

Title

The Effectiveness of Telehealth program on Cardiac Symptom Distress, Self-care and Quality of Life in Patients with Coronary Artery Disease after Coronary Artery Bypass Surgery: A Randomized Controlled Trial

NCT Number: NCT06648291

Version Number: Version 3

Document Date: 2023/08/09

1. Introduction

Cardiovascular disease accounts for over 30% of global deaths, 40% of which are caused by coronary artery disease (CAD) (CDC , 2024; Pooria et al., 2020) and that the number of deaths caused by CAD surged to 3.7 million in 2021 (American Heart Association [AHA], 2024). Coronary artery bypass grafting (CABG) is one of the most widely performed surgical procedures for treating CAD, with approximately 8 million CABG surgeries conducted globally each year (Gohari et al., 2022). Although the success rate of CABG has improved, patients still encounter numerous physical, psychological, and social challenges after discharge. Physical issues include, but not limited to, pain at the chest or leg incision site, difficulty breathing, sleep disturbances, fatigue, weakness, and loss of appetite. Psychological challenges encompass depression, anxiety, and stress caused by changes in social and occupational life (Ilgin et al., 2024). These symptoms may persist for weeks and, if unresolved, could mask worsening wound pain, infection, or weakness from malnutrition (Khodaveisi et al., 2020). According to a study by Montrief et al. (2018), 7% of CABG patients experience multiple emergency visits and readmissions within one month post-surgery, due to chest pain, wound infections, and heart failure. Given these challenges, patients undergoing heart surgery should be educated and learn self-care skills to manage the problems they may face in the future (Veronovici et al., 2014).

The ability to self-care is critical to promote recovery and reduce symptom severity in

CABG patients (Alkuwaisi et al., 2024). For patients following cardiovascular surgery, the implementation of self-care activities includes healthy eating habits, regular exercise, smoking cessation, weight control, and adherence to prescribed medications (Tippinit & Polsook, 2023; Knuuti et al., 2020). Prior studies have shown a positive association between self-care behaviors and knowledge, suggesting that those patients who gain sufficient knowledge about disease management are more likely to perform effective self-care behaviors (Kassahun et al., 2016). However, the length of hospital stay for patients following CABG is decreasing, with the average discharge time being day 7 post-surgery, the time to prepare for discharge is limited, and patients are discharged with a large amount of information from healthcare professionals, which is not fully absorbed by the patient and is stressful (Lin et al., 2024; Steenbergen et al., 2022). As a result, patients often have poorer self-care behaviors during the transition from hospital to home, which in turn affects quality of life after discharge (Hundiyawati et al., 2023).

Quality of life is the ability of individuals to function normally and feel satisfied with their capacity to engage in daily activities. This includes being physically active, maintaining independence, assisting others, participating in social interactions, achieving emotional stability, being free from pain or other symptoms of discomfort, and having adequate sleep and rest (Pačarić et al., 2020). Studies have shown that approximately 25% of CABG patients experience a decline in quality of life after surgery due to deterioration in overall health status

and the body's reduced ability to function as they did before surgery. This decline often results in poor disease compliance and unhealthy lifestyle habits (Nobari et al., 2021; Kidd et al., 2016). Nair et al. (2018), in a study tracking the lifestyle and health problems of 500 CABG patients six months after surgery, found that only 11.6% maintained a healthy lifestyle. The associated risk factors include obesity, poor glycemic control, hypertension, and high cholesterol, affecting 9.6%, 20.2%, 35%, and 48.4% of patients, respectively. Postoperative recovery and quality of life largely depend on how well patients manage these risk factors (Mohesnipouya et al., 2016). Therefore, it is crucial to provide ongoing counseling and health education to help patients acquire the necessary self-care knowledge and skills, and encourage them to adopt a healthier lifestyle (Nobari et al., 2021).

With the rapid development of smartphones and related device technologies, remote monitoring for patients with various diseases has become increasingly common. This is particularly evident in the home-based follow-up care of patients discharged after cardiac surgery, which has emerged as a growing trend (Sarkar et al., 2022). Telehealth programs encompass a wide range of health-related services that utilize electronic and communication technologies to remotely deliver health or medical information (Dosaj et al., 2021). In this model, nurses play a crucial role by providing supportive care, continuous monitoring, evidence-based professional guidance, health education, effective counseling, and follow-up services (Zhou et al., 2023; Gimenez et al., 2024). Moriyama et al. (2021) emphasized that

telenursing can improve the lifestyles of patients with chronic diseases and help manage cardiovascular conditions. Several studies have shown that telehealth can reduce healthcare costs, decrease emergency room visits, readmission rates, and mortality (Purcell et al., 2014; Scalvini et al., 2018; Dawson et al., 2021), Telehealth has also been shown to be more effective than conventional care in motivating patients to engage in self-care (Kotsani et al., 2018), and to improve patient compliance and self-efficacy (Gohari et al., 2022; Bikmoradi et al., 2016; Bikmoradi et al., 2017). However, research on the impact of telehealth program cardiac symptom distress, self-care behaviors, and quality of life in post-CABG patients remains limited. The purpose of this study was to examine the effect of telehealth services on symptom distress, self-care behaviors, and quality of life in patients discharged after undergoing CABG. We hypothesized that telehealth program will alleviate symptomatic distress, enhance self-care, and improve quality of life.

2. Methods

2.1 Study Design

A randomized controlled trial (RCT) was conducted in a teaching hospital in northern Taiwan using a two-parallel-group design. Participants were recruited postoperatively and randomly assigned to either the experimental or control group before hospital discharge. Following discharge, the experimental group received a 4-week telehealth care intervention, whereas the control group received standard care only.

2.2 Participants recruitment

Participants were recruited between September 2023 and January 2025 from the cardiac surgery ward at the National Taiwan University Hospital. The inclusion criteria for the study were: 1) 18 years of age or older; 2) underwent CABG for the first-time; 3) ability to read and respond to questionnaires; and 4) possession of an internet-enabled mobile device (e.g., smartphone or tablet). The exclusion criteria were: 1) cognitive impairment that prevents clear communication; and 2) being bedridden or physically disabled, unable to care for oneself.

2.3 Randomization

Eligible patients were provided with detailed information about the study and its objectives. Those who agree to participate were randomly assigned to the experimental group or the control group in a 1:1 ratio. The random numbers were generated by an independent person using a random number generator. Sealed envelopes were used to ensure allocation concealment. Due to the need for the experimental group to download and learn the electrocardiogram equipment, participant blinding was not feasible. However, the primary care physician and nurses are blinded to the allocation of the two groups.

2.4 Ethical consideration and study registration

This study was approved by the Ethics Committee of the National Taiwan University Hospital (approval number: 202307014RINA, approval date: August 4, 2023). Written informed consent was obtained from all participants. All data were anonymized to maintain confidentiality and were securely stored in locked file cabinets. Participants were informed

that they had the right to withdraw from the study at any time without the need to provide any reason.

2.5 Sample size

The sample size was calculated using the effect size 0.50 from a similar study by Nobari et al. (2021), with G Power-3.1.9.2, the significance level at 0.05, and the power at 0.80, resulting in a minimum required sample size of 128 subjects. Considering potential attrition, an additional 20% subjects was included. Therefore, the total sample size was 160 patients, with 80 patients in the experimental group and 80 patients in the control group.

2.6 The control group

Patients in the control group received standard care and were instructed by the ward nurses on nursing care, including wound assessment, education on diet, exercise, bathing, and medication, according to the post-coronary artery bypass surgery hygiene manual developed by the hospital. They were also instructed to monitor their blood pressure, blood glucose levels, and weight daily, and were scheduled for a follow-up phone call on the seventh day after discharge

2.7 The intervention group

In addition to standard care, starting from the day of discharge from the hospital, patients in the intervention group were scheduled for telephone interviews every three days, conducted by nine well-trained telenursing specialists. Each interview lasted approximately 10 to 15 minutes, for four weeks. The objective of these telephone interviews was to encourage and monitor the patients' adherence to effective self-health management practices, which included: (1) assessing daily blood pressure, weight, blood glucose levels, and lower

limb edema; (2) providing counseling on medication adherence, physical activity, and dietary hygiene; (3) offering guidance on wound care; (4) advising on the avoidance of cardiovascular risk factors, including smoking and exposure to secondhand smoke, as well as facilitating referrals to appropriate outpatient services, such as nutrition or rehabilitation clinics, based on individual needs. Additionally, patients were provided with a portable electrocardiogram device (ecg103, Quanta Computer Inc, Taipei, Taiwan).

During hospitalization, the research team assisted in installing the ECG software on the patient's mobile device and provided demonstrations until the patient was proficient in independently operating the device. A detailed operation manual was provided, which instructed the patient to measure ECG once in the morning and once in the evening. Patients were instructed to upload ECG data immediately if experiencing chest discomfort. The patient was provided with the website and operating procedures of the telehealth platform. The patient was also instructed to input daily physiological data, including blood pressure and blood glucose levels. Should any abnormalities in heart rhythms, blood pressure, or glucose levels be detected, the researcher contacted with the patient to assess their clinical condition and provide 24-hour online counseling.

2.8 Data collection

Outcomes were evaluated at three time points: two days before discharge (baseline, T0), at the first outpatient visit (7–10 days post-discharge, T1), and at the end of the intervention (4 weeks post-discharge, T2).

2.8.1 Demographic

Demographic questionnaires included gender, age, education, marital status, occupation,

and economic status, place of residence, smoking history, and alcohol consumption, combined valve surgery, and presence of comorbidities.

2.8.2 Cardiac Symptom distress

The Cardiac Symptom Survey (CSS) was developed by Nieveen et al. (2008) over 20 years ago to assess the symptoms experienced by cardiac surgery patients, particularly those undergoing coronary artery bypass grafting (CABG). The questionnaire includes 10 symptoms, which are evaluated on two dimensions—frequency and severity—ranging from 0 (none) to 10 (extremely severe) (Subih et al., 2018). The specific symptoms listed on the scale include angina, shortness of breath, fatigue, depression, sleep disturbances, incisional pain, leg edema, palpitations/rapid heartbeat, anxiety, and loss of appetite. The frequency and severity scores for each symptom are combined and averaged to reflect the overall level of symptom distress, with higher scores indicating more severe distress. The traditional Chinese version was developed by Yang et al. (2014), with a content validity index of 0.97 and an internal consistency reliability coefficient of 0.95.

2.8.3 Self-care behavior

This scale was developed by Yu et al. (2008) for patients undergoing coronary artery bypass surgery. The scale consists of 16 questions, focuses on patient self-care activities and controlling risk factors (e.g., not smoking, taking medications correctly, regularly measuring blood pressure, attending follow-up appointments, exercising regularly, and controlling diet). The questionnaire uses a 4-point Liker scale, with 4 points for “always” and 1 point “never”,

and total scores ranging from 16 to 64, with higher scores indicating better self-care practices. The scale has a content validity index of over 0.85 and an internal consistency reliability of 0.75.

2.8.3 SF-12

The SF-12 questionnaire is a well-validated self-administered survey derived from the SF-36 questionnaire, consisting of 12 items, used to assess participants' health-related quality of life (HRQoL) over the past four weeks (Ware et al., 1996). The scale originates from the Medical Outcomes Study, a long-term follow-up study of patients with chronic diseases (Goldfarb & Casillas, 2016). The SF-12 primarily covers eight dimensions of physical and mental health and can further calculate two composite indices: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). Each dimension uses a different scoring method, with final scores standardized on a scale of 0 to 100, Scores >50 are above average, where higher scores indicate better health status (Suonpera et al., 2024). Studies conducted in the United States and the United Kingdom on different populations have shown that the Cronbach's α values are all greater than 0.70 (Lin, 2017). Additionally, the SF-12 has been proven effective for assessing the quality of life of patients undergoing coronary artery bypass grafting (CABG). According to the findings of Pačarić et al. (2020), the SF-12 is suitable for measuring the health status of CABG patients.

2.9 Data analysis

Descriptive statistics of continuous variables are presented in mean and standard deviation (SD). Categorical variables are presented using frequencies and percentages. A Pearson's chi-square test or Fisher's exact test was used to analyze categorical variables, depending on whether the expected cell count was less than five. Continuous variables were compared using the independent t test. The paired t test was applied to compare the means

of the scores in each group before and after the interventions, and the independent t-test to compare the means of the scores in the two groups. To analyze the changes in cardiac symptom distress, self-care, and quality of life at different time points for the same study participant, the analysis was performed using the generalized estimating equations (GEE). An overall alpha-level of 0.05 was used as for statistical significance and all statistical tests were two-tailed. Statistical analyses were performed in SPSS versi