SELF-MANAGEMENT AND ITS ASSOCIATED FACTORS AMONG PATIENTS AFTER HEART VALVE REPLACEMENT THERAPY

HU XIAOJING

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR MASTER DEGREE OF NURSING SCIENCE
(INTERNATIONAL PROGRAM)
IN ADULT NURSING PATHWAY
FACULTY OF NURSING
BURAPHA UNIVERSITY
2025

การจัดการตนเองและปัจจัยที่เกี่ยวข้องในผู้ป่วยหลังผ่าตัดเปลี่ยนลิ้นหัวใจ

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Self-management plays an important role for patients after heart valve replacement to promote their recovery, prevent complications, and improve their quality of life. The purposes of this correlational study were to examine self-management and its relationships with age, self-efficacy, social support, and depression among patients after heart valve replacement. A simple random sampling technique was used to recruit 135 adults after heart valve replacement who came to the cardiac surgery outpatient department at a hospital in Wenzhou, Zhejiang Province, China. Research instruments included the demographic information questionnaire, the Chinese version of the self-management scale of patients after mechanical heart valve replacement, the Chinese version of the General Self-Efficacy Scale, the Chinese version of the perceived social support scale, and the Chinese version of the Self-Rating Depression Scale. The Cronbach's alpha coefficients were .905, .960, .901, .796 respectively. Data were analyzed using descriptive statistics and Pearson product-moment correlation.

The results showed that participants reported moderate self-management scores (M = 102.07, SD = 5.86). Self-efficacy and social support correlated positively with self-management (r = .347, p < .01; r = .474, p < .01, respectively). Age and depression correlated negatively with self-management (r = –.201, p < .05; r = –.325, p < .01, respectively).

The results suggest that an intervention aimed at improving self-management for patients after heart valve replacement should focus on enhancing their self-efficacy, providing social support, and depression management to prevent complications, promote recovery, and improve quality of life.

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CHAPTER 1
INTRODUCTION

Background and significance of the study

Valvular heart disease (VHD) is an abnormal structure or function of the heart valves. It can change the cardiac hemodynamics of patients, resulting in palpitation, burnout, fatigue, reduced activity endurance, dyspnea, and other symptoms (Li, 2021). VHD is strongly associated with cardiac dysfunction and death (Liu et al., 2014). It is estimated that more than 42 million people worldwide suffer from valvular heart disease (VHD) (Wen et al., 2020). In a study from 2012 to 2015, the prevalence of heart valve disease was found to be 3.8%, and it was estimated that there were 25 million people with heart valve disease in China (Yang et al., 2021). In the past few decades, the epidemiology of VHD has changed dramatically with the development of society and economy and the intensification of population aging (Shu et al., 2016). In the European Heart Survey, the main etiology of VHD was degeneration, which was present in about 63% of patients with valvular heart disease. However rheumatic heart disease is still the main cause of VHD in developing countries (Shang-Fei et al., 2021). Although the incidence of rheumatic fever has decreased significantly in recent years, rheumatic heart disease (RHD) is still the main cause in China, but the incidence of degenerative heart disease (DHD) has increased significantly (Yang et al., 2021).

Although the incidence of VHD is high, treatment options are limited, the only viable primary clinical approach is surgery (Zeng et al., 2016). Heart valve surgery has significantly improved patients' survival and health-related quality of life over the past few decades, with approximately 30 million heart valve implants performed globally each year (S. Zandi et al., 2021). Valvular heart disease surgery accounts for 28.2% of all cardiac surgery in China (Hei et al., 2017).

All patients will need lifelong follow-up by a cardiologist after valve surgery to detect early deterioration of artificial valve function or ventricular function or progression of another heart valve disease (Baumgartner et al., 2018). Mechanical heart valves are durable, but they cause blood clots (David, 2021). Oral anticoagulants are an effective means of preventing thromboembolic complications. All patients who

receive this mechanical valve usually require anticoagulant therapy for the rest of their lives. Vitamin K antagonists are the only effective oral administration option, and warfarin is the most commonly used (Zhang et al., 2020).

However, warfarin can cause potentially fatal bleeding complications (Zhao et al., 2017). Previous studies have shown that the annual risk of bleeding was 12%, and anticoagulation was responsible for 60% to 75% of mechanical valvular-related mortality (Yanagawa et al., 2016). Insufficient anticoagulation can lead to blood clots, and a high dose of anticoagulation can lead to bleeding, oral anticoagulant therapy control is complex and requires frequent analysis (de Queiroz Almeida et al., 2011). For patients who taking warfarin, regular patient monitoring can assess the time it takes for blood to clot, known as the International Normalized Rate (INR) (Clarkesmith et al., 2017). The safety and efficacy of warfarin depend heavily on maintaining INR within the target range (Tideman et al., 2015). Within the recommended intervals, the incidence of serious complications was low (INR 2.0–3.5 for the majority of cases) (Corrochano et al., 2020). In addition, age, weight, diet, race/ethnicity, and drug interactions affect an individual's INR (David, 2021). Therefore, it is important to monitor INR regularly and adjust the warfarin dose according to INR results.

Heart valve replacement is the beginning of cardiac function maintenance (Zhou et al., 2018). After surgery, patients need to pay attention to an appropriate diet, eat small and frequent meals to avoid overeating and increasing the burden on the heart, avoid foods high in vitamin K (Wen et al., 2016), avoid alcoholism (Witt et al., 2016), appropriate exercise (Wen et al., 2016). Patients must pay attention to personal hygiene, keep warm, and avoid respiratory infection, if infection occurs, treatment should be timely to avoid infective endocarditis (Zhou et al., 2018). Patients need to take cardiotonic and diuretic drugs to help the recovery of cardiac function (Yuan & Chen, 2015). Also, have regular blood check-ups, take warfarin regularly, and learn to observe the symptoms of bleeding and embolism (Chen & Zhang, 2020). If there is an occurrence of bleeding, embolism, or cardiac insufficiency, patients should see a doctor in time. This is a long-term process, all of which require patients to have good self-management ability.

However, previous studies showed that the self-management ability of patients after heart valve replacement needs to be improved (Chen et al., 2021; Lu, 2016; Wen et al., 2016; Zheng et al., 2021). Lu (2016) indicated that patients' self-management level after heart valve replacement was at a low to medium level, which needed to be further improved, especially, the lack of exercise (Lu, 2016). Furthermore, results from a study found that the readmission rate of patients with heart valve replacement after one year was 26.58%, mainly due to poor compliance with medication and poor regular review (Zhou et al., 2018). Another study indicated that patients who underwent mechanical valve replacement showed poor compliance with medications and follow-up visits (Zheng et al., 2021). Other studies have shown that the incidence of anticoagulant complications was 37.23%, and 80.95% in patients with poor treatment compliance (Chen & Li, 2018). In addition, thrombosis, thromboembolism, and anticoagulation-related complications account for 75% of all complications, and these complications usually occur within 6 months after surgery, they are a major cause of morbidity and mortality, impose a psychological burden on people and harm the quality of life (Javan et al., 2019).

Therefore, to reduce the occurrence of postoperative complications and promote the recovery of cardiac function, patients are required to have good self-management ability (Yuan & Chen, 2015). Self-management refers to “the ability of the individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of health conditions” (Richard & Shea, 2011). Self-management of patients after heart valve replacement includes symptom management (patients can observe the symptoms of complications such as cardiac insufficiency, bleeding, and thrombosis and seek timely medical attention), treatment compliance management (whether to take medicine on time and following the doctor's advice, regular follow-up examination), daily life management (patients change their behavior in daily life, such as reasonable exercise, reasonable diet, pay attention to personal hygiene and so on), emotion management (patients can control their emotions and adjust their emotions reasonably), information management (patients can actively acquire knowledge and information about diseases, medicines, and so on), self-

efficacy management (degree of patient confidence in self-management behavior) (Mou et al., 2016).

Self-management can improve INR control, self-efficacy, and medication adherence, and result in a reduced risk of all-cause mortality, thromboembolism, and major bleeding (Javan et al., 2019). In a cohort study, patients in the self-management group after heart valve replacement had a lower risk of death five years later than those in the conventional therapy group (Christensen et al., 2016). A study indicated that self-management programs had a positive impact on self-efficacy and medication compliance in patients with mechanical heart valves (Javan et al., 2019). Another study showed that self-management programs had a significant effect on improving self-efficacy, self-management behavior, and maintaining the therapeutic range of INR in patients undergoing cardiac valve replacement (Jeon & Park, 2015).

The self-management of patients after heart valve replacement is very important (Kil & Shin, 2020; Park & Jang, 2021; Wang et al., 2018). Understanding factors influencing a patient's ability to self-manage after heart valve replacement is important. It may improve the assessment of self-management and may inform interventions that meet individual needs and improve health outcomes (Schulman-Green et al., 2016). Results from previous studies showed that there were many factors related to self-management among patients after heart valve replacement, such as gender, age, education level, social support, warfarin-related knowledge, medication adherence, self-efficacy, depression (Kil & Shin, 2020; Park & Jang, 2021; Wang et al., 2018). Based on the literature review and based on Ryan and Sawin's (2014) Model of the Individual and Family self-management Theory, this study identified four important factors including age, self-efficacy, social support, and depression, these are important correlates of patient self-management after heart valve replacement. Those factors in this study are as follows.

Age is an important factor in the self-management of patients after heart valve replacement (Chen, 2020; Chen et al., 2021; Wang et al., 2018; Zhou et al., 2018). Younger patients are more likely to understand disease knowledge and are more familiar with the use of information technology such as mobile phones and the Internet than older patients (Wang et al., 2018). In addition, older people have limited mobility and need to be accompanied by family members for regular follow-up visits,

resulting in reduced self-management (Chen, 2020). A study found that older patients had lower self-management ability than younger patients (Wang et al., 2018). Another study showed that adherence among older patients was lower than among younger patients, mainly due to memory and cognitive impairment in older patients (Chen et al., 2021).

Self-efficacy reflects patients' confidence in managing their disease (Schulman-Green et al., 2016). The higher the self-efficacy, the higher the confidence in recovery from the disease, which is conducive to improving the patient's behavior and helping to manage the disease (Yao et al., 2019). A multivariate logistic regression study showed that self-efficacy was significantly associated with self-management behavior (odds ratio = 1.06; 95% confidence interval: 1.04–1.08) (Yao et al., 2019). A study showed that patients' self-efficacy and self-management were positively correlated after cardiac valve replacement ($r = .41$, $p < .01$), and the higher the patients' self-efficacy, the higher the level of their self-management ability (Lu, 2016). Another study indicated that patients with higher self-efficacy have stronger confidence in coping with disease recovery, which is conducive to improving patients' health behaviors and long-term disease control (Li, 2021).

Social support refers to support from family members, friends, and peers, as well as medical professionals and organizations (Strom & Egede, 2012). It also is a very important factor, and many studies have concluded that good social support can improve patients' self-management ability and behavior (Yuchi Chen et al., 2018; Irani et al., 2019; Strom & Egede, 2012). Patients with weak social support lack confidence in disease self-management and have poor self-management ability, while good social support can positively affect patients' self-management ability (Chen, 2020). A study showed that good social support improves the level of self-management of patients, and the higher the level of social support, the better the quality of life of patients (Chen et al., 2019). Other studies have shown that social support is also one of the important factors for the higher incidence of complications of warfarin anticoagulant therapy in patients after mechanical heart valve replacement (Chen & Li, 2018).

Depression is a negative emotion and it is negatively associated with self-management (Sun et al., 2020). Heart valve replacement surgery relieves the patient's

symptoms, but it is also more traumatic, higher risk, higher cost of surgery, the operation itself, the need for anticoagulation and close follow-up, and other factors will bring anxiety and depression to patients (Chen & Zhang, 2020). Liu's study shows that the degree of depression is an influential factor in self-management ability, the more severe the depression, the worse the early postoperative self-management ability (Liu, 2018). Depression is also associated with medication compliance in patients with mechanical heart valves (Huang et al., 2015; Park & Jang, 2021). Patients with depression have poor treatment compliance, and the incidence of complications such as bleeding and thrombosis is higher (Chen & Li, 2018).

In recent years, self-management has been widely used in studies of patients with chronic diseases. Many previous studies have shown that active self-management can reduce complications, decrease mortality, improve quality of life, and reduce costs (Chen et al., 2019; Lu, 2016; Richard & Shea, 2011; Wen et al., 2016; S. Zandi et al., 2021). According to a survey, the number of heart valve surgeries in China was 77,077 in 2021, accounting for 27.7% of the total number of extracardiac surgeries, an increase of 17.1% from 2020. While in 2021, 3,995 heart valve surgeries were performed in Zhejiang Province, China, accounting for 42.8% of the total number of cardiac surgeries (Zhao et al., 2022). As more people undergo heart valve surgery, post-operative self-management is becoming increasingly important. Especially in the early postoperative period (6 months) after heart valve replacement is prone to a variety of complications that increase patient burden and severely impact patient quality of life. However, according to the literature review, there is a paucity of literature on self-management in the early postoperative period after heart valve replacement in China, which suggests that the level of research in this field is still at a low level in China (Chen et al., 2019).

Therefore, it is necessary to study the self-management of patients in the early postoperative period after heart valve replacement and its related factors. After understanding the influencing factors of self-management in patients in the early postoperative period after heart valve replacement, nurses can develop nursing interventions to help patients better manage themselves, reduce complications, promote recovery of cardiac function, maintain health, and improve their quality of life.

Research objectives

1. To describe self-management among patients after heart valve replacement.

2. To examine the relationships between age, self-efficacy, social support, and depression with self-management among patients after heart valve replacement.

Research hypotheses

1. There is a negative correlation between age and self-management among patients after heart valve replacement.

2. There is a positive correlation between self-efficacy and self-management among patients after heart valve replacement.

3. There is a positive correlation between social support and self-management among patients after heart valve replacement.

4. There is a negative correlation between depression and self-management among patients after heart valve replacement.

Scope of the study

The purpose of this study was to assess self-management and to examine the relationship between the independent variables including age, self-efficacy, social support, depression, and self-management among patients with heart valve replacement. The subjects were patients who had undergone mechanical valve replacement open surgery for the first time, after discharge one month to six months, and followed up at the cardiac surgery outpatient department of the First Affiliated Hospital of Wenzhou Medical University in Wenzhou, Zhejiang Province, China. Data were collected from September 19th, 2022, through May 31st, 2023.

Conceptual framework

This study is based on Ryan and Sawin's (2014) Model of the Individual and Family self-management Theory. The theory holds that self-management is a complex dynamic phenomenon with three dimensions: context, process, and outcome (Ryan & Sawin, 2009). *Contextual factors* are risk or protective factors and include condition-

specific, physical, and social environments and individual and family characteristics. Characteristics of the individual and family that enhance or diminish SM, for example, developmental stages, perspectives, literacy, information processing, and capabilities. *Process dimensions* include knowledge and beliefs, self-regulation skills and abilities, and social facilitation. Knowledge and beliefs impact behavior-specific self-efficacy, outcome expectancy, and goal congruence. Social facilitation occurs in interpersonal relationships and enhances an individual's capacity for change: including social influence, support, and negotiated cooperation (Ryan & Sawin, 2009). *Outcomes* in this theory include proximal or short-term outcomes that lead to the attainment of distal outcomes. In conclusion, contextual factors will affect individual and family participation in the SM process and directly affect the outcomes, strengthening the process produces positive outcomes, the proximal and distal outcomes (Ryan & Sawin, 2009).

In this study, age and depression, self-efficacy, and social support can be classified respectively in the following order individual characteristics (context dimension), knowledge and beliefs (process dimension), and social facilitation (process dimension). Regarding the IFSMT (Ryan & Sawin, 2009), this study hypothesized that older patients may have lower self-management than younger patients, patients with high self-efficacy and social support may have higher self-management, and those with high levels of depression may have lower self-management than those with low levels of depression. The research conceptual framework for this study is shown in Figure 1.

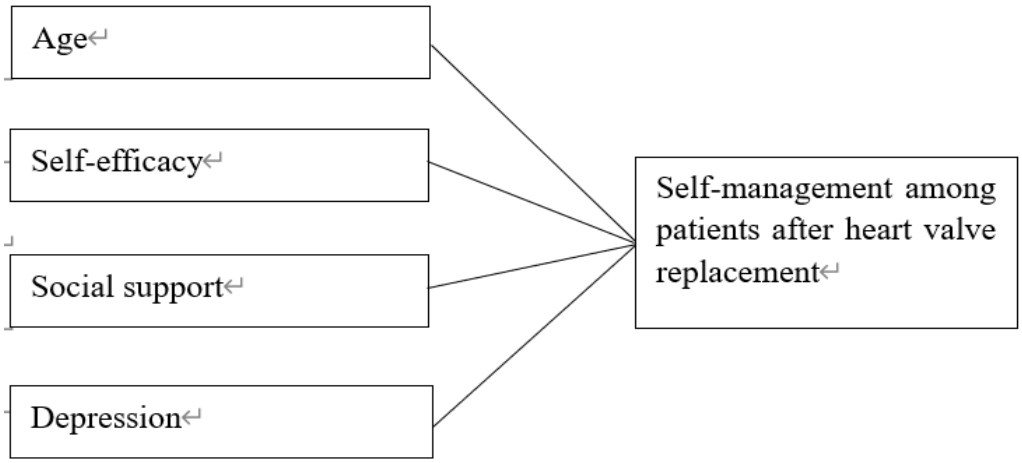

Figure 1 Conceptual framework

Definition of terms

Patients with heart valve replacement are referred to adults who have been diagnosed with heart valve disease and underwent mechanical heart valve replacement open surgery for the first time.

Self-management refers to the activities of patients with heart valve replacement to follow the treatment regimen to control the disease and prevent complications after heart valve replacement. It includes symptom management, treatment compliance management, daily life management, emotion management, information management, and self-efficacy management. The self-management was measured by the self-management scale of patients after mechanical heart valve replacement (Deng, 2016).

Self-efficacy refers to the degree of confidence of patients with heart valve replacement in their ability to self-manage after heart valve replacement surgery. Self-efficacy was measured by the Chinese version of the General Self-Efficacy Scale (GSES) (Wang et al., 2001).

Social support refers to the perception of assistant received by patients with heart valve replacement from family, friends, and significant others after heart valve replacement. In this study, social support was measured by the Chinese version of the Perceived Social Support Scale (PSSS) (Huang et al., 1996).

Depression refers to the unpleasant emotion or feeling of patients with heart valve replacement related to their condition which includes low mood and loss of interest in daily life. Depression was measured by the Chinese version of the Self-Rating Depression Scale (SDS) (Peng et al., 2013)

CHAPTER 2
LITERATURE REVIEWS

This chapter presents the literature reviews including an overview of valvular heart disease (VHD), self-management among patients after heart valve replacement, the theory of Individual and Family self-management, and factors related to self-management among patients after heart valve replacement.

Overview of Valvular heart disease (VHD)

Definition of valvular heart disease

Valvular heart disease (VHD) is one of the most common cardiovascular diseases (Zandi et al., 2021). VHD is defined as a heart valve (mitral, tricuspid, and aortic valve and pulmonary valve) abnormal structure or function leads to valve insufficiency and valve stenosis, cardiac hemodynamics can change, resulting in fatigue, palpitations, fatigue, loss of physical strength, dyspnea, and other symptoms (Li, 2021). It is an important health problem, and the presence of severe VHD may be an important cause of disability, reduced quality of life, cardiac dysfunction, and premature death from cardiovascular disease (Chen & Yiu, 2016).

Etiology of valvular heart disease

Valvular heart disease (VHD) is caused by damage or loss of one of the four heart valves: the aortic, mitral, tricuspid, and pulmonary valves. Defects in these valves can be congenital or acquired. Age, sex, tobacco use, hypercholesterolemia, high blood pressure, and type 2 diabetes all increase the risk (Zeng et al., 2016). Valves in the heart control the one-way flow of blood through the body. Each valve opens and closes 30-40 million times a year, a total of 3 billion times over its life cycle. Valvular heart disease is characterized by the gradual narrowing of the valve due to calcification of the leaflets or regurgitation of one of the four heart valves due to inadequate valve closure. Valve stenosis (too narrow or hardened to fully open) or failure to fully close (unable to fully close) causes the blood flow between several ventricles to become pathological, increasing the mechanical load on the ventricles,

leading to ventricular enlargement, thickening, and progressive systolic failure (Soares et al., 2016).

There are significant differences in the epidemiology of valvular heart disease between industrialized and developing countries, mainly related to differences in etiology (Iung & Vahanian, 2014). In developed countries, the main causes of VHD are degenerative calcification changes and congenital diseases, while in developing countries, rheumatic heart disease (RHD) is dominant (Thomson Mangnall et al., 2015). RHD is a late consequence of acute rheumatic fever, caused by a pharyngeal or skin infection caused by β hemolytic streptococcus. The most common consequence of infection in adolescents or adults is delayed valvular disease, caused by chronic valvular inflammation and scarring (Iung & Vahanian, 2011).

Great improvements have been made in China's economy and people's living conditions since the policy of reform and opening in 1978. Infectious diseases, as well as RHD, have declined significantly. Although rheumatic fever has decreased significantly in the past few years, it has been shown that RHD is still the main cause in China (Yang et al., 2021). However as the population ages, the rate of degenerative heart disease (DHD) is increasing year by year, according to the 2018 annual report of the National Center for Cardiovascular Disease and the Chinese Academy of Medical Sciences (Wen et al., 2020).

Signs and symptoms

Valvular heart disease patients are characterized by signs and symptoms such as dyspnea, fatigue, syncope, edema, chest pain, palpitations, and so on. With the development of the disease, these signs and symptoms increase day by day (Anjos et al., 2016). In a study, it showed physical symptoms in patients with VHD, usually fatigue (53.5%) and difficulty breathing (50%) (Anjos et al., 2016).

Diagnosis and examinations

Due to the slow, progressive nature of many valve lesions, patients may not recognize symptoms as they may gradually limit the level of daily activity. A detailed physical examination should be performed based on the results of all tests, palpation, and auscultation to diagnose and assess the severity of valvular lesions (Nishimura et al., 2014).

According to the American Heart Association (AHA) (2014), the use of an electrocardiogram (ECG) to confirm the heart rate and chest X-rays to assess for pulmonary congestion and other lung pathology may be helpful in the initial assessment of patients with known or suspected VHD. A comprehensive transthoracic echocardiography (TTE), including two-dimensional (2D) imaging and Doppler inquiry, should then be performed to link findings to initial impressions based on preliminary clinical evaluation. Additional adjunctive tests such as transesophageal echocardiography (TEE), computed tomography (CT), cardiac magnetic resonance imaging (CMR), stress testing, and diagnostic hemodynamic cardiac catheterization may be required to determine the optimal treatment for patients with VHD. Echocardiography is a key technique for diagnosing VHD and evaluating its etiology, mechanism, function, severity, and prognosis (Vahanian et al., 2021).

Treatments

Careful monitoring, adequate medication, and perfect timing of surgery or intervention are key to the successful treatment of VHD (Tamuleviciute-Prasciene et al., 2018). Heart valve disease treatment mainly includes medication, open-heart surgery, and minimally invasive intervention.

Medical therapy for asymptomatic chronic heart valve disease or symptomatic patients with contraindications to surgery (Otto et al., 2021). It is aimed at controlling the consequences and preventing complications. Pharmacological groups applicable to valvular heart disease include digitalis, β -blockers, diuretics, vasodilators, antiarrhythmic agents, and anticoagulants (Anjos et al., 2016).

Open-heart surgery is the mainstay of treatment for valvular disease. It can slow the rate of functional deterioration, physiological and hemodynamic changes, and/or progression of heart failure. Valve replacement surgery can improve symptoms, prolong survival, and minimize the risk of complications. It is recommended when cardiac function associated with valve deterioration causes symptoms and/or when angiography or echocardiography shows evidence of severe valve damage (Thomson Mangnall et al., 2015). According to the American Heart Association (AHA) (2014), indication for intervention in patients with VHD is dependent on 1) the presence or absence of symptoms; 2) the severity of VHD; 3) the response of the left and/or right ventricle to the volume or pressure overload caused

by VHD; 4) the effect on the pulmonary or systemic circulation; and 5) a change in heart rhythm. About 30 million heart valves are implanted worldwide each year (S. Zandi et al., 2021). According to statistics, the number of heart valve replacement surgeries in China in 2020 was 65,822, accounting for 29.6% of the total cardiac surgery operations, an increase of 0.6% compared with 2019 (Hao et al., 2021). However, open-heart surgery is traumatic, takes a long time to perform, requires extracorporeal circulation, is prone to various postoperative complications, and requires a long period of recovery for the patient (Chen & Zhang, 2020).

Minimally invasive intervention is another technique used for heart valve treatment. With the development of interventional cardiology, several interventional techniques are increasingly being used to treat valvular disease in a less invasive manner, which can greatly improve the quality of life of patients. Mitral balloon dilation can be used to treat patients with mitral stenosis. Transcatheter aortic valve replacement (TAVR) can be used in elderly patients with symptomatic severe aortic stenosis. There is also transcatheter repair of the mitral and tricuspid valves that have made important advances in recent years (Gao, 2018).

Type of replacement valve

Clinical implants currently used for surgical valve replacements are either mechanical valves (usually made from pyrolytic carbon or titanium) or valves made from biological soft tissue (Soares et al., 2016). The choice of valve prosthesis in individual patients is based on several factors, including valve durability, expected hemodynamics for a particular valve type and size, surgical or interventional risk, potential need for long-term anticoagulation, and patient preference (Nishimura et al., 2014).

According to the American Heart Association (AHA) (2014), biological valves are reasonable for patients over 70 years of age. Biological valves are prone to tissue degeneration or pannus formation (Nishimura et al., 2014), and future intervention and/or replacement will be required (Thomson Mangnall et al., 2015). Failure rates increase with age, with almost all bioprosthetic heart valves failing before the age of 15 in patients under 50. However, these valves are less thrombotic and do not require long-term anticoagulant therapy (David, 2021). However, patients using the biological valve were also more likely to develop embolism symptoms, such

as ischemic stroke or peripheral embolism, within three months of surgery. Therefore, vitamin K antagonist (VKA) should be used for anticoagulation for 3-6 months after surgery.

American Heart Association (AHA) (2014) guidelines for the management of patients with valvular heart disease suggest that mechanical prosthesis is reasonable for patients younger than 60 years of age. For patients aged 60 to 70 years, biological prostheses or mechanical valves are reasonable. Mechanical valves are more durable than biological valves but are more prone to thrombosis (David, 2021), it will activate coagulation factors in the body, thrombosis, and even thromboembolism and other complications, and patients need to take VKA anticoagulant therapy for life after surgery (Wang et al., 2018).

The anticoagulant standard of VKA is expressed by the international standardized ratio (INR) (Corrochano et al., 2020). Some studies have shown that the dose of warfarin required by Chinese people is lower than that of white people, and the INR value is determined to be 1.8-2.5 (1.8-2.2 for aortic valve replacement, 2.0-2.5 for mitral valve replacement, and 2.0-2.5 for double valve replacement) (Zhu et al., 2021). Inadequate anticoagulation can lead to thrombosis and excessive anticoagulation can lead to bleeding. Therefore, regular laboratory tests of the international standardized ratio (INR) must be performed, and the dose of vitamin K antagonists adjusted according to the results of INR (Pozzi et al., 2016).

Care after heart valve replacement

For patients with heart valve disease, having surgery can effectively improve heart function and enhance the quality of life. However, Heart valve replacement is the beginning of cardiac function maintenance (Zhou et al., 2018). Patients also need dietary management, taking medication on time, regular review, and observation of adverse reactions after surgery to prevent complications such as bleeding and embolism. To reduce the occurrence of postoperative complications and promote the recovery of cardiac function, patients need to follow many precautions after surgery (Chen, 2020; Chen & Zhang, 2020; Li, 2021).

For 3 months after surgery, patients should pay attention to the condition of the surgical incision and consult the doctor immediately if symptoms such as oozing/redness/swelling are detected. Avoid chest expansion exercises and do not do

heavy physical activities that may affect the sternum's healing. The patient can exercise properly but should rest immediately if the patient has chest pain/tightness during the activity.

Three to six months after the operation, patients need to judge the intensity of exercise, choose the right form of exercise, and reasonably allocate the time to exercise and rest to achieve the best results (Liu & Chen, 2021). According to the state of cardiac function, the patient can gradually increase the amount of activity, mainly light physical activity, and transition to normal work and life.

In terms of diet, patients need to control their diet reasonably to avoid excessive food to avoid the burden on the heart (Wen et al., 2016). Avoid alcohol, and avoid the accumulation of vitamin K in the body caused by taking a large amount of the same vegetables for a long time, thus affecting the blood concentration of warfarin (Witt et al., 2016).

Patients should be careful to prevent infection, as bacteria, once introduced, can easily cause infective endocarditis (Cahill et al., 2017), which can affect the mobility of the prosthetic valve. Therefore, patients should usually pay attention to keeping warm, and avoid colds, and if there are skin infections, pneumonia, periodontitis, nephritis, etc., they should be treated promptly to control the infection.

In terms of anticoagulation, patients need to take warfarin on time. One week after discharge, patients must have their INR rechecked, followed by weekly labs, and then every 2-4 weeks after the INR results have been stabilized. To control INR at a relatively stable level and avoid the occurrence of embolism and bleeding (Li et al., 2021). Patients need to correctly recognize the manifestations of bleeding and embolism and seek medical attention as soon as possible when vomiting blood/bloody stools/platonic stools/nosebleeds/gum bleeds occur (Wen et al., 2016). Do not take other medications without permission while taking Warfarin, as the medications may interact with each other and increase complications. Patients should inform their doctor that they are taking Warfarin when they go to see other diseases (Witt et al., 2016).

Patients should go to the hospital for regular follow-ups so that doctors can keep abreast of the recovery situation and adjust the treatment program. This is a

long-term process, and patients need to have good self-management ability to reduce complications and promote health.

Early period (6 months) after heart valve replacement

Thrombosis, thromboembolism, and anticoagulation-related complications account for 75% of all complications, which typically occur 6 months after cardiac valve replacement, they are a major cause of morbidity and mortality, impose a psychological burden on people and harm quality of life (Javan et al., 2019). A study has shown poor self-management behavior in patients early (6 months) after heart valve replacement (Chen et al., 2021), 36.5% of patients had poor adherence to anticoagulant therapy (Gu, 2015). Another study showed that the incidence of bleeding and embolism was 27.78% and 3.34% in the early period (6 months) after mechanical cardiac valve replacement (Qu et al., 2014).

Self-management among patients after heart valve replacement

Self-management has been described and considered for more than 40 years, In recent years, self-management has been widely used in the management of chronic diseases (Grady & Gough, 2014). Self-management goes beyond traditional disease management to include a larger concept of prevention, emphasizing that people with chronic diseases still need preventive interventions to promote health and mitigate further deterioration of health (Grady & Gough, 2014). Many studies have shown that the consequences of good self-management include improved outcomes, reduced mortality, improved quality of life, and lower costs (Irani et al., 2019; S. Zandi et al., 2021)

Self-management refers to the daily activities that individuals undertake with their families, communities, and healthcare professionals to manage chronic diseases, including symptom management, treatment, and lifestyle changes, as well as the psychological, cultural, and spiritual impacts of health conditions (Schulman-Green et al., 2016). Other authors indicated that self-management is what people do physically or mentally for themselves, their families, or others to help them stay healthy and able to carry out daily social and physical activities (Toback & Clark, 2017).

Self-management of patients after heart valve replacement refers to the management of the patient's self-disease after heart valve replacement, it includes symptom management, treatment compliance management, daily life management, emotion management, information management, and self-efficacy management (Deng, 2016). *Symptom management* refers to patients observing the symptoms of complications such as cardiac insufficiency, bleeding, and thrombosis, seeking timely medical attention. *Treatment compliance management* refers to patients taking medicine on time, following the doctor's advice, and regular follow-up examinations. *Daily life management* refers to patients changing their behavior in daily life, such as reasonable exercise, reasonable diet, paying attention to personal hygiene, and so on. *Emotion managem*ent refers to patients who can control their emotions and adjust their emotions reasonably. *Information management* refers to patients actively acquiring knowledge and information about diseases and medicine. *Self-efficacy management* refers to the degree of patient confidence in self-management behavior (Deng, 2016).

Self-management of patients after heart valve replacement is very important, it can improve INR control, self-efficacy, and medication adherence, and result in a reduced risk of all-cause mortality, thromboembolism, and major bleeding (Javan et al., 2019). In a cohort study, patients in the self-management group after heart valve replacement had a lower risk of death five years later than those in the conventional therapy group (Christensen et al., 2016). Another study indicated that good self-management after heart valve replacement can effectively reduce complications associated with anticoagulation therapy (Zandi et al., 2021). Good self-management behaviors of patients after heart valve replacement can reduce the occurrence of complications, which is conducive to improving patients' adherence to treatment, developing good dietary behaviors, and improving postoperative quality of life (Chen & Li, 2018).

However, many previous studies have shown that the self-management of patients after heart valve replacement needs to be improved in China (Chen, 2020; Chen et al., 2021; Lu, 2016). In a survey of 571 patients living in rural China after heart valve replacement, it was found that the overall level of self-management was low, with 86.16 % of patients having moderate or lower levels of self-management

and only 13.84 % having high levels of self-management (Chen, 2020). In another survey of 220 patients after valve replacement in China, it was found that the level of self-management of patients was at a moderate to low level and needed to be further improved (Lu, 2016). In addition, a study found that the readmission rate of patients with heart valve replacement after one year was 26.58%, mainly due to poor compliance with medication and poor regular review (Zhou et al., 2018). Furthermore, patients in the early stages of cardiac mechanical valve replacement have a high incidence of complications such as bleeding and thrombosis due to poor compliance with treatment (Chen & Li, 2018).

Therefore, it is important to improve the self-management ability of patients after heart valve replacement, which can reduce the occurrence of postoperative complications, promote the recovery of cardiac function, maintain health, and improve the quality of life.

The Theory of Individual and Family Self-Management

After cardiac valve replacement, patients are discharged from the hospital and returned to their families and society. Patients need to change their behavior in daily life, take medicine on time and follow up regularly, observe the symptoms of complications, control their emotions, and acquire knowledge and information about diseases, which is not only the individual activities of patients but also the participation of families and society. In Chinese culture, strong family ties and close family relationships are very important (Luo et al., 2015). Family plays an important role after patient discharge, self-management of patients living alone was lower than that of patients living with family (Chen et al., 2021).

This study based on the Ryan and Sawin (2014) Model of the Individual and Family Self-management Theory (IFSMT) to examine the relationships among age and depression (characteristics of the individual), self-efficacy (knowledge and beliefs), social support (social facilitation), and overall self-management among patients after heart valve replacement.

The theory of individual and family self-management emphasizes the integration of individual and family self-management. Individuals or families take responsibility for chronic disease self-management (SM) or engage in health

behaviors by purposefully implementing a set of learned behaviors (Ryan & Sawin, 2009). SM is a multidimensional, complex phenomenon that can be understood as affecting individuals, couples, or families at all stages of development (Ryan & Sawin, 2009), they are closely related and constantly changing throughout the life cycle, self-management occurs in the context of family management in almost all cases (Grey et al., 2015), changes in one family member lead to changes in the system and all of its members.

Individual and Family SM involves the purposeful incorporation of health-related behaviors into the daily functioning of the individual or family, extending the individual to the individual and family. Individuals and Families SM involves knowledge and beliefs, self-regulation skills and abilities, and social facilitation of managing chronic illness or engaging in healthy behaviors. Individuals and families share responsibility for managing chronic diseases, to strengthening self-management by individuals and families leads to more positive outcomes. It can promote healthy behaviors, reduce costs, and improve quality of life (Ryan & Sawin, 2009).

Patients' and their families of self-management are very important to the prognosis of patients with chronic diseases, so patients and families provide information and skills, to help them to improve the ability of self-management is very important, it is not only part of the management of chronic diseases, is a part of disease prevention, but also reduce the economic burden of chronic diseases individuals, families, and communities (Grey et al., 2015).

The theory of individual and family self-management proposes that self-management (SM) consists of three dimensions: context, process, and outcomes. Contextual factors will affect individual and family participation in the SM process and directly affect the outcomes, strengthening the process produces positive outcomes, the last dimension of the theory is related to outcomes (Ryan & Sawin, 2009). The three dimensions of individual and family self-management as described by Ryan and Sawin (2009) are as follows:

Context dimension: risk and protective factors

Contextual factors are condition-specific factors that challenge or protect individuals and families from engaging in SM, including condition-specific factors, physical and social environments, and individual and family characteristics.

Individual/family factors are those characteristics of the individual and family directly (Ryan & Sawin, 2009). Individual characteristics are defined as person-specific attributes such as demographic variables (age, gender, education), physical health, and psychological factors (Notthoff et al., 2017).

Process dimension

The process dimension refers to self-management processes that improve one's ability to manage chronic disease or risky behavior and promote health. It includes condition-specific knowledge and beliefs, acquisition and use of self-regulation skills and abilities, and social facilitation and negotiation. The concept of knowledge and beliefs refers to factual information, as well as perceptions of health conditions and health behaviors including self-efficacy, outcome expectancy, and goal congruence. Self-efficacy is a specific behavioral concept that refers to a person's degree of confidence in his or her ability to successfully engage in a behavior under normal and stressful circumstances (Ryan & Sawin, 2009). Self-regulation is an iterative process that people engage in to achieve health behavior change. Self-regulation includes many skills and abilities such as goal setting, self-monitoring and reflective thinking, decision making, planning and action, self-evaluation, and emotional control. Social facilitation occurs in interpersonal relationships and enhances an individual's capacity for change, including social influence, support, and negotiated collaboration. Social support includes emotional, instrumental, or informational support provided to individuals or families with the explicit goal of helping or facilitating their participation in healthy behaviors (Ryan & Sawin, 2009).

Outcome dimension

Outcomes include proximal and distal outcomes. Proximal outcomes refer to individual and family self-management behaviors: including participation in activities/treatment programs, symptom management, or use of recommended medications. Distal outcomes refer to health status as an indicator of disease trajectory (indicating prevention, decay, stabilization, deterioration), quality of life/perceived well-being, and costs including both direct and indirect costs. The outcomes are divided into three main parts: health status; quality of life or perceived well-being and health costs (Ryan & Sawin, 2009).

Factors related to self-management among patients after heart valve replacement

Factors of self-management influence a patient's ability to self-manage and behave, understanding the factors may improve the assessment of self-management and may inform interventions that meet individual needs and improve health outcomes (Schulman-Green et al., 2016). The previous studies showed that there were many factors have been identified to be related factors of self-management among patients after heart valve replacement, such as gender, age, education level, social support, warfarin-related knowledge, medication adherence, self-efficacy, depression (Kil & Shin, 2020; Park & Jang, 2021; Wang et al., 2018). Based on the literature review and based on Ryan and Sawin's (2009) Model of the Individual and Family Self-management Theory, this study identified four important factors (age, self-efficacy, social support, and depression) that are important correlates of patients' self-management after heart valve replacement.

According to the IFSMT (Ryan & Sawin, 2009), in this study, age and depression belong to the concept of characteristics of the individual and it can affect individual and family self-management. Self-efficacy belongs to knowledge and beliefs, and social support belongs to social facilitation, these two factors all belong to the process dimension and they can affect individual and family self-management.

Age

Age is an individual factor affecting patients' self-management ability. The annual number of valve surgeries in China is more than 60,000, and the average age of patients is 52 years old (Gao, 2018). With the aging of Chinese society, the number of patients with degenerative heart valvular disease is increasing year by year (Shang-Fei et al., 2021), which means that more and more people receive heart valve replacement (Rostagno, 2019). Some studies have shown that treatment adherence in older patients is lower than in younger individuals, mainly due to memory and cognitive impairment in older patients (Chen et al., 2021). Older patients generally have a low education level and do not use the Internet to obtain information, resulting in lower self-management ability than younger patients (Wang et al., 2018). In Li's

study, the self-management score of patients after cardiac valve replacement was significantly affected by age (Li, 2021). A study showed that age was a factor affecting patient self-management, and elder patients had low self-management ability (Chen, 2020). In another study among 106 patients after heart valve replacement surgery, age (52.35±11.31), the results showed that the age of patients after cardiac valve replacement was related to patient self-management ability, the total scores of self-management behavior and treatment compliance of patients < 60 years old were higher than those of patients > 60 years old (Chen et al., 2021).

Therefore, this research chose age as an independent variable to study the relationship between age and self-management among patients after heart valve replacement.

Self-efficacy

Self-efficacy is defined as "a behavior-specific concept and refers to the degree of confidence one has in his/her ability to successfully engage in a behavior under normal and stressful situations" (Ryan & Sawin, 2009). In this study, self-efficacy refers to the degree of confidence of patients with heart valve replacement in their ability to self-manage after heart valve replacement surgery. Patients with higher self-efficacy have stronger confidence in coping with disease, which is conducive to improving patients' health behavior and self-management ability (Li, 2021). Lu's study showed that there were statistically significant differences in the effects of self-efficacy on total scores of self-management behaviors and medication compliance, there was a positive correlation between self-efficacy and total score of self-management after cardiac valve replacement ($r = .41$, $p < .01$), that is to say, the higher the self-efficacy of patients, the higher their self-management ability and level (Lu, 2016). In a study, the results showed that the compliance of senile patients with warfarin was positively correlated with self-efficacy ($r = .292$, $p < .01$) (Kil & Shin, 2020). Another study showed that there was a positive correlation between self-efficacy ($r = .337$, $p < .001$) and self-management behaviors (Irani et al., 2019).

Therefore, this research chose self-efficacy as an independent variable to study the relationship between self-efficacy and self-management among patients after heart valve replacement.

Social support

Social support refers to support from family members, friends, and peers, as well as medical professionals and organizations (Strom & Egede, 2012). In this study, social support refers to the perception of assistance received by patients with heart valve replacement from family, friends, and significant others after heart valve replacement. A study showed that social support was an influential factor after cardiac valve replacement (Huang et al., 2015). Another study found that based on personalized home care plan is built on the patient's condition, lets the family participate in the self-management of patients, and can play a role for patients to assist and promote, is helpful to improve the effect of the patient's self-management (Chen et al., 2019). Chen's study indicated that social support was positively correlated with patients' self-management ability ($r = .36$, $p < .05$), found that patients with high social support had high self-management, positive social support not only gave patients emotional and material support but also helped patients to face various pressures and take a positive attitude towards the disease and improve their self-management level (Chen, 2020).

Therefore, this research chose social support as an independent variable to study the relationship between social support and self-management among patients after heart valve replacement.

Depression

Depression is a negative emotion, emotions can have positive or negative effects on self-management, and depression is associated with poor self-management in patients (Grey et al., 2015). In this study, depression refers to unpleasant emotions or feelings of patients with heart valve replacement related to their condition which includes low mood and loss of interest in daily life. The trauma of surgery, the high cost of surgery, and the need for long-term medication can bring anxiety and depression to patients after heart valve replacement (Chen & Zhang, 2020). Many studies indicated that depression is a factor in the self-management ability of patients after cardiac valve replacement (Huang et al., 2015; Liu, 2018). A study indicated that medication adherence exhibited a negative correlation with depression ($r = -.223$, $p = .006$) (Park & Jang, 2021). Park and Jang (2021) found that depression affects

medication compliance, and the higher the degree of depression, the lower the medication compliance, this leads to a reduction in patients' self-management ability. In addition, another study indicated that psychological status will have a certain impact on patients' compliance with anticoagulant therapy, patients with depression and anxiety have poor compliance and self-management ability, so the incidence of bleeding, thrombosis, and other complications is higher (Chen & Li, 2018).

Therefore, this research chose depression as an independent variable to study the relationship between depression and self-management among patients after heart valve replacement.

Summary

Valvular heart disease has become an increasingly serious problem and a threat to people's health in China. As more people are diagnosed with valvular heart disease, more patients are undergoing heart valve replacement surgery. However, patients will face many challenges after surgery, patients need to manage their daily lives, regularly take medicine, review, observe the symptoms of complications, and so on. This is a long-term process, which requires patients to have good self-management ability.

However, according to the literature review, it was found that the self-management ability of patients after cardiac valve replacement was not high, which leads to the occurrence of many complications, especially within six months after surgery, which not only threatens the lives of patients but also increases the burden of family and society. On the other hand, patients return to their families after discharge, and the family plays an important role in supporting and caring for the patients. When the family participates in the disease management of the patients, the self-management ability is improved, which can reduce complications and promote health. Therefore, after understanding the influencing factors of patients' self-management after cardiac valve replacement, nurses can formulate nursing interventions to help patients and their families better self-management, promote the recovery of cardiac function, maintain health, reduce the incidence of complications, and improve the quality of life of patients.

CHAPTER 3
RESEARCH METHODOLOGY

This chapter presents the research methodology including, research design, population and sample, research setting, research instruments, psychometric properties of the instruments, protection of human rights, data collection, and data analyses.

Research design

A descriptive correlational design study was used to investigate the relationships between age, self-efficacy, social support, and depression with self-management among patients after heart valve replacement.

Population and sample

Population

The population of this research were adults who had undergone mechanical valve replacement open surgery for the first time, after discharge one month to six months, and followed up at the cardiac surgery outpatient department of the First Affiliated Hospital of Wenzhou Medical University in Wenzhou, Zhejiang province, China.

Sample

The sample was adults who had undergone mechanical valve replacement open surgery for the first time, after discharge one month to six months, and came to the cardiac surgery outpatient department at the First Affiliated Hospital of Wenzhou Medical University, Zhejiang Province, China. The inclusion criteria of the sample included:

1. Age: ⩾18 years old, under 65 years old
2. Have a certain ability to speak, read, and write in Chinese
3. No history of intellectual disability or mental illness, information from the medical record
4. Have a stable health condition and can cooperate in completing the study

5. Have no serious physical illness or physical disability

Sample size

The sample sizes were calculated by using the G*Power 3.1.9.7 program for correlational design. The researcher tested the relationship between self-management and each independent variable. Therefore, the correlation-bivariate normal model was chosen as the type of statistical test in the G*Power program with a significance level of .05, a statistical power of .80, and an effect size was 0.25 (Cohen, 2013). Based on this formula, 123 participants were needed. Participants were considered to have dropped out if they did not complete the study for any reason, a 10% dropout rate was considered (Chen et al., 2020), and 135 participants were recruited into the study.

Sampling technique

A simple random sampling method was used in this study. Each participant was chosen entirely by chance and each member of the population had an equal chance, or probability, of being selected.

The researcher numbered the participants who met the criteria (outpatient nurses reviewed relevant medical records and determined if the criteria were met). The application program with simple random sampling was used to select the queue number to recruit participants (wrote the number on the paper, put the paper in the bag, took a piece of paper). After signing in for attendance at the cardiac surgery outpatient department, the participants were guided by the outpatient nurse to the special private room. The researcher introduced the study simply. With the consent of the selected patient, the researcher guided the participant to sign the consent form and complete the questionnaires. About 3 to 5 participants were recruited a day, five days a week. When the samples reached the required sample size, the recruitment was stopped for the next phase of the study.

Research setting

The study was conducted in the cardiac surgery outpatient department (OPD) of the First Affiliated Hospital of Wenzhou Medical University in China, which is one of the first four comprehensive hospitals in Zhejiang province that have passed the third-grade hospital accreditation. There are two hospital districts: the old hospital in the Lucheng district and the new one in the Ouhai district. This study was

conducted in the new hospital (the Ouhai hospital district, where the cardiac surgery OPD is only located), with a construction area of 355,000 m^2 and a larger number of attendances compared to the other sites. The cardiac surgery OPD is open five days a week, and services from 08:30 am to 11:30 am and from 01:30 pm to 04:30 pm, and it serves about 5 to 20 patients after heart valve replacement in a day.

The cardiac surgery department is managed by 1 ~ 2 cardiac surgeons and 1 nurse every day. After cardiac valve replacement, patients can visit the cardiac surgery outpatient department according to the doctor's recommended follow-up time (INR needs to be monitored monthly after discharge). Most patients who come to the outpatient department are accompanied by family or friends. Patients wait at the door until their names are called. The doctor then orders a series of tests, including INR, blood routine, biochemistry, and an ECG or echocardiogram. The nurse will guide the patient to do the examination. After the examination, the patient will return to the clinic again, and the doctor will adjust the medication according to the examination results. The nurse guides the patient on how to take medication and precautions and helps the patient make an appointment for the next visit.

Research instruments

Data were collected using five questionnaires: the demographic information questionnaire, the Chinese version of self-management scale of patients after mechanical heart valve replacement, the Chinese version of General Self-Efficacy Scale (GSES), the Chinese version of the perceived social support scale (PSSS), and the Chinese version of Self-Rating Depression Scale (SDS).

The demographic information questionnaire

The demographic information questionnaire was developed for this research by the researcher. It includes age, gender, marital status, educational level, living condition, individual income, payment method of medical expenses, working status, distance from the hospital, how long after surgery, type of surgery, current cardiac function status, current symptoms, and warfarin-related complications.

The self-management scale of patients after mechanical heart valve replacement (MHVR)

The self-management scale of patients after mechanical heart valve replacement was designed by Deng (2016) in China, this study was based on self-management and combined with the Chinese cultural background and characteristics of mechanical valve replacement, established 6 dimensions 27 items, including symptom management (5 items), treatment compliance management (3 items), daily life management (5 items), emotional management (3 items), information management (5 items) and self-management efficiency (6 items).

This questionnaire used the Likert scoring method to assign 1-5 points to each item: always (5 points), often (4 points), sometimes (3 points), rarely (2 points), no (1 point). Higher scores indicated better self-management skills. The score of each dimension was the sum of all items in this dimension, and the sum of all dimensions was the total score of self-management, range of the total scores = 27-135. The scoring rate was used to standardize the total score of the scale and the score of each dimension. The scoring rate = (actual score of the scale (dimension)/maximum score of the scale (dimension) x100%. The higher the score rate, the higher the self-management ability of patients after MHVR surgery. High: the scoring rate > 80%, moderate: 60% > the scoring rate < 80%, low: the scoring rate＜60%, the validity of the scale was 0.91, and the Cronbach's coefficient was 0.92 (Chen, 2020).

The Chinese version of the General Self-Efficacy Scale (GSES)

In this study, self-efficacy was measured with the Chinese version of the General Self-Efficacy Scale (GSES) which was translated and revised by (Wang et al., 2001) from the General Self-Efficacy Scale (GSES) developed by Schwarzer et al. (1981). The GSES has been translated into at least 25 languages and was widely used internationally. Schwarzer and colleagues (1981) found that the construct of general self-efficacy was universal across cultures, it refers to an individual's overall confidence in coping with the challenges of various environments or facing new things (Wang et al., 2001).

The GSES adopts the form of a 4-point Likert scale, it has 10 items. Each item was scored 1- 4: 1 = not at all true, 2 = hardly true, 3 = moderately true, and 4 = exactly true, according to their situation. The GSES was a one-dimensional quantity without a subscale, so only the total table score was counted. The total score was 10 - 40 points, the higher the score, the better the self-efficacy, and divided self-efficacy

into three levels, high level = 31-40, moderate level = 23-30, and low level = 10-22 (Li, 2021).

The internal consistency coefficient (Cronbach α) of GSES was 0.87. The retest reliability was 0.83 and the half-fold reliability was 0.90 at an interval of about 10 days. These figures suggested that the GSES was a very reliable measure (Wang et al., 2001).

The Chinese version of the perceived social support scale (PSSS)

The PSSS scale was compiled by Zimet et al. (1988) and later translated into Chinese by Jiang (1996). The scale was mainly used to measure social support from various aspects (Zimet et al., 1988), including family support, friends support, and significant other support in 3 dimensions, with 12 items in total. The scale used a 7-point Likert scale (1 = very strongly disagree; 2 = strongly disagree; 3 = mildly disagree; 4 = neutral; 5 = mildly agree; 6 = strongly agree; 7 = very strongly agree). The overall score was 12-84, the total score reflects the social support level of individual comprehension, with 12-36 as the low support level, 37-60 as the moderate support level, and 61-84 as the high support level. For family support, friends support, and significant other support subscale score from 4 to 12 was considered low level, 13 to 20 was considered moderate level, and 21 to 28 was considered high level (Huang et al., 1996).

The total Cronbach α coefficient of the Chinese version of the perceived social support scale was 0.816, and the split reliability coefficient was 0.852. Chen et al. evaluated the reliability and validity of the Chinese version of the perceived social support scale in the elderly with chronic diseases, and the results showed that the Chinese version of the perceived social support Scale had good reliability and validity in the elderly with chronic diseases, could effectively evaluate the social support status of the elderly with chronic diseases (Yuan Chen et al., 2018).

The Chinese version of the Self-Rating Depression Scale (SDS)

SDS was developed by Zung in 1965. It was simple to use and could effectively reflect the changes in symptoms and severity of depression (Zung, 1965), with good validity (Cronbach α coefficient 0.92) and wide application (Sun et al., 2020). The Chinese version of SDS was translated by Wang in 1984, with a total of 20 items (Wang & Chi, 1984).

For each item, the response choices were “1 = a little of the time”, “2 = some of the time”, “3 = good part of the time”, and “4 = most of the time”, and items 2, 5, 6, 11, 12, 14, 16, 17, 18, and 20 were scored inversely. The overall score was 20-80, the standard score was obtained by multiplying the sum of the scores for all 20 items by 1.25, ranging from 25-100, the score below 50 indicated no depression, 50-59 indicated minimal to mild depression, 60-69 indicated moderate to marked depression, 70 and over indicated severe to extreme depression (Sun et al., 2020). Peng et al. analyzed the reliability and validity of the Chinese version of the Self-rating Depression Scale, the Cronbach coefficient was 0.784, indicating that the reliability and validity were good (Peng et al., 2013).

Psychometric properties of the instruments

The Chinese version of all the instruments were used in this study, and they were tested and validated by the experts in some previous studies, which meant all instruments had good validities. Cronbach’s α could be found in previous studies to show that the reliability of all instruments applied in this study was ideal. The reliability instrument used Cronbach’s alpha to determine the reliability of each questionnaire with 30 adults after heart valve replacement, who had the same characteristics as the sample of the study. Cronbach’s alpha of the self-management scale of patients after mechanical heart valve replacement, the General Self-Efficacy Scale (GSES), the perceived social support scale (PSSS), and the Self-Rating Depression Scale (SDS) for tryout are presented in Table 1.

Table 1 The reliability of the instruments

	Cronbach’s Alpha
Self-management Scale of patients after mechanical heart valve replacement	.905
The Chinese version of the General Self-Efficacy Scale	.960
The Chinese version of the Perceived Social Support Scale	.901
The Chinese version of the Self-Rating Depression Scale	.796

Protection of human rights

This study was approved by the Institutional Review Board of Burapha University (Protocol code G-HS029/2565) and the Ethics Committee of the First Affiliated Hospital of Wenzhou Medical University (Protocol code KY2022-144). This study was carried out after approval.

During data collection, all participants were carefully informed about the purpose of the study. The researchers described the nature of the study and the respondents' right to participate or refuse to participate. All the forms used to collect data were anonymous, and there was no harm to participants participating in the study. Because no names were given in the study, secrecy had been maintained. Participants volunteered to participate in the study. They had the right not to answer any questions they felt uncomfortable with and could withdraw at any time if they wished. Completed consent before data collection. Before data collection, participants were asked for signed consent forms. All data were stored in a secure location and used only for research purposes. If any participant wanted to know the results of this study, they could contact the researcher who would provide the report.

Data collection

Data were collected by the researcher from September 19, 2022, through May 31, 2023. The data collection procedures were as follows:

1. After the researcher got approval from the Faculty of Nursing at BUU, the researcher submitted the research proposal to IRB at BUU and the First Affiliated Hospital of Wenzhou Medical University, China for ethical review.

2. The researcher asked permission for data collection from the Faculty of Nursing at BUU and the First Affiliated Hospital of Wenzhou Medical University, China.

3. After the researcher got permission, the researcher introduced the purposes of this study and the data collection process to the physicians and nurses who worked in the cardiac surgery outpatient department of the First Affiliated Hospital of Wenzhou Medical University, to obtain cooperation.

4. The researcher went to the cardiac surgery outpatient department of the First Affiliated Hospital of Wenzhou Medical University from 8:30 am to 11:30 am and from 1:30 pm to 4:30 pm every weekday (from Monday to Friday). The researcher followed the registration record to find the participants appropriate to the inclusion criteria by talking with participants. Then, the researcher used a simple random sampling technique to recruit participants.

5. At the entrance to the clinic, participants were required to wear masks, have their temperatures checked, and use their mobile phones to show the Wenzhou health code (the official measure for COVID-19 control). Participants with green code passing and body temperature lower than 37.3℃ could enter the outpatient department.

6. The participant was taken by the outpatient nurse to the special private room. Participants and researchers were kept at least one meter away from each other in the room, wore masks all the time, and were asked to disinfect their hands with hand sanitizer before and after filling out the form.

7. The researcher informed participants about the purposes of the study, ethical issues, and human protection. Then requested their permission to participate in the study by giving consent forms for signature verification.

8. The data was collected through self-reported questionnaires in a special private room. Reading glasses were prepared to make sure the participants saw clearly. It took about 15-20 minutes to complete the whole set of questionnaires. The researcher made sure that the participants could see the doctors in time as soon as the questionnaires were completed.

9. The researcher checked if the questionnaires had been filled in after the participants submitted them. All the participants were informed if they chose not to answer some of the questions purposely, they could leave them unanswered.

10. This process was repeated until the required sample size was reached.

Data analysis

Data was analyzed by using statistical software (SPSS 27.0). The result of the study was evaluated using a conventional statistical criterion ($\alpha = .05$), and data analysis included:

1. The descriptive statistics including frequency statistics, mean and standard deviation were used to describe the demographic characteristics of the subjects.

2. Various functions of the statistics were used to test the assumptions of Pearson product-moment correlation analyses (normality of variables, linear relationship, no outlier).

3. Pearson product-moment correlation analyses were used to investigate associations between age, self-efficacy, social support, depression, and self-management.

CHAPTER 4
RESULTS

This chapter presents the results of the study about self-management among patients after heart valve replacement and its related factors (age, self-efficacy, social support, depression). The results are divided into three parts. The first part describes the level of the demographic characteristics. The second part presents the level of self-management, self-efficacy, social support, and depression. The third part presents the relationships between age, self-efficacy, social support, depression, and self-management among patients after heart valve replacement.

Description of demographic characteristics of the sample

A total of 135 sets of questionnaires were distributed, and all questionnaires were completed and returned 100 %. The demographic characteristics of the participants are described in Table 2.

Table 2 Description of demographic characteristics of the sample (n = 135)

Variables	**Number (n)**	**Percentage (%)**
Age (Max = 64, Min = 29, M = 49.32, SD = 7.57)		
29 - 44 years	29	21.5
45 - 59 years	97	71.8
60 - 64 years	9	6.7

Table 2 (Continued)

Variables	**Number (*n*)**	**Percentage (%)**
Gender		
Male	68	50.4
Female	67	49.6
Marital status		
Single	5	3.7
Married	126	93.3
Divorced	2	1.5
Widowed	2	1.5
Educational level		
Illiteracy	9	6.7
Primary school	69	51.1
Junior high school	39	28.9
Senior high school and above	18	13.3
Living condition		
Living alone	11	8.1
Living with family members or others	124	91.9
Individual income (CNY)		
Less than ¥ 3,000	78	57.8
¥ 3,000 – 5,000	44	32.6
¥ 5,000 – 10,000	11	8.1
More than ¥ 10,000	2	1.5
Payment method for medical expenses		
Medical insurance	131	97
Self-paying	4	3

Table 2 (Continued)

Variables	**Number (*n*)**	**Percentage (%)**
Working status		
Have a work now	45	33.3
No job	68	50.4
Retirement	22	16.3
Time from home to hospital		
Less than 1 hour	42	31.1
1 hour - 2 hours	75	55.6
More than hours	18	13.3
Duration after surgery		
1 month	16	11.9
2 months	16	11.9
3 months	14	10.3
4 months	10	7.4
5 months	29	21.5
6 months	50	37.0
Operation type		
Mitral valve replacement	79	58.6
Aortic valve replacement	28	20.7
Double valve replacement	28	20.7
Current cardiac function status		
Level 1	107	79.3
Level 2	28	20.7

Table 2 (Continued)

Variables	Number (*n*)	Percentage (%)
Current symptoms		
None	121	89.6
Dyspnea	7	5.2
Chest tightness	4	3.0
Edema	2	1.5
Others (palpitations)	1	.7
Warfarin-related complications		
None	124	91.9
The lower extremities thrombosis	4	2.9
Rhinorrhagia	7	5.2

Table 2 shows that 135 participants after heart valve replacement had an age - range from 29 to 64 years (M = 49.32, SD = 7.57), 71.8% of the participants aged between 45 and 59 years. 50.4% were men and 49.6% were women, most of them were married (93.3%). Regarding educational level, 51.1% graduated from primary school. Most participants lived with family members (91.9%). 57.8% of them had a low average monthly income of less than ¥3,000. Almost all participants had insurance (97%). Half of them had no job (50.4%). More than half of them needed 1-2 hours to get from home to the hospital (55.6%). 21.5% of participants were 5 months after surgery, and 37% were 6 months after surgery. The majority of participants had mitral valve replacement (58.5%). They had level 1 heart function (79.3%) and had no clinical symptoms (89.6%) or warfarin-related complications (91.9%).

Description of the study variables

Description of self-management

The self-management scale used in this study was based on self-management combined with Chinese cultural background and characteristics of mechanical valve replacement. It can reflect the self-management ability of

participants after surgery, establishing 6 dimensions, including symptom management, treatment compliance management, daily life management, emotional management, information management, and self-management efficiency. Description of the results is described in Table 3.

Table 3 Self-management and its dimensions among the participants (n = 135)

Variables	**Possible score**	**Actual score**	***M*** **(*SD*)**	**Scoring rate (%)**	**Level**
Self-management	27-135	80-132	102.07 (5.86)	75.60	Moderate
Symptom management	5-25	15-25	19.85 (1.25)	79.40	Moderate
Treatment compliance management	3-15	8-15	13.98 (1.43)	93.20	High
Daily life management	5-25	17-25	19.88 (1.29)	79.52	Moderate
Emotional management	3-15	8-15	11.41 (1.00)	76.06	Moderate
Information management	5-25	7-23	16.02 (2.21)	64.08	Moderate
Self-management efficiency	6-30	14-30	20.91 (2.13)	69.70	Moderate

Table 3 shows overall scores in self-management ranged from 80 to 132 with a mean score of 102.07 (*SD* = 5.86, the scoring rate = 75.60%), indicating that the participants had a moderate self-management level. Considering the sub-categories of the scale, treatment compliance management was at a high level (*M* = 13.98, *SD* = 1.43, the scoring rate = 93.20%), the other five dimensions were at a moderate level, symptom management (*M* = 19.85, *SD* = 1.25, the scoring rate = 79.40%), daily life management (*M* = 19.88, *SD* = 1.29, the scoring rate = 79.52%), emotional management (*M* = 11.41, *SD* = 1.00, the scoring rate = 76.06%), self-

management efficiency *(M* = 20.91, *SD* = 2.13, the scoring rate = 69.70%), and information management (*M* = 16.02, *SD* = 2.21, the scoring rate = 64.08%) had the lowest score rate.

Description of self-efficacy, social support, and depression

Self-efficacy was tested using the Chinese version of the General Self-Efficacy Scale (GSES), which measured the degree of confidence in participants' ability to self-manage after heart valve replacement surgery. GSES was a one-dimensional quantity without a subscale, it had 10 items in total. The Chinese version of the Perceived Social Support Scale (PSSS) was used to measure the social support of participants from various aspects, including family support, friends support, and significant other support (leaders, colleagues, relatives) 3 dimensions, with 12 items in total. Depression was tested using the Chinese version of the Self-Rating Depression Scale (SDS), which has 20 items in total.

Table 4 Self-efficacy, social support, and depression among the participants (n = 135)

Variables	**Possible score**	**Actual score**	***M***	***SD***	**Level**
Self-efficacy	10-40	17-40	26.63	4.53	Moderate
Social support	12-84	53-84	64.38	4.37	High
Family support	4-28	20-28	24.08	1.12	High
Friends support	4-28	12-28	16.98	2.86	Moderate
Significant other support	4-28	17-28	23.31	1.71	High
Depression	25-100	25-53	41.19	5.38	

Table 5 Level of depression (*n* = 135)

Depression level	**Score range**	***n***	**%**
Normal	25-49	121	89.6
Mild	50-59	14	10.4

Table 4 shows that the self-efficacy score ranged from 17 to 40, with a mean of 26.63 (*SD* = 4.53), indicating moderate self-efficacy. The social support had a mean score of 64.38 (*SD* = 4.37), ranging from 53 to 84, indicating a high social support level. Considering the sub-categories of social support, family support was at a high level (*M* = 24.08, *SD* = 1.12), friends support was at a moderate level (*M* = 16.98, *SD* = 2.86), significant other support was at a high level (*M* =23.31, *SD* = 1.71). Depression scale ranged from 25 to 53, with a mean of 41.19 (*SD* = 5.38). Table 5 shows that 10.4% had mild depression, and 89.6% had no depression.

Relationships among age, self-efficacy, social support, depression, and self-management among patients after heart valve replacement

Before conducting the analysis, the assumptions testing for Pearson's product-moment correlation were examined. The normality test was performed with a P-P plot and the Q-Q plot test, and results showed that all variables including age, self-efficacy, social support, depression, and self-management were normal distribution. Other assumptions for Pearson's correlation were satisfied including all variables were interval level, the related pairs of each variable and the self-management, a linearity of the relationship, and the homoscedasticity of all variables. Then Pearson's product-moment correlation was used to examine relationships among age, self-efficacy, social support, depression, and self-management. A p-value of less than 0.05 was considered statistically significant which indicated a significant association between the variables. The results are presented in Table 6.

Table 6 Association between self-management and its related factors (n = 135)

Variables	Self-management
Age	-.201*
Self-efficacy	.347**
Social support	.474**
Depression	-.325**

* $p < .05$, ** $p < .01$

Table 6 indicates that age had a significantly low negative relationship with self-management among patients after heart valve replacement (r = -.201, p < .05). Self-efficacy and social support had significantly moderate positive relationship with self-management (r = .347, p < .01; r = .474, p < .01 respectively). In addition, depression had a significantly moderate negative relationship with self-management (r = -.325, p < .01).

CHAPTER 5
CONCLUSION AND DISCUSSION

This study aims to understand the self-management and its related factors among patients after heart valve replacement. This chapter presents the summary and discussions of the study, implications of the study findings, limitations, and recommendations for future research.

Summary of the findings

The purpose of this study was to describe self-management and its related factors among patients after heart valve replacement. Factors included age, self-efficacy, social support, and depression. A simple random sampling method was used to recruit 135 patients who came to the outpatient department of Cardiac Surgery, the First Affiliated Hospital of Wenzhou Medical University, Wenzhou City, Zhejiang Province, China. All participants were discharged from the hospital 1 to 6 months after mechanical valve replacement open surgery for the first time. Data were collected by using five research instruments which included the demographic information questionnaire, the Chinese version of the self-management scale of patients after mechanical heart valve replacement, the Chinese version of the General Self-Efficacy Scale (GSES), the Chinese version of the perceived social support scale (PSSS), and the Chinese version of Self-Rating Depression Scale (SDS). The Cronbach's alpha coefficients of the self-management scale of patients after mechanical heart valve replacement, the Chinese version of the General Self-Efficacy Scale (GSES), the Chinese version of the perceived social support scale (PSSS), and the Chinese version of Self-Rating Depression Scale (SDS) were .90, .96, .90, and .79, respectively. Data were analyzed using descriptive statistics and Pearson's product-moment correlation.

The findings revealed that the age of 135 participants after heart valve replacement ranged from 29 to 64 years with a mean age of 49.32 years, 71.8% of them aged between 45 and 59 years. 50.4% were men and 49.6% were women, most of them were married (93.3%). They had low education levels, 51.1% graduated from

primary school, and 28.9% graduated from secondary school. Most lived with family members (91.9%). 57.8% of them had a low average monthly income of less than ¥3,000. 97% had insurance, and half of them had no job (50.4%).55.6% needed 1-2 hours to get from home to the hospital. 21.5% were 5 months after surgery, and 37% were 6 months after surgery. The majority of the participants had mitral valve replacement (58.5%), had level 1 heart function (79.3%), and had no clinical symptoms (89.6%) or warfarin-related complications (91.9%).

The mean score of self-management was 102.07 out of 135 (*SD* = 5.86), indicating moderate self-management. Its 6 dimensions include symptom management, treatment compliance management, daily life management, emotional management, information management, and self-management efficiency. Among others, treatment compliance management was at a high level (*M* = 13.98, *SD* = 1.43), the other five dimensions were at a moderate level, and information management (*M* = 16.02, *SD* = 2.21) had the lowest score rate. The mean score of self-efficacy was 26.63 out of 40 (*SD* = 4.53), indicating moderate self-efficacy. The mean score of the social support was 64.38 out of 84 (*SD* = 4.37), indicating a high social support level, its three dimensions include family support (*M* = 24.08, *SD* = 1.12) was at a high level, friends support (*M* = 16.98, *SD* = 2.86) was at a moderate level, significant other support (*M* = 23.31, *SD* = 1.71) was at a high level. The mean score of depression was 41.19 out of 100 (*SD* = 5.38), 10.4% had mild depression, and 89.6% had no depression.

Age had a significantly low negative relationship with self-management among patients after heart valve replacement ($r = -.201$, $p < .05$). Self-efficacy and social support had a significantly moderate positive relationship with self-management ($r = .347$, $p < .01$; $r = .474$, $p < .01$ respectively). In addition, depression had a significantly moderate negative relationship with self-management ($r = -.325$, $p < .01$).

Discussion

Self-management among patients after heart valve replacement

In this study, the mean score of the self-management was 102.07 out of 135 (*SD* = 5.86, scoring rate = 75.60%), this means that participants' self-management was at a moderate level, which was consistent with the result of some other investigations in China (Liu et al., 2023; Wang et al., 2018). Treatment compliance management at a high level (*M* = 13.98, *SD* = 1.43), the other five dimensions were at a moderate level, symptom management (*M* = 19.85, *SD* = 1.2), daily life management (*M* = 19.88, *SD* = 1.29), emotional management (*M* = 11.41, *SD* = 1.00), self-management efficiency (*M* = 20.91, *SD* = 2.13), information management (*M* = 16.02, *SD* = 2.21) had lowest score. High treatment compliance management levels indicated that participants attach importance to regular review and taking medicine on time. At the same time, it can be seen that the score of self-management efficiency was lower, this reflected the participants' lack of confidence in self-management. In addition, information management was the lowest, which may be related to participants' lack of timely and active access to information.

The study results can be explained by the Model of the Individual and Family Self-management Theory (IFSMT) which proposed that demographic factors such as educational degree, income, living conditions, distance from home to hospital, and heart function, influence self-management (Ryan & Sawin, 2009).

In this study, half of the participants had a primary school education (51.1%), and only 13.3% of participants had a high school education or higher. Compared to those with lower educational levels, highly educated adults have a higher degree of acceptance and mastery of disease knowledge, knowing how to get the information to help them manage the disease, and having more confidence to manage the disease (Lu et al., 2018). Almost all of them lived in a traditional house with family members (91.9 %) and 93.3% of them were married, this means that they have family support and home care, and good family support can help improve their treatment compliance, supervise them to take medicine on time and have regular check-ups (Chen et al., 2021; Irani et al., 2019).

57.8% of participants' income was less than ¥3,000 a month, 32.6% of participants' income was between ¥3,000 and ¥5,000, and half of them had no job

(50.4%). Generally speaking, a good job has a good income, low income means no job and more economic pressure, they don't have favorable conditions and facilities to manage the disease, and they don't have more money at their disposal, only when there is a problem they will seek the help of the doctor (Lu, 2016). Furthermore, more than half of the participants needed 1-2 hours to get from home to the hospital (55.6%), participants who were remote from the hospital often needed to transfer to multiple buses, spending a lot of time and energy, and the cost was high (Chen, 2020). In addition, economic pressures and transportation problems were barriers to obtaining the resources needed for self-management, which directly affected their self-management (Richard & Shea, 2011). In addition, 79.3%% of the participants had level 1 heart function, this means that they had recovered from their heart function well and were capable of taking care of themselves.

Factors related to self-management among patients after heart valve replacement

In this study, the results of Pearson's product-moment correlation analysis showed that age had a significantly low negative relationship with self-management among patients after heart valve replacement (r = -.201, p < .05). Self-efficacy and social support had a significantly moderate positive relationship with self-management (r = .347, p < .01; r = .474, p < .01 respectively). In addition, depression had a significantly moderate negative relationship with self-management (r = -.325, p < .01). It can be discussed as follows.

Age

Age is an individual factor in the context dimension of IFSMT, contextual factors are condition-specific factors that challenge or protect individuals and families from engaging in SM (Ryan & Sawin, 2009). This study showed that age had a significantly small negative relationship with self-management (r = -.201, p < .05). Many studies had shown that age was one of the factors related to self-management (Chen, 2020; Li, 2021; Wang et al., 2018). Older patients were less compliant than younger patients, and their memory and cognitive abilities were also weakened, they lacked access to disease and health knowledge, and could not fully understand and accept disease management knowledge (Chen et al., 2021). In addition, the older 's

mobility was reduced, they could not use smart devices, and they needed the company of family members for regular follow-up visits, leading to reduced self-management (Chen, 2020). However, the weak correlation between age and self-management in this study may be due to the younger age of the participants. One study showed that the average age of heart valve surgery was 52 years old (Gao, 2018). In another cross-sectional study, the age of 106 patients after heart valve replacement was 52.35 (*SD* = 11.31) (Chen et al., 2021). The mean age of participants in this study was 49.32 (*SD* = 7.57), and 71.8% were in the middle age group (45 - 59 years), which means the participants in the study were younger. Also, 97% of the participants had health insurance, and they could enjoy free physical examinations every year according to Chinese policy. Some participants found themselves with the valvular disease at the time of physical examination, prompting them to choose to seek medical treatment when the disease was not serious, and who had health insurance, even if they needed surgery, the cost of surgery was not high, they would not choose to delay surgery because of economic pressure (Lu, 2016).

Self-efficacy

Self-efficacy belongs to the process dimension of IFSMT, the process dimension refers to self-management processes that improve one's ability to manage disease or risky behavior and promote health (Ryan & Sawin, 2009). Self-efficacy was defined as “a behavior-specific concept and refers to the degree of confidence one has in his/her ability to successfully engage in a behavior under normal and stressful situations” (Ryan & Sawin, 2009). In this study, the self-efficacy of participants was at a moderate level ($M = 26.63$, $SD = 4.53$), and it had a significantly moderate positive relationship with self-management ($r = .347$, $p < .01$). This was consistent with previous studies (Li, 2021; Lu, 2016; S. Zandi et al., 2021). The higher the sense of self-efficacy, the more likely they were to acquire disease-related knowledge, and the more likely they were to seek help from doctors and family members, which was of great help to the maintenance of their self-management behaviors (Yao et al., 2019). One study showed a positive correlation between self-efficacy and treatment compliance ($r = .292$, $p < .01$) (Kil & Shin, 2020). Another cross-sectional study of 220 patients after heart valve replacement found that self-efficacy was one of the factors influencing self-management and was positively

associated with self-management ($r = .41$, $p < .01$) which indicates that the higher the self-efficacy, the higher the self-management ability among individuals (Lu, 2016)

Social support

Social support belongs to the social facilitation of the process dimension of IFSMT. Social facilitation occurs in interpersonal relationships and enhances an individual's capacity for change (Ryan & Sawin, 2009). The result obtained from this study revealed that social support was at a high level ($M = 64.38$, $SD = 4.37$), and it had a positive relationship with self-management ($r = .474$, $p < .01$). Social support has a positive influence and support them to engage in preventive health behaviors (Ryan & Sawin, 2009). Sources of social support include family members, friends, and peers, as well as medical professionals and organizations (Strom & Egede, 2012). A study result indicated that social support was positively correlated with patients' self-management ability ($r = .36$, $p < .05$). The current finding is similar to a finding from a previous study which found that patients with high social support had high self-management (Chen, 2020). Positive social support not only helps patients with emotional and material support, but also helps patients take a positive attitude toward the disease and improve their self-management level (Irani et al., 2019). From the results of social support, the score of family support was at the highest level ($M = 24.08$, $SD = 1.12$), followed by other support ($M = 23.31$, $SD = 1.71$), and the score of friend support was the lowest ($M = 16.98$, $SD = 2.86$). This indicated that family support was the most important social support for participants. The main reason may be that Chinese people have a strong sense of family and prefer to live with their families. In this study, 93.3 % of participants were married, and 91.9 % of participants were living with family. One study showed that patients who lived with family members were better at self-management than those who lived alone (Chen et al., 2021). Another reason was that because of the COVID-19 pandemic, participants spent more time at home and less time out, so they spent more time with their families and less time interacting with other people or friends, so their families played a primary care and support role for them.

Depression

Depression is an individual factor in the context dimension of IFSMT (Ryan & Sawin, 2009), it is a risk factor. In this study, depression was negatively correlated

with self-management (r = -.325, $p < .01$), indicating that the more severe the depression, the worse the self-management. One study showed that depression can affect medication adherence, with higher levels of depression associated with lower medication adherence ($r = -.223$, $p = .006$) (Park & Jang, 2021), resulting in decreased quality of life, and increased mortality (Drudi et al., 2018). Previous studies have shown a higher incidence of depression after heart valve replacement, one study found a 19.6% incidence of depression among patients after heart valve replacement (El-Sabawi et al., 2023), and another study found a 23.6% incidence (Bäz et al., 2020).

However, participants in this study showed very low levels of depression ($M = 41.19$, $SD = 5.38$), 10.4% had mild depression, and 89.6% had no depression. Depression is mainly caused by various factors such as greater surgical trauma, higher risk, higher surgical cost, the need for anticoagulation, and close follow-up (Chen & Zhang, 2020). In addition, participants in this study lived in economically developed areas in China, where the local medical conditions were good, and the success rate of surgery was high. Also, 97% of the participants had medical insurance, and the operation cost was not high, they had less financial stress (Chen, 2020). A study showed that people who had valve replacement had lower levels of depression than other chronic patients, possibly because they had regular outpatient visits to talk to their doctors, which can help alleviate their depression (Park & Jang, 2021). In addition, in this study, 91.9% of the participants lived with family members, and they reported receiving family support at a high level. In Chinese culture, where strong family ties and close family relationships are very important and highly valued, strong family support can provide an opportunity for patients to express their feelings and concerns (Luo et al., 2015). These reasons explain why participants had low levels of depression.

Conclusion

The results of this study show that patients in the early postoperative period (6 months) after cardiac mechanical valve replacement had moderate levels of self-management. The findings revealed that self-efficacy and social support were positively related to self-management, and age and depression were negatively related

to self-management. Based on the results of this study, medical personnel can take appropriate preventive and intervention measures in time to improve patients' self-management ability in the early postoperative period (6 months), reduce the occurrence of complications, promote the recovery of cardiac function, and improve the quality of life.

Limitations

This study was only conducted at one hospital in Wenzhou, China, which cannot be a representative of the overall self-management of patients after heart valve replacement in this region. In addition, these data were collected from the outpatient department where patients who did not have serious complications and not include patients who were hospitalized for a second time or came to the emergency department. Therefore, the participants in this study were in a good and stable stage of postoperative recovery and were not representative of the status of all patients after valve replacement.

Implications and Recommendations

The results of this study have certain implications for clinical nursing practice and nursing research. The results of this study will help nurses better understand patients' self-management after heart valve replacement in the early postoperative period (6 months) and its associated factors. In addition, identifying the relationship between age, self-efficacy, social support, depression, and self-management will provide a basis for nurses to develop appropriate interventions. According to the results of this study, interventions should focus on improving patients' information management, helping patients acquire disease-related knowledge through health education during hospitalization, and communicating with patients through telephone follow-up or WeChat groups after discharge.

This study found that self-efficacy and social support had a positive relationship with self-management. Nursing staff can improve patients' confidence in disease management through some methods, such as giving encouragement, helping patients to make self-management plans, and regular follow-up visits. In terms of

social support, nursing staff can educate family members about disease knowledge and encourage family members to participate in patients' self-management, helping patients improve their self-management ability. Patients are also encouraged to communicate with friends and others for more social support. Besides, nursing staff should also pay attention to older patients, strengthen health education for them, and guide them to use smart devices to improve self-management ability.

The psychological state of the patient also needs attention, and for patients with depression, professional psychological experts should be invited to intervene. In addition, screening for depression among patients after heart valve replacement is important for early detection and management in time to promote their self-management and quality of life.

In the future, the investigation can be carried out in multiple hospitals or other settings to maximize the generalizability or credibility of the study. Also, how to improve the self-management ability of patients after heart valve replacement is worth further research and discussion.

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APPENDIX

APPENDIX A

Questionnaires in English and Chinese version

QUESTIONNAIRES
SELF-MANAGEMENT AND ITS ASSOCIATED FACTORS AMONG PATIENTS AFTER HEART VALVE REPLACEMENT THERAPY

The questionnaires include five parts as follows:

Part 1 The Demographic questionnaire with 17 items.

Part 2 Self-management Scale of patients after mechanical heart valve replacement with 27 items.

Part 3 The Chinese version of the General Self-Efficacy Scale (GSES) with 10 items.

Part 4 The Chinese version of the Perceived Social Support Scale (PSSS) with 12 items.

Part 5 The Chinese version of the Self-Rating Depression Scale (SDS) with 20 items.

Please read each question carefully and then choose the answer that you think is suitable for your conditions.

Part 1: The Demographic Information Questionnaire

Direction: Please read the questions in part 1 carefully and give an honest answer. Answers to question part 2 will be collected from the medical record by the researcher. Please write "√" in the box of your answer or write your information in the space provided.

Section 1: General information (To be completed by the participant)

1. Age:
2. Gender
   ☐ Male ☐ Female
3. Marital status
   ☐ Single ☐ Married ☐ Divorced ☐ Widowed
4. Education level
   ☐ Illiteracy ☐ Primary school
   ☐ Junior high school Senior ☐ Senior high school and above
5. Living condition
   ☐ Living alone ☐ Living with family members or others
6. Individual income (mouth/CNY)
   ☐ Less than ¥ 3,000 ☐ ¥ 3,000 - 5,000
   ☐ ¥ 5,000 - 10,000 ☐ More than ¥ 10,000
7. Payment method for medical expenses.
   ☐ Medical insurance
   ☐ Self-paying
8. Working status
   ☐ Have a work now ☐No job ☐ Retirement
9. How long does it take to get from your home to the hospital?
   ☐ Less than 1 hour ☐ 1 hour - 2 hours ☐More than 2 hours

Section 2: Health information (To be collected by the researcher from the patient record)

1. How long after surgery: ____months
2. Operation type

   ☐ Mitral valve replacement ☐ Aortic valve replacement

   ☐ Tricuspid valve replacement ☐ Double valve replacement
3. Current cardiac function status

   ☐ Level 1: suffering from heart disease, but not restricted in physical activity, daily physical activity does not cause palpitations, dyspnea, or excessive fatigue.

   ☐ Level 2: mild limitation in physical activity, no symptoms at rest, but general daily physical activity may cause fatigue, palpitations, and dyspnea.

   ☐ Level 3: physical activity is obviously limited, no symptoms at rest, but less than normal daily physical activity can cause palpitations, asthma, and excessive fatigue.

   ☐ Level 4: no physical activity, palpitations, asthma, and other symptoms will occur at rest.
4. Clinical symptoms

   ☐ None ☐ Dyspnea ☐ Chest tightness ☐ Edema ☐ Others, specify …..
5. Warfarin-related complications

   ☐ None ☐ The lower extremities thrombosis ☐ Cerebral embolism ☐ Cerebral hemorrhage ☐ Gastrointestinal hemorrhage ☐ Others, specify

Part 2: The self-management scale of patients after mechanical heart valve replacement

Direction: The following statements describe your self-management activities. Thinking about your self-management after mechanical heart valve replacement, please specify the extent to which each statement applies to you. Please choose the answer by ticking "√".

	No	Rarely	Some times	Often	Always
1. When there are symptoms of cardiac insufficiency such as decreased urine volume, palpitation, discomfort, loss of appetite, wet and cold skin of limbs, or edema, I will seek medical treatment in time	1	2	3	4	5
2. If there are frequent nosebleeds, tooth acid bleeding, hematuria, hematochezia, unknown, cause of large subcutaneous bruising or increased menstrual volume, and other bleeding symptoms, I Will be timely medical treatment	1	2	3	4	5
3. In case of embolism symptoms such as dizziness, distorted mouth and eyes or poor limb movement, numbness, blue, and pain, I will inform my family members and seek medical treatment in time	1	2	3	4	5
…….					
…….					
…….					
…….					
…….					
27. I have confidence in the self-management of the disease	1	2	3	4	5

Part 3: General Self-Efficacy Scale (GSES)

Direction: The following topic is to understand your confidence status about yourself. Please read each statement and choose the one that fits you best by ticking "√".

	Not at all true	Hardly true	Moderately true	Exactly true
1. I can always manage to solve difficult problems if I try hard enough	1	2	3	4
2. If someone opposes me, I can find the means and ways to get what I want	1	2	3	4
3. It is easy for me to stick to my aims and accomplish my goals	1	2	3	4
4……				
5……				
6……				
7……				
8……				
9……				
10. I can usually handle whatever comes my way	1	2	3	4

Part 4: Multidimensional Scale of Perceived Social Support

Direction: Here are 12 sentences, each followed by seven answers. Please choose an answer at the end of each sentence according to your situation. For example, choose ① to indicate that you strongly disagree, that is, your actual situation is very inconsistent with the sentence; Choose ⑦ to indicate that you strongly agree with this sentence, that is, your actual situation is very consistent with this sentence. Select ④ to indicate the intermediate state.

	Very strongly disagree	Strongly disagree	Mildly disagree	Neutral	Mildly agree	Strongly agree	Very strongly agree
1. There is a special person who is around when I am in need.	1	2	3	4	5	6	7
2. There is a special person with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
3. My family really tries to help me	1	2	3	4	5	6	7
4……							
5……							
6……							
7……							
8……							
9……							
10……							
11……							
12. I can talk about my problems with my friends.	1	2	3	4	5	6	7

Part 5: Zung Self-Rating Depression Scale (SDS)

Direction: Here are 20 questions. Please read each one carefully. After each one, there are four boxes.

A little of the time (no more than one such day in the past week);

Some of the time (1-2 days in the past week)

Good part of the time (3-4 days in the past week)

Most of the time (5-7 days in the past week)

Then choose an answer that best fits your situation, based on how you felt in the last week.

	A little of the time	Some of the time	Good part of the time	Most of the time
1. I feel down-hearted and blue.	1	2	3	4
2. Morning is when I feel the best.	4	3	2	1
3. I have crying spells or feel like it.	1	2	3	4
4.....				
5.....				
6.....				
7.....				
8.....				
9.....				
10.....				
11.....				
12.....				
13.....				
14.....				
15.....				
17.....				
18.....				
19.....				
20. I still enjoy the things I used to do.	4	3	2	1

《心脏瓣膜置换术后患者的自我管理现状及其相关因素的分析》问卷表格

问卷调查包括以下四个部分:

第一部分：人口数据问卷，共 17 个项目。

第二部分：心脏机械瓣膜置换术后患者自我管理量表，共 27 题。

第三部分：一般自我效能感量表中文版，共 10 项。

第四部分：领悟社会支持量表中文版，共 12 项。

第五部分：抑郁自评量表，共 20 项。

请仔细阅读每个问题，然后根据自己的情况选择合适的答案。

第一部分：人口数据问卷

指导:请仔细阅读第一部分的问题，并诚实回答。问题 2 的答案将由研究人员从病历中收集。请在答题方框内填写“✔”字或在空白处填写你的个人信息。

第 1 部分:基本信息(由参与者填写)

1. 年龄:____岁
2. 性别:

   □男　□女
3. 婚姻状况

   □已婚　□单身　□离婚　□丧偶
4. 学历：

   □文盲　□小学　□初中　□高中及以上
5. 生活状况

   □独居　□与家人或其他人生活在一起
6. 收入水平（平均月收入/人民币）

   □少于 3000　□3000-5000　□5000-10000　□大于 10000
7. 医疗支付方式

   □医保　□自费

8. 工作状态

□工作中 □无业 □退休

9. 现住址距离医院的路程

□小于 1 小时 □ 1-2 小时 □大于 2 小时

（以下部分由研究者从患者的就诊记录中获取）

第 2 部分:健康信息(由研究人员从参与者门诊记录中收集)

1 术后时间____月

2. 手术方式

□二尖瓣置换数 □主动脉瓣置换术

□三尖瓣置换术 □二尖瓣+主动脉瓣置换术

3. 目前心功能状态

□Ⅰ级 体力活动不受限制。一般体力活动不引起过度疲劳、心悸、气喘或心绞痛。

□Ⅱ级 体力活动轻度受限制。休息时无症状，一般体力活动引起过度疲劳、心悸、气喘或心绞痛。

□Ⅲ级 体力活动明显受限制。休息时无症状，但小于一般体力活动即可引起过度疲劳、心悸、气喘或心绞痛。

□Ⅳ级 休息时也有心功能不全或心绞痛症状，进行任何体力活动均使不适增加。

4. 目前临床表现和症状

□无 □呼吸费力 □胸闷 □水肿 □其他

5. 华法林相关并发症

□无 □下肢静脉血栓 □脑栓塞 □脑出血 □消化道出血

□其他

第二部分：心脏机械瓣膜置换术后患者自我管理量表

指导:以下描述您的自我管理活动。考虑到您在机械心脏瓣膜置换术后的自我管理，请说明每种说法适用于您的程度。请在答案前打“ √ ”。

指标条目	没有	很少	有时	经常	总是
1. 当出现尿量减少、心慌不适、食欲不振、四肢皮肤湿冷或水肿等心功能不全症状,我会及时就医	1	2	3	4	5
2. 若出现经常流鼻血、牙银出血、血尿、便血、不明,原因大面积皮下淤紫或女性经量增多等出血症状,我会及时就医	1	2	3	4	5
3. 当出现头晕、口眼歪斜或肢体活动不畅、麻木青紫疼痛等栓塞症状,我会告知家属,并及时就医	1	2	3	4	5
.....					
.....					
.....					
.....					
.....					
.....					
27. 我有信心做好疾病的自我管理	1	2	3	4	5

第三部分：一般自我效能感量表中文版

指导:下面的问卷是了解你对自己的信心状况。请阅读每句话，并选择最适合你的，在框里打“√”。

题目	完全不正确	有点正确	多数正确	完全正确
1.如果我尽力去做的话,我总是能够解决问题的	1	2	3	4
2.即使别人反对我,我仍有办法取得我所要的	1	2	3	4
3.对我来说,坚持理想和达成目标是轻而易举的	1	2	3	4
4.....				
5.....				
6.....				
7.....				
8.....				
9.....				
10 无论什么事在我身上发生,我都能应付自如	1	2	3	4

第四部分：领悟社会支持量表（PSSS）

指导语：以下有 12 个句子，每一个句子后面各有 7 个答案。请您根据自己的实际情况在每句后面选择一个答案。例如，选择①表示您极不同意，即说明您的实际情况与这一句子极不相符；选择⑦表示您极同意，即说明您的实际情况与这一句子极相符；选择④表示中间状态。余类推

	极不同意	很不同意	稍不同意	中立	稍同意	很同意	极同意
1.在我遇到问题时有些人（领导、亲戚、同事）会出现在我的身旁	1	2	3	4	5	6	7
2.我能够与有些人（领导、亲戚、同事）共享快乐与优伤	1	2	3	4	5	6	7
3. 我的家庭能够切实具体地给我帮助	1	2	3	4	5	6	7
4.....							
5.....							
6.....							
7.....							
8.....							
9.....							
10.....							
11.....							
12. 我能与朋友们讨论自己的难题	1	2	3	4	5	6	7

第五部分：抑郁自评量表（SDS）

指导语：下面有 20 条题目，请仔细阅读每一条，每一条文字后有四个格，分别表示：没有或很少时间（过去一周内，出现这类情况的日子不超过一天）;小部分时间（过去一周内，有 1-2 天有过这类情况）;相当多时间（过去一周内，3-4 天有过这类情况）;绝大部分或全部时间（过去一周内，有 5-7 天有过这类情况）。然后根据最近一星期以内你的实际感受，选择一个最相符合的答案。

	没有或很少时间	小部分时间	相当多时间	绝大部分或全部时间
1. 我觉得闷闷不乐，情绪低沉	1	2	3	4
2. 我觉得一天之中早晨最好	4	3	2	1
3. 我一阵阵地哭出来或想哭	1	2	3	4
4.....				
5.....				
6.....				
7.....				
8.....				
9.....				
10.....				
11.....				
12.....				
13.....				
14.....				
15.....				
16.....				
17.....				
18.....				
19.....				
20.平常感兴趣的事我仍然照样感兴趣	4	3	2	1

APPENDIX B

Permission letter

Permission letter to use Self-management Scale of patients after mechanical heart valve replacement

19:02 5G

回复： 邓老师， 您好， 想征求您的同意！ 万分感谢！

742367920 详情

好的， 没问题的。

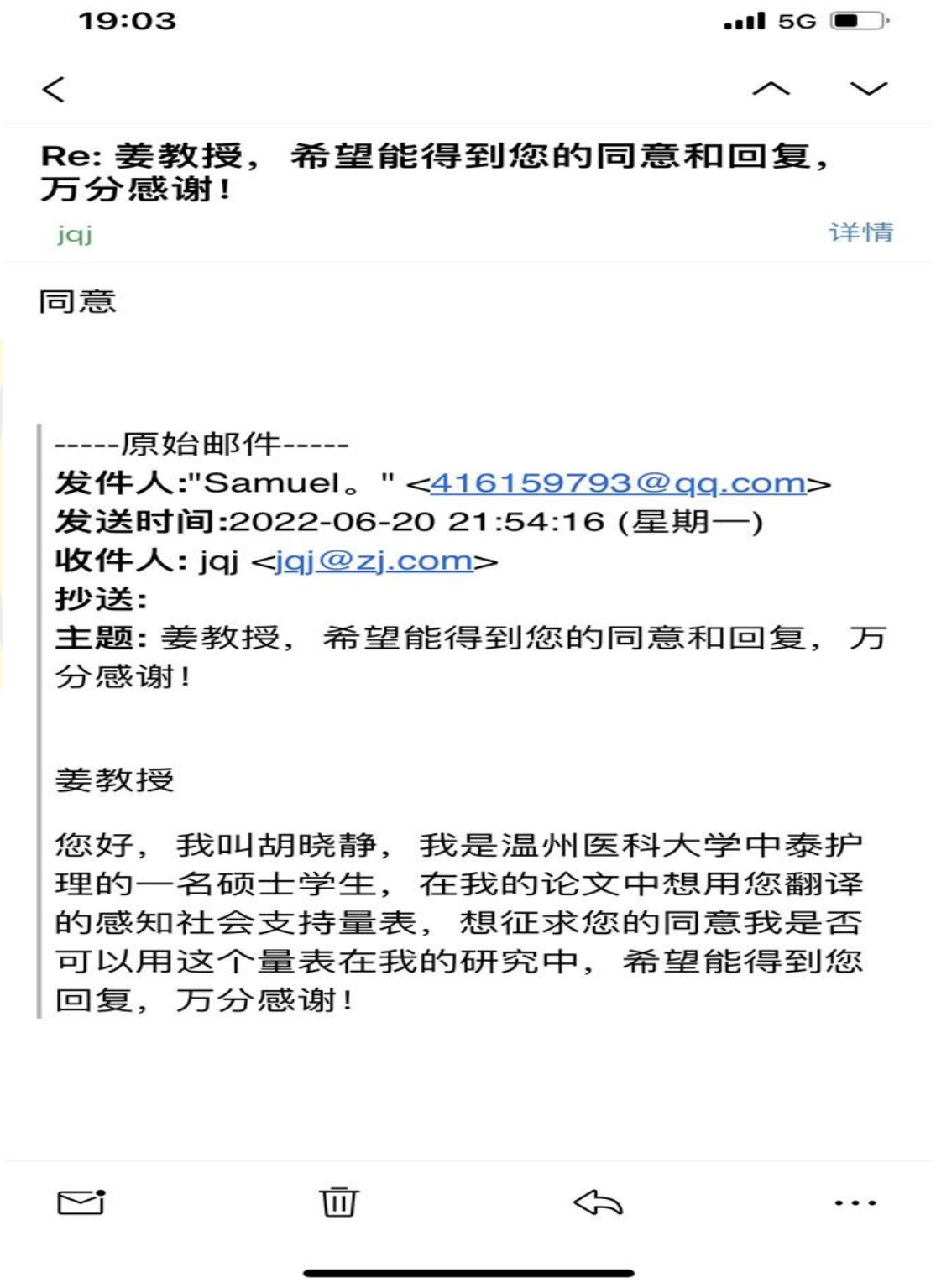
---原始邮件---

发件人："Samuel。"<416159793@qq.com>
发送时间：2022年6月20日(周一) 晚上8:44
收件人："742367920"<742367920@qq.com>;
主题：邓老师， 您好， 想征求您的同意！ 万分感谢！

邓老师

您好， 我叫胡晓静， 我是温州医科大学中泰护理硕士班的一名学生， 我的硕士论文是关于心脏瓣膜病术后的抗凝自我管理， 在我的论文中想用您设计的心脏机械瓣膜置换术后患者自我管理量表， 想征求您的同意我是否可以用您的量表在我的研究中， 希望能得到您回复， 万分感谢！

Permission letter to use The Chinese version of the Perceived Social Support Scale



19:03 5G

Re: 姜教授， 希望能得到您的同意和回复，万分感谢！

jqj 详情

同意

-----原始邮件-----
发件人:"Samuel。" <416159793@qq.com>
发送时间:2022-06-20 21:54:16 (星期一)
收件人: jqj <jqj@zj.com>
抄送:
主题: 姜教授， 希望能得到您的同意和回复， 万分感谢！

姜教授

您好， 我叫胡晓静， 我是温州医科大学中泰护理的一名硕士学生， 在我的论文中想用您翻译的感知社会支持量表， 想征求您的同意我是否可以用这个量表在我的研究中， 希望能得到您回复， 万分感谢！

Permission letter to use The General Self-Efficacy Scale

Everything you wanted to know about the
General Self-Efficacy Scale
but were afraid to ask

by Ralf Schwarzer, January 5, 2009

The purpose of this FAQ is to assist the users of the scales published at the author's web pages http://www.ralfschwarzer.de/

DOWNLOAD of PDFs: http://userpage.fu-berlin.de/~health/self/selfeff_public.htm

Before attending to the questions below you might want to study our web pages. You might not have any questions after reading the web pages.

Do I need permission to use the general perceived self-efficacy (GSE) scale?

You do not need our explicit permission to utilize the scale in your research studies. We hereby grant you permission to use and reproduce the General Self-Efficacy Scale for your study, given that appropriate recognition of the source of the scale is made in the write-up of your study.

The international source is:
Schwarzer, R., & Jerusalem, M. **(1995)**. Generalized Self-Efficacy scale. In J. Weinman, S. Wright, & M. Johnston, *Measures in health psychology: A user's portfolio. Causal and control beliefs* (pp. 35-37). Windsor, England: NFER-NELSON.

The source for the German version is:
Schwarzer, R., & Jerusalem, M. (Eds.). (1999). *Skalen zur Erfassung von Lehrer- und Schülermerkmalen: Dokumentation der psychometrischen Verfahren im Rahmen der Wissenschaftlichen Begleitung des Modellversuchs Selbstwirksame Schulen*. Berlin: Freie Universität Berlin.

APPENDIX C

Ethical Letter

MHESI 8137/1374

Graduate School, Burapha University
169 Longhaad Bangsaen Rd.
Saensuk, Muang, Chonburi
Thailand, 20131

September 22nd, 2022

To The president of the First Affiliated Hospital of Wenzhou Medical University,

Enclosure: 1. Certificate ethics document of Burapha University
2. Research Instruments (Try out)

On behalf of the Graduate School, Burapha University, I would like to request permission for Mrs. Hu Xiaojing to collect data for testing the reliability of the research instruments.

Mrs. Hu Xiaojing, ID 63910137, a graduate student of the Master of Nursing Science program (International Program) in Adult Nursing Pathway, Faculty of Nursing, Burapha University, Thailand, was approved her thesis proposal entitled: "Self-management and its associated factors among patients after heart valve replacement therapy" under supervision of Assist. Prof. Dr. Khemaradee Masingboon as the principle advisor. She proposes to collect data from 30 patients with heart valve replacement after discharge one month to six months, who follow up at the Cardiac surgery outpatient department of the First Affiliated Hospital of Wenzhou Medical University in Wenzhou, Zhejiang province, China. The participants will be recruited from patients who aged 18 - 65 years old, have a certain ability to speak, read, and write in Chinese, no history of mental illness screen by reviewing the patient's medical record, have stable conditions such as no limitation of physical activity caused by complications or comorbidities, and have no major physical disability such as reduced physical mobility requiring assistants.

The data collection will be carried out from September 19 to October 19, 2022. In this regard, you can contact Mrs. Hu Xiaojing via mobile phone +86-1598-8775-871 or E-mail: 416159793@qq.com

Please do not hesitate to contact me if you need further relevant queries.

Sincerely yours,

(Assoc. Prof. Dr. Nujjaree Chaimongkol)
Dean of Graduate School, Burapha University

Carbon Copy: Mr. Jue Wang
Director of Cardiac surgery outpatient department

Graduate School Office
Tel: +66 3810 2700 ext. 701, 705, 707
E-mail: grd.buu@go.buu.ac.th
http://grd.buu.ac.th

MHESI 8137/1375

Graduate School, Burapha University
169 Longhaad Bangsaen Rd.
Saensuk, Muang, Chonburi
Thailand, 20131

September 22nd, 2022

To The president of the First Affiliated Hospital of Wenzhou Medical University,

Enclosure: 1. Certificate ethics document of Burapha University
2. Research Instruments

On behalf of the Graduate School, Burapha University, I would like to request permission for Mrs. Hu Xiaojing to collect data for conducting research.

Mrs. Hu Xiaojing, ID 63910137, a graduate student of the Master of Nursing Science program (International Program) in Adult Nursing Pathway, Faculty of Nursing, Burapha University, Thailand, was approved her thesis proposal entitled: "Self-management and its associated factors among patients after heart valve replacement therapy" under supervision of Assist. Prof. Dr. Khemaradee Masingboon as the principle advisor. She proposes to collect data from 135 patients with heart valve replacement after discharge one month to six months, who follow up at the Cardiac surgery outpatient department of the First Affiliated Hospital of Wenzhou Medical University in Wenzhou, Zhejiang province, China. The participants will be recruited from patients who aged 18 - 65 years old, have a certain ability to speak, read, and write in Chinese, no history of mental illness screen by reviewing the patient's medical record, have stable conditions such as no limitation of physical activity caused by complications or comorbidities, and have no major physical disability such as reduced physical mobility requiring assistants.

The data collection will be carried out from October 20, 2022 to May 31, 2023. In this regard, you can contact Mrs. Hu Xiaojing via mobile phone +86-1598-8775-871 or E-mail: 416159793@qq.com

Please do not hesitate to contact me if you need further relevant queries.

Sincerely yours,

(Assoc. Prof. Dr. Nujjaree Chaimongkol)
Dean of Graduate School, Burapha University

Carbon Copy: Mr. Jue Wang
Director of Cardiac surgery outpatient department

Graduate School Office
Tel: +66 3810 2700 ext. 701, 705, 707
E-mail: grd.buu@go.buu.ac.th
http://grd.buu.ac.th

温州医科大学附属第一医院临床研究伦理委员会审查批件

（Review of Ethics Committee in Clinical Research (ECCR) of the First Affiliated Hospital of Wenzhou Medical University）

受理编号 Acceptance Number：KY2022-144　批件号：临床研究伦审 Issuing Number（2022）第（144）号

项目名称 Project	心脏瓣膜置换术后患者的自我管理及其相关因素分析 Self-management and its associated factors among patients after heart valve replacement therapy		
申办者 Applicant	温州医科大学附属第一医院	试验目的 Objective	临床科研 Clinical research
试验科室 Department	心脏外科		
试验项目负责人 Principal Investigator	王珏		
审查方式和时间 Form and Date	☐ 会议审查 Review Conference，时间：_____ ☑ 快速审查 Fast track，时间：2022 年 9 月 22 日		
审查地点 Review Site	新院 1-4A22 会议室		
审查材料 Documents for Review	1、医学临床科研项目及伦理审查申请表，v1.0 版； 2、临床研究方案，v1.0 版，2022.5.22； 3、受试者知情同意书，v1.0 版，2022.5.31； 4、研究者团队成员目录（职责）； 5、主要研究者、团队成员简历及 GCP 证书，v1.0 版； 6、研究者责任声明； 7、CRF/临床观察表，v1.0 版。		
审查意见 Comments	根据国家卫健委《涉及人的生物医学研究伦理审查办法》(2016)、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，**同意**该项目开展。 According to the Regulations and Rules of "Ethical Reviews for Biomedical Research Involving Human Subjects" (2016) the National Health Commission of PRC , "Declaration of Helsinki" of WMA, and "International Ethical Guidelines for Human Biomedical Research" of CIOMS , the project was **approved** by **ECCR** .		
主任委员/副主任委员签字 Signature of the **ECCR** Chair		签发日期 Date	2022.9.25
温州医科大学附属第一医院临床研究伦理委员会（盖章） Ethics Committee in Clinical Research of the First Affiliated Hospital of Wenzhou Medical University (Seal)			

附注（Note）：

1. 临床研究应在批准之日起 1 年内实施，逾期未实施，本批件自行废止。临床研究过程中将接受伦理委员会的跟踪审查，审查频度为自批准之日起每 12 个月一次。（伦理委员会有权根据临床试验实际开展情况改变跟踪审查频度）
   The clinical study shall be implemented within 1 year from the date of approval. If overdue, the approval for this project shall be revoked. During the implementation of clinical research, tracking review will be conducted by **ECCR** every 12 months from the effective date of the initial approval (the ethics committee has the right to change the frequency of tracking review according to the actual implementation of clinical trials)
2. 请严格遵从已批准的研究方案，如果方案修改需以书面形式报告伦理委员会，经伦理委员会批准后方可执行。
   Please strictly follow the approved research protocol. Any revisions of the protocol must be reported to **ECCR** in written form. It can be conducted only after the modification was approved by **ECCR**.
3. 发生严重不良事件以及影响研究风险受益比的非预期不良事件，须在 24 小时内报告本伦理委员会。
   Serious adverse events and unanticipated adverse events that affect the risk-to-benefit ratio of the project must be reported to **ECCR** within 24 hours.
4. 暂停、方案违背或提前终止临床研究，请及时上报本伦理委员会。
   Any suspension, project violation or early termination of the clinical research, should be reported to **ECCR** promptly.
5. 完成临床研究，须提交研究完成报告给本伦理委员会。
   Please submit a completion research report to **ECCR** after completion of the project.

温州医科大学附属第一医院临床研究伦理委员会委员签到表

会议时间：2022 年 9 月 22 日

会议地点：新院 1-4A22 会议室

审查内容：心脏瓣膜置换术后患者的自我管理及其相关因素分析 Self-management and its associated factors among patients after heart valve replacement therapy

姓　名	性别	工作单位	专　业	职　称	伦理委员会职务	签到
陈咨苗	男	温州医科大学附属第一医院	内分泌科	副主任医师	主任	
黄晓颖	女	温州医科大学附属第一医院	呼吸内科	教授/主任医师	副主任	
蔡雪黎	女	温州医科大学附属第一医院	心内科	副教授/副主任医师	委　员	
徐　卫	男	温州医科大学附属第一医院	预防医学	副主任医师	委　员	
孙彩霞	女	温州医科大学附属第一医院	护　理	主任护师	委　员	
卢明芹	男	温州医科大学附属第一医院	感染科	主任医师	委　员	
陈　雷	男	温州医科大学附属第一医院	骨　科	教授/主任医师	委　员	
郑祥武	男	温州医科大学附属第一医院	放射影像	教授/主任医师	委　员	
林观样	男	温州医科大学附属第一医院	药　学	主任药师	委　员	
俞　康	男	温州医科大学附属第一医院	血液内科	教授/主任医师	委　员	
陈永平	男	温州医科大学附属第一医院	感染科	教授/主任医师	委　员	
张秀华	女	温州医科大学附属第一医院	临床研究中心	主任药师	委　员	
苏小芳	女	浙江震瓯律师事务所	法　律	律　师	委　员	
胡建芬	女	退　休	统计学	高级统计师	委　员	
方　耀	男	温州理工学院	伦理学	讲　师	委　员	

临床研究伦理委员会 专用章

伦理委员会声明：

★ 温州医科大学附属第一医院临床研究伦理委员会组成及工作程序遵循中国 GCP、ICH-GCP 及相关法律法规，其审查过程不受伦理委员会以外任何组织及个人影响。

★ 本伦理委员会各委员已签署保密协议，所有标准操作规程文件、机密信息、会议记录等及其副本的所有权均归伦理委员会。

地址：浙江省温州市瓯海区南白象温州医科大学附属第一医院新院区　　邮编：325000
联系电话：0577-55578055　　传真：0577-55578033　　E-mail:wyyyclinical@126.com

สำเนา

ที่ IRB3-084/2565

เอกสารรับรองผลการพิจารณาจริยธรรมการวิจัยในมนุษย์

มหาวิทยาลัยบูรพา

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา ได้พิจารณาโครงการวิจัย

รหัสโครงการวิจัย : G-HS029/2565

โครงการวิจัยเรื่อง : Self-management and its associated factors among patients after heart valve replacement therapy

หัวหน้าโครงการวิจัย : MRS.HU XIAOJING

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์

BUU Ethics Committee for Human Research has considered the following research protocol according to the ethical principles of human research in which the researchers respect human's right and honor, do not violate right and safety, and do no harms to the research participants.

Therefore, the research protocol is approved (See attached)

1. Form of Human Research Protocol Submission Version 2 : 22 August 2022
2. Research Protocol Version 1 : 15 May 2022
3. Participant Information Sheet Version 2 : 22 August 2022
4. Informed Consent Form Version 2 : 22 August 2022
5. Research Instruments Version 2 : 18 July 2022
6. Others (if any) Version - : -

วันที่รับรอง : วันที่ 30 เดือน สิงหาคม พ.ศ. 2565

วันที่หมดอายุ : วันที่ 30 เดือน สิงหาคม พ.ศ. 2566

ลงนาม *ผู้ช่วยศาสตราจารย์ แพทย์หญิงรมร แย้มประทุม*

(ผู้ช่วยศาสตราจารย์ แพทย์หญิงรมร แย้มประทุม)

ประธานคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา

ชุดที่ 3 (กลุ่มคลินิก/ วิทยาศาสตร์สุขภาพ/ วิทยาศาสตร์และเทคโนโลยี)

APPENDIX D

Participant Information Sheet and consent form

เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย
(Participant Information Sheet)

รหัสโครงการวิจัย : .....G-HS 029/2565.....
(สำนักงานคณะกรรมการพิจารณาจริยธรรมในมนุษย์ มหาวิทยาลัยบูรพา เป็นผู้ออกรหัสโครงการวิจัย)
โครงการวิจัยเรื่อง : **Self-management and its associated factors among patients after heart valve replacement therapy**

Dear participants

I am Mrs Xiaojing Hu, a student in Master of Nursing Science (International Program) Faculty of Nursing, Burapha University Thailand. My study is “Self-management and its associated factors among patients after heart valve replacement therapy”. The objectives are to describe self-management among patients after heart valve replacement, and to examine the relationships between age, self-efficacy, social support, and depression with self-management among patients after heart valve replacement.

Participating in this study is voluntary. If you agree to participate in this study, you will answer the following questionnaires, which will take approximately 20-30 minutes. During the data collection period, the researcher will clarify any questions posed by the participants for clarity regarding the language or content. You will not get any direct benefits by participating in this study. However, the information you provide will be valuable to identify factors influencing self-management among patients after heart valve replacement. After understanding the influencing factors of patients' self-management after cardiac valve replacement, nurses can formulate nursing interventions to help patients better self-management, promote the recovery of cardiac function, maintain health, reduce the incidence of complications, and improve the quality of life of patients. There will be no identified physical and psychological risk to the person participating in the study and no risk to the society.

During the study, you have the right not to answer questions, and you also have the right to change your minds and refuse to participate in the project at any time, and the refusal would not affect the medical services you received. Any information collected from this study, including your identity, will be kept confidential. A coding

number will be assigned to you and your name will not be used. Findings from the study will be presented as a group of participants and no specific information from any individual participant will be disclosed. All data will be accessible only to the researcher which will be destroyed one year after publishing the findings. You will receive a further explanation of the nature of the study upon its completion if you wish.

The research will be conducted by Mrs Xiaojing Hu **under the supervision of my major-advisor, Assistant Professor Dr.Khemaradee Masingboon. If you have any questions, please contact me at mobile number: + 86 15988775871 or by email 416159793@qq.com and/or my advisor's e-mail address khemaradee@nurse.buu.ac.th Or you may contact Burapha University Institutional Review Board (BUU-IRB) telephone number 038 102 620. Your cooperation is greatly appreciated. You will be given a copy of this consent form to keep.**

Xiaojing Hu

参与者信息表

研究项目代码: G-HS 029/2565

课题研究：心脏瓣膜置换术后患者的自我管理及其相关因素分析

亲爱的参与者:

我叫胡晓静，是泰国东方大学护理学院护理学硕士(国际项目)的学生。我的研究是“心脏瓣膜置换术后患者的自我管理及其相关因素分析”。目的探讨心脏瓣膜置换术后患者的自我管理情况，并探讨年龄、自我效能、社会支持、抑郁与自我管理的关系。

参与本研究是自愿的。如果您同意参加本次研究，您将回答以下问卷，大约需要 20-30 分钟。在数据收集期间，研究人员将澄清参与者提出的任何关于语言或内容的问题。您不会从本次研究中获得任何直接利益。然而，你所提供的信息对于确定心脏瓣膜置换术后患者自我管理的影响因素是有价值的。了解心脏瓣膜置换术后患者自我管理的影响因素后，护士可以制定护理干预措施，帮助患者更好地自我管理，促进心功能恢复，保持健康，减少并发症的发生，提高患者的生活质量。这不会对您造成身体和心理风险，也不会对社会造成风险。

在期间，您有权不回答问题，也有权随时改变主意，拒绝参与该项目，拒绝不影响您获得的医疗服务。从本次研究中收集的任何信息，包括您的身份，都将被保密。我们会给你一个编号，你的名字不会被使用。研究结果将以一组参与者的身份展示，不披露任何个人的具体信息。所有数据将只对研究人员开放，并将在发表研究结果一年后销毁。如果您愿意，您将在完成研究后收到有关研究性质的进一步说明。

该研究将由胡晓静女士在专业导师 khemaradee Masingboon 助理教授的指导下进行。如果您有任何问题，请联系我的手机号码:+ 86 15988775871 或通过电子邮件 416159793@qq.com 和/或我的导师的电子邮件地址

khemaradee@nurse.buu.ac.th 或您可以联系泰国东方大学机构审查委员会(BUU-IRB)电话 038 102 620。非常感谢您的合作。您将获得一份同意书的副本。

胡晓静

เอกสารแสดงความยินยอม

ของผู้เข้าร่วมโครงการวิจัย (Consent Form)

รหัสโครงการวิจัย : .....G-HS 029/2565.....

(สำนักงานคณะกรรมการพิจารณาจริยธรรมในมนุษย์ มหาวิทยาลัยบูรพา
เป็นผู้ออกรหัสโครงการวิจัย)

โครงการวิจัยเรื่อง .....การจัดการตนเองและปัจจัยที่เกี่ยวข้องของผู้ป่วยหลังผ่าตัดลิ้นหัวใจ

Date of data
collection …….....……Month….....…….……Year ……

Before giving my signature below, I have been informed by researcher, Mrs. Xiaojing Hu, about the purposes, method, procedures, benefits, and possible risks associated with participation in this study thoroughly, and I understood all of the explanations. I consent voluntarily to participate in this study. I understand that I have the right to leave the study any time I want, without fearing that it might affect the medical services i will receive.

The researcher Mrs. Xiaojing Hu has explained to me that all data and information of the participants will be kept confidential and only be used for this study. I have read and understood the information related to participation in this study clearly and I am signing this consent form.

Signature ……..……
…….. Participant

(…….)

同意书

研究项目代码: G-HS 029/2565

研究项目：心脏瓣膜置换术后患者的自我管理及其相关因素分析

日期：　年　月　日

在我签字之前，我已经被研究人员胡晓静女士详细告知了参与本次研究的目的、方法、程序、益处以及可能存在的风险，我理解了所有的解释。本人自愿同意参加本次研究。我明白我有权在任何我想要的时候离开研究，而不用担心这会影响我将接受的医疗服务。

研究人员胡晓静女士已向我解释，所有参与者的数据和信息将被保密，只用于本次研究。我已经清楚地阅读并理解了参与本次研究的相关信息，并在此签署此同意书。

参　与　者　签

BIOGRAPHY

NAME	Xiaojing Hu
DATE OF BIRTH	18 July 1991
PLACE OF BIRTH	China
PRESENT ADDRESS	Qidu Street, Lucheng District, Wenzhou City, Zhejiang Province
POSITION HELD	nurse-in-charge
EDUCATION	2009-2012 Wenzhou Medical University, Nursing Speciality 2013-2016 Wenzhou Medical University, Bachelor of Nursing 2020-2023. Master of Nursing Science (International Program) (M.N.S), Faculty of Nursing, Burapha University, Chonburi, Thailand