

**THE EFFECTS OF NURSE LED TRANSITIONAL CARE MODEL ON ELDERLY
PATIENTS UNDERGOING OPEN HEART SURGERY: A RANDOMIZED
CONTROLLED TRIAL**

Short running title: *Nurse Led Transitional Care Model in Cardiac Surgery*

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BACKGROUND

Rate and number of successful cases in open heart surgery has been increasing due to the advances in medical technology and surgery. To improve patient convalescence results and reduce rate of post-discharge readmission to hospital and unplanned post-discharge rehospitalization, home-care and follow-up process of patients should be managed successfully. We have not come across examples of a care model in literature that has actively been used on elderly patients undergoing open heart surgery in Turkey. However, in practice, patients undergoing open heart surgery are discharged from the hospital in an average of 4-5 days which is a period retaining patients and their families to experience a successful post-op transition process. Finally, all of these can provide a basis for the problems that patients undergoing open heart surgery and their relatives may experience throughout post discharge healthcare. In addition, problems due to increased health care expenses may arise in line with the repeated post discharge referrals to hospital and rehospitalization rates.

In this study we have used a Transitional Care Model (TCM) developed by Mary Naylor basically for elderly patients undergoing open heart surgery, aiming to support defenseless/vulnerable elderly individuals with chronic diseases and their families and to prevent problems that cause an increase in repeated post discharge referrals to hospital and rehospitalization rates and aimed to evaluate the effect of the model on the quality of life, functional autonomy and repeated post discharge referrals to hospital and rehospitalization rates of elderly patients undergoing surgery.

Aim of the study and hypotheses

The purpose of this study is to evaluate the effectiveness of the Nurse Led Transitional Care Model. The hypotheses are as follows;

H₀: Nursing care carried out in collaboration with a multidisciplinary team in line with TCM for elderly patients who have undergone open heart surgery has no effect on decreasing the patients' functional autonomy, their quality of life levels and the rate of repeated post discharge referrals to hospital and rehospitalization.

H₁: Nursing care carried out in collaboration with a multidisciplinary team in line with TCM for elderly patients who have undergone open heart surgery may improve the patients' functional autonomy, their quality of life levels and decrease the rate of repeated post discharge referrals to hospital and rehospitalization.

STUDY PROTOCOL

1 | Study design

The research was carried out between November 2017 and December 2018 in a pretest-posttest design structured in accordance with the CONSORT guidelines (Figure 1), as a randomized controlled intervention study with parallel groups (Schulz, Altman, & Moher, 2010).

2 | Study participants and allocation

The study was carried out in an 11-bed cardiovascular surgery clinic of a university hospital located in the Black Sea Region of Turkey with a total capacity of 320 beds. The group of patients aged 60 and over, who were hospitalized for open heart surgery, constituted the universe of the study.

2.1 | Inclusion and exclusion criteria

Inclusion criteria for participation in the study are as follows: The Patient should a) be hospitalized for the first time and for elective open heart surgery; b) have no other surgical intervention other than an open heart surgery, c) have no psychological and mental disorders, d) have no major chronic problems such as kidney problems, neurological problems or cancer, e) be able to speak Turkish, f) be available to be communicated by phone, g) provide consent to participate in the study, h) live at a maximum distance of 50 km from the hospital (for easy access during post-discharge follow-up visits). Exclusion criteria are as follows: The Patient should a) ask to leave the study, b) be exposed to a disease or trauma that may affect his/her functional autonomy during the study, c) die throughout the study.

3.Data Collection

3.1 | Enrollment

A Ph.D. student and research assistant with clinical experience as a nurse for five years in the cardiovascular surgery clinic evaluated the participants who are decided to undergo an open heart surgery at their admission to the service and assigned those who met the application criteria to intervention and control groups respectively.

3.2 | Allocation

Patients were randomly assigned to the intervention and control groups respectively in line with the inclusion criteria of sampling through a computerized randomization system. Patients reached in the pre-application period ($n = 6$) were also included in the sample of the study, considering possible patient loss throughout the study. Ultimately, 66 patients were included in this study; the subjects were individually numbered and randomized by an individual outside of the investigation team using the website software program Research Randomizer

(<http://www.random.org>) to divide the subjects into the intervention group (33 patients) and control group (33 patients). The patients were not blinded. If someone declined, the next patient from the list was invited instead.

3.3 | Sample size

The sample of the study was determined by power analysis with the help of NCSS-PASS 2014 software. The study findings of Naylor et al. (2004) determine the standard deviation rate ($\pm 1,3$) with a 90% confidence level and a tolerance rate of 0.1%; each group consisting of 30 people, $n=60$ (Julious, 2009; Zar, 1984). The study began with a pre-application process for the first six patients. Since there is no difference between the forms used during the pre-application process and no problem was encountered in the maintenance process, the pre-application group was included in the study.

3.4 | Ethical considerations

A permission dated 25.05.2017 and No: 2017/42 was obtained from the University Clinical Research Ethics Committee for the implementation of the study. Furthermore, in order for the study to be carried out in the university hospital, necessary written permits were obtained from General Directorate of Turkish Public Hospitals, General Secretariat of the Provincial Public Hospitals Association, Head Physician and Nursing Services Department of the University Hospital in question. Written permission was obtained from the authors via e-mail for the scales used in the research. Verbal and written consent was obtained from the patients included in the study.

3.5 | Intervention

Patients in intervention group were given care based on the 'Nurse Led Transitional Care Model Protocol' (Figure 2) until the post discharge 9th week starting from date of hospitalization. Patients in control group were given standard care services.

The patients in both groups were interviewed face-to-face by the Researcher (Coordinator Nurse) in the first twenty-four hours following their admission to the hospital and administered "Introductory Information Form", "The Functional Autonomy Measurement System" and "SF-36 Quality of Life Scale". In addition, the Researcher (Coordinator Nurse) reached the patients in both groups after nine weeks following their discharge and reapplied the "The Functional Autonomy Measurement System" and "SF-36 Quality of Life Scale". Six months following their discharge these patients were called by phone and checked up on their repeated referrals to hospital and/or rehospitalization.

3.6 | Statistical methods

The data obtained throughout the study were evaluated by statistical analyzes (using IBM SPSS Statistics 23 software). Parametric tests were leveraged while evaluating research data based on the argument of Law of Large Numbers stating that (İnal & Günay, 2002) “The average of the results obtained from a large number of trials $n \rightarrow \infty$ will tend to become closer to the expected value”. The evaluation of the research data provides frequency distribution (number, percentage) for categorical variables and descriptive statistics (mean, standard deviation) for numerical variables. Difference between categorical variables with two groups was tested using Independent t-Test whereas the difference between the categorical variables with more than two groups was tested with "One Way Variance Analysis" (ANOVA). Following the analysis; initially, the homogeneity of the variance was controlled by Levene Test and then the group or groups causing the difference were controlled by "Multiple Comparison Test". The difference between the groups regarding the variables that provide variance homogeneity was evaluated via Bonferonni while Tamhane's T2 test was used to examine the difference between groups in variables that do not comply with variance homogeneity. In addition, the difference between the two numerical variables over time was evaluated with Dependent Sample t Test while the relationship between the two categorical variables was examined with the Chi-Square test. Statistical significance was considered as $p < 0.05$.

4 | Study Limitations And Recommendations For Future Research

This study has some limitations. Firstly, the sample size is quite small and the research was carried out in a single center with patients who lived within a 50 km. distance from the hospital where the study was carried out due to transportation limitations. No conclusions have been derived for patients residing at a greater distance. Secondly, WHO currently defines the elderly as individuals 65 years old and above. However, based on the cultural values of our country, average life expectancy and mean retirement age foreseen in our society, the population of elderly patients included in our study consisted of patients at 60 years of age and older.

5 | Acknowledgements

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6 | Results point of contact

Abant İzzet Baysal University, Abant İzzet Baysal University Clinical Research Ethics Committee, Phone: 0374 253 46 56 Ext: 3072 , Email: boluetik@ibu.edu.tr

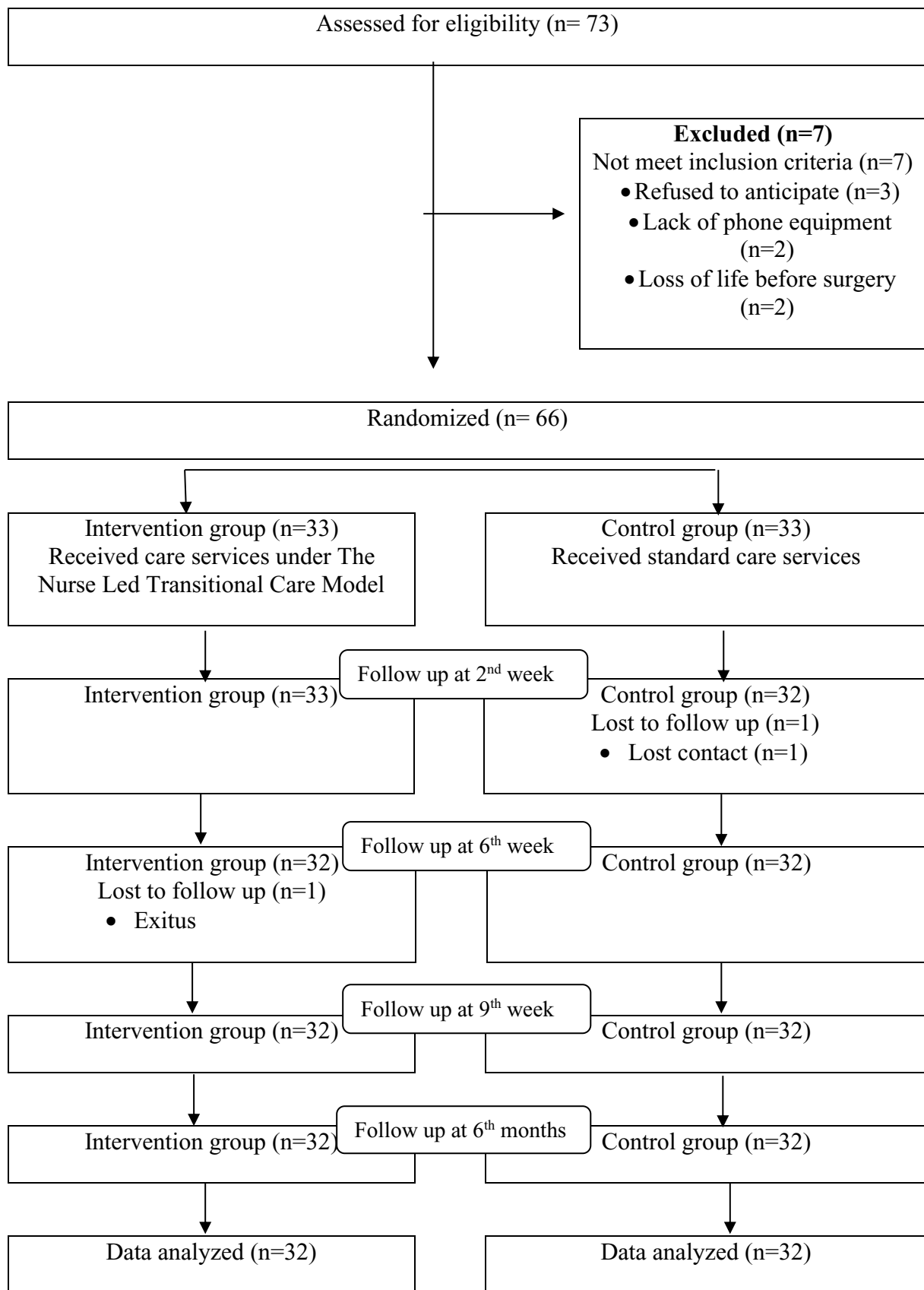


Figure 1. CONSORT diagram of the trial flow

Patients at 60 years of age and older who are decided to have open heart surgery			
Coordinator Nurse: <ul style="list-style-type: none"> ✓ Taking the Patient's Medical History ✓ Hospital and Clinic Promotion ✓ Providing Training Guide ✓ Daily Regular Patient Visits ✓ Coordinating the Healthcare Services 			
Case analysis (pre-operative period) Team members: physician, nurse, coordinator nurse, physiotherapist, dietician, evaluation of caregiving family member			
Coordinator Nurse: Post-operation training for patients Daily Patient Visits	Clinic Nurses: To execute healthcare services in line with designated healthcare plan Completion of the practices in the Clinical Pathway (post-op 1st, 2nd, 3rd, 4th, 5... days)	Dietician: To plan a nutrition program for the patient and train the patient accordingly	Physiotherapist: To plan the physical activity and exercise program for the patient and train the patient accordingly
Case analysis (post-operative period) Team members: physician, nurse, coordinator nurse, physiotherapist, dietician, evaluation of caregiving family member			
Coordinator Nurse: Post-operation training for patients Daily Patient Visits	Clinic Nurses: To execute healthcare services in line with designated healthcare plan Completion of the practices in the Clinical Pathway (post-op 1st, 2nd, 3rd, 4th, 5... days)	Dietician: To plan a nutrition program for the patient and train the patient accordingly	Physiotherapist: To plan the physical activity and exercise program for the patient and train the patient accordingly
Coordinator Nurse: <ul style="list-style-type: none"> ✓ Home visit within 24 hours after hospital discharge; <ul style="list-style-type: none"> • The patient's living conditions, • Understanding and executing the proposed treatment and drug regimen, • Assessment of the performance on executing practices to accelerate the recovery of the patient • To continue planning and executing healthcare services ✓ Providing consultancy service via telephone to the patient and family members within post discharge first week 			
Coordinator Nurse: <ul style="list-style-type: none"> ✓ Home visits at post discharge 2nd and 6th weeks; <ul style="list-style-type: none"> • "Post-Discharge Home Follow-Up Form of Elderly Person Undergoing Open Heart Surgery" • "Post-Discharge Recurrent Hospital Admission Follow-Up Form" • Providing training and consultancy in cooperation with the team members for the detected problems • Follow-Up for the detected problems 			
Coordinator Nurse: <ul style="list-style-type: none"> ✓ Home visits at post discharge 9th week; <ul style="list-style-type: none"> • "Post-Discharge Home Follow-Up Form of Elderly Person Undergoing Open Heart Surgery" • "Post-Discharge Recurrent Hospital Admission Follow-Up Form" • Providing training and consultancy in cooperation with the team members for the detected problems • Follow-Up for the detected problems • 'The Functional Autonomy Measurement System', • 'SF-36 Quality of Life Scale' 			
Coordinator Nurse: <ul style="list-style-type: none"> ✓ Telephone Communication at post discharge 6th month <ul style="list-style-type: none"> • "Post-Discharge Recurrent Hospital Admission Follow-Up Form" 			

Figure 2.'Nurse Led Transitional Care Model Protocol'