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Araştırma makalesi

Hipertansiyon Hastalarına Verilen Eğitim ve Telefon Danışmanlığının İlaç Tedavisi Uyumuna ve Akılcı İlaç Kullanımına Etkisi: Tek Kör Randomize Kontrollü Çalışma İçin Çalışma Protokolü

Effect of Training and Telephone Counseling Given to Hypertension Patients on Drug Medication Adherence and Rational Drug Use: Study Protocol For Single-Blind Randomized Controlled Trial

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Özet:
Amaç: Bu araştırma hipertansiyon hastalarına verilen eğitim ve telefon danışmanlığının ilaç tedavisi uyumuna ve akılcı ilaç kullanımına etkisini belirlemek amacıyla yapılacaktır.
Yöntem: Bu çalışma, tek kör, randomize, kontrollü deneysel bir çalışma olarak planlanmıştır. Çalışma protokolü SPIRIT rehber alınarak oluşturulmuş ve araştırmanın raporlanması CONSORT kontrol listesine göre yapılandırılacaktır. Araştırma Bir Devlet Hastanesinin Dâhiliye Polikliniğine başvuran hipertansiyon hastaları üzerinde Temmuz 2021- Haziran 2022 tarihleri arasında yürütülecektir. Araştırmanın evrenini polikliniğe başvuran hipertansiyon hastaları, örneklemini ise 46 deney ve 46 kontrol olmak üzere 92 hipertansiyon hastası oluşturacaktır. Bu araştırmada hastalar deney ve kontrol grubuna blok randomizasyon yöntemiyle rastgele atanacaktır. Araştırmanın verileri "Hasta Tanıtım Formu", "İlaç Tedavisine Uyum Öz-Etkililik Ölçeği Kısa Formu" ve "Akılcı İlaç Kullanımı Ölçeği" ile toplanacaktır. Deney grubundaki hipertansiyon hastalarına "Hipertansiyon Hastalarında İlaç Kullanımı ve Akılcı İlaç Kullanımı Eğitimi" verilecektir. Ayrıca deney grubundaki hastalara 1.ayda 2 kez (2. ve 4. hafta), 2. Ayda (8.hafta) 1 kez ve 3.ayda (12.hafta) 1 kez olmak üzere toplam 4 kez, ortalama 10-15 dakikalık telefon danışmanlığı verilecektir. Kontrol grubu hastalar rutin hastane bakımı alacaklardır.
Bulgular: Bu çalışma, tek kör randomize kontrollü deneysel çalışma için çalışma protokolüdür. Çalışma verileri toplanıp analiz edildikten sonra bulgular açıklanacaktır.
Sonuç: Bu protokol hipertansiyon hastalarına verilen eğitim ve telefon danışmanlığının ilaç tedavisi uyumuna ve akılcı ilaç kullanımına etkisi değerlendirilecektir.
Anahtar Kelimeler: Hipertansiyon; telefon danışmanlığı; akılcı ilaç kullanımı; ilaç tedavisi uyumu; hemşirelik.

Abstract:
Aim: This research will be performed with the aim of determining the effect of training and telephone counseling given to hypertension patients on drug medication adherence and rational drug use.
Methods: The research is planned as a single-blind, randomized, controlled experimental study. The study protocol will be created using the SPIRIT guide and reporting of the research will be constructed according to the CONSORT checklist. The research will be performed from July 2021 to June 2022 with hypertension patients attending in a state hospital. The population of the study will be hypertension patients who applied to the polyclinic, and the sample will be 92 hypertension patients, 46 of which are experimental and 46 control. In the research, patients will be randomly assigned to experiment and control groups with the block randomization method. Research data will be collected with the 'Patient Description Form', 'Drug Medication Adherence Self-Efficacy Scale Short Form' and 'Rational Drug Use Scale'. Hypertension patients in the experiment group will undergo 'Drug Use and Rational Drug Use Training for Hypertension Patients'. Additionally, patients in the experiment group will be given telephone counseling lasting mean 10-15 minutes a total of 4 times; 2 times during the 1st month (2nd and 4th week), 1 time during the 2nd month (8th week) and 1 time during the 3rd month (12th week). Control group patients will receive routine hospital care.
Results: This study is the study protocol for a single-blind randomized controlled experimental study. The results will be explained when the study data are collected and analyzed.
Conclusion: This protocol will assess the effect of training and telephone counseling given to hypertension patients on their adherence to drug medication and rational drug use.
Key Words: Hypertension; telephone counseling; rational drug use; drug medication adherence; nursing.

Introduction

Chronic diseases are non-infectious diseases with slow progression causing irreversible changes, requiring lifelong medical care and medication.[1-3] According to the World Health Organization (WHO), the main chronic diseases are cardiovascular diseases, cancer, diabetes mellitus and chronic respiratory tract diseases.[4] These four disease groups comprise 82% of all chronic diseases.[5] Among causes of death around the world, chronic diseases are in first place and it is stated that 71% of deaths are due to chronic disease. Globally, 17.9 million people die due to cardiovascular disease, 9.3 million people die due to cancer, 4.1 million people die due to chronic respiratory tract diseases and 1.5 million people die due to diabetes mellitus annually.[4] In Turkey, chronic diseases top the list of causes of death and 87.5% of all deaths are stated to be due to chronic diseases.[6.7] In 2019 in Turkey, 14.226 deaths occurred due to diabetes, 160.263 deaths occurred due to circulatory system diseases, 56.391 deaths occurred due to respiratory system diseases and 80.186 deaths occurred due to cancer.[8]

Hypertension is a chronic disease characterized by high blood pressure. It was stated there are 1.13 billion hypertension patients around the world, with hypertension disease observed in 1/4 of men and 1/5 of women.[4] According to the results of the Turkish Household Health Research (2017), 26.1% of men and 29.3% of women have high blood pressure and were identified to use medications for high blood pressure.[9] Regular use of medication, attention to diet, blood pressure monitoring and physical activity are important in terms of quality of life for hypertension patients.[10,11] Additionally, patients using drugs in the way prescribed by doctors contributes to medication adherence. Drugs used for hypertension disease regulate blood pressure though actions like ensuring excretion of water from the body, balancing water and sodium amounts in the body, relaxing blood vessels, ensuring the heart operates with less force and blocking nerve activity that will restrict blood vessels. In some situations it is necessary to use more than one medication for blood pressure to reach normal levels and rational drug use

is important for disease management.[12] If hypertension disease is untreated for long durations, it may cause permanent chest pain, heart attack, heart rhythm disorders, heart failure, sudden death, stroke and renal failure.[4] For this reason, management of hypertension is very important in terms of the quality of life of patients.[13] Additionally, correct and regular use of drugs necessary for medical medication by patients and abiding by rational drug use principles reduces morbidity and mortality.[14-15] The concept of rational drug use was first defined by WHO in 1985 as patients using drugs at adequate dose and duration appropriate for medication.[14] Patients not having adequate information about side effects of drugs, and when and how to use them may cause them not to obtain the clinical outcomes expected from the drugs and other unwanted outcomes.[15] The WHO stated that non-rational drug use is an important problem around the world, with more than half of drugs prescribed inappropriately and half of patients not using drugs correctly.[4] Rational drug use by patients increases adherence to drug medication.[16,17] Patient adherence to drug medication begins with accepting use of the drug, and continues with using or not using the drug at the recommended levels.[17] Patients may display poor adherence to medication due to reasons like misunderstanding medication, forgetfulness, not thinking they need the drug, not liking the taste of the drug, choosing to use non-drug medications, and fear of drug side effects. Medication adherence of patients may be affected by drug experiences, beliefs, cultural features, effect of their age group and self-efficacy. Additionally, medication adherence of patients may be affected by difficulty in accessing health services and drugs, low patient education level and costs.[17-19] Determined that medication non-adherence rates were 56.3% in a study aiming to assess adherence to medication. Among patients, 43.1% did not adhere to medication due to forgetting to take the drugs, 39.7% due to fear of drug side effects and 29.3% due to not thinking they need to use drugs regularly. Patients not adhering to medication may lead to increased hospital attendance, negative health outcomes, increasing care costs and increasing morbidity and mortality.[18]

It is necessary to educate patients for effective management of hypertension and to ensure patient adherence to medication.[20] A study by Erci et al. (2018) determined that patients receiving information about hypertension and with regular blood pressure monitoring had higher adherence to medication.[21] In terms of patient adherence to medication, training may ensure they take responsibility for their health, learn healthy lifestyle behaviors and are able to make accurate decisions about care.[22] Among the aims of education in disease management are informing the individual about the disease, ensuring adherence to the medication program, individuals being able to participate in medication plans, changing the person's lifestyle according to disease, developing problem-solving skills, preventing progression of disease, increasing disease adjustment and satisfaction, elevating quality of life, increasing independence, and reducing complications and mortality.[7,23] Training of patients by health professionals is emphasized to be necessary to prevent complications during disease management.[24]

Health professionals undertake important roles in the process of prescribing drugs, administering them to patients and during use. Nurses play a key role in administering prescribed drugs, rational drug use and patient education.[14] During disease management, nurses educate patients with the aim of controlling disease progression and reducing complications may occur linked to the disease.[25] Nurses organize health education studies considering the biological, psychological and social surroundings of patients.[22,23] Patient education is a dynamic process. This process comprises the stages of collecting data/determining educational needs, definition, planning, implementation, assessment and recording. During patient training, education should be given using appropriate language and terminology that the patient can understand, with methods appropriate for the patient in suitable durations and environments.[23] Disease adjustment of patients may be strengthened with a variety of training and teaching methods in order to successfully manage diseases.[26] Nurses

support hypertension patients in the stages of training about disease, care, counseling and adjusting to disease.[2,27] During training, nurses may use different methods and tools like handbooks, guides, video or rational phones.[7,17]

Telenursing implementations are used currently for management of increasing chronic diseases accompanying the aging of society.[28,29] In telenursing practice, technology like email, mobile phones, video conferencing systems, cameras, websites and devices operated linked to the internet are used.[28,30] With telenursing, nurses provide services like patient care, follow-up, data collection, pain management, training and counseling from a distance.[28,29,31] At the same time, patient training and counseling services are performed at home with regular telephone interviews.[25,28] Telephone use, messaging and other communication technologies are technology used in telenursing services.[25] Access to nursing services is expanded with these communication devices.[32] Care given with telenursing services increases quality and safety, accelerates patient access to nursing services and provides service more easily to patients experiencing access problems due to geographical conditions.[25,30,32,33] Telenursing services may reach individuals with chronic diseases requiring care at home, especially.[32] Currently, most individuals have a telephone providing the possibility to access individuals throughout the day.[11,32]

Nurses perform telephone counseling to monitor and increase adherence to medication of individuals with chronic disease.[10] Telephone counseling ensures continuity of patient care and increases the quality of care, reduces health service costs, increases communication between nurse and patient and provides support to the patient and family. Telephone counseling is very important for patients who wish to continue care and medication at home.[34] It is accessible especially for patients living distant from health centers and is cheaper than hospital costs, while giving telephone counseling to patients provides benefit in terms of ensuring appropriate referral and check-up procedures by identifying symptoms in the early period.[33,34]

It was stated that training along with telephone counseling provides significant benefits for disease management.[30,34]

Aim of the Research

This research was performed with the aim of determining the effect of training and telephone counseling given to hypertension patients on drug medication adherence and rational drug use.

Research Hypotheses

H1: Training and telephone counseling given to hypertension patients increases drug medication adherence.

H2: Training and telephone counseling given to hypertension patients increas rational drug use.

Method

Research Type: This research was planned as a single-blind, randomized, controlled experimental study.

Location and Time of the Research: The research will be performed from July 2021 to June 2022 with hypertension patients attending in a state hospital.

Research Universe and Sample: The universe for the research will comprise hypertension patients attending in a state hospital. The sample for the research will comprise 92 patients attending the internal medicine clinic, abiding by the research criteria and accepting participation in the research. Power analysis was performed with the G-Power 3.1.9.4 program to determine the size of the research sample. Calculations were performed using the effect size in the study by Cakmak (2019) for the rational drug use scale.[35] Calculations according to the double-sided independent samples t test taking the effect size as 0.62, error share (α=0.05) and 80% power calculated the sample number as 84.[36.37] Additionally, sample size was calculated using the effect size in the study by Kes (2017) for drug medication adherence.[38] Calculations according to the double-sided independent samples t test taking the effect size as 0.80, error share (α=0.05) and 80% power calculated the sample number as 52.[36.37] Noting the calculations

according to the rational drug use scale with higher sample numbers for the sample size calculated according to the two measurement tools in the research, the study was planned with a total of 84 people. Additionally, considering data loss during the research process, the plan was to include 10% more patients than the calculated sample size for a total of 92 patients with 46 in the experiment and 46 in the control group.

Inclusion Criteria for the Research:

- Diagnosis of hypertension
- A least 6 months hypertension disease duration
- Using at least one medication due to hypertension
- Aged over 18 years, literate, living in the county center
- Owning a telephone, open to communication and cooperation
- Volunteering to participate in the study.

Exclusion Criteria for the Research:

- Psychiatric disease
- Hearing loss
- Unable to understand and speak Turkish
- Not wishing to continue with the research.

Randomization in the Research

After receiving consent from patients attending the internal medicine clinic, abiding by the research criteria and accepting participation in the research, the pretest in the research will be applied. After applying the pretest, patients will be assigned to experiment and control groups with the block randomization method. For block randomization, firstly 4 paired combinations of A and B will be created to obtain 6 different outcomes: ABAB(1); ABBA(2); BBAA(3); AABB(4); BAAB(5); BABA(6) (6 combinations) 92/4=23. Numbers from 1 to 6 will be randomly distributed 23 times using randomizer.org.

(randomizer.org)

1 Set of **23** Numbers

Range: From **1** to **6**

Set #1

4, 6, 5, 6, 1, 2, 5, 2, 2, 4, 5, 3, 3, 5, 4, 6, 5, 6, 2, 3, 4, 6, 4.

Combinations will be ranked accordingly: AABB; BABA; BAAB; BABA; ABAB; ABBA; BAAB; ABBA; ABBA; AABB; BAAB; BBAA; BBAA; BAAB; AABB; BABA; BAAB; BABA; ABBA; BBAA; AABB; BABA; AABB. Then A and B numbers will be named experiment and control group according to a lottery method and patients will be randomly assigned to experiment and control groups in this way.

Blinding/Prevention of Bias in the Research

The study protocol for the research will be created using the SPIRIT guidelines and research reporting will be constructed according to the CONSORT checklist.[39-40] To prevent selection bias in the research, patients will be assigned to the experiment and control groups with the block randomization method. Patients will not know whether they are in the experiment or

control group. This assignment will be performed by a researcher not included in implementing the procedures and group assignments will be announced in order during randomization with opaque envelopes. To prevent detection bias during research measurements, the posttest for the research will be applied by a graduate nurse who is not one of the researchers. To prevent attrition bias, if necessary, intention-to-treat (ITT) analysis will be performed. To prevent reporting bias, research data will be analyzed by an expert statistician.

Research variables

Dependent variables: Mean points on the Drug Medication Adherence Self-Efficacy Scale Short Form and Rational Drug Use Scale.

Independent variables: Education and telephone counseling given to hypertension patients.

Control variables: Sociodemographic and disease-related characteristics of patients.

Outcome Criteria

The primary outcome criteria in the study were the 'Patient Description Form', 'Drug Medication Adherence Self-Efficacy Scale Short Form' and 'Rational Drug Use Scale'. The secondary outcome criteria were the systolic and diastolic blood pressure values of patients.

Primary Outcome Criteria

Patient description form: This form was prepared in line with the literature by the researcher.[38,41-47] The form includes sociodemographic characteristics of patients and features related to disease.

Drug medication adherence self-efficacy scale short form: The scale developed by Ogedegbe et al. (2003) was revised by Fernandez et al. (2008) and Turkish validity and reliability of the scale was performed with hypertension patients by Hacıhasanoğlu et al. (2012).[48-50] The scale comprises 13 items and determines the adherence self-efficacy/confidence levels of individuals with hypertension in relation to drug medication. Each

question on the scale is assessed with points from 1 to 4. The lowest points that can be obtained from the scale are 13, with highest points of 52. Increases in scale points show the adherence to antihypertensive drug medication of the individual increases in a positive way. The original scale had Cronbach alpha coefficient of 0.93.

Rational drug use scale: The scale, developed by Cakmak and Cınar Pakyuz (2020), is used with the aim of determining the rational drug use status of adult individuals.[51] The scale contains 36 items with 3-point Likert rating. The scale includes 6 subdimensions of behavioral beliefs (items 1-9), control beliefs (items 10-16), attitude (items 17-21), subjective norm (items 22-23), intention (items 24-28) and knowledge (items 29-36). Points for scale items are given as never (0), sometimes (1) and all the time (2); for negative items (items 13, 14, 17, 18, 19, 20, 21 and 24) points are given as never (2), sometimes (1) and all the time (0). Points that can be obtained on the scale vary from 0-72. As points obtained on the scale increase, rational drug use levels increase. The original scale had Cronbach alpha value of 0.85.

Secondary outcome criteria

In the research, systolic and diastolic blood pressure measurements will be performed for patients.

Data Collection

In the research, the researcher will apply pretests in the hospital to patients in the experiment and control groups, attending at State Hospital Internal Medicine Clinic, abiding by the research inclusion criteria and accepting participation in the research. Pretest data in the research will be collected in mean 20 minutes with the face-to-face interview technique using the ‘Patient Description Form’, ‘Drug Medication Adherence Self-Efficacy Scale Short Form’ and ‘Rational Drug Use Scale’. Posttest data in the research will be collected from patients in the experiment and control groups with the ‘Drug Medication Adherence Self-Efficacy Scale Short Form’ and ‘Rational Drug Use Scale’ 3 months after the beginning of the research. Data will

be collected by a graduate nurse, outside of the researchers, in mean 15-20 minutes with the face-to-face interview technique in hospital.

Intervention

Training about drug use and rational drug use for hypertension patients: In the research, the content of Training about Drug Use for Hypertension Patients was prepared in line with the literature[52-54] and the content of Rational Drug Use Training was prepared according to the Republic of Turkey Ministry of Health Rational Drug Use Guidelines[55] Training will be given to patients in the experiment group in a single session lasting mean 45-50 minutes. Training content will be presented as a PowerPoint presentation and a training booklet prepared related to the topic will be given to patients in the experiment group after training.

Telephone counseling: Patients in the experiment group will be given mean 10-15 minutes of telephone counseling a total of 4 times; 2 times in the 1st month (2nd and 4th week), 1 time in the 2nd month (8th week) and 1 time in the 3rd month (12th week). In the first 10 minutes of telephone counseling, patients will be given information and reminders about hypertension and drug use. In the last 5 minutes, regular use of drugs will be questioned and patient questions will be answered. Telephone counseling will be performed by the researcher between the hours of 16.00-18.00 on week days as suitable for the patients.[44,45]

Control Group: Patients in the control group in the research will not receive any training or telephone counseling. They will receive routine hospital follow-up.

Ethical Dimension of the Research

Permission to use the Drug Medication Adherence Self-Efficacy Scale Short Form and Rational Drug Use Scale in the research were obtained by email from the authors. Institutional permission as obtained from Ordu Provincial Directorate of Health and ethical committee permission was obtained from Ordu University Clinical Research Ethics Committee (Decision no: 163). People agreeing to participate in the study will provide verbal and written consent

after the aims and benefits of the study are explained. The rules of the Helsinki Declaration will be abided by during the study. Participants will be told they are free with regard to participation in the research and able to leave the research at any stage. They will be told the results of the research will be published for scientific aims without any identifying information. For ethical purposes, patients in the control group will be given the training booklet after applying the posttest in the research.

Analysis of Data

Analysis of data will be performed in the computer environment by an expert statistician. Fit of data to normal distribution will be assessed. Significance level in the research will be taken as $p<0.05$. Descriptive statistics will be used for distribution of sociodemographic and disease-related characteristics of patients in the experiment and control groups. Comparison of control variables will use the chi-square test and independent groups t test. The self-efficacy scale of adherence to drug therapy and rational drug use scale scores of the patients in the experimental and control groups will be compared according to the group and time. The relationship between the self-efficacy scale of adherence to drug therapy and the pre-post test scores of the rational drug use scale of the experimental and control group patients will be examined.

Limitations of the Research

Limitations of the research are the inability to include those who are illiterate and do not have telephones and inclusion of only patients with hypertension living in a state hospital.

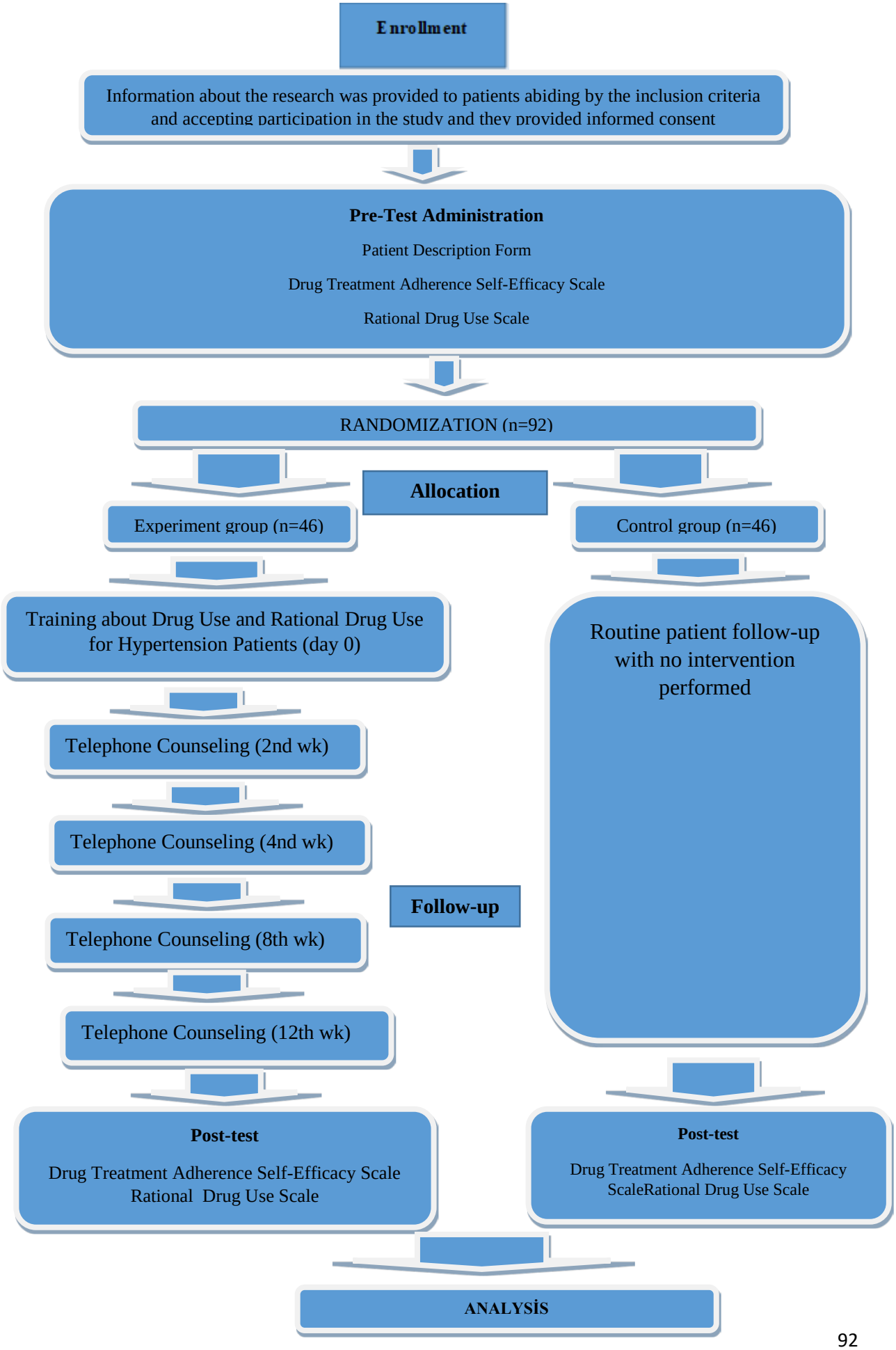

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) Flowchart

Discussion

Hypertension is an important public health problem in the world in general. If hypertension is not controlled, serious complications may develop. To prevent complications, adherence of patients to medication is important.[56] In hypertension patients, basic lifestyle changes include preserving body weight, regulating diet, limiting sodium and alcohol intake, stopping tobacco use, increasing physical activity and definitely abiding by regular drug use.[57] Nurses should support patients by providing training and counseling about medication adherence for hypertension patients. Providing support in the home environment is important for hypertension patients.[58] It is necessary to benefit from technological developments to prevent complications and ensure medication adherence during management of chronic diseases like hypertension.[56] In the literature, it appears that training and telephone counseling were provided separately for hypertension patients. However, studies about monitoring and supporting hypertension patients with training in the hospital environment and telephone counseling at home are inadequate. In this study, patients will be given 'Training about Drug Use and Rational Drug Use for Hypertension Patients' face-to-face in the hospital supported by telephone counseling in the home environment. In this way, the target is to increase drug medication adherence and rational drug use of hypertension patients.

Conclusion

The results of this study will contribute to the literature about increasing drug medication adherence and rational drug use of patients through education and telephone counseling given to hypertension patients. The findings obtained in this study will create a database for future research and contribute to preventing complications that may develop in patients with hypertension, reducing hospital admissions, increasing quality of life of individuals and contributing to the economy with cost-effectiveness.

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Conflict of interest

"No conflict of interest has been declared by the authors."

Author contributions

Authors had a substantial contribution to the manuscript. HA and HGU in-volved in conceptualisation, study design, screening, data collection, quality appraisal, writing–original draft, review and editing, and final approval.

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