Study protocol

Certificate of Approval No 1880/GCN – HMUIBR dated 14/04/2025

Research proposal version 1 date 16/11/2024

Project title: Effectiveness of cardiac rehabilitation with remote connection device for patients after surgery for acquired heart valve disease.

1. Introduction: Valvular heart disease (VHD) is a major cause of cardiovascular mortality worldwide. With the global trend of population aging and advancements in diagnostic imaging and surgical techniques, the prevalence of VHD has been steadily increasing. Valve surgery, including valve repair or replacement, has significantly improved patient outcomes by enhancing quality of life and reducing mortality. However, a considerable proportion of patients continue to face postoperative complications, such as prolonged mechanical ventilation, hospital-acquired pneumonia, and sepsis.

Cardiac rehabilitation (CR) has emerged as a vital component of post-surgical care, proven to enhance physical function, shorten hospital stays, reduce readmission rates, and lower mortality. In many high-income countries, structured CR programs are well-integrated into standard care and supported by health insurance policies. In Japan, for instance, patients are eligible for up to 150 days of insurance-covered CR services.

In Vietnam, while inpatient CR has gained attention in recent years at major hospitals, long-term outpatient or home-based CR remains limited. Moreover, patients do not receive insurance coverage for post-discharge CR services, creating barriers such as travel difficulties, time constraints, and financial burden. These challenges significantly hinder access to continuous rehabilitation, which is essential for optimal recovery after valve surgery.

Given the development of digital health technologies, remote-connected cardiac rehabilitation (tele-rehabilitation) has become an emerging solution to support patient recovery at home. International studies have demonstrated the effectiveness of tele-rehabilitation in improving outcomes and increasing accessibility. However, no domestic research has been conducted to evaluate the effectiveness of tele-rehabilitation for patients in the recovery phase after acquired valvular heart surgery in Vietnam.

Recognizing the advantages and suitability of remote rehabilitation for cardiovascular patients in Vietnam, we propose this study: **" Effectiveness of cardiac rehabilitation with remote connection device for patients after surgery for acquired heart valve disease."**

Study Objectives:

1. To evaluate the outcomes of cardiac rehabilitation using remote support device for patients after surgery for acquired valvular heart disease at Hanoi Medical University Hospital.
2. To analyze factors associated with the outcomes of cardiac rehabilitation using remote support device in this patient population.

2. Subjects and Methods

2.1 Study Subjects

2.1.1 Inclusion Criteria

- Patients undergoing first-time surgery for acquired valvular heart disease, including valve repair or replacement involving the aortic, mitral, tricuspid, pulmonary valve, or any combination thereof.
- Aged 18 to 70 years.
- Willingness to participate and provide informed consent.

2.1.2 Exclusion Criteria

- Contraindications to participation in cardiac rehabilitation.

2.2 Sample Size

Sample size was calculated based on the comparison of mean differences in Six-minute Walk Test result between the intervention and control groups, using a two-sided test with a significance level (α) of 0.05 and a power ($1-\beta$) of 0.80. The final sample size was adjusted to account for an anticipated dropout rate. (Detailed calculation is available in the appendix.)

2.3 Study Design

This was a **prospective, randomized controlled trial** conducted at the Cardiac Center and Rehabilitation Department – Hanoi Medical University Hospital, Hanoi Capital

2.4 Randomization

Patients who completed the inpatient phase I and phase IIa cardiac rehabilitation program and met the inclusion criteria were randomly assigned to either the intervention or control group using a simple randomization method (rolling a die). Patients rolling an even number were allocated to the intervention group; odd numbers were assigned to the control group. Randomization was conducted by a researcher not involved in outcome assessment.

2.5 Intervention

Both groups received standard inpatient cardiac rehabilitation (Phase I and Phase IIa) during hospitalization. After discharge:

- **Control group**: Received routine outpatient follow-up and general advice for home-based physical activity.
- **Intervention group**: Participated in a structured, supervised **home-based cardiac rehabilitation program** supported by the Open TeleRehab software.

Details of the Intervention Program:

- **Duration**: 4 weeks after hospital discharge.
- **Frequency**: 3 sessions of aerobic exercise and lower limbs resistant exercise per week at home.
- **Modality**: Walking or cycling, with progressive intensity guided by heart rate reserve (HRR), based on the Karvonen formula and Cardiopulmonary Exercise Testing result; lower limbs resistant exercise with body weight, plastic band, dumbbells.
- **Monitoring**: Patients were provided with pulse oximeters and blood pressure monitors. Exercise sessions were supervised remotely via the Open TeleRehab application, which allowed real-time data collection and feedback.

- **Follow-up**: Weekly online meetings were held between patients and the rehabilitation team to assess adherence, answer questions, and adjust exercise plans if necessary.

2.6 Outcome Measures

Primary Outcome:

- **Peak oxygen uptake (VO_2 max)** measured via cardiopulmonary exercise testing (CPET) at baseline (pre-surgery), pre-discharge, and 1 month post-discharge.

Secondary Outcomes:

- **Functional capacity** assessed by:
    - **Six-minute walk test (6MWT)**
    - **Two-minute step test (TMST)**
- **Pulmonary function**: inspiratory lung capacity using spriro-ball spirometer.
- **Heart rate recovery (HRR)** post-CPET.

Assessment Time Points:

Time Point	**Assessment Parameters**
T1: Pre-operative	TMST, 6MWT, spriro-ball spirometer
T2: Post-operative, Day 1 Phase I	Inspiratory lung capacity (spriro-ball spirometer)
T3: Post-operative, Day 7	CPET, 6MWT, TMST, spriro-ball spirometer
T4: Pre-discharge	CPET, TMST, 6MWT, spriro-ball spirometer
T5: 1 month post-discharge	CPET, TMST, 6MWT

2.7 Data Analysis

Data were analyzed using SPSS version 26. Continuous variables were tested for normality using the Shapiro-Wilk test. Descriptive statistics are presented as mean

± standard deviation or median (IQR) as appropriate. Between-group comparisons were performed using the independent t-test or Mann-Whitney U test. Paired t-tests or Wilcoxon signed-rank tests were used for within-group comparisons.

Categorical variables were compared using the chi-square or Fisher's exact test. A p-value < 0.05 was considered statistically significant.