Disease Management for Coronary Artery Patients

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Study Protocol

Setting and samples

This study was planned as a single-blind randomised controlled trial with pretest–posttest and followed the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) statement. The population of the study was composed of the patients diagnosed with coronary artery disease (CAD) staying in cardiology clinic of a State Hospital in Southeast Anatolia Region, Turkey (March, 2019–March, 2020). The sample size of the study was determined according to the result of the power analysis. The minimum sample size required for the difference to be significant in terms of compliance questionnaire (CQ) scores in patients who received and did not receive training was determined to be at least 26 patients in each group ($\alpha = .05$, $1- \beta = .80$, effect size = .80). The patients, who were aged between 18 and 79, were diagnosed with CAD for at least 2 months, had no hearing and vision problem, had no perception and expression deficiency, were not diagnosed with any psychiatric dis-ease and were voluntary to participate in the study, were included in the study. A total of 74 patients meeting the inclusion criteria (37 in the intervention group and 37 in the control group) were included in the sample. However, the study was terminated within the scope of COVID-19 pandemic measures that started abroad and affected Turkey too. The sample of the study consisted of 58 patients (30 in the intervention group and 28 in the control group) whose data were completely collected until the pandemic period.

Data collection tools

The data of the participants were collected by using personal information form, anthropometric measurements, Framingham risk score and compliance questionnaire.

Personal information form

It was prepared by the researchers by reviewing the related literatures. In this form, there were questions investigating the patients' socio- demographic characteristics, anthropometric measurements and CAD risk factors.

Compliance questionnaire

Compliance Questionnaire (CQ) is a form allowing to investigate 11 different areas such as the use of medication causing maladaptation in disease management in individuals with chronic illnesses, diet, weight loss, limiting physical activity, exercise, coping with stress, alcohol use, smoking, sexual activity problems, caffeine intake and working/job life. It was developed by Marston in 1969. In the form allowing Likert-type evaluation, the participant is expected to select one of the options 0 (never), 1 (very rarely), 2 (sometimes), 3 (most of the time) or 4 (always) while expressing his/her adherence level for each adaptation area. The scores corresponding to the given expression are summed, and CQ score for each participant is determined. The maximum score is 44. High score signifies an increase in the adherence level to the disease. In the validity and reliability study, internal consistency of CQ was determined as Cronbach's Alpha value .56 and intraclass correlation coefficient value .69. In this study, the internal consistency Cronbach's Alpha value of the responses given to CQ was found as .701.

Anthropometric measurements

Anthropometric measurements (height, weight, waist circumference and hip circumference) were performed by the researcher when the patients had thin clothes that would not change their weights. In repeated measurements, attention was paid to ensure that the clothes were in similar weights. For example, the patient, who wore a thin pyjama in the first measurement, was asked to change his clothes if he/she wore a thick sweater in the second measurement. In addition, care also given during the weight measurements that the patients were hungry and did not need defecation/micturition. Weight measurements were made using a digital scale showing decimal values and measuring weights in kilograms. While measuring the height, waist circumference and hip circumference, a plastic tape measure divided by 0.1 cm intervals without stretching feature was used. In the measurements made with tape measure, the patients were asked to stand upright position and leave their abdomen freely by not pulling in. The obtained data were recorded in the related form.

Randomisation

The patients informed at the beginning of the study were randomised into the intervention and control groups. Randomisation was performed using random numbers produced in the computer (SPSS version 20 software) by a statistician who had no contact with the participants and did not participate in the study. All patients participating in the study were blinded during the randomisation process but the researchers were not blinded due to the nature of the intervention research. The patients in the control group continued to receive standard care by being unaware that they were in a training programme about treatment adherence in CAD. On the other hand, the patients in the intervention group were invited to participate in a training programme on treatment adherence in CAD.

Data collection

The data collection process of the study was carried out in two stages using data collection tools.

First stage

Personal Information Form and Compliance Questionnaire were applied to all patients in both groups. After anthropometric measurements, FR score was determined. The data collection forms were filled with the patients using face-to-face interview technique. The data collection process lasted for approximately 10–15 min. After the data collection, the patients in the intervention group were trained. The patients in the control group were given only standard care protocol by clinicians. During study, no training programme was given to the patients in the control group by researcher but they received a 'Coronary Artery Disease Adherence Guide' end of study.

Second stage

12 weeks after the first interview, the patients were interviewed again face-to-face interview technique and the forms and measurements applied initially were repeated. The content of the collected data was the same as first stage.

Standard care protocol

In the standard care protocol provided by clinicians, no printed/visual material was provided to the patients, only verbal information was given. In this protocol, only unstructured basic information about the disease, treatment and risk factors is given to the patients. However, behavioural changes in patients are not followed. Standard care protocol was applied by clinicians to all patients participating in the study. In addition, coronary artery disease training programme was applied to the patients in the intervention group by first researcher.

The training programme is not only more structured training than the standard care programme but also includes patient follow-up at certain periods. Thus, the effect of the given education and follow-up on patient behaviour is monitored. A training guide named 'Coronary Artery Disease Adherence Guide' was given to the patients in the intervention group. This training guide includes information about basic information about CAD, risk factors (hypertension, diabetes, obesity, smoking, alcohol, stress and sedentary life), adherence with treatment (drug use and clinical check-up appointments) and healthy lifestyle behaviours (exercise and weight control). The training guide was prepared by the researchers by bringing guides prepared by national and international organisations about the subject and the related literature together. While preparing the training guide, attention was paid to use plain language and 16 font size so that patients could easily read and understand. It was prepared in a comprehensive enough way to meet the patients' need for information about disease, treatment process, risk factors and coping mechanisms. In addition, the guide was put into final form by obtaining opinions of different experts from fields of internal medicine nursing, psychiatric nursing, physiotherapy and rehabilitation, nutrition and dietetics for independent assessment. The training programme was applied to patients in intervention group by the first author who also works as an academic nurse. After the nurse explained the information in the training guide for each patient as a standard, the question / answer part started. During the training, patients' relatives were allowed to be in the room if they wanted and patients/their relatives were encouraged to ask questions. The questions asked were answered in accordance with the explanations in the training guide. Exercises and relaxation movements that the patients had difficulty understanding were demonstrated by the researcher. Afterwards, the patient was asked to repeat these movements. During the study, the researcher examined the patients' behaviours, encouraging the correction of the wrong ones and the continuation of the correct ones. The contact information of the patients was

obtained and the contact information of the researcher was also given to the patients. In order to consolidate the information given, the training guide was given to the patients in the intervention group. After the training, the patients in the intervention group were contacted again in the 2nd week by using face-to-face interview and in the 4th– 8th and 12th weeks by phone calls. Training in the first meeting took approximately 30– 40 min, each of the next four interviews took approximately 10– 15 min. During these telephone interviews, the questions of the patients, if any, were answered and the problems they faced regarding the treatment adherence were tried to be solved. In the last interview, an appointment day was determined to meet face-to- face at home, workplaces or hospital according to the preferences of the patients. During the appointment day, personal information form and CQ were filled again. Last meeting took approximately 20– 30 min. The patients in the control group received only the standard care protocol provided by the clinicians. After the collection of post-test data, the content of the training was also explained to these patients and the study was completed by giving them the training guide.

Data analysis

The data were investigated using IBM SPSS Statistic 20.0 program. As the descriptive statistics, frequency, percentage, mean and standard deviation were used. In the adherence control of continuous variables to normal distribution, Shapiro–Wilk test was used. While independent samples t test was used in the comparison of two independent groups having normal distribution, Mann–Whitney u test was used for the non-normal distributed data. In the determination of the correlation between categorical variables, Chi-Square test was used. Since measurements were repeated twice (initial–12thweeks), p- values for continuous variables are obtained from general linear model repeated measures analysis. The group was used as the between-subject factor, and time as the within-subject factor. Mean values with their 95% confidence intervals and p- values for group, time and group × time interaction

were reported. In this way, type I error rate within- and between-groups variation was controlled. Effect size (Cohen's d) was used for measure of the magnitude of the experimental effect. It was suggested that d = 0.2 be considered a ‘small’ effect size, 0.5 represents a ‘medium’ effect size and 0.8 a ‘large’ effect size. The larger the effect size the stronger the relationship between two variables. Statistical significance level was accepted as $p < .05$.