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STATISTICAL ANALYSIS PLAN

OFFICIAL TITLE: Investigation of The Effect of Training Given According to Roy
Adaptation Model On Adaptation to The Disease in Patients With Hypertension A
Single-Blind Randomized Controlled Study With Pretest-Posttest

DATE OF DOCUMENT: July 20, 2018

Statistical Analysis Plan

As a result of the power analysis performed using Gpower version 3.1.9.2; while Type 1 error amount (alpha) was 0.05, test power (1-beta) was 0.8, effect size was 0.91 and alternative hypothesis (H1) was two-sided, the minimum sample size required to obtain a significant difference by using this test was determined as 21 subjects in each group. However, considering that there might be losses in the study, the sample of the study was composed of a total of 68 patients including 34 in the experimental group and 34 in the control group who applied to the cardiology clinic and outpatient clinic of a university hospital, met the inclusion criteria and were diagnosed with hypertension. The study was completed with a total of 60 patients including 30 in the experimental group and 30 in the control group because of the communication problem with two (2) patients from the experimental group and the death of two (2) patients from the experimental group during the study.

Randomization was performed by a statistician who had no contact with the participants and randomized them to the experimental and control groups by generating random numbers from MedCalc 18.2.1 software. The participants were randomly divided into intervention and control groups including 34 participants in each. However, four patients from the experimental group and four patients from the control group were excluded from the study while the study was continuing. The patients were informed about the study and their informed consents were obtained. In this study, the participants of the experimental and control groups were blinded to each other; however, the researcher was not blind to the group assignment due to the nature of the study. The participants in the experimental group were invited to be a part of a hypertension training program. This study lasted for approximately 5 months. The training program was given in an appropriate room in the cardiology outpatient clinic of a university hospital and the interaction between the two groups was inhibited. Figure 1 shows the flow chart of the study.

The statistical evaluation of the data obtained as a result of the study was performed by using 24.0 version of SPSS program and p <0.05 was accepted as statistically significant. In order to control if the continuous variables are suitable for normal distribution, Shaphiro Wilk test was used. For the statistical analysis of the data obtained as a result of the study, mean±standard deviation, percentage, Chi-square test, Mann Whitney U test, Wilcoxon test and Cronbach's alpha internal consistency test were used.

