. The Cronbach Alpha coefficient of the original scale is 0.94 and the Cronbach Alpha values of the subdimensions of the scale vary between 0.79 and 0.87. The scale was adapted to Turkish by Bahar et al. (2008). In the study in question, Cronbach's alpha reliability coefficient was determined as 0.92 and the reliability coefficients of the sub-dimensions of the scale were determined as; Health responsibility 0.77, Physical activity 0.79, Nutrition 0.68, Spiritual development 0.79, Interpersonal relations 0.80, Stress management 0.64. In this study, Cronbach's Alpha reliability coefficient was found as 0.904 in the first measurement, 0.928 in the second measurement and 0.926 in the third measurement. The scale measures health-improving behaviors in relation to the individual's healthy lifestyle. The overall score of the scale gives the healthy lifestyle behaviors score. The lowest score for the entire scale is 52, and the highest score is 208.

1.9.5. Blood pressure measurement

Blood pressure was measured by the researcher using a calibrated mercury-manual sphygmomanometer (sphygmomanometer-Erka Perfect Aneroid/Germany) and stethoscope. Blood pressure values were evaluated according to the information in the Turkish Hypertension Consensus Report, and individuals with blood pressure values lower than 120/80 mmHg were defined as “well-managed” and individuals with values above this were defined as “poorly managed.” The steps followed in blood pressure measurement according to the office blood pressure measurement criteria specified in the Directive on Family Medicine Screening and Follow-up Coefficient, the Turkish Hypertension Consensus Report, and the ACD are shown in Figure 2 (Aydogdu et al., 2019; Official Gazette, 2021; American Heart Association, 2022).



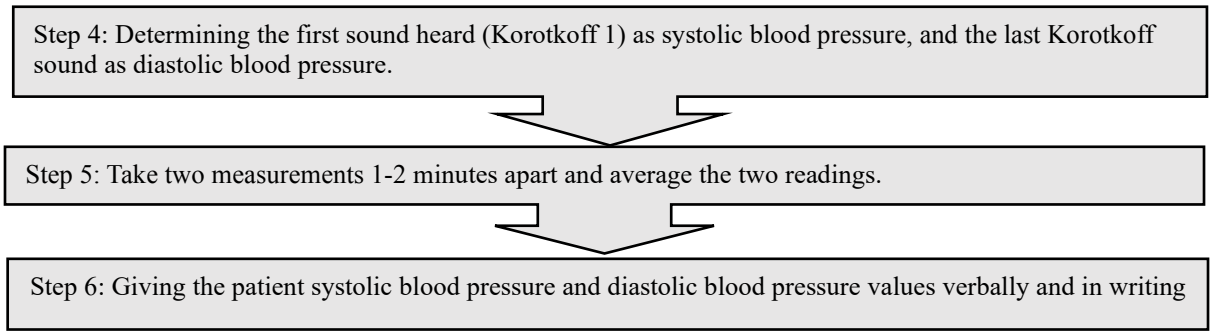


Figure 2. Steps followed in blood pressure measurement (Aydogdu et al., 2019; Official Gazette, 2021; American Heart Association, 2022).

Blood pressure measurements were taken a total of three times (between 09:00 and 17:00 on the day of measurement) for the control group and the intervention group, T0, T1 and T2.

1.9.6. Telephone follow-up form

This form includes 1 question to assess whether the SMSs sent by the researcher were read by the patient. As part of the study, confirmation phone calls were made once a week for the first two weeks and twice thereafter to ensure that the messages were received. No information was provided other than the confirmation that the SMS was received.

1.9.7. Short message service tracking chart

This form, prepared by the researcher using literature (Kes, 2017), includes SMS messages created based on KMT, the patient's name, telephone number, and information indicating the date and time the SMS will be sent.

1.9.8. Measuring results

The primary outcomes of this study were the level of compliance with antihypertensive drug treatment and healthy lifestyle behaviors. Secondary outcomes were changes in SBP and DBP levels. Primary and secondary outcomes were assessed at the first month (T_0), the end of the third month (T_1), and the end of the sixth month (T_2).

Preliminary application: After obtaining permissions for the study, 8 hypertensive individuals (10% of the sample) who met the inclusion criteria were provided with data collection tools and an evaluation of the clarity of the questions; no problems were encountered. These 8 individuals were excluded from the sample.

1.10. Data Collection

Pre-test forms were administered to hypertensive individuals who agreed to participate in the study in November 2023, T1 data in March 2024, and T2 data in May 2024 at the ASM and were filled out by the researcher according to the hypertensive individual's self-report.

1.11. Implementation Process of the Research

The research consisted of the creation of nursing interventions (hypertension education materials (education brochure, education presentation) and SMS messages) and research implementation processes.

1.11.1. Establishing nursing interventions

Nursing interventions were based on KMT and consisted of hypertension education and SMS messages prepared to provide hypertensive patients with medication compliance and healthy lifestyle behaviors. The KMT conceptual framework was used to design nursing interventions. KMT is a common framework explaining the use of health-protective behaviors (Rogers, 1983). In order to engage in health-protective behaviors, it is desired for patients to develop protective motivations. According to the theory, protective motivation is formed as a result of patients' assessments of threats related to their current situation and coping with this threat (Rogers, 1983). In this context, the nursing interventions included in our study were prepared in line with the KMT principles of threat assessment (perceived susceptibility, perceived severity), coping assessment (response efficacy, self-efficacy, response costs) and taking action. In line with these principles, the individuals to be included in the training program, the topics to be included in the program, training methods and materials and SMS messages were determined.

Creation of training materials

The training consisted of a training program including a training presentation and training brochure prepared by the researcher according to KMT variables by scanning the literature (Rogers W., 1983; Aydogdu et al., 2019; World Health Organization, 2021). The hypertension training presentation included the topics specified in Table 1 according to KMT variables;

Table 2 Hypertension training topics

Protection Motivation Theory Variables	Topics
Threat Assessment	Definition of hypertension
	Normal and high blood pressure values
	Importance of hypertension
	Unchangeable and changeable risk factors

	Complications of hypertension
Coping Assessment	Being a treatable disease
	Treatment of hypertension
	Patients' belief that they can control hypertension
	Importance of compliance with antihypertensive drug treatment
	Importance of compliance with healthy lifestyle behaviors
Taking Action	Compliance with antihypertensive medication
	Performing healthy lifestyle behaviors

The training presentation to be made aims to initiate threat assessment (perceived susceptibility, perceived severity) and coping assessment (response efficacy, self-efficacy, response costs) of the variables of KMT, to create protective motivation in patients and to ensure protective actions (medication compliance and gaining healthy lifestyle behaviors). The training brochure was prepared in line with the principles of theory to inform patients, to draw attention to the importance of the subject and to ensure that the given training is remembered later.

Expert opinion was sought in the evaluation of the content validity of the educational material (brochure and educational presentation) and SMS messages prepared for patients with hypertension. The Lawshe technique was used in the process of determining the content validity of the developed educational material and SMS messages. The prepared educational material (brochure and educational presentation) was presented to expert opinion with "expert evaluation forms". The expert opinions obtained in the last stage were evaluated and "content validity rates" and "content validity indices" were determined. Since all experts gave 2-3 suitability points in the suitability score, the content validity index of the educational material (brochure and educational presentation) was determined to be "1". When the critical values determined by Lawshe (1975) by considering 5 experts were taken into consideration, it was determined that the content validity of the developed educational material (brochure and educational presentation) was high since the content validity index was "1" (KGI ≥ KGO).

Phone messages

SMS text messages based on KMT were prepared by the researcher in line with the literature (Aydogdu et al., 2019; World Health Organization, 2020; Turkish Endocrinology and Metabolism Association, 2022; World Health Organization, 2022; Republic of Turkey Ministry of Health, General Directorate of Public Health, 2021, 2023). A total of 24 text messages were designed according to KMT variables.

Implementation of the research

The intervention consisted of two components and lasted 14 weeks (November 2023–March 2024). The first component was hypertension education based on KMT. The second component was sending regular KMT-based SMS messages aimed at reminding, encouraging and motivating patients to maintain medication adherence and healthy lifestyle changes.

Applications made to the intervention group:

1. Hypertension Education:

• Hypertension education was organized as a training session for each participant in the ASM training room and was carried out face to face.

• These trainings were carried out by the researcher. First, the researcher made a hypertension training presentation, then the subject was understood and reinforced with questions and answers. The training period lasted 30-40 minutes for each participant.

• First, the training plan was explained, and their opinions were taken regarding the application day and time. In case of any unexpected situation, an attempt was made to determine a different day of the week with the patients for the make-up training session.

• PowerPoint presentation and training brochures prepared within the scope of the research were used as training materials.

2. Sending SMS Message:

Participants received SMS messages prepared with expert opinions after the approval of the ethics committee twice a week (Tuesday-Friday) for 12 weeks to remind them of the topic after the last training session. 24 different SMS messages prepared according to the KMT variables in order to create protection motivation in hypertensive individuals were sent to the participants in the intervention group twice a week (Tuesday-Friday) between 09:00-17:00 for 12 weeks after the last training session.

Applications made to the control group:

The control group was not subjected to any intervention by the researcher during the study. The control group was given an information note and brochure prepared within the scope of the research along with the collection of post-test data.

1.12. Variables of the Study

Dependent variables: Antihypertensive drug treatment compliance scale score averages, healthy lifestyle behaviors scale score averages, SBP and DBP values.

Independent variables: Nursing interventions based on Protection Motivation Theory.

1.13. Limitations of the Study

- The study was limited to only patients diagnosed with hypertension who were followed up at the 7th ASM affiliated to the Karaman Provincial Health Directorate during the relevant dates.
- The fact that the study was conducted over a six-month period is also a limitation of our study. However, despite this, the group*time effect was evaluated during the analysis phase and as a result, it was shown that the nursing interventions created a statistically significant change during the six-month application period.
- The researcher could not be blinded due to the nature of the study.
- There was an appointment for another time to provide individual education to the patients in the intervention group.

1.14. Strengths of the Research

- The results of this research have shown that remote health services can be provided to hypertensive individuals via mobile phones, and in this respect, it has contributed to the literature on the use of digital health technologies.
- It is thought that the research will contribute to evidence-based nursing due to the fact that the research was conducted in a randomized controlled manner, blind technique was used, and ITT analysis included effect size and confidence intervals.
- The fact that the nursing interventions (SMS message and education) applied in the research were free, easy and simple shows that they are feasible in terms of cost.
- In addition, the use of theory in the foundation of nursing interventions in this research is one of the strengths of the research.

1.15. Analysis of Data

In this study, data analyses were performed using the IBM SPSS Statistics Standard Concurrent User V 26 (IBM Corp., Armonk, New York, USA) program. Descriptive statistics were given as number of units (n), percentage (%), mean (X), standard deviation (SS), median (M), minimum (min) and maximum (max) values. Reliability for scales and their sub-dimensions was examined using Cronbach's Alpha coefficient. Scales with a Cronbach's Alpha coefficient above 0.60 were considered reliable. Skewness and kurtosis values were examined to test whether the data met the assumption of normality. In the decision phase, if the absolute skewness (Skewness) value is below ± 2.0 and the kurtosis value is below 7.0, it is decided that the data is normally distributed (Kim, 2013). In the comparison of numerical descriptive characteristics of the patients between groups, independent sample t test was used, and in the

comparison of categorical descriptive characteristics between groups, chi-square tests (Pearson chi-square/Fisher exact test) were used. In the comparison of variables in the groups according to the follow-up times, mixed order analysis of variance (ANOVA) was used. Bonferroni correction was applied in the comparison of main effects in the analyses. The value of $p<0.05$ was considered statistically significant. Intention to treat (ITT) analysis was performed in the evaluation of the data. Since it was not possible to reach the 7 individuals who left during the research process for the ITT analysis of this study, the post-tests were filled by repeating the answers given by the patients in the pre-tests, and the missing data were completed in this way.

1.16. Ethical Dimension of the Research

Before the research, ethical approval was obtained from Necmettin Erbakan University Health Sciences Scientific Research Ethics Committee with the decision number 404 dated 05.04.2023 and written permission was obtained from Karaman Provincial Health Directorate. This research was conducted in accordance with the Helsinki Declaration Principles. Before filling out the questionnaire form, participants were informed about the research and their written and verbal consents were obtained. Necessary permissions were obtained via e-mail from the authors who adapted the scales into Turkish for scale use.

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