A PREOPERATIVE EDUCATION INTERVENTION TO REDUCE ANXIETY AND IMPROVE RECOVERY AMONG CHINESE CARDIAC PATIENTS: A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Background: Patients awaiting cardiac surgery typically experience physical and psychological stress. Although there is evidence that preoperative education can improve postoperative outcomes among general surgical patients, less is known about preoperative education for patients undergoing cardiac surgery, particularly in the context of healthcare delivered in China.

Aim: The aim of this study was to evaluate whether a preoperative education intervention designed for Chinese cardiac patients could reduce anxiety and improve recovery.

Methods: A randomised controlled trial was conducted between December 2009 and May 2010 at two public hospitals in Luoyang, China. Adult patients undergoing cardiac surgery were randomly allocated to usual care or preoperative education that included usual care plus an information leaflet and verbal advice. All outcomes were recorded at seven days following surgery. The primary outcome was change in anxiety measured by the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes were change in depression (HADS), change in pain as measured by the Brief Pain Inventory short form (BPI-sf), length of ICU stay and postoperative hospital stay. A qualitative evaluation was carried out with a sample of 20 trial participants (ten from each group) to explore their views on preoperative education and their experiences of taking part in the trial.

Results: A total of 153 patients were recruited to the trial, 77 of which were randomly allocated to usual care and 76 to preoperative education. Of these, 135 (88.2%) completed the trial. The participants who received preoperative education experienced a greater decrease in anxiety score (mean difference -3.6 points, 95% CI -4.62 to -2.57; $P<0.001$) and a greater decrease in depression score (mean difference -2.1 points, 95% CI -3.19 to -0.92; $P<0.001$) compared with those who did not. There was no difference between groups in average pain, current pain, and interference in general activity, mood and walking ability. Patients in the preoperative education group reported less interference from pain in sleeping (mean difference -0.9 points, 95% CI -1.63 to -0.16; $P=0.02$). There was borderline evidence to suggest a reduced number of hours spent in the ICU among preoperative education patients ($P=0.05$) but no difference in length of postoperative hospital stay ($P=0.17$).

Eleven themes were generated from the qualitative interviews. These were collapsed into three categories: the process and context of information giving and trial experience. Most interview participants commented that communication between patients and healthcare providers was limited, reactive and rarely interactive. Those who received the preoperative education intervention reported that they valued both the written and verbal information. Participants welcomed the opportunity to engage with the trial, and made suggestions concerning future preoperative education.

Conclusions: This form of preoperative education is effective in reducing anxiety and depression among Chinese cardiac patients. Preoperative education should be incorporated into routine practice to prepare Chinese cardiac patients for surgery. More trials of complex interventions delivered in China are needed to provide evidence for Chinese healthcare.

Trial registration: Current controlled trials ISRCTN87451169.

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LIST OF ABBREVIATIONS

BAI	Beck Anxiety Inventory
BHIS	Urban Employee Basic Health Insurance Scheme
BPI-sf	Brief Pain Inventory - short form
CABG	Coronary Artery Bypass Grafting
CHD	Coronary Heart Disease
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
COREQ	Consolidated Criteria For Reporting Qualitative Research
CROQ	Coronary Revascularisation Outcome Questionnaire
CT	Computerised Tomography
GDP	Gross Domestic Products
HADS	Hospital Anxiety and Depression Scale
ICU	Intensive Care Unit
LDL	Low Density Lipoprotein
MOH	Ministry of Health
MRI	Magnetic Resonance Imaging
NICE	National Institute for Health and Clinical Excellence
NRCMS	New Rural Cooperative Medical System
PCI	Percutaneous Coronary Intervention Procedures
PE	Preoperative Education
QOL	Quality of Life
RCT	Randomised Controlled Trial
SD	Standard Deviation
STAI	Self-Evaluation Questionnaire for State Anxiety Inventory
UC	Usual Care
VAS	Visual Analogue Scale
WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION AND OVERVIEW

1.1 Significance of the study

Undergoing cardiac surgery can be physically and psychologically stressful for patients and their families. Patients awaiting cardiac surgery may experience high levels of anxiety and significant symptoms of depression due to fears, worries, and uncertainties about surgery (Fitzsimons et al., 2000, Gallagher and McKinley, 2007). These can exacerbate symptoms of existing cardiovascular disease, adversely affect physiological parameters before and during anaesthesia, and can result in prolonged recovery (Andrew et al., 2000, Pignay-Demaria et al., 2003, Duits et al., 1997). Preoperative education has been used to improve patients' experiences by providing health care relevant information, coping skills, and psychosocial support before surgery (Kruzik, 2009, Scott, 2004). Compared to usual care, preoperative education can promote positive postoperative outcomes in mixed groups of surgical patients (Shuldham, 1999a, Shuldham, 1999b).

Although there is evidence to support the use of preoperative education in reducing anxiety and enhancing postoperative outcomes for surgical patients, specific evidence for its effectiveness among cardiac surgery patients remains inconclusive. Previous studies have reported conflicting findings. Some studies have highlighted the effects of preoperative education on improving physical recovery (McHugh et al., 2001) and psychosocial recovery for coronary artery bypass surgery (McHugh et al., 2001, Sørlie et al., 2007, Shelley and Pakenham, 2007) while other studies found no evidence that cardiac patients' anxiety is reduced (Shuldham et al., 2002, Arthur et al., 2000, Goodman et al., 2008, Asilioglu and Celik, 2004) or of any effect on pain (Shuldham et al., 2002, Watt-Watson et al., 2004) or hospital stay (Shuldham et al., 2002, Sørlie et al., 2007, Watt-

Watson et al., 2004). Among various forms of preoperative education interventions designed for cardiac surgery patients, few attempts have been made to evaluate the effectiveness of verbal communication assisted with the use of written information. Furthermore, most studies were undertaken in western countries. Evidence generated from these studies cannot be directly transferred to a Chinese context without a more critical and context specific investigation as there is evidence to suggest that cultural factors may influence patients' responses to such interventions (Cheung et al., 2003).

In China, a country with a rapidly growing economy and sophisticated technologic advances in medicine today, the culture of healthcare delivery does not prioritise the provision of preoperative education for patients. A lack of communication and interaction between healthcare providers and patients in Chinese hospitals is of key concern (Henderson and Chien, 2004). One possible explanation for the inadequate provision of preoperative information is a lack of current guidelines from Chinese national health organisations addressing the preoperative information needs for patients. Good communication between healthcare providers and patients is essential. In the UK, offering surgical patients (or, as appropriate, their carer and/or family) verbal and evidence-based written information about treatment and care has been emphasised within NICE guidelines (National Clinical Guideline Centre, 2011, National Institute for Clinical Exellence, 2003, National Collaborating Centre for Women's and Children's Health, 2008). These guidelines promote the provision of information tailored to patients' needs and covering such topics as diagnosis, choice of anaesthesia, choice of analgesia and other medications, surgical procedures, possible complications, postoperative

care, rehabilitation programme, long-term outcomes and healthcare professionals involved.

Based on adult learning theory, a preoperative education intervention was specially designed for Chinese cardiac surgery patients aimed at reducing their anxiety and improving postoperative outcomes. This intervention included verbal communication assisted with the use of a patient information leaflet 'Your Heart Surgery'. A randomised controlled trial was conducted at two public hospitals in Luoyang, China to investigate the effect of the intervention on health outcomes among Chinese patients undergoing cardiac surgery. The primary interest of this trial was to determine whether providing such an intervention could reduce anxiety among Chinese cardiac patients. This trial also aimed to evaluate whether this form of preoperative education intervention could reduce symptoms of depression, decrease perceived pain, and shorten length of Intensive Care Unit stay and postoperative hospital stay.

To get a broader understanding of why this preoperative education intervention might succeed or fail and how it might be optimised, a qualitative evaluation was also conducted with a sample of trial participants through individual in-depth interviews before hospital discharge. Specifically, this qualitative evaluation aimed to explore patients' perceptions of preoperative information giving, their feelings about the preoperative education intervention and their experiences of taking part in the trial.

The results from this study not only generated evidence of the effect of this preoperative education intervention on Chinese cardiac patients' anxiety, but also provided greater insights into the contents and process of the

intervention implemented and the context in which the intervention was delivered. It is hoped that this study can help healthcare providers in China to make evidence based decisions regarding whether or not this form of preoperative education should be incorporated into routine practice to prepare Chinese cardiac patients for surgery.

1.2 Conventions and terminology used in the thesis

Where the term 'developed countries' is used in the thesis, it refers to those regions or areas which are more economically developed such as Canada and the United States in Northern America, Europe, Japan in Asia, and Australia and New Zealand in Oceania (United Nations Statistics Division, 2011). China is widely regarded as a 'developing country' although it became the world's second largest economy in 2010 and increasingly, is playing an important and influential role in the global economy. According to the World Bank Report (World Bank, 2011), China is classified as an upper middle-income country and ranks 120th in the world with a per capita gross national income of about $4,260 in 2010, compared with the UK's $38,560 (ranking 31st), Japan' $42,130 (27th) and the US' $47,240 (16th) .

The term 'cardiac surgery' refers to any types of open heart surgery performed to replace and/or repair diseased valves, to bypass blocked vessels, to correct acquired or congenital defects, and to graft a prosthesis or transplants. During open cardiac surgery, the thoracic cavity is opened to expose the heart and the blood is recirculated and oxygenated by a heart-lung machine. Heart prosthesis and heart transplantation are not performed at the two hospitals where the study took place.

The terms 'anxiety' and 'depression', throughout the thesis, refer to symptoms of anxiety and symptoms of depression reported by the patient or observed by health care providers, which are generally considered as distinct from a diagnosis of clinical anxiety and depression. These symptoms are situational and reactive and associated with grief, loss or a major social transition and can last for at least two weeks and interfere with everyday life of patients.

The term 'I' is used in the thesis to make it clear to the reader where I was responsible in taking particular actions in conducting the study. This has avoided the necessity of writing in the third person which I believe would have the effect of distancing myself from the work. I hope that choosing such a style has added clarity to my writing.

1.3 Structure of the thesis

The purpose of this thesis is to present my doctoral work which set out to evaluate the effect of a preoperative education intervention to reduce anxiety and improve recovery among cardiac patients in China. To help orientate the reader, the structure of the thesis is described here. The first chapter introduces the area of study, some of the key terms used in the thesis, and the structure of the thesis. It provides an overview of the study and sets the scene for the thesis.

To understand the context of the study, the relevant literature is reviewed in Chapters Two, Three and Four. Chapter Two describes the epidemiology of cardiovascular disease and covers the areas of prevalence, risk factors, currently available treatment options, and patients' negative experiences associated with surgical treatment. Preoperative education interventions based on adult learning theory are described as a way of improving

patients' experiences in this chapter. Chapter Three reviews the literature concerned with the effect of preoperative educations for cardiac patients through a systematic approach. The review critically appraises available evidence reported in randomised controlled trials using a two group comparison design. Chapter Four introduces the Chinese health care system and preoperative education practice for cardiac patients at the two study hospitals in Luoyang. It highlights the unique Chinese context in which the study was undertaken. Chapter Four ends with a statement of the aims of the study (the trial and qualitative evaluation) reported in the remainder of the thesis.

Chapter Five describes the methodology and methods of the study. Rationale for the design of the study is discussed. Participants' recruitment, baseline measures, the process of randomisation and the preoperative education intervention, and follow-up measures are explained for the trial. With regard to the qualitative evaluation, the access and sampling of interview participants is explained and the methods of data collection and data analysis are described. This chapter discusses the ethical considerations made in connection to the design and implementation of the study.

The results of the trial and qualitative evaluation are reported in Chapters Six and Seven respectively. Chapter Six describes the recruitment and participant flow for the trial, baseline characteristics of the two study groups, uptake and adherence of the interventions, and presents the difference between groups in terms of primary, secondary and other outcomes. Chapter Seven presents the categories and themes generated from the analysis of the interview data.

Finally in Chapter Eight, the methodological strengths and limitations of the study are discussed. The results of the study are compared with other studies in this field. Chapter Nine, the last chapter of the thesis, brings the findings from the trial and qualitative evaluation together to examine the implications for practice, education and policy making. Based on the lessons learnt from carrying out the study, this chapter also provides recommendations for the possible directions of future research.

CHAPTER TWO

ANXIETY AND DEPRESSION AMONG CARDIAC SURGERY PATIENTS AND PREOPERATIVE PATIENT EDUCATION

2.1 Introduction

The aim of this chapter is to provide the reader with the background information necessary to understand the significant symptoms of anxiety and depression among cardiac surgery patients and the importance of preoperative patient education as an intervention to alleviate these symptoms and improve patients' recovery. This chapter describes the epidemiology of cardiovascular disease and covers the areas of mortality associated with cardiovascular disease, economic burden and increasing need for surgical treatment. The psychological burden placed on patients in the preoperative period is significant. This chapter discusses anxiety and depressive symptoms, the impact of preoperative anxiety on patient surgical outcomes, and possible methods of alleviating these symptoms. The concept of preoperative education and its intended effects on various groups of surgical patients are demonstrated. Finally, this chapter explores the literature concerning patients' experience of preoperative education and factors influencing the delivery of preoperative education in nursing practice.

2.2 The epidemiology of cardiovascular disease

2.2.1 Mortality associated with cardiovascular disease

Cardiovascular disease is an overarching term that refers to a group of disorders involving the heart or blood vessels. It includes coronary heart disease, stroke, peripheral arterial disease, rheumatic heart disease, congenital heart disease and heart failure. Cardiovascular disease is the leading cause of mortality worldwide, with a rising incidence in both the developed part of the world and in developing countries (Lee and

Carrington, 2007, Waldman and Terzic, 2011). In 2008, an estimated 17.3 million people died from cardiovascular disease, which accounted for 30% of all global deaths. Of these deaths, 7.3 million were due to coronary heart disease and 6.2 million were due to stroke (Figure 2.1) (World Health Organisation, 2011a). Coronary heart disease can present with symptoms such as chest pain and breathlessness. The main forms of coronary heart disease are acute myocardial infarction and angina.

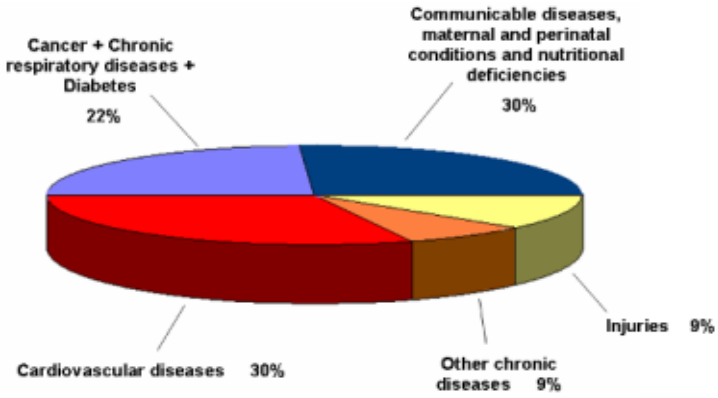


Figure 2.1 Causes of global deaths

Source: WHO. Cardiovascular diseases. http://www.who.int/cardiovascular_diseases/en/index.html.

The major risk factors associated with most deaths in cardiovascular disease are tobacco use, elevated blood cholesterol, hypertension, diabetes, obesity, physical inactivity, unhealthy diet, increased level of anxiety and depression, and alcohol use (Scholte op Reimer et al., 2006, Health Development Agency, 2001, Yusuf et al., 2004). A large proportion of cardiovascular disease can be prevented through adopting a healthier lifestyle such as stopping tobacco use, improving diet and nutrition, avoiding stress and depression, and engaging in regular physical activity (Haskell, 2003, Graham et al., 2007). In the National Institute for Health and Clinical Excellence (NICE) guidance on prevention of cardiovascular disease at population level (National Institute for Health and Clinical

Exellence, 2010), 12 policies were recommended to reduce the incidence and mortality of cardiovascular disease. A major element of the guidance was an assessment of the key risk factors for cardiovascular disease and the potential impact which changes in risk behaviour could deliver.

Some studies have shown nurse-led or nurse-coordinated cardiovascular disease secondary prevention programmes to be effective and feasible in managing patient risk factors (Wood et al., 2008a, Murchie et al., 2003, Campbell et al., 1998). In the Randomised Evaluation of Secondary Prevention by Outpatient Nurse SpEcialists (RESPONSE) trial (Deaton, 2010), 754 patients discharged from 11 medical centres in the Netherlands within eight weeks of their acute coronary syndromes were randomised to usual care or usual care plus a nurse-led prevention programme involving four half-hour-long nurse visits over six months. The RESPONSE trial found that patients in the intervention group had a 17% relative risk reduction in 10-year mortality compared with those in the usual care group. In addition, the intervention patients had better results for systolic blood pressure, low density lipoprotein (LDL) cholesterol, physical activity and a healthy diet compared with usual care. These results suggest that this type of nurse-led intervention is an effective means of improving secondary prevention and could be widely implemented across Europe.

There is evidence highlighting the relationship between socioeconomic deprivation and the prevalence and incidence of cardiovascular disease (Lee and Carrington, 2007). Low socioeconomic status is associated with an increased prevalence and incidence of heart failure (Philbin et al., 2001, Stewart et al., 2006, Rosengren et al., 2009) and a higher mortality rate from myocardial infarction (Chang et al., 2007, Donyavi et al., 2011, Macintyre et al., 2001, Murphy et al., 2006). According to the World Health

Organisation report (2011), the mortality of cardiovascular disease increases with age and affects men and women equally. Over 80% of the global deaths from cardiovascular disease take place in low- and middle-income countries where the resources for surveillance, prevention, and treatment are severely limited, and people are more exposed to the risk factors for cardiovascular disease and have less access to effective disease prevention and healthcare services (Gaziano et al., 2010). Table 2.1 reports the male death rate from coronary heart disease across the world in 2010 (Euromonitor International, 2011).

Table 2.1 Coronary heart diseases: male deaths 2010 in selected countries (Number per 100,000 inhabitants)

Rank	Country	Male deaths	Rank	Country	Male deaths
1	Ukraine	665.12	29	China	130.08
3	Russia	445.25	30	Pakistan	128.88
13	Finland	228.39	31	Australia	125.30
14	Nigeria	215.14	35	India	116.34
16	Sweden	185.49	38	Denmark	94.02
18	Germany	166.96	49	France	73.17
21	USA	158.19	50	Japan	72.32
22	United Kingdom	156.53	51	Jordan	71.93
23	New Zealand	148.85	52	Saudi Arabia	70.12
26	Italy	134.38	56	Chile	62.53
27	Canada	133.62	60	Brazil	54.03

Source: World Health Databook 2011.

Annually in the United Kingdom, there are 200,000 deaths from cardiovascular disease (60,000 premature deaths with health and social costs exceeding 30 billion) (World Health Organisation, 2003). In 2007, coronary heart disease caused around 91,000 deaths in the UK, compared to around 34,500 deaths from lung cancer, just over 16,000 deaths from colo-rectal cancer, and almost 12,000 deaths from breast cancer. In 2007,

141,000 people suffered from a myocardial infarction and 720,000 had heart failure (British Heart Foundation, 2010).

Within a country with high population growth and a rapidly expanding economy, cardiovascular disease has increased in China and become one of the leading causes of death among Chinese adults due in part to changing health behaviours and dietary habits (Critchley et al., 2004). Over three million Chinese people die of cardiovascular disease each year which accounts for approximately 33% of all deaths in rural areas and 39% of deaths in urban areas (Wu et al., 2011).

Risk factors of cardiovascular disease for Chinese people are similar to those factors affecting the wider global population. Liu (2007) reported that, according to the World Health Organization, the death rate for cardiovascular disease attributable to tobacco was 6.0% worldwide and 9.2% in China in 1990 projected to reach 16.6% by 2020. The number of Chinese people defined as overweight and obese has increased by 39% and 82% respectively in the past decade. The prevalence of hypertension and diabetes mellitus in China, the two key risk factors of cardiovascular disease, has also increased significantly in the past 20 years (Liu, 2009). An integrated management of comprehensive risk factors is urgently required to address China's increasing cardiovascular disease burden (Liu, 2007).

It is estimated that, by 2030, almost 23.6 million people will die from cardiovascular disease globally and the largest increase in number of deaths will occur in South-East Asia. Although the mortality rate of cardiovascular disease and prevalence of major cardiovascular risk factors has generally decreased in economically developed countries, the

corresponding mortality rate and risk prevalence of the disease has substantially increased in China (Sanderson et al., 2007, He et al., 2005, Gu et al., 2007, Sun et al., 2010). Cardiovascular diseases are projected to remain the single leading cause of death (World Health Organisation, 2011). As part of the WHO global strategy, effective interventions and programmes have been developed in order to reduce major risk factors for cardiovascular disease throughout the entire population, to monitor and treat individuals at high risk or with established cardiovascular disease, and ultimately to reduce global morbidity, disability and mortality due to cardiovascular disease.

2.2.2 The global burden of cardiovascular disease

Cardiovascular disease has become a major public health issue worldwide (Deaton et al., 2011). It not only affects individuals' physical and psychosocial function, health-related quality of life as well as symptom management, but places a heavy economic burden on both families and societies across the world (Deaton and Grady, 2004, Deaton and Namasivayam, 2004). People with established cardiovascular disease are at greatly increased risk for developing further cardiovascular events and deaths. They are targeted in the National Service Framework for Coronary Heart Disease as a high risk group in whom risk factor modification and treatment with aspirin and statins should be highlighted (Lawlor et al., 2003, Department of Health, 2000).

The health care provided for people with cardiovascular conditions is costly and prolonged, which involves primary prevention through hypertension and cholesterol management and screening, medical and surgical treatment through hospitalisation, and need for follow-up clinical care. The indirect costs of cardiovascular disease mainly encompass productivity loss

owing to either significant morbidity or premature mortality (Yusuf et al., 2001). Cardiovascular disease disrupts the future of individuals and families by affecting their health adversely during their peak mid-life years, and therefore undermining the development of nations by depriving valuable human resources at a time of life when they are likely to be most productive (Yusuf et al., 2004, Clarke et al., 2009).

The total economic burden of cardiovascular disease has been estimated between 2010 and 2030 on a global scale (Gaziano et al., 2009, Lloyd-Jones et al., 2009, World Health Organisation, 2005). According to a report by the World Economic Forum and the Harvard School of Public Health (Bloom et al., 2011), in 2010, the global cost of cardiovascular disease was estimated at US$863 billion (an average per capita cost of US$125), of which about US$474 billion (55%) was due to direct healthcare costs and the remaining 45% to productivity loss, or time loss from work because of illness or the need to seek care. The cost of cardiovascular disease is estimated to rise by 22% to US$1,044 billion in 2030. The incidence of coronary heart disease is estimated to increase from 24 million in 2010 to over 32 million in 2030. During the 20-year period, the overall cost of cardiovascular disease could be as high as US$20 trillion (Table 2.2).

Table 2.2 Global costs attributable to cardiovascular disease, and cardiovascular disease incidence (in 1000s) between 2010 and 2030 from Bloom et al. (2011)

Year	Total cost (billions of US$)	Congestive heart failure incidence (in 1000s)	Coronary heart disease incidence (in 1000s)	Stroke incidence (in 1000s)
2010	863	10,072	24,167	28,299
2015	906	10,821	25,933	30,370
2020	957	11,830	28,284	33,122
2025	1,002	12,754	30,369	35,571
2030	1,044	13,637	32,339	37,886
Total, 2010-2030	**20,032**			

2.2.3 Management of cardiovascular disease: cardiac surgery

Coronary heart disease is among the major causes for hospitalisation and mortality across the world. The prevalence of coronary heart disease in some countries such as the United Kingdom appears to be rising, especially for men aged 75 years and older (Scarborough et al., 2010). However, with the improvement of prevention and diagnostics, the introduction of new medications, and advanced surgical technologies, there has been a significant decline in mortality associated with coronary heart disease (Deaton and Namasivayam, 2004) and total cardiovascular disease over the past two decades worldwide (Capewell and O'Flaherty, 2008). Since the 1980s, mortality rates from coronary heart disease have fallen in many developed countries such as Australia, Canada, the United Kingdom, France and the United States (Tunstall-Pedoe et al., 1999, Scarborough et al., 2010, Okrainec et al., 2004).

Effective and inexpensive medication is available to treat nearly all cardiovascular diseases. When the symptoms of these diseases cannot be controlled by pharmacologic treatment, increased awareness on the benefits of surgical treatment is needed in disease management. Cardiac surgery is typically the treatment of choice for many congenital or acquired heart conditions. It includes coronary artery bypass grafting (CABG) to treat coronary heart disease, valve surgery to repair or replace damaged heart valves from rheumatic fever, and congenital surgery to correct malformations of heart structure existing at birth such as arterial and ventricular septal defect.

Coronary heart disease occurs when the walls of the coronary arteries which supply oxygen and nutrients to the heart become narrowed or blocked by a gradual build-up of fatty material called atheroma. CABG

surgery is a widely used method to bypass or get around the narrowed part of the coronary arteries and improve the blood supply to the heart, which effectively relieves signs and symptoms of angina and increases life expectancy (Eisenberg et al., 2005). CABG is particularly common in developed countries having annual procedure rates of more than 515,000 in the United States. In 2007, an estimated 1,178,000 percutaneous coronary intervention procedures (PCI), 408,000 bypass procedures, and 1,061,000 diagnostic cardiac catheterisations were performed for inpatients in the United States. The estimated direct and indirect cost of heart disease in the same year was $177.5 billion (American Heart Association, 2011).

Although surgical treatment has shown its superiority to medical treatment with great advances in surgical techniques and care in the past decade (Martens et al., 2006), cardiac surgery is still classified as high risk because of its complexity. It has higher risks of death and postoperative complications and takes longer recovery time, as compared to other minimally invasive cardiac procedures like balloon angioplasty and stenting (Granton and Cheng, 2008). A wide number of risk stratification models for cardiac surgery have been developed and used as tools to help to preoperatively predict the incidence of mortality and morbidity (Nilsson et al., 2006). However, the outcomes of cardiac surgery are difficult to predict as some of these models cannot account for factors such as skill and experience of the surgeons and health care providers as well as other resources within the institutions where the surgery is performed (Granton and Cheng, 2008). Undergoing cardiac surgery is a challenging and distressing event for patients and families and can trigger negative emotional, physiological and cognitive responses (Screeche-Powell and Owen, 2003, Fitzsimons et al., 2003, Koivula et al., 2002). Vingerhoets argued (1998) that surgery with an uncertain outcome produces more

psychological problems than surgery with relative little ambiguity about the course and outcomes of events.

2.3 Anxiety and depression among cardiac surgery patients

Cardiac surgery patients are confronted with the risk of death from surgery and the risk of complications such as postoperative atrial fibrillation, graft failure, myocardial infarction, stroke, pneumonia, renal failure, serious bleeding and wound infection which may lead to a longer hospital stay, a blood transfusion, dialysis, further surgery or even loss of life (Karlsson, 2008). Being faced with the risks of death and complications from surgery, however small, has a direct impact on patient well-being. When confronted with the news about the need to undergo cardiac surgery, patients are likely to have concerns regarding how his or her disease and its treatment will affect life, work and relationships with others. These concerns can stimulate patients to ask questions about treatment and care and seek help from health care providers. However, a qualitative study interviewing twenty male cardiac surgery patients found that when patients' concerns could not be dealt with appropriately by health care providers, preoperative anxiety and symptoms of depression are increased (Vargas et al., 2006).

2.3.1 Anxiety and depressive symptoms

Anxiety is a vague and disturbing feeling of discomfort or fear that affects cardiac surgery patients psychologically and physically. In a prospective cohort study 55.8% patients who were admitted for elective cardiac surgery reported preoperative state anxiety (Detroyer et al., 2008). Anxiety is a common emotional response to situations and threats perceived to be uncontrollable or unavoidable. It is a sign that heightens awareness of an imminent danger, accompanied by an automatic reply (Ohman, 2000).

Fear and worry are the primary psychological symptoms of anxiety (Barlow, 2004). There are many possible reasons for developing anxiety before surgery. The heart problem itself that needs surgical treatment is often one of the most significant causes of anxiety. Being in hospital can be another. People may be consumed by fear of being uncertain, and lack of control and by worrying about the recovery process (Fitzsimons et al., 2000, Gallagher and McKinley, 2007). Typically patients awaiting cardiac surgery experience an increased level of anxiety related to surgery itself, surgical outcomes, and any complications following surgery, pain or discomfort, and their ability to return to normal life and work. In addition, preoperative anxiety can be caused by a fear of unfamiliar procedures during their hospital admission, preoperative preparation, surgery, and postoperative care in hospital (Fitzsimons et al., 2003). A survey showed that many patients expressed fear and apprehension towards the need for myocardial revascularisation surgery. These feelings were even more pronounced among individuals who were undergoing a surgical procedure for the first time (Lindsay et al., 2000).

Anxiety may trigger activation of the sympathetic nervous system and the hypothalamic-pituitary-adrenal axis. This activation produces a variety of physiological responses such as increased oxygen consumption, reduced immune response, and altered coagulation and autonomic tone (Frazier et al., 2002). Regarding cardiac reactivity to psychological stressors, many studies have shown that anxiety affects autonomic nervous system regulation, platelet activation, activity of the hypothalamo-pituitary-adrenal axis and myocardial effusion which in turn cause increased blood pressure, heart rate, and cardiac output (Thomas et al., 2008, Tsigos and Chrousos, 2002). In the meantime gastrointestinal activity is inhibited and immune

function is decreased (Marieb, 2006, Roth-Isigkeit et al., 2002, Macleod et al., 2002).

Cardiac patients with a high level of anxiety can experience physical symptoms including headache, dizziness, nausea, muscle weakness, fatigue, sweating, and difficulty falling asleep, or even more intense symptoms such as chest pain, palpitations, shortness of breath. Chest pain is a common symptom of anxiety and may take the form of a sharp pain or a feeling of visceral tightness that lasts greater than half an hour. It could also indicate the possibility of a fatal heart attack (Braunwald et al., 2005). Previous studies have suggested a robust relationship between psychological factors and the development of hypertension (Rutledge and Hogan, 2002), and the influence of psychological factors in the incidence and progress of cardiovascular diseases (Hamer et al., 2008, May et al., 2002, Stansfeld et al., 2002, Franco et al., 2003), or in morbidity and mortality among patients with acute myocardial infarction and heart failure (Frazier et al., 2002, Robinson et al., 2004, Yasuda et al., 2002).

In a sample of patients awaiting coronary artery bypass grafting, 43% had significant symptoms of depression before surgery (Pirraglia et al., 1999). Stroobant and Vingerhoets's follow-up study (2008) indicated that one-third of the patients undergoing CABG showed mild to moderate cognitive-affective symptoms of depression before surgery and patients with preoperative moderate cognitive-affective depression could be at risk for sustained feelings of depression for up to five years following surgery. The presence of depression has been associated with an increased risk of developing coronary heart disease and an increased risk of morbidity and mortality from established coronary heart disease (Malhotra et al., 2000, Sharpe, 2003, Rumsfeld and Ho, 2005) and to be an important predictor of

returning to work after coronary heart disease events (Söderman et al., 2003).

The degree or amount of anxiety or depression is influenced not only by the complexity and severity of the disease and surgery but also by many other factors such as age and gender (Naqvi et al., 2005, Vaccarino et al., 2003, Detroyer et al., 2008). Other aggravating factors can lead to anxiety and depression such as poor social support, low standard of education, and moderate or severe dyspnoea (Karlsson, 2008). Shen et al. (2008) conducted a study with 735 older men (mean age 60 years) without a history of coronary disease or diabetes at baseline to investigate whether anxiety characteristics independently predicted the onset of MI over 12 years and whether this relationship was independent of other psychological variables and risk factors. Anxiety characteristics were assessed with four scales (psychasthenia, social introversion, phobia, and manifest anxiety) and an overall anxiety factor derived from these scales. They concluded from their study that anxiety characteristics independently and prospectively predicted MI incidence and anxiety-prone dispositions appeared to be a robust and independent risk factor of MI among older men with coronary heart disease.

Vanhout et al. (2004) observed that there was a gender difference in the association between anxiety and mortality in a large, community-based random sample (n=3107) of older men and women (55–85 years) in The Netherlands. They concluded that men with anxiety disorders had 87% higher risk of mortality over 7 years of follow-up but in women with anxiety disorders no association was found with subsequent mortality. Koivula et al.'s study (2001b) with 207 patients scheduled for coronary artery bypass grafting surgery concluded that patients' fears differed with respect to their

objects and intensity, with women reporting more intense fears. Men also had fears, but the objects of fear differed from those in women. Apart from gender, the intensity of fear was associated with physical exercise, emotional problems and depression. They suggested that nursing interventions could be developed to meet the different needs for information and support, especially among women but also among men, to help relieve their fears during the wait for bypass surgery. This provides the foundation and serves as impetus for developing and evaluating a preoperative education intervention for patients awaiting cardiac surgery in the present study.

2.3.2 Preoperative anxiety causing poor cardiac surgical outcomes

Underlying psychological problems, particularly panic disorder, anxiety and depression can not only independently increase the risk of cardiovascular disease, exacerbate symptoms of the existing disease, but can also adversely affect physiological parameters before and during anaesthesia, and result in the possibility of prolonged recovery from surgery (Duits et al., 1997, Andrew et al., 2000, Pignay-Demaria et al., 2003). Preoperative anxiety was found to contribute to delayed wound healing, decreased immune response, fluid and electrolyte imbalance, increased rate of infection, and abnormal vital signs and was also associated with increased postoperative pain (Scott, 2004, Vaughn et al., 2007).

Such psychological problems risk compromising the rehabilitation process, which could eventually result in poor health related quality of life, considerable health expenditure, and ongoing mortality and morbidity (Szekely et al., 2007, Mayou et al., 2000). Anxiety disorder, present preoperatively, was found to be associated with increased risk of cardiac mortality (Tully et al., 2008, Hemingway et al., 2001, Roest et al., 2010).

Shibeshi et al. (2007) and Rosenbloom et al. (2009) found that following a diagnosis of coronary artery disease, a high level of anxiety increases the risk of MI or sudden cardiac death among patients with coronary artery disease.

Many recent studies have demonstrated a link between preoperative anxiety or depressive symptoms and postoperative psychological status (Rymaszewska et al., 2003). Duits et al. (1997) reviewed 17 prospective studies between 1986 and 1996 and suggested that preoperative anxiety and depression were strong predictors of psychological problems that occur after CABG. Another study by Douki et al. (2011) showed significant positive association between preoperative state anxiety and postoperative state anxiety. They concluded that identifying patients likely to experience anxiety before CABG and to highlight risk groups would enable health providers to design specific interventions that predominantly focus on reducing patients' anxiety and improving their quality of life. Recently anxiety and depression screening questionnaires such as the Generalised Anxiety Disorder (GAD) and Primary Care Evaluation of Mental Disorders 9-item Patient Health Questionnaire (PHQ) have been developed and validated, which are easy to administer and take less than five minutes for patients to complete (Rumsfeld and Ho, 2005, Spitzer et al., 2006). Once significant symptoms of anxiety and depression are identified, establishing appropriate interventions to relieve symptoms is essential.

2.3.3 Anxiety relief interventions

Anxiety is a normal human response particularly when people are facing a serious situation or a life-threatening procedure like cardiac surgery. Koivula et al. (2001a) suggested that the uncertainty and waiting for CABG disturbed many patients more than their chest pain. A long wait for CABG

can result in deterioration of patients' emotional state and physical activity. During this time, patients' ability to cope with anxiety and depression may depend on support from family, friends, and health care providers. Although individuals may have their own coping approaches, patients and their families and friends may require special care and additional support from professionals. Health care providers have a role in monitoring patients' anxiety, identifying what causes their anxiety, and then determining possible solutions to preventing or decreasing it and helping them prepare for the surgery (Frazier et al., 2002).

Although anxiolytic or antidepressant medications can help with relieving severe anxiety, they carry risks of potential side effects, dependence and withdrawal. Various distraction or relaxation techniques such as yoga-based interventions and therapeutic massage are considered to be important complementary and alternative medical treatments for anxiety reduction by keeping patients' attention away from fearful thoughts and increasing their calmness (Subramanya and Telles, 2009, Sherman et al., 2010). Manzoni et al. (2008) undertook a meta-analysis of 27 studies published between 1997 and 2007 (including randomised controlled trials, observational and without control group studies) which evaluated the efficacy of a variety of relaxation techniques for anxiety problems and disorders including Jacobson's progressive relaxation, autogenic training, applied relaxation and meditation. The results showed consistent and significant efficacy of relaxation techniques in the treatment of anxiety. In addition, meditation proved to be most effective in reducing anxiety compared to other techniques. This meta-analysis provided a better understanding of the variability and clinical significance of anxiety improvement subsequent to relaxation techniques. However, it may significantly overestimate the effect being examined as previous work

suggests that there is a tendency for the inclusion of non-randomised controlled trials within a meta-analysis to yield greater treatment effects than when the included studies are restricted to those where treatments have been randomly allocated (Schulz et al., 1995, Wood et al., 2008b, Kunz and Oxman, 1998).

In the surgical field, from the last two decades, guided imagery has played an important role not only in reducing preoperative anxiety but also reducing postoperative pain in patients undergoing same-day surgical procedures (Gonzales et al., 2010) and in patients having cardiac surgery (Halpin et al., 2002). Some recent studies also found that music therapy had a positive effect on patients' pain intensity and anxiety for cardiac surgery patients by creating calm, relaxing atmosphere geared towards reducing anxiety (Kshettry et al., 2006, Sendelbach et al., 2006, Twiss et al., 2006). However, in a review (Pittman and Kridli, 2011) synthesising the data from 11 articles to assess the efficacy of music intervention in reducing preoperative anxiety in adults, they concluded that there was inconsistent evidence regarding the effectiveness of music in lowering blood pressure, heart rate and respirations in anxious patients.

Information may be beneficial in reducing patients' anxiety and improving their experience of hospitalisation (Bailey, 2010). Patients who perceived they had less control developed higher levels of anxiety and experienced more complications (Moser et al., 2007). Patients' information needs are likely to be greater in the run up to cardiac surgery. They are dependent on health care providers to explain their current heart condition, procedures and future surgery. Although there is no universal agreement regarding what works best or how its effects can be measured, most researchers consider that timely preoperative education may be an important

intervention to lessen fear of the unknown and make patients feel more control over their situation.

2.4 Preoperative education

The presence of anxiety and depression before cardiac surgery leads to poor surgical outcomes. There is a need for health care providers to find ways to respond to and manage these psychological problems patients experience preoperatively and prepare them for surgery in order to reduce mortality and hasten postoperative recovery (Vargas et al., 2006). In recent years there has been increasing emphasis placed on informed consent for both treatment and research globally. The basic requirements of informed consent focus on patients' access to information, competence to make a decision, and involvement in health care (Gammelgaard et al., 2004).

In terms of informed consent for surgical treatment, patients need to be provided with adequate information to understand the risks, benefits, and alternatives available in order to make the right decisions and engage in their health care (Angelos et al., 2003). Preoperative education has been considered as an interactive process of providing information and explanations about surgical procedures, expected patient behaviours and anticipated sensations as well as providing appropriate reassurance and psychosocial support to patients who are about to undergo surgery. The main aim of preoperative education is to prepare patients for surgery and to facilitate their recovery after surgery by helping them understand their health and care and implement the information provided to achieve better health outcomes (Bernier et al., 2003).

2.4.1 Importance of preoperative education

The concept of preoperative education originated in the 1950s. Preoperative education has become increasingly viewed as an important and complex intervention in surgical nursing (Johansson et al., 2005). It is designed to help patients obtain information on their operation and after-care (Leino-Kilpi et al., 1998, Poskiparta et al., 2001), reduce anxiety and experience a shorter length of stay (Cashman, 2001). It may also help patients play a more active role in the management of their own situation (Anderson and Sharpe, 1991, Anderson, 1995, Leino-Kilpi et al., 1999). Additionally it also enables nurses to acquire the necessary information about patients such as mobility difficulties and psychological problems and decide whether they can successfully adapt to, or cope with, their current situation, and, if not, what might be done to assist them (Johnson and Anderson, 2007).

Most importantly, preoperative education may reduce anxiety by making the unknown familiar. According to Spalding's study with patients awaiting a total hip replacement surgery (2003), such familiarity can be achieved in three ways by (1) providing an understanding of the experiences patients will encounter during and after surgery; (2) giving opportunity to meet the staff that will be caring for them; and (3) familiarising patients with the environments they will meet when in hospital. Preoperative education not only provides specific information about what to expect during the preoperative and postoperative period but also influences the attitudes and behaviours of patients with respect to their health and care.

2.4.2 Theories of preoperative education

The most widely applied theories in preoperative education are stress, self-efficacy and adult learning. In stress theory, psychological stress has a

deleterious impact on patients' health leading to anxiety. Teaching patients about their forthcoming surgery can increase their ability to cope with stress and influence their behaviour in managing their surgery (Cupples, 1991, LeRoy et al., 2003). This overlaps with the theory of self-efficacy, which refers to people's sense of confidence in their ability to take control of their lives and to perform a certain behaviour (Bailey, 2010, Wong et al., 2010). The underlying assumption of self-efficacy theory is that the greater their confidence, the more likely it is that people will initiate behavioural change and persist in that particular behaviour (Bandura, 1986, Bandura, 1997). Self-efficacy is considered to be the mediator between knowledge and action. Enhancing patient preoperative education may provide them with knowledge and skill to cope with the anticipation of surgery and decrease their anxiety. Self-efficacy theory is commonly used to underpin the educational intervention for orthopaedic patients (Pellino et al., 1998, Yeh et al., 2005, Heye et al., 2002).

Some studies in preoperative education were based on the theories of adult education or learning, emphasising that education can be designed to assist patients in meeting their needs to care for themselves and consequently patient can learn to perform particular behaviours with an improvement in well-being (Stolic, 2004, Shuldham, 1999a, Walsh and Shaw, 2000). Education aims to remove irrational beliefs, influence behaviours and enhance patient empowerment by providing or receiving accurate information and advice on how the patient can best engage in his or her own health and care (Dixon-Woods, 2001). To some extent these educational theories rely on the concept of cognitive reappraisal which has an impact on emotion and well-being (Heikkinen et al., 2008, Callaghan and Li, 2002, Persson and Lilja, 2001).

2.4.3 Components of preoperative education

Traditionally information given to patients during preoperative education to provide an understanding of the experiences patients will encounter during, and after surgery falls into three categories: procedural, sensory, and coping information. Procedural information relates to the explanation of medical events such as the reason and consequences of surgery, specific surgical procedures, behavioural instructions during the postoperative period, and discharge from the hospital. Sensory information addresses the sensations that patients can feel during or after the procedure such as pain and discomfort. Finally coping information includes areas like deep breathing and cough exercises to minimise complications and increase postoperative function (Suhonen and Leino-Kilpi, 2006).

It is important to provide an appropriate amount of information to patients undergoing surgery. But patients vary considerably in the amount of information they feel comfortable with or are able to assimilate (Bernier et al., 2003). This variation is not only between individuals but even in the same individual at different times and depending on the specific context. Preoperative education should be tailored according to individual needs at a particular point in time to provide a proper balance between enough and too much information (Lilja et al., 1998). There is controversy around providing information regarding risk and complications of surgery prior to the procedure. Some studies have assumed that unnecessary anxiety develops if excessive detailed information regarding the risks and complications are given to the patients (Mitchell, 2000) but elsewhere it has been observed that explicit information which successfully increased knowledge about the risk of anaesthesia did not increase anxiety in a group of patients awaiting cardiac surgery (Garden et al., 1996).

2.4.4 Methods of preoperative education

Preoperative education has been administered in various approaches and formats including written materials, audio-visual presentations, oral information in the form of one-to-one counselling or group discussion, or combinations of some or all of these. Previous studies have shown that each approach has both advantages and limitations (Lithner, 2000). Fitzpatrick and Hyde (2005) interviewed twelve experienced surgical nurses in Ireland regarding how preoperative education is practised in clinical contexts. The results suggested that the quality of preoperative education depended largely upon the individual nurse caring for the patient. Her or his choice about delivery methods depended on the availability and accessibility of teaching tools or materials. If educational resources are unavailable, oral explanation would be the only way for nurses to deliver information to their patients.

However, oral explanations can be forgotten or misunderstood. One study showed that, on average, adult patients forget approximately half of what they had been told within five minutes of leaving the consultation (Kenny et al., 1998). In general, people may only retain about 20% of what they hear but this may increase to 50% if there is additional visual or written input (Kenny et al., 1998). Additionally, due to an increasing trend toward shorter times between hospital admission and surgery, there has been limited time that nurses can spend with patients before surgery. Thus reliance on verbal information giving alone may not always be effective. The use of media such as leaflets (van Zuuren et al., 2006) and videos (Roth-Isigkeit et al., 2002) can help to deliver information in a potentially more efficient and interesting way. A systematic review of randomised controlled trials concluded that the use of video and printed information about the general process and risks of anaesthesia for preoperative

education has a positive impact on anxiety and knowledge (Lee et al., 2003).

It is argued that written information offers many advantages over other teaching media as it is reusable and readable at any time as well as easy to reproduce and distribute. Research-based disease-specific written information can be developed to reinforce and assist with verbal communication (Walsh and Shaw, 2000, Lewis and Newton, 2006). Patient information leaflets, as an important source of health information for patients, have a long history in health care and are the most cost-effective and time-efficient means of communicating health messages (Semple and McGowan, 2002). Traditionally they were seen as a way of giving information to a passive recipient but more recently as part of patient empowerment (Dixon-Woods, 2001). Written information should be short and presented in simple language avoiding jargons or any difficult medical terms. A study concluded that a one page information handout would be a low-cost and efficient way of measurably reducing the anxiety and fears that a significant number of patients have about anaesthesia and surgery (Fitzgerald and Elder, 2008).

Many studies have demonstrated a positive effect of written information provided preoperatively and have shown surgical patients' better understanding of their condition and treatment (Ivarsson et al., 2005a, Ferrús-Torres et al., 2011). It has been observed that written information helps patient recall and that patients find written information easier to discuss with family and friends. The use of information leaflets is strongly recommended in emergency care settings to improve patient satisfaction (Arnold et al., 2009). But Johansson et al.' (2005) in their systematic review of 11 trials involving 1044 adult orthopaedic patients, investigating

the effect of preoperative nursing patient education reported that leaflets alone will not have beneficial effect unless they are given with oral information. Without oral explanation, patients find the written materials complex to understand and difficult to remember. The provision of written materials, in combination with oral information to patients may be one of the more effective methods in preoperative education (Stern and Lockwood, 2005, Hodgkinson et al., 2000).

2.5 Effects of preoperative education in general surgery

Preoperative education has been used in an attempt to improve patients' experiences by providing relevant information about health care and coping skills (Kruzik, 2009, Scott, 2004). Several meta-analyses (Hathaway, 1986, Devine and Cook, 1986, Devine, 1992) and reviews (Shuldham, 1999b, Oshodi, 2007) of preoperative information provision have been conducted. All of these have shown that compared with usual care, preoperative information is generally beneficial to adult surgical patients.

Hathaway (1986) reviewed 68 experimental studies and concluded that patients having some form of preoperative instruction, particularly those receiving instruction containing psychological and mixed forms of content, helped to improve adult surgical patients' welfare and postoperative outcomes. The meta-analysis found that the greatest effects were achieved with patients who had high levels of fear and anxiety. The meta-analysis of Devine and Cook (1986) included 102 studies and found a positive effect of psycho-educational interventions on pain, psychological well-being and satisfaction with care outcomes. Subsequently, Devine's updated review (1992) synthesised 191 studies of any form of psycho-educational care, of which 69% used random assignment to treatment condition. This meta-analysis confirmed earlier findings but also found pre-surgical psycho-

educational interventions produced small to medium effects on length of hospital stay, medical complications, respiratory function and resumption of activities. Devine stated that the overall efficacy of psycho-educational care provided to adult surgical patients found in this review was reliable and could not be attributed to the biases associated with the decision to publish, low internal validity, measurement subjectivity, or Hawthorne effects.

However, the latest meta-analysis above is now nearly twenty years old and surgical practices, patterns of hospitalisation and nursing as well as patients' knowledge and expectations have changed substantially. Shuldham (1999b) reviewed more recent studies in this field and demonstrated that preoperative education for patients about what to expect before major surgery had a beneficial impact on a variety of patient outcomes. These included objective measures such as length of hospital stay as well as subjective measures such as anxiety, pain, and satisfaction. Although many questions remain unanswered about the effect of preoperative information on patients' outcomes, none of the meta-analyses and reviews raised concerns that the information itself increased anxiety.

The effects of preoperative education may differ according to type of surgery. With reference to patients undergoing orthopedic surgery, the meta-analysis of Johansson et al. (2005) found that preoperative education can improve patients' anxiety and knowledge. A Cochrane review undertaken by McDonald et al. (2004) concluded that there was evidence of a modest beneficial effect of preoperative education on preoperative anxiety among patients undergoing hip or knee replacement surgery. But little evidence was found to support the effect of preoperative education on postoperative outcomes, such as pain, functioning and length of hospital

stay. These reviewers suggested that there might be beneficial effects when preoperative education was tailored according to anxiety, or targeted at those most in need of support (e.g. those who are particularly disabled, or have limited social support structures).

Some trials or quasi-experimental studies have shown that preoperative information of various types and in different forms appear to have positive effects on the ability of patients to cope with and recover physically and psychologically from their planned surgery (Wong et al., 2010). A randomised controlled trial (Pager, 2005) demonstrated that preoperative information by the use of video-tapes showing patients what to expect from cataract surgery resulted in less anxiety, and greater understanding of, and satisfaction with, their treatment. This finding was supported by Zieren et al.'s trial (2007) showing that an informative video before inguinal hernia surgical repair can lead to better quality of life postoperatively.

Another randomised controlled trial conducted by Lin and Wang in Taiwan (2005) found that a preoperative nursing intervention for pain through oral explanation had a positive effect on anxiety and pain for patients undergoing abdominal surgery. In Blay and Donoghue's trial (2005), pre-admission education intervention with the use of verbal and written information on pain management, wound care, diet and elimination helped reduce pain following laparoscopic cholecystectomy and significantly increased patients' knowledge of self-care and complication management.

Studies of preoperative education are characterised by poor design in terms of patient assignment, blinding of participants and researchers, follow-up procedures and statistical analyses (Shuldham, 1999a). There is

considerable space for improvement in trial design as a basis for promoting evidence based nursing. In addition although there are a relatively large number of studies on preoperative education and some evidence to show its value on patients undergoing minor surgeries, for some major areas of health care such as heart disease, sufficient evidence does not yet exist to enable firm conclusions to be drawn (Shuldham, 1999b).

More specifically, there is a lack of information on the needs of patients who are undergoing cardiac surgery. It has been observed that cardiac surgery can cause more anxiety and can create negative physiological, psychological, and social health changes in patients as compared to other minor surgeries (Fitzsimons et al., 2003, Screeche-Powell and Owen, 2003). This group may therefore be in greater need of information to support their understanding about their health and preoperative preparation. Evidence of the effectiveness of preoperative education interventions for patients undergoing general surgery may not be transferable to those who are undergoing cardiac surgery.

2.6 Patients' experience of preoperative patient education

Preoperative patient education is important for patients awaiting surgery who become vulnerable and anxious before surgery (Aquilina and Baldacchino, 2007, Moene et al., 2006). They depend on health care providers to communicate with them about useful information and advice to help them prepare for their surgery. Chan et al. (2012) systematically reviewed eleven qualitative studies (six were conducted in the UK and others in Sweden, the USA, Canada, Ireland and Malta) on patients' experiences of preoperative communication. They found that patients showed different needs and desire for the content, form and sources of preoperative information. Most surgical patients prefer to receive extensive

information preoperatively in order to meet their need for control over their care of disease and surgery (Hall et al., 2008). Patients report being irritated by not being given sufficient or clear information or being given inconsistent information by different health care providers (Gilmartin and Wright, 2008). More importantly, the review also showed that patients were sensitive to the attitude of health care providers. A caring, respective and empathic attitude shown by health care providers determined patients' levels of satisfaction and confidence as well as their overall impressions of the health care team. However, not all health care providers demonstrated such a positive attitude (Mottram, 2009).

As nurses have a fundamental role in delivering preoperative education, they need to be able to identify and meet patients' needs for preoperative education. However, providing patients with adequate preoperative information is challenging in nursing practice (Fitzpatrick and Hyde, 2005, Fitzpatrick and Hyde, 2006, Suhonen and Leino-Kilpi, 2006). In Fitzpatrick and Hyde's study (2006), a sample of 12 experienced surgical nurses was interviewed in depth aiming to explore the factors relating to nurses that influence the delivery of preoperative patient education in everyday surgical clinical contexts in Ireland. Findings indicated that nurses' different understanding of the importance of preoperative education and views about what preoperative education should be led to inconsistency in preoperative care across patients. The majority of participants believed that nurses' knowledge, skills and experience of preoperative education and communication influenced the standard of preoperative education delivered to patients. Lack of confidence due to less knowledge and skill and inexperience was seen to result in limiting the opportunity for patients and their families to ask questions or avoiding communication and engagement with patients and families.

Other related factors identified from the interview data included the content of materials delivered in the preoperative education process and the form of preoperative education as well as wider structural components of the learning environment. Fitzpatrick and Hyde (2006) argued that organisational investment in the area of preoperative education is essential, which requires a clear conceptualisation of this aspect of patient care and the development and evaluation of preoperative education materials and interventions which are patient centred. In addition, nurses face the challenge of having to deliver preoperative education within a confined time frame. In the context of shortened length of hospital stays, especially preoperatively, the optimal form and process by which preoperative education can be delivered effectively and efficiently needs to be determined (Fitzpatrick and Hyde, 2006, Ong et al., 2009).

Sub-optimal provision of information has been attributed to health care providers' misunderstanding of the information patients prefer (Mordiffi et al., 2003). In other words, preoperative information is often based on what health care providers perceive is important for patients. However, this can be quite different to patients' actual needs. Keulers et al. (2008) found that surgeons thought that their patients desired more extensive information on cause, effect, and prognosis of the disease itself. However, in contrast, patients demonstrated their need for receiving more specific information regarding the preoperative period, anaesthesia, operation, postoperative period, self-care, and general hospital information. The study concluded that surgeons generally underestimate their patients' desire for preoperative information.

2.7 Summary

Cardiovascular disease is the leading cause of morbidity and mortality worldwide, with economic effects at the levels of both the individual and society. Cardiac surgery is associated with a range of unintended negative physical, psychological and social health changes. Patients awaiting cardiac surgery can experience physical and psychological stress, including anxiety and depression due to fears, worries, and uncertainties about surgery. These can exacerbate symptoms of the existing disease, adversely affect physiological parameters before and during anaesthesia, and can result in prolonged recovery from surgery.

Previous studies have shown that preoperative education, as a nursing intervention, can reduce anxiety and improve postoperative outcomes in various groups of surgical patients. Patients' experience of preoperative education is varied but most surgical patients prefer to receive extensive information preoperatively in order to maintain some control over their health. Factors influencing the quality of preoperative patient education include the value placed on preoperative education by nurses, nurses' knowledge of and skills in the delivery of preoperative education, content and form of preoperative education, and organisational investment in this aspect of care. Previous randomised controlled trials evaluating the effects of preoperative education interventions for patients undergoing cardiac surgery are critically reviewed in the following chapter.

CHAPTER THREE

EVIDENCE FROM RANDOMISED CONTROLLED TRIALS OF PREOPERATIVE EDUCATION INTERVENTIONS FOR CARDIAC SURGERY PATIENTS

3.1 Introduction

This chapter presents a detailed review of the effects of preoperative education among cardiac patients from previously published randomised controlled trials. Although there is evidence that preoperative education interventions can lead to positive postoperative outcomes for surgical patients in general, less is known about their effectiveness for patients undergoing cardiac surgery. This review critically appraises available evidence reported in recent randomised controlled trials with two group comparison design.

3.2 Moving from a narrative review to a systematic review

A previous review has demonstrated the impact of preoperative education on a variety of outcomes including both objective measures such as length of hospital stay as well as subjective parameters such as anxiety, pain and satisfaction among a mix of general surgical patients (Shuldham, 1999b). However the review concluded that it was difficult to apply the findings to a particular group of patients undergoing surgery such as for cancer or heart disease. Shuldham (2001) therefore carried out a narrative review of ten studies evaluating preoperative education for those undergoing cardiac surgery. It suggested that there was limited evidence to support the positive impact of preoperative education on patients' recovery from cardiac surgery.

The effect of preoperative education for cardiac surgery patients is far from clear. In the review by Shuldham (2001), only one of the ten studies included was a randomised controlled trial in which random allocation of

patients to intervention and control groups was handled effectively (Anderson, 1987). The remaining studies were either descriptive (Recker, 1994, Grady et al., 1988) or random assignment was not explicit (Cupples, 1991, Lamarche et al., 1998, Mahler and Kulik, 1998, Rice et al., 1992). In addition, the review is now ten years old and the studies included were published between the years of 1978 and 1998. Preoperative waiting time, cardiac surgical practices, and preoperative and postoperative care as well as patients' knowledge and expectations have changed substantially during the last decade.

Another review is called for to look at more recent studies in this field with robust study designs. In contrast to a narrative review, a systematic review limits bias by using explicit and transparent methods to search, critically appraise and systematically synthesise the studies addressing specific clinical questions (Satya-Murti, 2000, Sackett et al., 2000, Akobeng, 2005c). Systematic reviews have increasingly replaced traditional narrative reviews as a way of summarising research evidence for effectiveness of diagnostic and treatment interventions and for the outcomes of natural and therapeutic exposures, including adverse events and costs (Collins and Fauser, 2005). Systematic reviews of randomised controlled trials (RCTs) are considered to be evidence of the highest level in the hierarchy of research designs evaluating effectiveness of interventions (Akobeng, 2005c, Evans, 2003). A systematic review of recent randomised controlled trials examining the effectiveness of preoperative education interventions for cardiac surgery patients was carried out. The process for conducting the systematic review included clear and reproducible eligibility criteria for selection of studies, a comprehensive search for relevant studies that met the eligibility criteria, critical appraisal of the quality of included studies, and synthesis of results.

3.3 Aim of the review and selection criteria

The aim of this review was to update evidence regarding whether preoperative education interventions have effects on a range of health outcomes of patients undergoing cardiac surgery and to identify the outcomes affected. Secondly, the review sought to specify the contents and forms of preoperative education interventions for patients undergoing cardiac surgery. Studies were included in the systematic review if they met the following selection criteria: (1) the studies were published in English between 2000 and 2011; (2) the studies involved adult patients (aged 18 and over) undergoing cardiac surgery; (3) the studies compared any form of preoperative education interventions to usual care; (4) studies evaluated the effect of preoperative education on one or more outcomes including biological, psychological, length of stay, the utilisation of service and cost outcomes; (5) the studies were randomised controlled trials.

3.4 Search strategy

A comprehensive search strategy was developed to obtain all relevant studies. Electronic databases including the Cochrane Central Register of Controlled Trials from the Cochrane Library, MEDLINE, CINAHL, PsycINFO, EMBASE, and Web of Science were searched. The following subject headings or key words used in the search were: cardiac surgery, preoperative education, anxiety, and recovery (Table 3.1). Searches were limited to adult population, English language, and 2000 to 2011 periods. As randomised controlled trial is the most appropriate research design for evaluating an intervention (Moher et al., 2010), 'randomised controlled trial' was used as a keyword to map to the title, abstract and full text for identifying the best quantitative evidence. All searches were screened and duplicated studies were discarded. Reference lists of all retrieved articles

were followed up for additional studies that investigated the effect of preoperative education for cardiac patients.

Table 3.1 Search terms used

Key Concepts	Keywords
Cardiac surgery	'Cardiac surg*', 'cardiac oper*', 'open heart'.
Preoperative education	'Patient education', 'patient counsel*', 'patient teach*', 'patient learn*', 'patient inform*', preoperative & preadmission.
Anxiety or postoperative recovery	Anxiety, depression, stress, pain, knowledge, length of stay, recovery.
Research methodology	Randomised controlled trial.

3.5 Studies identified

After filtering out duplicate studies retrieved from the databases, 266 potentially relevant studies were assessed. The full texts of 35 studies were obtained through the search strategy and reviewed in further detail. Of these, 29 articles were excluded because they did not meet the inclusion criteria (Figure 3.1). Reasons for exclusion fell into the following categories: (1) the studies were non randomised controlled trials (n=5) or uncontrolled studies or qualitative designs (n=12); (2) the studies involved only surgical procedures but not open heart surgery (n=3); (3) focus of interventions was not preoperative education (n=6); (4) usual care was not used as control group (n=3).

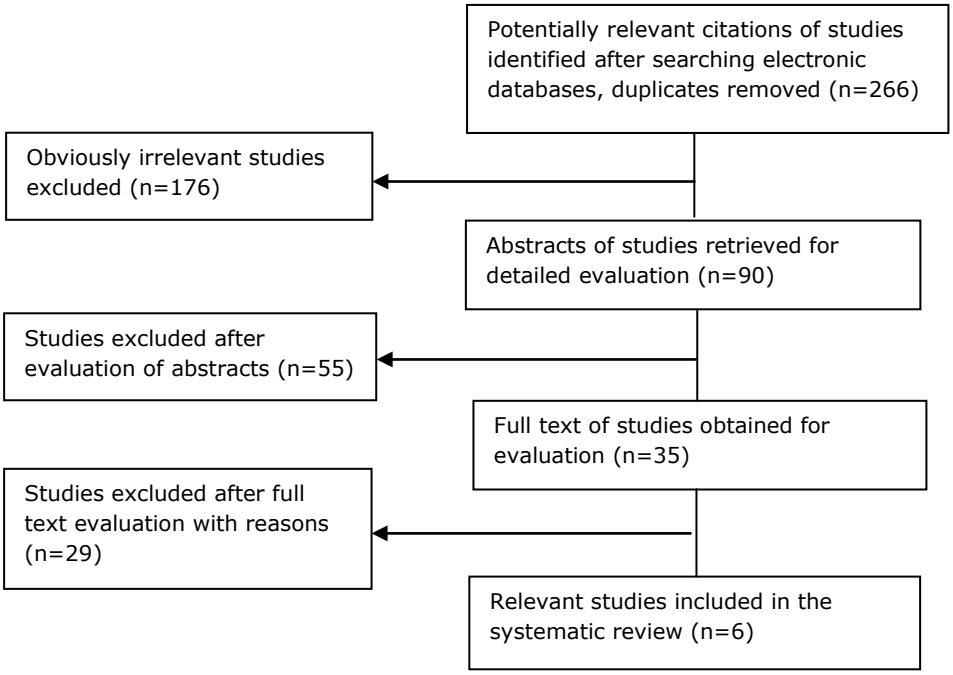


Figure 3.1 Flow diagram of study selection process

Consequently, a total of six randomised controlled trials were included in the review. Three studies were carried out in the UK (Goodman et al., 2008, McHugh et al., 2001, Shuldham et al., 2002), two in Canada (Arthur et al., 2000, Watt-Watson et al., 2004), and one in Norway (Sørlie et al., 2007). As the individual trials differed considerably in interventions and outcome measures, it was decided not to pool results but synthesise them descriptively. Data were synthesised in terms of methodological quality assessment, intervention characteristics, outcomes and reported qualitative evaluation of the interventions.

3.6 Assessing methodological quality of the trials

All of the six trials were critically evaluated based on a checklist recommended by the Centre for Review and Dissemination (Table 3.2) (Centre for Review and Dissemination, 2009). The quality of the six trials

varied (Table 3.3), although in general, design, conduct, and reporting were better in randomised controlled trials published after the adoption of the first Consolidated Standards of Reporting Trials (CONSORT) statement in 1996 (Kane et al., 2007, Schulz et al., 2010). The sample sizes ranged from 98 (McHugh et al., 2001) to 406 (Watt-Watson et al., 2004). Random allocation was performed effectively in all six trials reviewed.

Table 3.2 Checklist for assessing validity of randomised controlled trials (from the Centre for Review and Dissemination)

Item No.	Topic	Checklist item
1	Randomisation	Was the assignment to the treatment groups really random?
2	Blinding of participants	Was the randomisation of participants blinded?
3	Follow-up	Was relatively complete follow-up achieved?
4	Analysis of withdrawal	Were the outcomes of people who withdrew described and included in the analysis?
5	Blinding of outcome assessors	Were those assessing outcomes blind to the treatment allocation?
6	Baseline	Were the control and treatment groups comparable at entry?
7	Identical except intervention	Were the groups treated identically other than for the named interventions?

Patients in the trials were generally not blind to the intervention though this was not explicitly stated in three of the six trials. Given the nature of the preoperative education interventions and the requirements of patient informed consent, it is probably unrealistic to expect blinding of participants though this raises the issue of potential bias in participant responses to self-report questionnaires. Of the six trials, only two of them reported that blinding of the outcome assessors was accomplished (Shuldham et al., 2002, Watt-Watson et al., 2004) and the remainder did not make it clear who acted as outcome assessors and whether they were blinded or not.

Table 3.3 Quality assessment of the randomised controlled trials

Studies	Random allocation	Blinding of patients	Complete follow-up	Analysis of withdrawal	Blinding of assessor	Groups comparable at baseline	Equivalent treatment other than interventions
Arthur et al.	Yes	No	No	No	Not stated	No, gender & peak oxygen use	Not clear
Goodman et al.	Yes	Not stated	Yes	No	Not stated	Yes	Not clear
McHugh et al.	Yes	Not stated	No	No	Not stated	Yes	No
Shuldham et al.	Yes	No	Yes	Yes	Yes	No, marital & length of wait	Yes
Sørlie et al.	Yes	No	No	Yes	Not stated	Yes	Yes
Watt-Watson et al.	Yes	Not stated	Yes	No	Yes	Yes	Yes

Not all study reports accounted for all participants lost to follow-up. Sørlie et al.'s (2007) and Shuldham et al.'s (2002) trials included all participants randomised to the intervention or control group in the analysis. However the use of a strict intention to treat analysis was impossible in cases of missing data such as loss to follow-up, any withdrawals or non-compliers. Four trials did not use strict 'intention to treat' analysis and did not further explain how missing data and/or deviation from protocol were dealt with, although they provided information about the characteristics and reasons for withdrawals (Arthur et al., 2000, Goodman et al., 2008, McHugh et al., 2001, Watt-Watson et al., 2004). Exclusion of any withdrawn participants who have sustained severe side effects to the intervention will affect the results of a trial (Abraha and Montedori, 2010, Unnebrink and Windeler, 2001, Touloumi et al., 2001).

3.7 Interventions tested

A full description of the reviewed trials including the interventions and outcomes are detailed in Table 3.4 below. Broadly speaking, the content of preoperative education interventions in most trials was similar. The

education interventions covered comprehensive preoperative information on a range of topics including procedures, surgery preparation, postoperative progress, psychological support and coping skills. The exception is Watt-Watson et al. (2004), who focused mainly on the importance of pain relief for recovery and pain relief methods. In three trials, the preoperative education intervention emphasised the provision of individualised information whereby patients were encouraged to express their questions and worries (Arthur et al., 2000, McHugh et al., 2001, Sørlie et al., 2007).

Most of the trials used media based educational interventions combined with verbal explanations. Written materials were used in the form of manual or booklet or package in three trials (Goodman et al., 2008, Watt-Watson et al., 2004, Shuldham et al., 2002). In Goodman et al.'s and Watt-Watson et al.'s trials, nurses guided the participants in the intervention group to read the written material through, discussed important points contained in the written materials, and answered patient questions. One trial used a 12 minute video combined with 40 minute patient-centred information session delivered by specially trained nurses. The video was shown twice: preoperatively and again during the session at admission (Sørlie et al., 2007).

In Arthur et al.'s trial (2000), the intervention group received an 8 week multidimensional preoperative education involving individualised, prescribed exercise training twice per week in a supervised environment, with education and reinforcement during the waiting period. Additionally, monthly nurse-initiated telephone calls, as another important component of

Table 3.4 Summary of the reviewed randomised controlled trials (n=6)

Author/Setting	Population	Interventions	Outcome measures	Results
Arthur et al. (2000) Canada	249 patients awaiting elective CABG	Intervention group (n=123): exercise training; education & reinforcement; monthly telephone calls. Usual care group (n=123): followed by primary care physicians, cardiologists or surgeons.	Primary: Postoperative length of hospital stay. Secondary: Health-related quality of life (QOL SF-36). Anxiety (STAI). Peak exercise performance, social support & utilization of health care services.	1 less day for intervention group* & less time in ICU* SF-36 physical/mental: positive effect/no difference. Anxiety: no difference. Other outcomes: no difference.
Goodman et al. (2008) UK	188 patients awaiting cardiac surgery	Intervention group (n=94): a cardiac risk assessment, monthly lifestyle counselling & preparation; the manual & nurses' explanation. Control group (n=94): standard care consisting of the hospital helpline telephone numbers and a pre-surgery information day.	Primary: Anxiety & depression (HADS). Length of stay. Change in blood pressure (BP). Body Mass Index & Serum Cholesterol. Secondary: Change in smoking rate (by self-report). Blood glucose (by the Trust laboratories). Quality of life (CROQ & SF-36). Postoperative complications (medical and nursing notes).	Anxiety & depression: no difference. Median length of stay: no difference. BP and total cholesterol: no difference. BMI or HDL cholesterol: no change. Numbers of smokers too small for analyses. Change in glucose levels: no difference. QOL: no difference except for physical QOL on SF-36*. Post-operative complications: no difference. Cost analysis: less in intervention group*.
McHugh et al. (2001) UK	98 patients awaiting elective CABG	Nurse led shared care group (n=49): health education & motivational interviews monthly. Control group (n=49): usual care.	Risk factors: Smoking status. Obesity. Physical activity. Blood pressure. Plasma cholesterol. General health (SF-36). Anxiety & depression (HADS). Patient satisfaction (questionnaire).	Higher cessation rate in intervention*. Intervention patients more likely to reduce obesity*. Time spent being physically active*. Systolic/diastolic BP: decreased in intervention group*. Patients' proportion with cholesterol exceeding target values: no difference. SF-36: improved in intervention group*. Anxiety & depression: improved*. Patients were satisfied with the service.

Shuldham et al. (2002) UK	356 elective CABG patients	Experimental group (n=188): a day of preadmission education by multidisciplinary members plus usual care. Control group (n=168): usual care involving individual teaching on admission by staff complemented by information sessions on the ward.	Anxiety & depression (HADS). Well-being (General Well-Being questionnaire). Pain (VAS). Length of hospital stay.	HADS: no difference 6 month after surgery. Wellbeing: no difference 6 month after surgery. Pain: no difference 6 month after surgery. Significant difference with the experimental group having the longer hospital stay.
Sørlie et al. (2007) Norway	109 elective CABG patients	Intervention group (n=55): video combined with individualised information sessions by nurses at admission and at hospital discharge. Control group (n=54): standardised information but no video.	Anxiety (BAI). Subjective health (SF-36). Depression (Zung self-rating scale). Length of postoperative stay.	Less anxiety in intervention group at discharge* & up to 1year*. Better subjective health in intervention group at discharge* and during 2 years*. Depression: no difference at discharge but less in the intervention during 2 years*. Mean length of postoperative stay: no difference.
Watt-Watson et al. (2004) Canada	406 CABG patients	Pain education group (n=202): a booklet plus standard care. Standard care group (n=204): a booklet & a video including general procedural information.	Primary outcome: Pain-related interference (BPI-I). Secondary outcome: Postoperative pain (McGill Questionnaire). Analgesic use (patient's charts). Concerns about taking analgesia (subscale from Barriers Questionnaire). Satisfaction (American Pain Society). Impact of gender. Hospital stay (patients' charts).	Pain-related interference: no difference. Postoperative pain: no difference. Analgesics: no difference. Fewer concerns about analgesic in intervention group on day 5 after surgery*. Satisfaction: no difference. Women: greater interference due to pain in overall activities*. Length of stay: no difference.

BAI: Beck Anxiety Inventory
CROQ: Coronary Revascularisation Outcome Questionnaire
QOL SF-36: Quality of Life Short Form-36
VAS: Visual Analogue Scale
BPI: Brief Pain Inventory
HADS: The Hospital Anxiety and Depression Scale
STAI: Self-Evaluation Questionnaire for State Anxiety Inventory
* P<0.05

the intervention, were used to answer questions and provide reassurance for patients.

The trial by Shuldham et al. (2002) involved a more comprehensive intervention than any of the other trials. The intervention was given in the form of a day of education by trained multidisciplinary health care professionals prior to admission for surgery. This one day education programme provided information on coronary artery disease, hospital stay, medical care, and rehabilitation. It was informal, with questions and discussion encouraged, and family members were welcome to attend. Videos were used and a package of written information was given to each participant randomised to the intervention group. Also an optional visit to the wards and ICU was arranged. This preoperative intervention involved members of a number of health care professions (nurses, physiotherapists, and doctors). But a lack of evidence for a benefit from this form of preoperative education suggested that future research might use alternative methods such as CD-ROM or the internet.

In reports of various preoperative education interventions in the six trials, little attention was paid to the underlying theoretical basis of the intervention being tested. Two trials lacked detail about the 'normal' or 'usual' care given to patients (Arthur et al., 2000, McHugh et al., 2001). Even if the other trials included some description, control 'treatment' tended to be unmonitored so it is unclear how consistently it was delivered and whether its content changed during the trial.

3.8 Outcome measures

Each of the trials included in the review measured a variety of outcomes. Anxiety and depression, quality of life, patient satisfaction and length of

hospital stay were the most common. The majority of outcome measures heavily relied on self-report by the participants in the trials. Various measurement tools were utilised including generic or cardiac disease specific questionnaires.

Although some of the included trials focused more on psychological outcomes, others were interested in the efficacy of preoperative education on making changes to patients' lifestyle and modifying risk factors of heart disease before or after cardiac surgery and whether or not preoperative education might contribute effectively to postoperative recovery by increasing patients' knowledge about physiotherapy, exercises and deep breathing. Table 3.5 summarises the data on the outcomes of these trials into four categories: psychological, physiological, length of stay, and other outcomes.

3.8.1 Psychological outcomes

Of the trials included in the review, five of them measured anxiety except one (Watt-Watson et al., 2004) which focused on pain related outcomes. Individual trials have produced varied findings. Both Sørlie et al. (2007) and McHugh et al. (2001) showed a significant effect of preoperative education on anxiety whereas three trials did not demonstrate difference in anxiety scores between the invention and control groups (Arthur et al., 2000, Shuldham et al., 2002, Goodman et al., 2008). Caution should be applied when comparing results across trials as different tools were used. In three trials using the Hospital Anxiety and Depression scale (HADs) (Shuldham et al., 2002, Goodman et al., 2008, McHugh et al., 2001), only McHugh et al.'s trial reported a significant reduction in anxiety levels in patients receiving the intervention. Arthur et al. used the Self-Evaluation

Questionnaire for State Anxiety Inventory (STAI) and Sørlie et al. used Beck Anxiety Inventory (BAI) to measure anxiety.

Table 3.5 Outcomes of preoperative education interventions among cardiac patients

Studies / Outcomes	Arthur et al. (2000) n=249	Shuldham et al. (2002) n=356	Goodman et al. (2008) n=188	Sørlie et al. (2007) n=109	McHugh et al. (2001) n=98	Watt-Watson et al. (2004) n=406
Psychological						
Anxiety	=	=	=	↓	↓	
Depression		=	=	↓	↓	
Pain		=				=
Quality of life	=		=		↑	
Patient satisfaction					↑	↑
Physiological						
Modifiable risk factors					↓	
Blood pressure			=		↓	
Total cholesterol			=			
Recoveries & postoperative hypertension			=			
Exercise performance	=					
Length of stay						
Hospital stay	↓	↑	=			=
ICU stay	↓					
Postoperative stay	↓			=		
Other						
Costs			↓			
Use of services &social support	=					

=: No difference between two groups
↓: Significant decrease with intervention group
↑: Significant increase with intervention group

Four trials measured depression, of which three used the HADs (Shuldham et al., 2002, Goodman et al., 2008, McHugh et al., 2001). Of these only McHugh et al. found a positive effect of preoperative education on

symptoms of depression. Although McHugh et al.'s trial did show positive results in depression for the intervention group, the trial had a small sample size (n=98), compared to the other two with relatively large samples (n=356 and n=188). One trial by Sørlie et al. (2007) used the Zung self-rating scale as the measurement tool for depression and reported that patients who received the intervention had significantly reduced depression levels at six months and two years, but no differences were found between groups at discharge.

Pain was measured in two trials (Watt-Watson et al., 2004, Shuldham et al., 2002), of which neither demonstrated a significant difference between the two groups. Watt-Watson et al. randomly assigned 406 CABG patients to a 'standard care' or 'standard care plus pain booklet' group in order to test the effectiveness of a preadmission education intervention designed to reduce pain and related activity interference after CABG surgery. Results showed no evidence of a clinically significant improvement for the intervention group in pain management outcomes in terms of postoperative pain, pain-related interference, and analgesic use.

Quality of life was measured in three trials (Goodman et al., 2008, McHugh et al., 2001, Arthur et al., 2000) using the SF-36 questionnaire, a generic tool. Goodman et al. not only used the SF-36 but also a cardiac specific quality of life measurement tool, the Coronary Revascularisation Outcome Questionnaire (CROQ). There was no evidence of an effect of the intervention on quality of life scores as measured by both the SF-36 and CROQ, except for a statistically borderline improvement on the physical composite summary score of the SF-36 for those allocated in the intervention group. Similarly, Arthur et al.'s trial also found that patients in the intervention group showed statistically borderline improvement on the

SF-36 physical composite summary score, but no evidence of an effect of the intervention on mental composite summary score of the SF-36. However, McHugh et al. found that compared with patients who received usual care, those in the intervention group had a greater improvement in general health status scores across all eight domains of the SF-36.

Two trials examined the effect of preoperative education on patient satisfaction (McHugh et al., 2001, Watt-Watson et al., 2004). McHugh et al. reported that patients were satisfied with the service, which improved information about CABG and was supportive in making lifestyle changes and helped reduce anxiety for themselves and their family. Also in Watt-Watson et al.'s trial, patients were very satisfied with their overall care and health care providers' responses to their reports of pain. The booklet was rated as helpful, particularly by female trial participants.

3.8.2 Physiological outcomes

Three of the six trials included the effect of preoperative education on measures of physiological outcomes. Only one trial (McHugh et al., 2001) found that a nurse led preoperative intervention had a positive effect on modifiable risk factors. Specifically, the intervention participants were more likely to stop smoking and to reduce obesity and blood pressure. By contrast, in the other two trials, no evidence was demonstrated of the effect of the intervention on physiological outcomes such as blood pressure, total cholesterol, and physical recovery (Arthur et al., 2000, Goodman et al., 2008).

3.8.3 Length of stay

Five of the six trials included length of stay outcomes with the exception of McHugh et al. (2001). Arthur et al. (2000) found that patients in the

intervention group spent less time in ICU, and one less day in overall hospital stay and postoperative hospital stay than their counterparts in the control group. Goodman et al. (2008) and Watt-Watson et al. (2004) failed to detect a difference in the median length of hospital stay between groups. Sørlie et al. (2007) found no differences in mean length of postoperative stay between groups. Nevertheless, Shuldham et al. (2002) showed that there was a significant difference in length of hospital stay with the intervention group having the longer stay. They considered that the possible factors that might have led to one day longer stay in the intervention group were the severity of heart disease, length of time on cardiopulmonary bypass, number of grafts and intraoperative blood loss.

3.8.4 Other outcomes

Out of the six trials, only one trial (Goodman et al., 2008) conducted cost minimisation analysis and showed that the total costs were less in the intervention group due to fewer readmissions. Arthur et al. (2000) examined utilisation of health services and social support but found that the two groups did not differ. However, although not statistically signficant, more patients in the intervention group chose to participate in postoperative cardiac rehabilitation and the intervention group reported more support six months after surgery.

There is no clear and consistent pattern with regard to the outcomes of the six trials reviewed. One study did not show any effect of the preoperative education intervention on any of the measured outcomes, namely patients' anxiety, depression, pain and wellbeing. Further it reported that there was a significant difference in the length of hospital stay favouring the control participants although this result was not explicable and represented less than one extra day in the intervention group compared to the mean nine

days seen in the control group (Shuldham et al., 2002). All other trials reported the positive effects of preoperative education on one or more outcomes.

3.9 The use of qualitative data within trials

Only one of the six trials included in the review (Goodman et al., 2008) reported the use of qualitative semi-structured interviews and focus groups to explore patients' and nurses' perspectives of the nurse-led education and support intervention for patients awaiting coronary artery bypass surgery in London (Goodman et al., 2009). The trial failed to show that the intervention could affect anxiety and depression, quality of life, length of hospital stay, risk factors or postoperative fitness but might have an effect on total costs through fewer readmissions in the intervention group. Their qualitative study aimed to add to the evaluation of the intervention by exploring the patients' experience of waiting for surgery while taking part in the trial as well as exploring staff views of both the intervention and the patients' descriptions of their experience.

In the qualitative study, a purposive sample of 19 patients was selected from both intervention and control groups to be interviewed three months after discharge with interview transcriptions read back to staff during focus groups. The staff discussed what they had learned from the patients' experience and their own experience of the intervention. The findings showed that the patients appreciated the physical preparation and psychological support for surgery from the nurses. However, the patients varied in their understanding of the intervention and their degree of motivation to improve their health. The staff reported varying in their approach to preparing patients for surgery. It was suggested that engaging patients fully with the intervention, tailoring information according to

individual needs, perceptions of staff competence in performing physical assessment, and giving medical advice or referring back to the medical team were important factors in how patients received the intervention. These findings suggest a need for staff to improve communication both between themselves and with their patients.

The data from the qualitative study provide insight into the process and context of the intervention while the trial itself focused on the outcomes of the intervention. Patients' spontaneous responses and original comments might be limited or missed by the use of structured quesionnaires in the trial. Qualitative data are often used to explore the subjective meanings behind survey responses and to develop quantitative measures and scales which are more sensitive to respondents' meanings and interpretations (Coyle and Williams, 2000). Some have suggested that evaluating the context and process of the intervention should be considered as equally important as the outcomes (Clarke, 2001, Warburton and Black, 2002).

Goodman et al.'s qualitative study exploring patients' own views, experiences or perceptions of the intervention implemented in the trial through face-to-face interviews generated ideas for the development of a qualitative evaluation in the present study. Recently, it has been increasingly recognised that combining qualitative and quantitative methods in health research can help understand more fully the world of research subjects and capitalise on the strengths of different methods (Coyle and Williams, 2000, Sale et al., 2002). Additionally, the issues addressed in this qualitative study recommended several areas important to explore for future research with cardiac surgery patients from different cultural backgrounds, such as patients' attitudes towards their health, understanding of healthcare services, views on information provision, and

patients' experience of taking part in a trial. They served as the basis for fomulating the questions discussed during the interviews in the present study.

3.10 Gaps and application of existing evidence

There is evidence that preoperative education interventions can lead to positive postoperative outcomes for surgical patients in general, but less is known about their effectiveness for patients undergoing cardiac surgery. A review of randomised controlled trials published between 2000 and 2011 was conducted in order to analyse the existing evidence concerning the effect of preoperative education among cardiac surgery patients. A total of six randomised controlled trials were identified. The preoperative education interventions in these trials were designed with a range of topic areas, duration and frequency to compare with usual care. Among various forms of preoperative education interventions designed for cardiac surgery patients, few attempts have been made to evaluate the effectiveness of verbal communication assisted with the use of written information.

The trials included in the review have produced conflicting findings about the effectiveness of preoperative education for patients undergoing cardiac surgery. Some trials have demonstrated the effects of preoperative education on improving physical (McHugh et al., 2001) and psychosocial recovery of cardiac patients (McHugh et al., 2001, Sørlie et al., 2007) while others found no evidence that patients' anxiety is reduced (Shuldham et al., 2002, Arthur et al., 2000, Goodman et al., 2008) or of any effect on pain (Shuldham et al., 2002, Watt-Watson et al., 2004) or hospital stay (Shuldham et al., 2002, Sørlie et al., 2007, Watt-Watson et al., 2004). Evidence of the effect of preoperative education among cardiac surgery patients is inconclusive.

Most studies are conducted in Western countries. To date, no evaluation of preoperative education interventions has been performed among Chinese cardiac patients. Evidence generated from these existing studies cannot be directly transferred to the Chinese context of healthcare delivery without a more critical and context specific investigation as cultural and social factors may influence patients' responses to such interventions (Cheung et al., 2003).

Evidence based practice can improve clinical decision making and quality of patient care and treatment through the integration of best research evidence with clinical expertise, patient preferences and resource considerations (DiCenso et al., 2005, Akobeng, 2005a, MacPhee and Pratt, 2005). Decisions that are based on scientific clinical research, patient and family preferences and clinical expertise instead of purely experiential knowledge and intuition are considered to increase effectiveness, to minimise the possibility of error and to standardise practice (Rashotte and Carnevale, 2004, Parahoo, 2006). Despite the fact that clinical expertise, patient preferences and specific contexts and situations have been incorporated in the definition of evidence based practice, it appears that best research evidence remains the core element of evidence based practice (Mantzoukas, 2008). In defining the validity of evidence, randomised controlled trials and systematic reviews of randomised controlled trials are in essence the corner stone or the gold standard for the evidence based practice movement (Walker, 2003, Rycroft-Malone, 2006, Berwick, 2005, Franks, 2004).

Given the conflicting results from the previous trials included in the review and the inappropriateness of direct application of the existing evidence to a

Chinese context, there is a definite need for conducting well-designed trials at Chinese hospitals to provide an evidence base of whether or not newly developed preoperative education interventions are effective in reducing anxiety and improving recovery among Chinese cardiac surgery patients. In addition, the review has shown a lack of qualitative evaluation of cardiac preoperative education interventions.

CHAPTER FOUR

THE CONTEXT OF CARDIAC PREOPERATIVE EDUCATION IN CHINA

4.1 Introduction

The aim of this chapter is to provide the context, in particular that of the delivery of preoperative education in China, within which this study has taken place. The literature relating to patient education in Europe shows that patient education seems to be mainly influenced by the characteristics of the health care system (Albada et al., 2007, Visser et al., 2001). Therefore this chapter starts with presenting an overview of the Chinese healthcare system. This chapter moves on to describe how preoperative education for cardiac surgery patients is delivered in Chinese hospitals. Finally, the aim and objectives of the study are stated.

4.2 Healthcare in China

In the 1990s, China shifted away from the communist-model of free healthcare system to a more capitalistic, entrepreneurial era and put most of the financial burden to households and hospitals (Gao, 2005). Currently, revenue from the sale of medicine is closely linked to the income of hospitals and often the salaries of health care providers. Doctors therefore have a financial incentive to prescribe medicines. Consequently, some essential medicines, which are always affordable like penicillin antibiotics to treat the basic healthcare needs of the population, have become replaced by newer generation of cephalosporins due to low profitability of the former drugs.

In the Chinese healthcare system, the increasing cost of medicines and the limited availability of some essential medicines are preventing some people from seeking medical help (Yang et al., 2010, Chen et al., 2010). The Chinese Ministry of Health (Ministry of Health, 2004) conducted the third

National Health Service survey in 2003 and found that 48.9% of respondents had not seen a doctor and 29.6% reported not being admitted to hospital due to cost concerns. It is apparent that more than 500 million Chinese will continue to find medical treatment out of their reach due to its high cost (Ministry of Health, 2004). In response to this situation, the Minister of Health - Gao Qiang (2005) pointed out that "The gap between the need for healthcare services and the capabilities of current Chinese health insurance and delivery system is still immense…Development of the healthcare sector should depend on the government as well as the market…".

The Government is committed to increase healthcare spending and to implement health reform in order to provide affordable, efficient, and high-quality healthcare for hundreds of millions of Chinese, especially in rural areas. Healthcare expenditures have been increasing in China, but still remain low when compared to developed countries and even some other developing countries. For instance, in 2009 China spent 4.6% of its gross domestic product (GDP) on health with a total per capita expenditure on health of about $309, compared with the UK's 9.3% of GDP with total health expenditure of $3,399 per capita in the same year (World Health Organisation, 2011b). China having the largest population in the world (over 1.3 billion) has a low total per capita healthcare spend.

Various forms of health insurance have been introduced to widen coverage of health insurance in China such as Urban Employee Basic Health Insurance Scheme (BHIS), New Rural Cooperative Medical System (NRCMS), commercial and non-commercial forms of insurance. By the end of 2004, BHIS covered more than 124 million people including employees and retirees, and 34.1% of the employed population in the urban areas.

But vulnerable groups such as women, people on low income, employees with short-term contracts, and rural-urban migrant workers may be left out (Xu et al., 2007). The Chinese government initiated the NRCMS in 2003 aiming to reduce the financial burden on rural residents, which is a government run, voluntary participation, community-based, and cost-sharing medical insurance program (Shi et al., 2010, Dib et al., 2008). Shi et al. concluded that the coverage of NRCMS was high but it was not adequate to improve access to in-patient care and protect against financial catastrophe and household impoverishment due to health payment, especially for the poor and the chronically ill. Although to some extent these health insurance schemes can enhance the access to and use of health services, it is estimated that over half of healthcare costs in China are paid by consumers' out-of-pocket, which prevents people from seeking medical care (Yuanli, 2002, Gao et al., 2001)

In China, the Ministry of Health (MOH) is responsible for making healthcare laws, regulations and policies, adjusting the distribution of resources, and enacting standards for professions as well as medical service quality. Local Health Bureaus of provincial governments, city governments, and county governments play an important role in the delivery and management of medical services belonging to their own region. Broadly speaking, the Chinese medical service system is complex and can be classified into the following four kinds: outpatient clinics, community health centres, hospitals and other (Ministry of Health, 2009, Technomic Asia, 2011).

There were nearly 289,000 medical facilities in China in 2008, of which 19,700 (7%) were hospitals (Figure 4.1), 25% were community health centres, 66% outpatient clinics, and 2% other services. The latter included the health and anti-epidemic stations under the leadership of the Ministry

of Health or Health Bureaus of local governments at provincial, city, or county level as well as small sized medical stations. Community health centres can perform limited diagnosis or testing while clinics provide basic outpatient services. Hospitals provide a wide range of medical services and include general hospitals, Chinese traditional medicine hospitals, and specialist hospitals (e.g., maternity and child hospitals, cardiac surgery hospitals, eye hospitals, or cancer hospitals) at provincial, city, or county level (MOH, 2009, Technomic Asia, 2011).

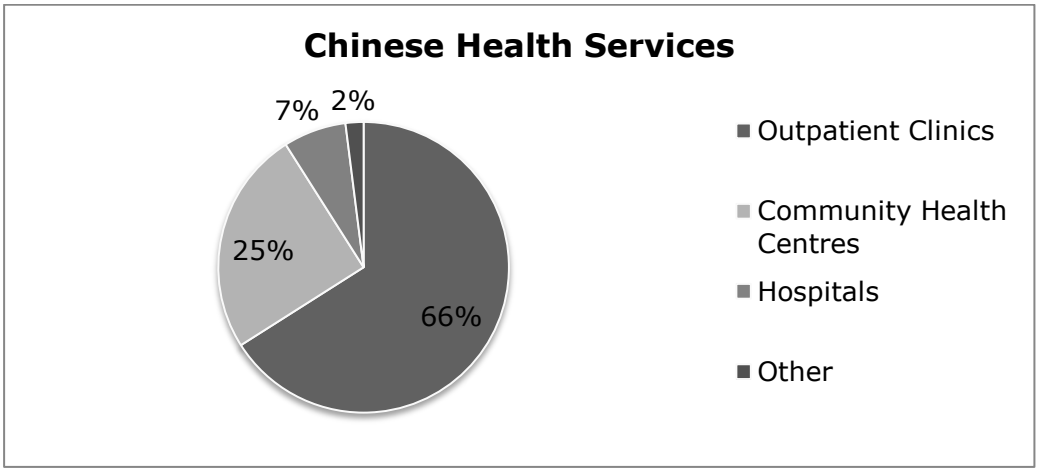


Figure 4.1 Chinese health services

More than 90% of Chinese hospitals are government owned or socially owned non-profit hospitals such as military hospitals, hospitals funded by ministries, and university hospitals. Less than 10% of medical services are privately owned or foreign invested health facilities (Ministry of Health, 2009). Those private profit medical centres and foreign hospitals play a supplemental role and are guided by different policies (Liu, 2005). Their target patient group is people from overseas or wealthy Chinese people. The structures and quality of care between these medical services vary greatly across the country due to different administrative management according to their locations, grades and ownership.

4.3 The patients' journey from admission to discharge when undergoing cardiac surgery

With the rapid increase of cardiovascular disease in China, the Chinese Government and Ministries of Health need to take national action to increase financial resources for prevention and management of cardiovascular disease and support the education and training of healthcare providers in health promotion and risk reduction. Apart from disease prevention, it is estimated that over 8 million Chinese are in need of cardiac surgery with over 74,000 cardiac operations taking place in Chinese hospitals each year (Pezzella, 2006, Zhang and Chen, 2007).

In order to explore how the usual preoperative education is practiced at the cardiac surgical wards of the two study hospitals, it is important to have a broad understanding of what processes people need to go through in China after their heart problems occur. The journey a patient undergoing cardiac surgery will typically face in China is different from that of many western countries due to different health care systems. In China, individuals are not registered with a general practitioner and there is little in the way of appointment systems in Chinese hospitals. If people feel sick or have chest pain, they will directly go to the outpatient department in the nearest hospital where a nurse is responsible for deciding which specialist at the outpatient department is appropriate for onward referral according to their presenting symptoms.

After consulting with the specialist on the same day, the heart problems might be identified and then possible treatment options would be suggested. If the complex or serious heart problems could not be treated in the local hospital, the specialist would refer them to other hospitals. If the

specialist considers that the patient needs to be hospitalised for further observation or surgical procedures, the patient will be advised to directly contact the cardiac ward in the inpatient department and arrange the hospital admission as soon as possible. The outpatient service normally ends at this point when patients decide whether they go ahead with the specialist's advice or not. The majority of patients visit the ward and talk with the doctor on the ward before being admitted.

The admission process to Chinese hospitals is as quick and efficient as possible and can take place on the same day of the initial consultation. As patients have a choice as to which hospital they will receive treatment from, they may wish to visit other hospitals at this point. Generally speaking, the date and time of admission mainly depends on the availability of the ward beds, patients' requirements and preference as well as the doctor's recommendation. Emergency admissions normally come through the emergency department and allow for little planning, with a swift admission process and prompt in-patient assessment and treatment. The doctor at the emergency department will inform the relevant ward in order that preparations can be made and the appropriate tests can be organised for the patient's arrival.

Almost 75% of cardiac surgery patients have had some related consultations and basic examinations from other hospitals before they are admitted to the First Affiliated Hospital of Henan University of Science and Technology and Luoyang Central Hospital which constitute the research setting for the present study (First Affiliated Hospital of Henan University of Science and Technology Records, 2009, Luoyang Central Hospital, 2009). The journey taken by cardiac surgery patients from hospital admission to discharge at the two study hospitals is illustrated in Figure 4.2. After

admission, the patient will be directed by the staff at the main reception of the hospital to the cardiac surgery ward area if he or she is unfamiliar with the hospital. Once arriving at the ward, a nurse will meet and greet the patient and take them to their allocated bed. An introduction to the ward layout, its facilities and routine will be explained by a nurse.

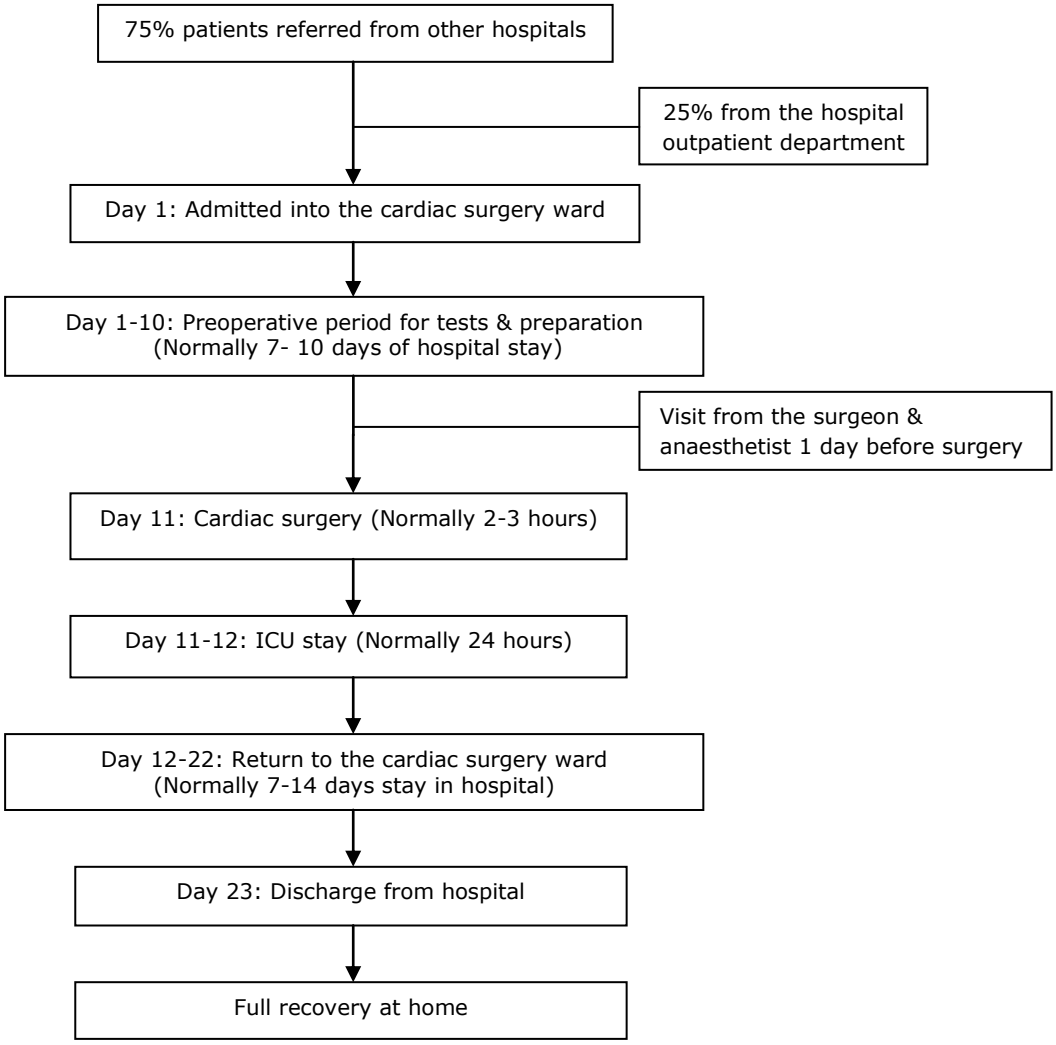


Figure 4.2 Typical journey of a cardiac surgery patient from hospital admission to discharge

Each cardiac surgery ward accommodates about 60 patients. There is a doctor available at all times and five to six nurses on duty in the daytime and one nurse during the night. The duty doctor is in charge of all patients and present on the ward. That is the first person for nurses and patients to

contact when needed. In addition, a routine morning meeting provides the chance for all of the doctors and nurses to discuss each patient's condition, treatment and care. All patients, and where appropriate their relatives and friends, are involved in the care process from the moment they are admitted to the hospital. They are informed to contact nurses at the nursing station whenever they want.

The patient may choose their own doctor. Otherwise the duty doctor on admission will be allocated to him or her. The patient's doctor will be informed of the patient's arrival on the ward as soon as possible, to allow for prompt assessment, clinical examination and the ordering of any relevant tests. All patients usually undergo cardio-coloured ultrasound and if necessary, cardiac catheterisation, Computerised Tomography (CT), or Magnetic Resonance Imaging (MRI). If the need for cardiac surgery is indicated after these tests and examination, the doctor then discusses the surgical procedures with the patient and their family and schedules a surgery date with the operation theatre. The patient's doctor may not necessarily be the chief surgeon. The chief surgeon can be nominated by the patient's doctor or the patient. At the two study hospitals, it typically takes around seven to ten days between the date of hospital admission and surgery. Patients are required to stay in the hospital during this preoperative period in order for them to be closely observed and prepared for cardiac surgery. This potentially increases the risk of raised anxiety during this extended preoperative period.

Once the surgery date is confirmed by the operation theatre, the surgeon and anaesthetist will separately visit the patient one day before surgery. These visits allow them to have a final assessment of the patient, inform the patient about the surgery, discuss any questions the patient and family

members have, and obtain consent. At the two study hospitals, cardiac surgery is normally performed in the morning, so skin and bowel preparation will be made by the nurse the night before surgery. After that, the nurse reminds the patient of the need for fasting for at least six to eight hours before surgery.

After two or three hours of surgery, the patient will be transferred to the Intensive Care Unit and stay normally 24 hours in the ICU before they can return to the cardiac surgery ward. The doctor and nurses on the ward continue to monitor the patient and help the patient to recover from surgery until the doctor is satisfied with progress and the patient is discharged. The majority of patients are discharged between seven and fourteen days after surgery. Patients are reminded to return for regular assessments if necessary, for instance monitoring and guidance of medication dosages. Apart from that, the two study hospitals do not provide cardiac rehabilitation programmes and subsequent care after hospital discharge for their patients. After discharge from the hospital, patients are left very much to their own care at home or are referred to the local hospitals or outpatient clinics for wound care.

4.4 Preoperative education for cardiac patients at study hospitals

4.4.1 Information needs and lack of communication

With the improvement in health care in China, meeting the individual patient's needs and delivering patient centred care is recognised as important aspects of nursing practice. A descriptive study of the information needs of 83 Hong Kong Chinese patients undergoing surgery emphasises that although there are social and cultural differences between Chinese and western countries and different traditions regarding the delivery of information and education, patients' desire and needs for

information about surgery was fairly consistent (Henderson and Chien, 2004). Preoperative education providing preoperative information and emotional support for Chinese cardiac surgery patients can help them become more aware of what is going on in their overall treatment and care. It can minimise physical, psychological and social factors that impact on an individual and prepare them for surgery and postoperative recovery (Liou et al., 2008).

Although the need for patient education prior to cardiac surgery is clear, there are no current guidelines from Chinese national health organisations regarding preoperative information needs for this group of patients. This leads to more difficulties for health care providers to deliver preoperative education for their patients at Chinese hospitals. Contemporary health care in many western countries aims to reinforce the rights of patients to information about their condition and treatment through the establishment of the Patients' Charters and other guidelines (Schmidt, 2007). Compared with the United Kingdom, the United States, and other European countries, the culture of healthcare delivery does not prioritise the provision of preoperative education for patients in China. A lack of communication and interaction between health care providers and patients in Chinese hospitals is of key concern (Henderson and Chien, 2004).

My experience of working in the cardiac surgery ward at the First Affiliated Hospital of Henan University of Science and Technology has indicated that many cardiac surgery patients tend to be poorly informed about their condition and surgery process prior to surgery. Patients undergoing cardiac surgery are often fearful, anxious and feel stress during their preoperative period, and require preoperative information and emotional support. Many patients have impoverished financial conditions and in comparison to the

way cardiac surgical patients are managed in countries such as the UK, a relatively long preoperative hospital stay may create new stressors and add to their worries about existing disease and surgery. Preoperative education is under developed in cardiac surgical care at Chinese hospitals. Cardiac nurses have an important role in providing preoperative information, advice and guidance to reduce patients' anxiety and fears about surgery. How to deliver preoperative information for their patients undergoing cardiac surgery is a great challenge for nurses. The actual preoperative information giving in current practice is usually given responsively, with relatively little interaction between patients and cardiac nurses, and information rarely supported by written information. It is not uncommon that patients increasingly become anxious.

4.4.2 Cardiac preoperative education in nursing practice

Usually cardiac nurses at the two Chinese study hospitals do not provide complete preoperative information for their patients. They place a low priority on providing preoperative information compared to other clinical duties, especially when faced with issues of time availability and heavy workloads. Although patients normally stay more than one week in the hospital before cardiac surgery, there is limited time for nurses to spend with each patient on carrying out teaching activities due to the nursing shortage in both hospitals. Limited time has been identified as the main impediment to patient education in previous studies (Turner et al., 1999, Tse and So, 2008, Marcum et al., 2002). Tse and So (2008) conducted a descriptive cross-sectional study in 2005 to examine 91 nurses' perceptions of the importance of preoperative education for ambulatory surgical patients in two public hospitals in Hong Kong. They found that 65.9% of the nurses said that they did not often tell patients everything needed to

know and 81.7% ranked time availability as the most influential factor affecting the amount of information provided to patients.

Although it is acknowledged that Hong Kong appears to be within a largely western health care system, the mostly Chinese population creates a strong traditional Chinese identity. The findings from Tse and So's study in Hong Kong (2008) shed light on current practice in the provision of preoperative education at Chinese hospitals and the factors that affect nurses' provision of such teaching. In their study, approximately 60% of the nurses thought that doctors were responsible for giving preoperative information to patients. At two study hospitals, routinely the surgeon and anaesthetist separately visit the patient before cardiac surgery. Nurses may be uncertain about the contents of preoperative information that have already been given or will be given by doctors, surgeons and anaesthetists. Often they may assume that patients have already received sufficient information from other health care providers if they do not ask. Thus cardiac nurses tend not to give further information to patients unless they raise questions and there is relatively little interaction between cardiac nurses and patients. Turner et al.'s study of registered nurses' perceptions of teaching (1999) also found that nurses had difficulties in embracing the role of patient educator and they often expressed confusion over their responsibility for delivering education to patients.

The preoperative information given at present is often based on what the health care providers feel the patients need and want to know rather than exploring the patients' perspective on what their information needs are for the preoperative period. Evidence from Mordiffi et al.'s study (2003) of information provided versus information needed by surgical patients and two case studies of current preoperative teaching practice in a surgical

ward in Hong Kong (Lee and Lee, 2000, Lee and Chien, 2002) suggest a lack of congruence between nurses' perceptions of patients' preoperative needs and actual need. At two study hospitals, it is also recognised that the preoperative information routinely given may not address individual patients' needs. A gap may exist between what surgical patients want to know of their condition or treatment and what their doctors or nurses think they should know, as health care providers tend to underestimate patients' desire for information (Keulers et al., 2008). Thus health care providers should not assume patients' information needs have been met and patients' perspective of preoperative education and information needs should be explored (Goodman et al., 2009, Ivarsson et al., 2007, Attree, 2001).

4.4.3 Preoperative teaching resources and interventions

The cardiac surgery wards of two study hospitals have limited teaching resources to assist health care providers for preoperative education. The resources available include wall posters and heart models to help doctors to explain the function of heart and the risks and effects of cardiac surgery, but there are no leaflets, booklets or videos explaining what to expect once patients are admitted to the hospital and how to prepare for surgery. Verbal communication is the most common method and perhaps is the only way for nurses to deliver information to their patients in current practice. A study interviewing twelve experienced surgical nurses about how the usual preoperative education is practised at one particular hospital in Ireland (Fitzpatrick and Hyde, 2005) revealed that the use of teaching tools depends on their availability and the practice of individual nurses. In line with the findings reported by Tse and So (2008), 91% of the nurses preferred to use face-to-face oral explanations as a method of information delivery and seldom used other teaching methods, suggesting that limited

teaching resources may have affected the amount of information delivery and hence the quality of care.

Verbal communication combined with other teaching resources such as written materials or videos can assist Chinese cardiac surgery patients in understanding the surgical preparation, postoperative care in hospital and subsequent post-discharge care. In a study by Liou et al. (2008), 91 adult patients preparing for coronary artery bypass grafting surgery in Taiwan were randomly allocated to a video-tape viewing group or to a teaching booklet group. Each form of preoperative education was followed by an oral explanation of respiratory and leg exercises, pain management, and early ambulation. The study demonstrated that preoperative instruction with video-tape was similarly effective as teaching booklets on patients' perceived stress, perceived helpfulness and recovery.

There is a need to increase health care providers' motivation to develop cardiac specific teaching resources and try structured preoperative education interventions through the use of these resources for cardiac patients at Chinese hospitals. It is essential that health care providers can demonstrate evidence about the effectiveness of these newly developed resources or interventions through rigorous research in order to identify the best way of providing preoperative education in improving quality of care.

In summary, patients undergoing cardiac surgery are often fearful, anxious and under stress during their preoperative period, and desire preoperative information. However, under the unique characteristics of health care system and health services in China, the culture of healthcare delivery does not prioritise the provision of preoperative education for patients. The

actual preoperative information giving in current practice is limited, with relatively little interaction between patients and cardiac nurses, and information rarely supported by written information. To improve the quality of preoperative education for Chinese cardiac patients in nursing practice, the development and evaluation of new cardiac specific teaching resources and interventions is called for.

4.5 Research aim and objectives

This study aimed to evaluate the effects of a preoperative education intervention designed for Chinese cardiac surgery patients on anxiety and recovery. More specifically, the objectives of the study were

(1) to determine whether provision of a preoperative education intervention comprising an information leaflet and verbal advice could reduce anxiety among Chinese patients undergoing cardiac surgery.

(2) to assess whether this form of preoperative education could reduce symptoms of depression, decrease perceived pain, and shorten the length of ICU and postoperative hospital stay.

(3) to explore patients' perceptions of and attitudes towards preoperative education and experiences of participating in the study.

CHAPTER FIVE

METHODS

5.1 Introduction

This chapter describes the methods of the Cardiac Preoperative Education Intervention Study. This was a randomised controlled trial to test the effectiveness of a preoperative education intervention (comprising an information leaflet and verbal advice) in reducing anxiety and improving postoperative recovery among Chinese patients undergoing cardiac surgery at two public hospitals in Luoyang, China. Qualitative interviews were also conducted to explore patients' attitudes towards preoperative education and experiences of taking part in the trial.

The following sections describe the study design and report the eligibility criteria for entry into the trial, the process of identifying, recruiting and consenting participants and recording baseline measures. The process of randomisation and the components of the intervention are described, and the follow-up process to endpoint of the trial is explained. The qualitative evaluation is described including the access to, and sampling of participants, the methods of interview data collection and data analysis are provided. The last section of this chapter discusses the ethical considerations made in connection to the design and implementation of the study.

5.2 Study design

A randomised controlled trial was considered to be the most appropriate way to evaluate the effectiveness of a new intervention. This Cardiac Preoperative Education Intervention Study was a two-centre randomised controlled trial. In this trial, participants in each centre were individually randomised to one of two 'parallel' groups. Randomisation is the most

robust method of preventing selection bias, and adjusting for known confounders such as age, sex, and stage of disease, as well as unknown confounding factors. The two groups were treated and observed identically apart from the intervention received, so that any differences detected in outcomes might be explained only by the intervention (Akobeng, 2005b). The aim of the trial was to compare usual care alone with usual care plus a preoperative education intervention comprising an information leaflet and verbal advice among Chinese patients undergoing cardiac surgery. More specifically, the objectives of this trial were to determine whether providing this form of preoperative education to cardiac surgery patients reduces anxiety, depression, pain, and accelerates postoperative recovery.

Randomised controlled trials are considered to represent the 'gold standard' or the most valid evidence on the effectiveness of interventions or treatments (Mantzoukas, 2008, Benton and Craib, 2001). This is achieved by applying strict methodological rules of objectivity and control of contextual variables such as objective observation and precise measurement (Weaver and Olson, 2006). The findings generated by properly conducted randomised controlled trials are likely to be closer to the true effect than the findings from other research methods (Evans, 2003, Craig and Smyth, 2002).

In a positivist world view, there should be strong associations between paradigm, methodology and methods, consequently such a view considers different methodologies and methods as incompatible and their combination logically impossible (Bazeley, 2004). However, randomised controlled trials cannot explain the complexity of daily practice and provide answers on why and how interventions work by understanding individual patient perceptions and experiences of specific interventions (Rolfe and

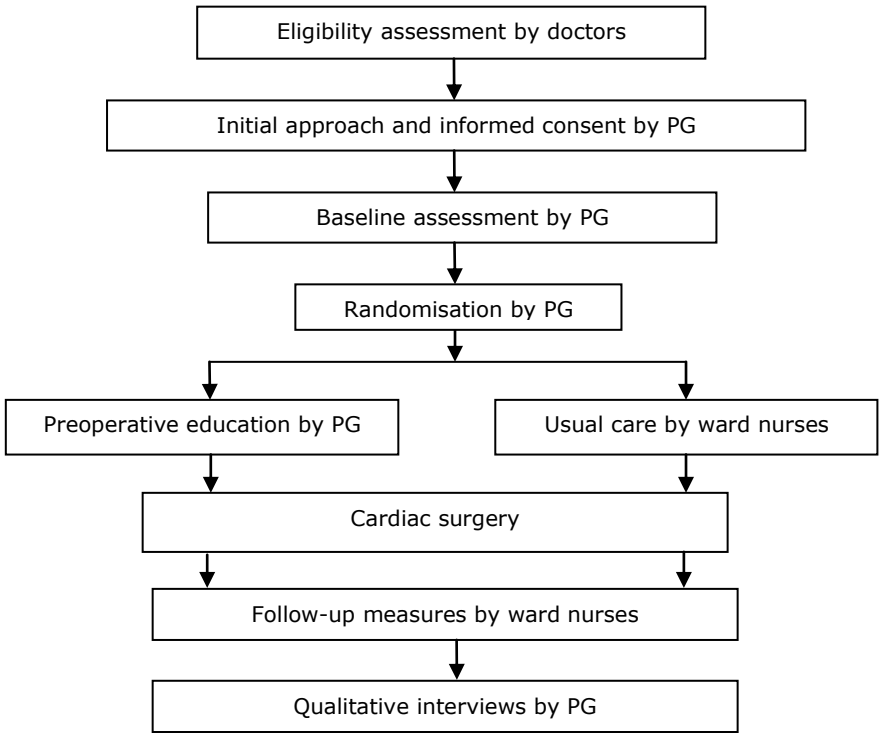
Gardner, 2006). The reality of practice appears to be much closer to the interpretive or constructive and postmodern paradigms which focus on meaning and understanding the phenomenon and at the same time acknowledge the influences of the researcher and the research process and context on the subject being studied (De Simone, 2006, Coyle and Williams, 2000).

While the trial investigated the outcomes affected by the intervention, a qualitative evaluation was included to probe deeper to make sense of findings generated by the quantitative data. The evaluation explored patients' views on preoperative education, emotional responses to heart disease and surgery, and experiences of taking part in the trial through interviews. It is emphasised that philosophically the qualitative and quantitative paradigms are not as diverse or mutually incompatible as often conveyed (Clark, 1998, Gillies, 2002, Burnard and Hannigan, 2000). Each method may have placed a different emphasis on the relative merits of the different approaches but quantitative and qualitative methodologies study different phenomena and encourage or allow expression of different facets of knowledge. If one takes this view then both can be combined in a single study for seeking complementarity which is considered both philosophically and practically sound (Sale et al., 2002, Fraenkel and Wallen, 2006, Burnard and Hannigan, 2000).

From a pragmatist's point of view, the diversity of truths is reachable through different forms of inquiry and a plurality of methods (Bryman, 2001, McCready, 2010). The inability to definitively exclude one approach from another has implications for the acceptability of mixing qualitative and quantitative research methods, although paradigmatic debates continue to exist (Bazeley, 2004, Johnson and Onwuegbuzie, 2004). As Burnard and

Hannigan (2000) suggested, perhaps the debate should not be about the primacy of one research method over another but that methods are chosen according to the questions addressed.

Combining qualitative and quantitative methods is often considered to be in an attempt to serve the dual purpose of generalisation and in-depth understanding – to gain an overview of social realities (Bazeley, 2004). Having adopted a pragmatic approach, the design of the Cardiac Preoperative Education Intervention Study is illustrated in Figure 5.1.



PG: Ping Guo

Figure 5.1 The design of the cardiac preoperative education intervention study

5.3 Settings

The study took place in the cardiac surgical wards of two public hospitals in my home city Luoyang, Henan province, China: the First Affiliated Hospital of Henan University of Science and Technology and Luoyang Central Hospital. Both hospitals are tertiary health care and urban teaching

hospitals with 1200 beds each. At each hospital approximately 300 cardiac surgical procedures are performed each year. I obtained access to each hospital by initially telephoning the hospital manager and director of nursing as a preliminary notification to explain about the overall research project and then emailing them to state the research aim and objectives, proposed methods and potential contribution from the research.

China is one of the world's largest countries with 9.6 million square kilometres and a population of about 1.37 billion in 2010. Henan province is located in eastern central China, on the plain between the Yellow and Huaihe rivers and includes 18 cities (Figure 5.2). It covers an area of 167,000 square kilometres and is similar to the size of England, Wales, and Northern Ireland together. According to Henan government statistics (2009), Henan has the largest population of the 22 Chinese provinces. At the end of 2007 its total population stood at 98.69 million (the population of the UK was estimated to be 60.98 million in July of 2007 according to National Statistics).

Henan is the 5th largest provincial economy of China and the largest among inland provinces in 2009 with its nominal GDP of about 2.29 trillion RMB (US$339 billion), although it ranks nineteen in terms of GDP per capita of the 22 Chinese provinces (Wikipedia, 2011). In relation to public health, at the end of 2005, there were a total of 14,536 medical and healthcare centres equipped with 212,000 beds and staffed with 287,000 medical professionals and technicians in Henan province. In addition, there were 184 centres for disease control and prevention, staffed with 14,000 professionals and technicians (Henan Government, 2009).

Luoyang, where the study setting is located, is the second largest city in Henan province, with a population of 6.46 million at the end of 2006. It covers 15,208 square kilometres and is slightly bigger than Northern Ireland. Luoyang borders the provincial capital of Zhengzhou to the east and administers six districts of Luoyang city, one county-level city and eight counties (Figure 5.3). Luoyang is one of the Eight Great Ancient Capitals of China, having more than three thousand years history. It is a major industrial city in China and also plays an important role in history, culture, and scientific knowledge (Luoyang Government, 2009). The two study hospitals are located close to the city centre and provide comprehensive health care services mainly for the residents of Luoyang.

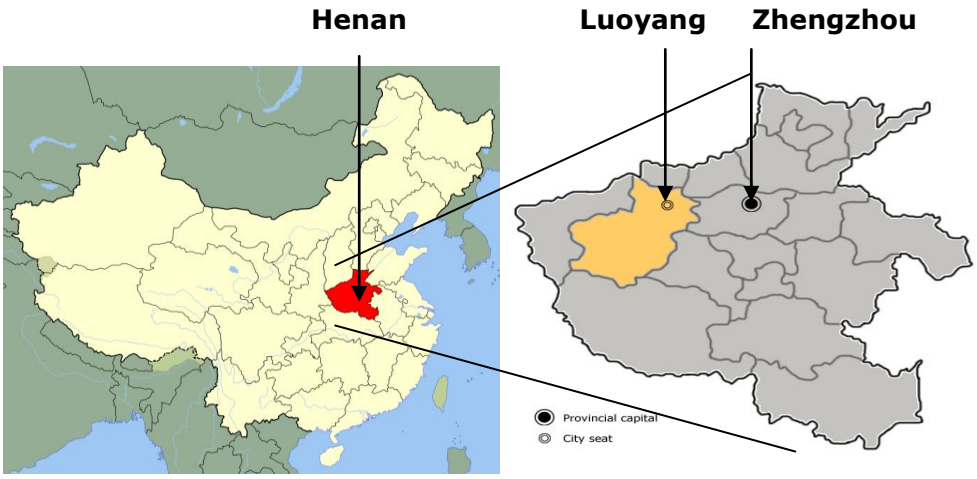


Figure 5.2 Locations of Henan province and Luoyang

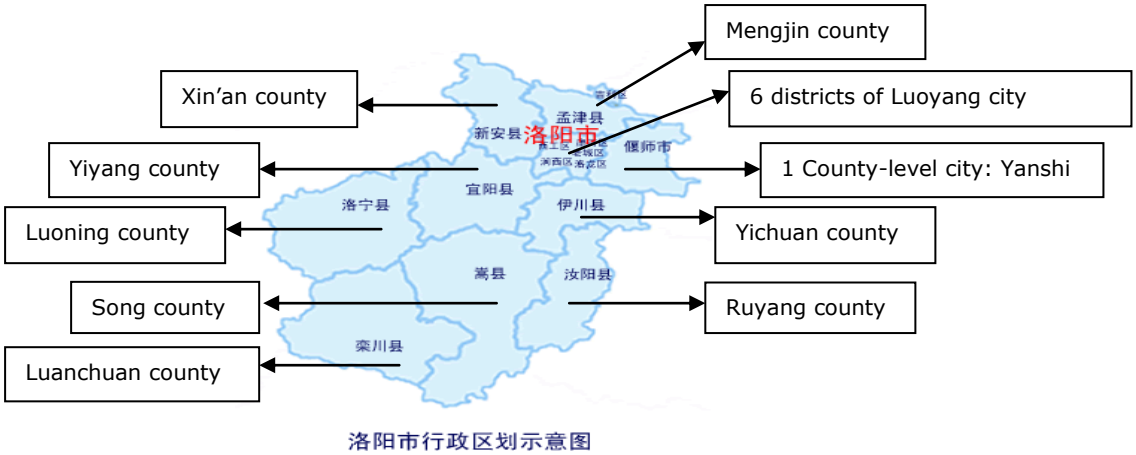


Figure 5.3 Administration map of Luoyang

5.4 Participants

5.4.1 Inclusion criteria

All adult patients (18 years old or above) undergoing any type of elective cardiac surgery were eligible for the trial if they were able to speak, read, and write Chinese. For the purposes of the trial, 'cardiac surgery' was defined as including coronary artery bypass grafting, valve surgery, congenital and other open heart surgery. Heart transplants are not performed at the two hospitals where the study took place. Patients who fell into the category of emergency cases and those who had undergone cardiac surgery on a previous occasion were excluded from the study.

5.4.2 Initial approach and informed consent

Typically, patients who require cardiac surgery are admitted seven days prior to the surgery to facilitate nursing and medical assessments, tests, and preparations. Patients eligible to participate in this trial were identified by the duty doctor responsible for providing diagnostic assessment. I contacted potentially eligible patients to confirm whether or not they met the inclusion criteria and then invited them to participate in the trial typically on the second or third day following hospital admission.

During this initial approach, I distributed an information sheet (Appendix 1) to the patient and the study was explained verbally in order to ensure that the patient received and understood the salient information at this point. Each patient was explicitly advised that inclusion in the study would not alter their treatment or duration of preoperative hospital stay, and that if they decided to participate they could freely withdraw from the study at any time.

Following the explanation of the purpose of the study and process of study involvement, patients were asked if they would consent to participate. I then asked those patients willing to take part in the study to sign a written consent (Appendix 2). Patients were not asked to give consent in the initial approach as it was considered important to make sure that patients had enough time to read the information sheet, think about participation, and discuss it with their family members or friends if they wish.

5.5 Baseline assessment

Once written consent was obtained, I carried out baseline assessments. The contents of the baseline assessment included patient socio-demographics, presence or absence of co-morbidities, type of surgery, previous hospitalisation, blood pressure, heart rate, anxiety, depression, and pain (Table 5.1). Firstly I conducted a face-to-face interview with each participant to obtain the participant's characteristics. The participant was then asked to self-complete the HADS and BPI questionnaires to avoid interviewer bias. An envelope was provided for the participant to return the questionnaires, thereby ensuring privacy and confidentiality. In this trial, the questionnaires were distributed by hand to reduce cost and improve the response rate.

Table 5.1 Contents of baseline assessment

Contents	Questionnaires	Number of items	Mode of completion	Completed by
Patient characteristics	Demographic information Clinical information Physical assessment	6 4 5	Face to face interview Face to face interview Medical records	PG
Anxiety & depression	HADS: Anxiety subscale Depression subscale	 7 7	Self-completed	Participant
Perceived pain	BPI: Pain severity subscale Pain interference subscale	 4 7	Self-completed	Participant

PG: Ping Guo

5.5.1 Patient characteristics

Participants' characteristics (Appendix 3) were gathered by asking a list of questions involving socio-demographic information (such as age, gender, marital and living status, education level, employment) and clinical information (such as type of surgery, co-morbidities, and any previous hospitalisation or operation history). In addition, the participant's physical assessment at admission including systolic blood pressure, diastolic blood pressure, heart rate, height, and weight was obtained by reviewing the individual medical records.

5.5.2 Anxiety and depression

Anxiety and depression was measured by using the Hospital Anxiety and Depression Scale (HADS), a self-reported instrument developed by Zigmond and Snaith. It was initially validated against formal psychiatric interviews in hospital out-patients (Zigmond and Snaith, 1983). HADS consists of 14 questions, seven relating to anxiety (anxiety subscale) and seven to depression (depression subscale). Each question has four response categories, with a possible score of 0-3, and the HADS produces scores on each subscale ranging from 0 to 21, with higher scores indicating a greater degree of anxiety and depression (Appendix 4).

The HADS has been found to be a reliable and valid instrument in previous studies, not only for detecting states of anxiety and depression in the setting of a hospital medical out-patients clinic but also for detecting and managing patients' emotional problems in medical and surgical departments (Shuldham et al., 1995, Snaith, 2003, Zigmond and Snaith, 1983). In addition, the HADS has been validated for use in native Chinese patients in general hospitals. The Chinese-Cantonese version of it was found to have good internal consistency and external validity, with

favourable sensitivity and specificity for screening for psychiatric disorders (Leung et al., 1999, Lam et al., 1995).

5.5.3 Pain

Perceived pain was measured with the Brief Pain Inventory-short form (BPI-sf) (Cleeland, 1989). It is a 11-item questionnaire that consists of a pain severity subscale to rate pain severity in four domains (worst, least, average and right now) and a pain interference subscale to measure the perceived degree to which pain interferes with daily activities in seven functional domains (general activity, mood, walking ability, work, relations with others, sleep, enjoyment of life) (Appendix 5). Each item is rated with a 10cm visual analogue scale, where '0' indicates 'none' and '10' indicates 'worst imaginable'. Patients were asked to rate their pain by circling the one number that best describes pain at its worst and least in the past 24 hours as well as on the average and right now, and to circle the one number that describes how, during the past 24 hours, pain has interfered with for example, their general activity.

The BPI-sf has been used to quantify the burden of painful diabetic peripheral neuropathy in previous studies in the USA (Gore et al., 2005, Zelman et al., 2005b, Zelman et al., 2005a) and in Asia, Latin America, and the Middle East (Hoffman et al., 2009). The Chinese version of the BPI-sf is a reliable and valid measure of pain among patients with cancer (Ger et al., 1999, Wang et al., 1996). The intraclass correlation coefficient for the test-retest reliability was 0.79 for the pain severity subscale and 0.81 for the pain interference subscale. The coefficient alpha for the internal reliability was 0.81 for the pain severity subscale and 0.89 for the pain interference subscale (Ger et al., 1999).

5.6 Randomisation and blinding

After baseline assessment, participants were randomly allocated to one of the two arms of the trial, usual care or usual care plus preoperative education. Allocation was determined by a stratified block randomisation, with random block size and stratified by the two study hospitals. To ensure there was distance between the preparation of the randomisation list and the actual random assignment of participants, the randomisation list was generated by my supervisor (AA) who had no contact with study participants. Stratified block randomisation was used to assign participants to either preoperative education group or usual care group. The two strata were the First Affiliated Hospital of Henan University of Science and Technology and Luoyang Central Hospital. The 'ralloc' command in Stata version 9.2 was used to assign randomly allocated treatments in block sizes of 2, 4, 6, 8 and 10. The size of each block was determined randomly and in unequal proportions to elements of Pascal's triangle (1:4:6:4:1). This prevented too great an imbalance in the number of participants allocated to each arm and avoided the risk of being able to predict the allocation in advance (Pocock, 1983).

Randomisation was implemented using a series of consecutively numbered, opaque, sealed envelopes. Each envelope contained a study number and the arm of the trial to which the participant was to be allocated. The envelope was opened in the presence of the participant after baseline assessment was completed. Participants had an equal chance of being randomised into the preoperative education or the usual care arm of the trial. Following the assignment to study group, it was explained to the participant in greater detail what would be expected of them.

It was not possible for participants to be blind to their allocation. The baseline data were collected by me who was also aware of each individual allocation. However, taking baseline measures prior to randomisation and having no role in determining the patients' readiness for discharge from the ICU or from the hospital would reduce my potential bias. The surgeons and nurses involved in the care of the patients who participated and therefore able to influence outcomes were not made aware of the group the participant had been randomly assigned to. However it was possible that the participant may have brought it up in conversation that she or he had been given the preoperative education intervention. In order to minimise this influence, participants in the preoperative education group were asked not to inform clinical staff about their allocation during the trial.

5.7 Interventions

5.7.1 Usual care

Both study hospitals are teaching hospitals and care provided in the two cardiac surgical wards was similar. All participants in the trial received usual care. It consisted of two separate visits from the surgeon and anaesthetist one day before surgery. These visits constituted the main opportunity whereby patients and family members could gain information related to the general process and risks of their surgery and anaesthesia, the use of analgesia and/or pain management. During these visits, the surgeon and anaesthetist would respond to specific concerns of the patient or their family and obtain informed consent for the proposed surgery and general anaesthesia. Additional information was available from the ward-based cardiac nurses though this tended to be responsive rather than proactive. No written materials were available for patients' use, nor were there any guidelines for nurses to standardise the information given to patients.

5.7.2 Preoperative education

For patients randomly allocated to the preoperative education intervention group, I delivered the preoperative education intervention. This intervention took place in a quiet area on the ward where patients were unlikely to be disturbed following randomisation (at least two to three days before surgery). It comprised an information leaflet 'Your Heart Surgery' written in Chinese (Appendix 6) together with approximately 15 to 20 minutes of verbal advice.

Creating written preoperative education materials for cardiac surgery patients, like other aspect of nursing work, should be guided by evidence. I designed this leaflet specifically for Chinese cardiac pre-surgical patients, their family and friends after reviewing previous literature around patient information leaflet development (Walsh and Shaw, 2000, Dixon-Woods, 2001, Mancunian Health Promotion Specialist Service, 1997). Ivnik and Jett (2008) suggest the basic principles which are an adequate staring point in the process of developing a new leaflet or handbook such as considering who needs to be involved (collaboration), why is the leaflet needed (purpose), what messages need to be conveyed (content), and how will it look (design).

The final version was reviewed using a leaflet evaluation checklist by ten representatives of Chinese cardiac surgery patients and five clinical experts regarding its content, technical characteristics and practicability (Appendix 7 and 8). These patients and experts thought that the leaflet was suitable for Chinese patients undergoing cardiac surgery and it covered useful and relevant information that patients would want to know. In particular, all ten cardiac patient representatives found that the style of language was

appropriate and the words used in the leaflet could be easily understood. Some patients suggested that a little red heart symbol could be used at the beginning of every paragraph to make the leaflet easy to read and more attractive, and that more content was needed relating to recovery at home. According to their feedback, the leaflet was then edited before use within the trial.

The leaflet was in the form of a double-sided A4 page, formatted so that it could be gate-folded into three to allow ease of use and printed in colour. Illustrations were used to improve clarity and understanding. The contents of the leaflet included pertinent procedural, sensory temporal and instructional information throughout the patients' journey from the preoperative phase until discharge (St. Mary's General Hospital Regional Cardiac Care Centre, 2003, Johnston and Charboneau, 2000, Margereson and Riley, 2003). It was divided into several short sections under the headings: preoperative tests and preparation; the stay in the Intensive Care Unit (ICU) after surgery; returning to the cardiac surgical ward; and recovery at home. The leaflet also provided a contact number to call for further help after discharge from hospital if required. It was designed to be short, simple, and suitable for application by clinical staff (Huebler, 2007).

The exact timing for the delivery of the intervention was arranged so that family members and friends could be present if desired by the patient. The intervention began with me welcoming the participant and (where present) family members, and giving them the information leaflet. The participant was given time to browse the leaflet. Then each section of the leaflet was explained in turn, practical advice was offered and any questions the participant had were discussed. The components of the preoperative education intervention are summarised in Table 5.2.

Table 5.2 Components of the preoperative education intervention

Discussion of topics	Information covered
Introduction	Welcome the participant and their family members. Distribute the leaflet and allow a few minutes to read it through. Start to talk through the sections of the leaflet.
Patients' journey (Diagram)	Explain the process from admission, preoperative care, operation time, postoperative recovery, discharge, and full recovery after discharge.
Preoperative preparation (Diagram)	Demonstrate preoperative procedure including a) Blood and urine analysis, chest X-ray, and electrocardiography; b) Visit from the surgeon and anaesthetist; c) Preparations a night before the surgery (gastrointestinal tract & skin); d) Preparations in the morning of the surgery (removing jewelry or prostheses, donning a hospital gown, and giving medications); e) Transporting to operation room, administration of anesthesia.
Postoperative expectation	Introduce ICU environment and explain about a) Uncomfortable feelings; b) Equipment used such as cardiac monitors, different catheters, chest tubes, and ventilator; c) Communications with clinical staff within patients' limitations; d) Advice regarding pain management and early mobilization, diet, deep breathing, coughing and leg exercises; e) Discharge, rehabilitation and medication after discharge, lifestyle change, and general check-up; f) Contact details.
Further advice	Answer any queries about the information provided. Encourage to reread the leaflet afterwards and to ask for clarification or seek further information about any of the content of the leaflet when necessary. Remind the participant to put the leaflet back in the envelope after use and not to pass it to others. Inform the follow-up measure will be taken on the postoperative 7th day.
Concluding remarks	Thanks for attending. Express best wishes for the forthcoming surgery.

The design of the intervention administered in the trial was underpinned by adult learning theory. It was underpinned by the following elements: (1) supplementing usual care with written information; (2) structured oral preoperative education using the leaflet as a way of facilitating this; (3) explaining the process of being hospitalised at the cardiac surgery unit and preparation for the operation; (4) discussing uncomfortable feelings likely to occur after the operation; (5) encouraging the expression of feelings and concerns the participant deemed important and answering questions; and (6) developing a trusting relationship and mutual respect during the process of the preoperative education intervention.

Adult learning theory refers to a collection of several concepts and theories that explain how adults learn such as social (cognitive) learning theory, transformational learning theory and self-directed learning theory. Adult learning has been considered as a process that adults engage in, which results in a relatively long-term change in the domains of attitude, knowledge, and behaviour (Smith, 2002a, Yannacci et al., 2006, Yang, 2004). Based on adult learning theory, the intention of the intervention was to reduce patients' anxiety and improve recovery, and enhance patients' self-regulation and capacity for cooperation with healthcare providers through active involvement in their own health management and care.

In order to minimise possible contamination between the two arms of the trial, a copy of the leaflet was put into an envelope for the participant to take away. Each participant was asked not to share it with other patients on the ward. The features of usual care and preoperative education intervention are described in Table 5.3. It provided a clear comparison between usual care and preoperative education regarding the general description, form, key content, use of written materials, mode and timing of delivery (Smith et al., 2010, Glasziou et al., 2010).

Table 5.3 The features of usual care and preoperative education

Element	Usual care	Preoperative education
General description	Unstructured verbal information only	Leaflet based advice, explanation and discussion
Form	Two separate visits from the surgeon and anaesthetist Responsive information from the cardiac nurses on the ward	Distribution of an information leaflet 'Your Heart Surgery' and provision of 15-20 minute verbal advice
Key content	General information about the surgery and anaesthesia	Specifically tailored procedural and instructional information throughout cardiac surgery patients' journey from admission, preoperative tests and preparation, postoperative ICU and ward stages, till recovery after discharge from hospital.
Use of written materials	None	The information leaflet with simple texts and diagrams handy for quick reference
Mode of delivery	Different staff members	Specialist cardiac nurse
Timing	One day before surgery	At least two to three days before surgery

5.8 Outcome measures

Three commonly used outcomes for evaluating the effectiveness of preoperative education interventions among cardiac patients were consistently used in the trials reviewed (Goodman et al., 2008, McHugh et al., 2001, Shuldham et al., 2002, Sørlie et al., 2007, Arthur et al., 2000, Watt-Watson et al., 2004). They included (1) psychological distress measured by medication use and/or stated anxiety levels; (2) postoperative pain measured by analgesic use and/or pain-rating scales; and (3) the rate of recovery measured by the length of stay and/or rate of postoperative complications. However, the findings were conflicting. Therefore these outcomes were re-examined in the present trial.

Follow-up measures were assessed on the seventh day after surgery by a cardiac nurse who was blinded to group assignment. The primary outcome was change in anxiety as measured by the anxiety subscale of the HADS between baseline and follow-up. As the intervention was designed to

decrease psychological stress for cardiac surgery patients through the form of preoperative education, anxiety as a measure of psychological health became the main focus of the trial. The secondary outcomes were change in symptoms of depression measured using the depression subscale of the HADS, change in pain as measured by the BPI-sf, length of ICU stay and postoperative hospital stay. A range of secondary outcome measures were chosen in recognition of the complex nature of the preoperative education intervention. Follow-up measures consisted of issuing the same questionnaires of HADS and BPI-sf to the participants from both arms of the trial seven days after open cardiac surgery (the endpoint of the trial). Data gathering on this occasion was undertaken by a nurse who was blinded to group assignment, as my physical presence may have affected responses from the participant.

The time point of the seventh postoperative day was chosen since determining whether the preoperative education intervention had any ongoing effectiveness was considered to be more important than assessing the effects of the intervention immediately after its completion. In addition, this allowed patients to have recovered sufficiently from surgery to be able to concentrate on the questionnaires and for the experience to be fresh in their mind. In cases where the participant was still in the intensive care unit at seven days after surgery then these questionnaires were given three days after transfer to the ward. For participants who were discharged without surgery, had care transferred, or died prior to their follow-up measures, then the date of leaving from the ward or the date of death was treated as the endpoint.

Data for the length of Intensive Care Unit (ICU) stay and postoperative hospital stay were obtained from the individual medical records at

discharge. The ICU stay was the actual number of hours the participant spent in the Intensive Care Unit and postoperative hospital stay was calculated from the day of surgery until hospital discharge. Because the disparity in the length of wait for operation in hospital varied largely, postoperative hospital stay was considered more accurate and appropriate to show the speed of recovery.

5.9 Sample size and statistical analysis

5.9.1 Sample size

A power calculation was based on the primary outcome of anxiety score on the HADS. Other studies (Arnold et al., 2009) have demonstrated that a difference of two points on the HADS anxiety score between trial arms constitutes a clinically meaningful change in anxiety. Assuming a standard deviation of four points as observed in previous studies (Arnold et al., 2009), it was calculated that 63 participants were needed in each arm to have 80% power at a significance level of 0.05. Therefore it was planned to recruit a total of 148 participants in order to allow for a 15% attrition rate.

5.9.2 Data management

Data from the trial were entered into an Access database and checked, blind to the participant's group. Firstly, each questionnaire was examined for missing responses. The HADS produced one overall summative score for anxiety and another for depression, while the BPI-sf comprised of a series of domains that did not produce one overall summative score and are presented separately.

It is acknowledged that multiple testing, where a set, or family, of statistical inferences is considered simultaneously, can create problems of artificially increasing the chance of a significant finding (type I error). In

order to prevent this from happening, an a priori approach was taken for the analysis of the pain outcome. It involved analysing six selected domains on the BPI-sf which were identified to be most relevant (average pain and current pain on pain severity subscale, and general activity, mood, walking ability, and sleep on pain interference subscale).

5.9.3 Data analysis

Analyses were carried out blind, with the groups known as 'arm 1' and 'arm 2'. The use of a strict intention to treat analysis is impossible in cases of missing data such as loss to follow-up (Abraha and Montedori, 2010). All participants who completed follow-up were analysed as part of the group to which they were randomised and those lost to follow-up were excluded from analyses.

Descriptive statistics were used to summarise baseline characteristics including demographic and clinical information including age, gender, marital status, employment status, education level, and type of surgery (Rugg, 2007). Categorical variables are presented using frequencies and proportions, and continuous variables using means and standard deviations (SD). Independent-samples t-tests were used for anxiety, depression, pain outcomes, and non-parametric Mann-Whitney U tests for length of stay outcomes.

Linear regression models were used to compare anxiety, symptoms of depression, and pain scores between the two groups at follow-up after adjusting for baseline score, age, gender, education level, and surgery type. Taking anxiety (the primary outcome) as an example, a linear regression model was performed whereby anxiety score on the HADS at seven days after surgery was the dependent variable, and baseline anxiety score, age,

gender, education level, surgery type, and treatment group were used as independent covariates. These covariates were chosen a priori to avoid 'data dredging'.

Data were checked to ensure that they met the assumptions required for linear regression analysis. Both adjusted and unadjusted results are reported (Petrie and Sabin, 2000). All reported P values are two-tailed, with $P<0.05$ considered as significant. The analyses were performed using SPSS version 16 (Bryman and Cramer, 2005).

5.10 Qualitative evaluation

If the trial provided evidence of the effect of the cardiac preoperative education intervention on a range of health outcomes, it would be of limited value to know that the intervention was successful without knowing why and how this particular intervention 'worked'. The qualitative evaluation aimed to add a qualitative perspective to the trial by exploring patients' thoughts and feelings about preoperative information and education and their experience of taking part in the trial. It was hoped that through the qualitative evaluation, an in-depth understanding of the intervention might be obtained and factors potentially influencing intervention outcomes explored. As suggested, qualitative evaluations can help to understand 'why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised' (Craig et al., 2008).

In the Cardiac Preoperative Education Intervention Study, while the trial generated quantifiable data on the outcomes of the intervention, qualitative interviews were conducted to provide valuable insight into the content, process and context of the intervention implemented and enrich

understanding of patients' experience of taking part in the trial by listening to what patients said they desired, wanted and needed and drawing together descriptions of their experience of illness and treatment (Oakley et al., 2006, Gillies, 2002, Holloway and Wheeler, 2002). The qualitative evaluation was crucial for truly understanding the context and possible reasons for the outcomes of the intervention obtained from the trial and promoting evidence-based decision making about the improvement of practice in preoperative education in China.

It is recognised that qualitative research is able to capture the patient perspective of healthcare by insightful interpretations and to enable health care providers to understand how patients perceive health services (Bryman, 2001). As a result, qualitative approaches have been increasingly used in health care research to complement or expand the knowledge base of health care obtained from quantitative methods, to influence health policy at a local, national and international level, and to help to improve patient care (Warburton and Black, 2002). Philosophically, although there is the ongoing argument that qualitative and quantitative methodologies come from different philosophical backgrounds and researchers should stay within one paradigm, many researchers including nurses and doctors tend to take a more pragmatic view and carry out mixing research methods across paradigms (Miller and Fredericks, 2006, Johnson and Onwuegbuzie, 2004, Chatterji, 2004).

The existing literature has indicated a lack of knowledge concerning cardiac patients and their experience of preoperative education. In such circumstances, in-depth interviews were considered as an essential means of developing the knowledge base on a relatively unexplored phenomenon (Holloway and Wheeler, 2010). Specifically, the purpose of gathering data

by means of interview was to capture the thoughts and feelings of the participants, and to document in their words their health care experience. An inductive research approach was used to conduct semi-structured interviews with patients before discharge.

5.11 Interview participant selection

All trial participants consented to be interviewed as part of the qualitative evaluation. A purposive sample of 20 trial participants (ten from the preoperative education group and ten from the usual care group) were approached before discharge from hospital to arrange an individual interview. A purposive sampling approach was to ensure that interviewees were invited not only from both arms of the trial but also from both genders, different types of cardiac surgery, and a range of age groups (Green and Thorogood, 2004).

5.12 Qualitative data collection

I carried out the interviews in a quiet area either in the patient's room or an office on the cardiac surgical ward which was convenient for the participants (Hansen, 2006). Family members and friends were also invited to contribute to the interviews. There was no time limit for interviews, and the majority lasted between 40 and 60 minutes. The interviews were semi-structured. An interview schedule with open questions was developed to guide the conversation in each interview (Appendix 9). Questions asked during the interview were formulated based on a literature review of surgical patients' information needs, their perception of the provision of information and the effect of individualized information (Suhonen and Leino-Kilpi, 2006) and a qualitative study exploring cardiac patients' experiences of a nurse-led preoperative education intervention (Goodman

et al., 2009). A digital audio recorder was used during each interview with the participant's consent.

During each interview, the participant was asked to express their thoughts and opinions about information needs, how preoperative information was usually delivered and could be improved in future practice, and to talk through their feelings about the illness, surgery, the preoperative education intervention, and taking part in the trial. Examples of such questions included: Can you describe the first experience of your heart problem? Tell me how you felt at the time when you were told you needed cardiac surgery. How did you find the preoperative information you received before surgery? What did you expect when you decided to participate in the study? If participants had their own questions relating to their health or treatment, these were dealt with as appropriate at the end of the interview and referred where necessary to their chief doctor. As data from the first interviews were gathered, their content provided direction for subsequent interviews in keeping with an inductive approach.

5.13 Qualitative data analysis

All interviews were carried out in Chinese. The interviews were transcribed verbatim by me, and repeatedly listened to in order to check and confirm accuracy. The transcribed data were then coded and thematically analysed in QSR NVivo 8 with a focus on the content, process and context of the intervention and the experience of taking part in the trial (de Laine, 2000). Transcribing and analysing the data in Chinese occurred simultaneously as the data collection was proceeding. Due to time limitations, transcripts were not returned to participants for comment and/or correction.

Interviewees' accounts were categorised and compared enabling identification of the themes that were common in the dataset. When a list of themes and subthemes had evolved, this was examined for overlapping themes merged under one descriptive label and spurious themes containing few quotations. Then the transcripts were revisited to determine if analysis of that theme had been applied to all transcripts. If not, they were re-examined for that theme, with attention being paid to indicate contradictory accounts or unusual cases. Throughout this process, the data were consistently analysed in order to gain insight to relationships between themes. The findings were interpreted within the context of the existing literature.

Barbour (2001) argues that the question is no longer whether qualitative research methods are valuable but how rigour can be assured or enhanced. Checklists of qualitative research design and data analysis (Pope et al., 2000, Greenhalgh and Taylor, 1997) and consolidated criteria for reporting qualitative research (COREQ) (Tong et al., 2007) have been introduced in an attempt to improve the rigour of qualitative research. Green and Thorogood (2004) suggest a number of features of rigorous qualitative analysis, which include transparency, providing a clear account of the procedures used, the analysis of the whole dataset including deviant cases and disconfirming data, using more than one analyst, providing simple frequency counts of key themes, comparing findings to other studies, and accounting for the role of the researcher in the research.

All of the principles outlined above were applied to the analysis of this qualitative evaluation, with the exception of the use of more than one analyst. Due to resources and time limitations, it was not possible to have more than one analyst to independently code and analyse the data.

However, I translated seven written transcripts (one third of the interviews) from Chinese to English in full and the rest for relevant codes. These translated transcripts were reviewed by my supervisors and checks were made on the interpretation of data.

Reflecting on the translation, it was a challenging process as not only the literal meaning of the words used by participants needed translation but also the contextual information such as humorous use of words and phrases, sarcasm and use of metaphors (Green and Thorogood, 2009, Chen and Boore, 2010). Some concepts in one language may be understood differently in another (Jagosh and Boudreau, 2009) and metaphors vary from culture to culture (van Nes et al., 2010). For example, qi (气 in simplified Chinese) is the central underlying principle in traditional Chinese medicine and martial arts. 'Qi' could be literally translated as breath, air, or gas. 'Qi' could mean life energy or energy flow. When combining it with the Chinese word for blood (making 血气, xue-qi, blood and breath), the concept could be used to account for motivational characteristics. So it is difficult to find an equivalent word in English. In order to preserve the cultural meanings and nuances of the original, having a good understanding of Chinese culture and being able to find an equivalent in English were key concerns (Chen and Boore, 2010).

However, translation between languages might hinder the interpretation of meaning of participants' experience and result in loss of meaning of participants' actual words which decreases the overall rigor of the qualitative study (van Nes et al., 2010). Back-translation is translating from the target language (English) back to the original source language (Chinese) and the equivalence between two language versions can be

evaluated. It may be considered as the most common and rigorous procedure to validate the conceptual equivalence of the translation (Lopez et al., 2008). But the back-translation approach has been criticised by some for its basis in positivism such that 'research is language free and that the same meaning in the source language can be found in the target languages' (Larkin et al., 2007, p.469). Others argue that its focus on linguistic equivalence rather than conceptual equivalence can be problematic (Jagosh and Boudreau, 2009). Squires (2008) argues that back-translation does not necessarily enhance the trustworthiness of reported findings any more than an independently critical review by a bilingual competent individual.

Time and financial constraints prevented either back-translation or an independent review by a bilingual individual in this study. All translations were undertaken by me, which had the advantage of translation consistency and improved conceptual congruency. Maintaining conceptual equivalence of participant views was the most important consideration in the translation process, as the quality of translation can considerably affect data analysis and findings (Squires, 2009).

5.14 Being an 'insider'

The study was conducted in my home city and one of the study hospitals was the hospital where I am employed. This was advantageous in that the study setting was familiar to me both culturally and contextually. Importantly I was able to easily develop rapport with patients and gain their trust with the continuous help and support from my colleagues. Such an insider perspective gives an awareness of current issues in the organisation (DeLyser, 2001, Galea, 2009). However, insider research has its disadvantages. It was acknowledged that my previous knowledge and

personal experience of nursing within the organisation meant that 'taken for granted' assumptions could limit the ability to probe for deeper meaning or understanding of the phenomenon under study and might lead to some important issues overlooked in the interview data analysis (Asselin, 2003). Awareness of these advantages and disadvantages can, to some extent, help minimise the potential side effect of being an 'insider', better understand individual experiences within a specific context, and enhance the trustworthiness or credibility of the qualitative evaluation (van Heugten, 2004).

It was important that participants were able to describe their feelings from their own perspective in the context of their culture as well as their own characteristics and background. During each interview, I tried to make the participant feel more comfortable about our conversation and encouraged the participant to talk freely and openly to me about their feelings of preoperative education and experiences of participating in the study. However, participants knowing that this study was designed and conducted for my PhD work at a British university and becoming familiar with me could influence some participants' perceptions or expectations of me and my study. The majority of the participants valued the UK higher education system I was studying within and this allowed me to gain credibility with them. Eventually they considered me as their friend. As a result, participants' accounts may have been affected in a subtle way.

From my perspective, I viewed my prior knowledge and preconceived ideas about the study settings and friendship with the participants as an advantage rather than a disadvantage. Finding ways to use my 'insider' status to help but not hinder insights was a key concern. I have attempted to separate my own experiences and prior assumptions from the

description of participants' experience and perceptions in the process of data collection and subsequent analyses. I took account of the influence my connection with the culture and study settings has on the findings and reported and interpreted the findings in a transparent way.

5.15 Ethical considerations

Ethical approval for this study was granted by the First Affiliated Hospital of Henan University of Science and Technology Teaching and Research Ethics Committee and the Luoyang Central Hospital Research Ethics Committee (Appendix 10). The study was registered by Current Controlled Trials (ISRCTN87451169) in November 2009 before the recruitment began. As this Cardiac Preoperative Education Intervention Study involves patients, the following ethical issues were carefully considered in designing and conducting the study.

A starting point was the question of equipoise. The concept of equipoise has been represented as a central ethical principle of human experimentation and requires that a patient should be ethically enrolled into a randomised controlled trial only when there is substantial uncertainty about which of the trial arms would most likely benefit him or her (Fries and Krishnan, 2004, Ashcroft, 2004, Miller and Veatch, 2007). Djulbegovic et al. (2000) suggested that, in the context of randomised controlled trials, equipoise means that participants will not suffer relative harm from random assignment to a particular treatment arm.

In this study, the participants from both groups received the same usual care as delivered by ward staff. Apart from the intervention itself, those in the control group did not have any aspect of care withheld from them that was of known benefit. Although a body of work has demonstrated the

positive effects of preoperative education on anxiety and postoperative recovery in many types of elective surgery, there are contradictory views of the role of preoperative education among cardiac surgery patients. Equipoise is dependent on the existence of uncertainty about the relative value of two treatments being compared. If there were no uncertainty, then trials would be both unnecessary and unethical (Djulbegovic et al., 2000, Felson and Glantz, 2004). To this extent, equipoise did exist in this study as the previous trials reviewed have not been able to provide conclusive evidence that preoperative education is superior to the usual care among cardiac surgery patients.

Secondly, the study did not involve any invasive procedures in the technical sense, so the risk of harm is low. However, effort and commitment were required from the participants when benefits could not be guaranteed. A range of questions were asked in the qualitative interviews, some of which were quite personal and might trigger anxiety or distress (Richards and Schwartz, 2002), such as patients' experiences of disease and seeking medical help and their perceptions of information they received. Therefore it was essential to be careful not to coerce people to take part. In view of this, all eligible patients were fully informed through the information sheets and verbal explanation on the aims and methods of the study and procedures that might be involved. Participation was entirely voluntary. Even though participants had given written consent to take part, it was made clear that they were still free to withdraw from the research at any time without having to give a reason and without their medical care being affected in any way (Gregory, 2003).

Informed consent from study participants is fundamental in undertaking ethical health research (Taljaard et al., 2011, Iphofen, 2005). In this study,

significant challenges were experienced in ensuring practical requirements for informed consent to be met. These challenges were partly attributable to differences in the understanding of research concepts and processes between patients due to gaps in access to resources, literacy levels, and perceptions of health and illness and information needs. When orally explaining the aim and process of the study to each patient, these differences between patients were considered so that simple language combined with a patient attitude help ensure every patient fully understood the information conveyed.

Finally, in order to ensure that the participants did not receive too great a burden from the study, the intervention was kept simple and the questionnaires were short. In addition, confidentiality and anonymity were considered throughout the study from data collection and analysis to publication, and ensured by appropriate use and storage of data through a password protected database and by nondisclosure of personal identifiable information such as participants' name and address (Gregory, 2003, Oliver, 2003).

5.16 Summary

The study on which this thesis is based was a randomised controlled trial evaluating the effects of a preoperative education intervention on anxiety and postoperative recovery among Chinese cardiac patients. The preoperative education intervention was specially designed and implemented for cardiac surgery patients to potentially reduce their anxiety and improve postoperative outcomes. This intervention included the development of preoperative information in the format of a patient leaflet 'Your Heart Surgery'. The initial idea was that it would be useful to put together a page of information which the patients and their family could

refer to whenever they want and which could provide specific information for verbal advice.

Adult patients undergoing elective cardiac surgery were randomised to one of two arms of the trial. The preoperative education group received a 15-20 minute leaflet-based preoperative education intervention, while all participants received usual care. The primary outcome measure was change in anxiety score on the HADS. Secondary outcomes were change in depression score on the HADS, perceived pain measured by the BPI-sf, and length of ICU stay and postoperative hospital stay. Measurement occurred at baseline (on the second or third day after admission) and follow-up (on the seventh day after the operation).

A qualitative evaluation was also conducted to gain a deeper insight into the process and outcomes of the intervention. Interviews were followed with a sample of trial participants before hospital discharge to add a qualitative perspective to the evaluation by exploring patients' perceptions of preoperative education and their experience of taking part in the study. The results of the trial and qualitative interviews are reported separately in the next two chapters.

CHAPTER SIX

TRIAL RESULTS

6.1 Introduction

This chapter reports the results of the Cardiac Preoperative Education Intervention Trial. The recruitment and participant flow for the trial is described in the next section. The third section focuses on baseline characteristics of the two study groups. The fourth section looks at the period between randomisation and follow-up and reports on uptake and adherence of the interventions. The fifth section describes the follow-up of the participants at seven days after their surgery. Then the difference between groups in terms of primary, secondary and other outcomes is presented in the sixth, seventh, and eighth sections respectively.

6.2 Recruitment and participant flow

The period of recruitment for the trial was between 1st December 2009 and 17th March 2010. A total of 245 patients were admitted into the Cardiac Surgery Ward of the two study hospitals during this period, of which 89 (36.3%) were excluded on the basis of age (being less than 18 years, n=82), four because they were emergency cases and three patients excluded because they were undergoing cardiac surgery for the second time. Of the remaining 156 patients who were eligible, two decided not to participate and one decided to leave the hospital shortly after admission giving an uptake rate of 98.1%. The trial ended when 153 patients were recruited. Participant flow through the trial is illustrated in Figure 6.1.

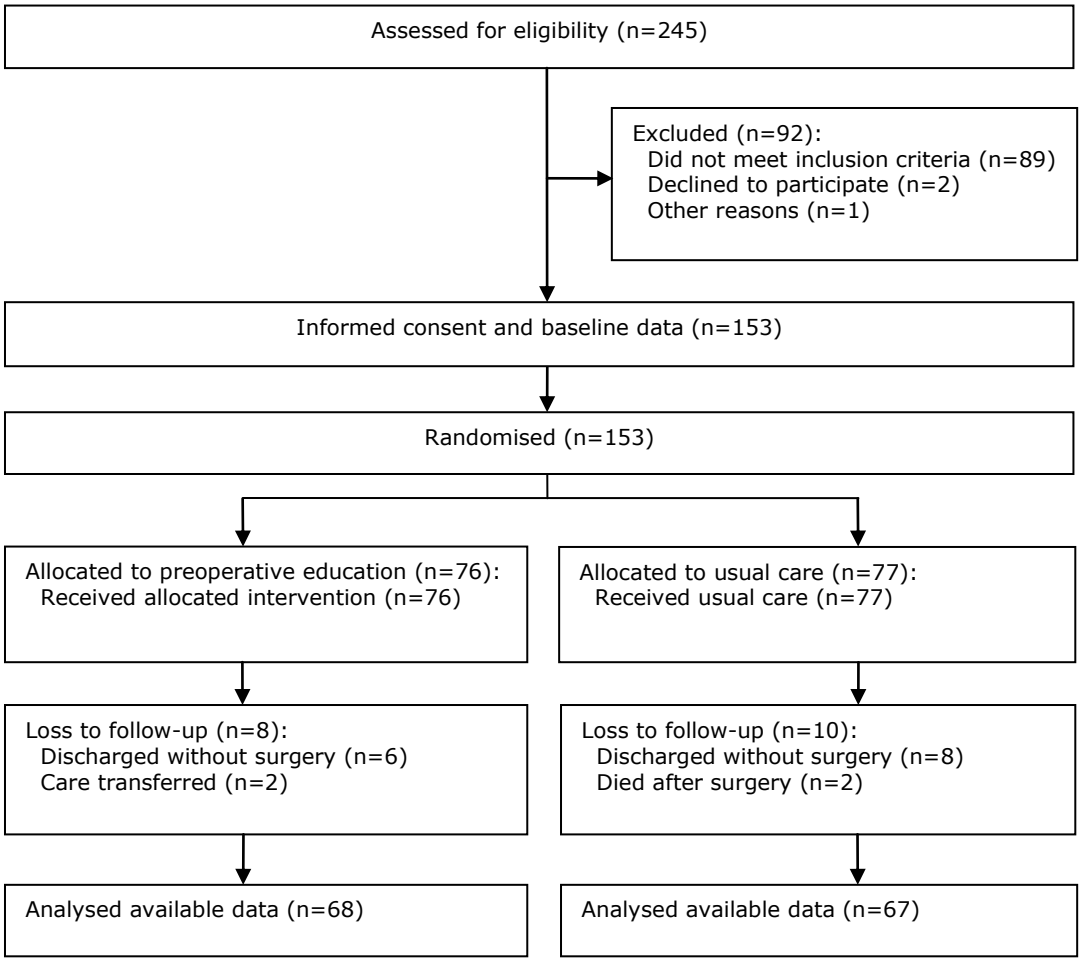


Figure 6.1 Flow diagram of the progress through the phases (enrolment, intervention allocation, follow-up and data analysis) of the trial of two groups

6.3 Baseline characteristics

Baseline data were collected from all 153 recruited participants before they were randomly allocated to either the usual care group (n=77) or preoperative education group (n=76). Table 6.1 presents a comparison of the two groups in terms of these demographic and clinical characteristics at baseline.

Table 6.1 Baseline characteristics of participants (n=153) randomised to the usual care or preoperative education group. Values are numbers (percentages) unless stated otherwise

Variables	Usual care (N=77)	Preoperative education (N=76)
Mean (SD) age in years	52.3 (15.99)	52.0 (16.12)
Gender		
Male	40 (51.9)	44 (57.9)
Female	37 (48.1)	32 (42.1)
Marital status		
Married	66 (85.7)	59 (77.6)
Widowed, separated, divorced	4 (5.2)	7 (9.2)
Single	7 (9.1)	10 (13.2)
Education		
≤9 years [a]	56 (72.7)	56 (73.7)
>9 years	21 (27.3)	20 (26.4)
Living alone	4 (5.2)	2 (2.6)
Employment status		
Employed	19 (24.7)	16 (21.1)
Unemployed	38 (49.4)	41 (53.9)
Retired	20 (26.0)	19 (25.0)
Type of surgery		
Coronary artery bypass grafting	33 (42.9)	37 (48.7)
Valve surgery	28 (36.4)	24 (31.6)
Congenital & others	16 (20.8)	15 (19.8)
Co-morbidities		
None	54 (70.1)	48 (63.2)
Hypertension	16 (20.8)	18 (23.7)
Diabetes	1 (1.3)	6 (7.9)
Others	6 (7.8)	4 (5.2)
Previous hospitalisation	6 (7.8)	9 (11.8)
Previous operations	6 (7.8)	9 (11.8)
Physical assessment mean (SD)		
Heart rate (beats/min)	76.3 (7.67)	78.9 (8.85)
Systolic pressure (mmHg)	116.8(14.15)	113.8 (11.78)
Diastolic pressure (mmHg)	72.1 (9.58)	71.0 (8.76)
Height (Cm)	165.2 (6.00)	165.4 (7.29)
Weight (Kg)	64.7 (12.51)	64.5 (13.04)
Anxiety and depression mean (SD)		
HADS anxiety subscale	7.3 (4.33)	6.0 (3.59)
HADS depression subscale	5.9 (4.35)	4.8 (3.17)
Pain measures mean (SD)		
BPI-sf pain severity items		
Average pain	1.1 (1.65)	0.8 (1.33)
Current pain	0.4 (1.00)	0.2 (0.66)
BPI-sf pain interference items		
General activity	1.6 (2.59)	1.3 (2.28)
Mood	1.8 (2.60)	1.6 (2.29)
Walking ability	2.3 (3.20)	2.1 (2.74)
Sleep	1.5 (2.72)	1.2 (2.38)

[a] Nine-years of compulsory education from elementary to junior high school.

There was no difference in the mean age of the two randomised groups (52.3 years for the usual care and 52.0 for the preoperative education) but slightly more men were allocated to the preoperative education group (44/76) than to the usual care group (40/77). Both groups were similar at baseline in terms of education level, marital, living and employment status, although the preoperative education group had a slightly higher proportion of coronary artery bypass grafting (37/76) than the usual care group (33/77) and more participants with diabetes were randomised to the preoperative education group (6/76 versus 1/77). There was no difference in previous hospitalisation, operation history or physical assessment (heart rate, blood pressure, height and weight) between the two groups.

However, the most important baseline difference between the two groups was mean anxiety and depression summary HADS scores. The mean HADS anxiety score was 1.3 points higher in the usual care group than in the preoperative education group (7.3 compared with 6.0). The mean HADS depression score was 1.1 points higher in the usual care group (5.9 compared with 4.8). This suggests there was a greater degree of anxiety and depression at baseline among the usual care group. Both groups had similar mean scores at baseline regarding all domains of pain severity subscale and pain interference subscale on the BPI-sf.

In summary, the two groups were broadly similar in terms of socio-demographic profile, the presence of co-morbidities, type of surgery, previous hospitalisation and operation history, physical attributes and pain, however those participants in the preoperative education group at the point of recruitment were slightly more likely to be male, be admitted for coronary artery bypass grafting, and have diabetes. There was a small difference between the groups in HADS score with the preoperative

education group appearing to be less anxious and with fewer depressive symptoms.

6.4 Uptake of and adherence to the interventions

The randomisation process took place as soon as baseline data were collected from each participant. The 153 randomised participants received usual preoperative care delivered by ward staff. All of the 76 participants randomised to the intervention arm of the trial received the preoperative education. As planned, the preoperative education occurred immediately after randomisation. Each session lasted only 15 to 20 minutes, which helped to ensure a 100% uptake rate of the intervention.

6.5 Follow-up

Out of the 153 participants, 135 (88.2%) in the trial were successfully followed up at seven days after surgery. There were a total of 18 losses to follow-up during the study period (eight from the preoperative education group and 10 from the usual care). Follow-up data were collected from 68 (89.5%) of those who had been allocated to the preoperative education group (n=76) and 67 (87.0%) of those who had been allocated to the usual care group (n=77).

The reasons for the 18 participants being lost to follow-up were various. Eight in the usual care group had to be withdrawn before undergoing cardiac surgery as half of those decided to leave the hospital without surgery due to unspecified reasons (perhaps financial or other family problems). The other half experienced an acute exacerbation of their illness so that doctors considered them unsuitable for surgery at that time. Two participants in the usual care group died after surgery when they were in the ICU and cause of death for both was recorded as acute cardiac failure.

The main reasons for drop-out in the intervention group were categorised in three ways: five were discharged without surgery due to unspecified reasons; one was considered not suitable for surgery; two participants' care was transferred to other hospitals before surgery.

Neither intervention nor usual care processes involved any invasive procedures in the technical sense and the risks and harms associated with them were low. Between the start of recruitment and the end of follow-up, no adverse events or side effects were noted for either group. Reasons for attrition did not appear to differ between those randomly allocated to the preoperative education group and those randomly allocated to the usual care group. Of the 135 who completed the trial, complete data were available for all outcomes with 100% item response for outcome scales.

6.6 Primary outcome - anxiety

The main outcome measure for the trial was change in HADS anxiety score between baseline and follow-up. As described in the previous chapter, the modified intention to treat was carried out not only for analysis of the primary outcome but also secondary and other outcomes. It involved analysing all participants as originally allocated except the 18 cases of unavailable data at follow-up of seven days after surgery. Their drop-out or withdrawal at some point in the trial (through leaving before surgery, death or care transfer) meant they were not assessed at follow-up. Finally 135 participants (preoperative education group n=68; usual care group n=67) were included in the analyses.

There was some imbalance in the two groups at baseline as reported earlier in this chapter. This was addressed by conducting prespecified adjusted analysis in which a linear regression model was used to control for

some baseline variables (HADS anxiety score at baseline, age, sex, education level, and types of surgery). An association between the preoperative education and clinical outcomes could be confounded by baseline score and participants' characteristics such as age, sex, education level and types of surgery. All of these potential confounding factors were taken into account. Both unadjusted and adjusted analyses are reported in Table 6.2 and a comparison of the two groups is described here.

Both groups had reduced anxiety scores at follow-up, but those randomised to the preoperative education group had a mean decrease in anxiety score of 3.5 points (Standard Deviation=4.50) between baseline and follow-up. By contrast, the mean change among the participants in the usual care group was a reduction of 0.7 points (SD=4.95). Figure 6.2 presents the distribution of change in anxiety scores by two groups. This comparison of the two groups was statistically significant and those in the preoperative education group experienced a more significant decrease in anxiety than those in the control group (mean difference -2.7; 95% Confidence Interval -4.35 to -1.13; t= 3.37; P=0.001).

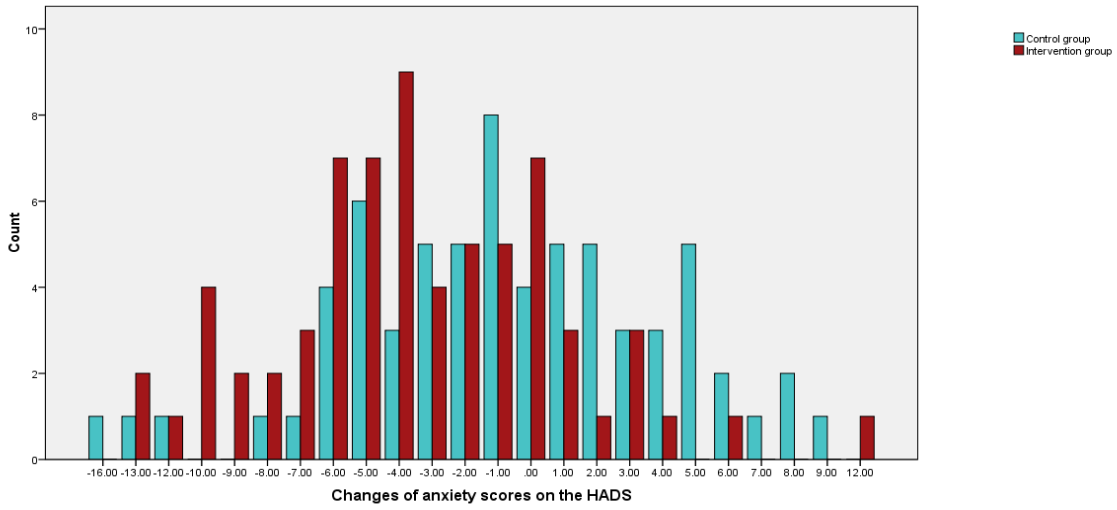


Figure 6.2 Change in anxiety scores by study groups

Table 6.2 Primary outcome - anxiety scores on the HADS for usual care group and preoperative education group

Outcome	Usual care	Preoperative education	Unadjusted[a]		Adjusted[b]	
			Mean difference (95%CI)	P value	Mean difference (95%CI)	P value
Mean (SD) anxiety score						
At baseline (n=153)	7.3 (4.33)	6.0 (3.59)				
At follow-up (n=135)	6.1 (2.87)	2.5 (3.10)				
Mean change (SD) from baseline	-0.7 (4.95)	-3.5 (4.50)	-2.7 (-4.35 to -1.13)	0.001	-3.6 (-4.62 to -2.57)	<0.001

[a] Independent-samples t-test.
[b] Linear regression: controlling for baseline anxiety score, age, gender, education level, and types of surgery.

Table 6.3 Secondary outcomes - depression and pain for usual care group and preoperative education group

Outcomes	Usual care (n=67)	Preoperative education (n=68)	Unadjusted[a]		Adjusted[b]	
			Mean difference (95%CI)	P value	Mean difference (95%CI)	P value
Depression subscale						
Mean change (SD) from baseline	-0.6 (4.94)	-2.3 (4.41)	-1.6 (-3.23 to -0.04)	0.04	-2.1 (-3.19 to -0.92)	<0.001
Pain intensity items						
Mean change (SD) from baseline						
Average pain	1.1 (2.23)	0.7 (1.94)	-0.4 (-1.07 to 0.36)	0.33	-0.4 (-0.96 to 0.13)	0.13
Current pain	0.8 (1.63)	0.6 (1.28)	-0.2 (-0.66 to 0.34)	0.53	-0.3 (-0.72 to 0.11)	0.14
Pain interference items						
Mean change (SD) from baseline						
General activity	1.6 (3.21)	1.4 (2.74)	-0.2 (-1.20 to 0.83)	0.72	-0.2 (-0.95 to 0.62)	0.67
Mood	0.7 (3.25)	-0.0 (2.86)	-0.8 (-1.83 to 0.25)	0.14	-0.8 (-1.60 to 0.02)	0.06
Walking ability	1.1 (3.77)	0.4 (3.03)	-0.7 (-1.87 to 0.46)	0.23	-0.6 (-1.43 to 0.14)	0.10
Sleep	0.9 (3.10)	-0.1 (2.77)	-1.0 (-2.03 to -0.03)	0.04	-0.9 (-1.63 to -0.16)	0.02

[a] Independent-samples t-test.
[b] Linear regression: controlling for baseline score, age, gender, education level, and types of surgery.

When adjustment was made for five baseline variables (baseline anxiety score, age, gender, education level, and type of surgery), it appeared to widen the difference between the two groups, with the preoperative education group having significantly lower HADS anxiety score at follow-up when compared to the usual care group (mean difference -3.6; 95% CI -4.62 to -2.57; P<0.001). Regardless of the method of analysis used, the participants in the preoperative education group appeared to have a greater reduction in anxiety than those in the usual care group.

6.7 Secondary outcomes - depression and pain

The secondary outcomes for the trial were change in depression score on the HADS between baseline and follow-up, and change in pain measured by the BPI-sf. Table 6.3 presents the unadjusted and adjusted analysis of the secondary outcomes.

6.7.1 Depression

Both groups had lower depression scores at follow-up: a mean reduction of 2.3 points (SD=4.41) was observed in the preoperative education groups compared with 0.6 points (SD=4.94) in the usual care group. There was a greater reduction in depression from baseline to seven postoperative days among the participants in the preoperative education group than those in the usual care group (mean difference -1.6; 95% CI -3.23 to -0.04; P=0.04).

When adjustments were made, there were some changes in the estimated mean difference between the two groups for certain secondary outcomes including depression. The mean difference in depression scores of the two groups, estimated from the linear regression model, was -2.1 points (95% CI -3.19 to -0.92; P<0.001). In both the unadjusted and adjusted

analyses, participants in the preoperative education group had significantly lower scores for depression than the usual care group.

6.7.2 Pain

At follow-up, both groups had higher scores for the majority of domains of pain measures indicating the participants had reported worse pain and increased pain interference at seven days after surgery, compared to baseline. However, mean changes from baseline to follow-up were greater in the usual care group for all these six tested domains of pain. According to the unadjusted analyses, there was no evidence that the preoperative education intervention was associated with any change in the five domains apart from sleep, demonstrated in findings from the adjusted analyses.

In the adjusted analyses, there was no difference between the two groups in the severity of average pain experienced and current pain experienced. Scores for average pain increased by a mean of 0.7 points in the preoperative education group and 1.1 points in the usual care group (mean difference -0.4; 95% CI -0.96 to 0.13; P=0.13). Mean scores for current pain increased 0.6 in the preoperative education group and 0.8 points in the usual care group (mean difference -0.3; 95% CI -0.72 to 0.11; P=0.14).

There was also no evidence of a difference between groups in the amount of general activity, mood, and walking ability interfered by pain. Mean change in general activity was very similar in the two groups at 1.4 points for the preoperative education group compared with 1.6 points for the usual care group (mean difference -0.2; 95% CI -0.95 to 0.62; P=0.67). Between the two groups, there was no difference in mood interference from pain (mean difference -0.8; 95% CI -1.60 to 0.02; P=0.06) and in

walking ability interference from pain (mean difference -0.6; 95% CI -1.43 to 0.14; P=0.10).

In terms of the domain of pain interference with sleep, mean change between baseline and follow-up was -0.1 in the preoperative education group compared with 0.9 in the usual care group. This means that at follow-up, the participants in the preoperative education group had less pain interference with sleep, while those in the usual care group reported worse sleep due to pain from baseline. In the independent samples t test, two groups had a difference of 1.0 points (95% CI -2.03 to -0.03; P=0.04). After adjusting for the potential confounders, the mean difference in sleep scores of the groups, calculated from the linear regression model, was -0.9 (95% CI -1.63 to -0.16; P=0.02), indicating that there was a difference between groups in sleep interference from pain.

6.8 Length of stay outcomes

In addition to the primary outcome of change in HADS anxiety score and secondary outcomes of depression and pain, other data for the length of stay outcomes were available from medical notes. Both actual hours participants spent in the ICU and days in the hospital after surgery were recorded at discharge in order to compare the preoperative education and usual care groups. Analysis was carried out as before, comparing groups according to a modified intention-to-treat approach, but this time the nonparametric Mann-Whitney U test was used instead of parametric t test due to the violation of the assumption of distribution normality and equality of variance. Table 6.4 presents a comparison of the two groups on the length of stay outcomes.

Table 6.4 Length of stay outcomes for usual care group and preoperative education group

Length of stay	Median (interquartile range)		P value[a]
	Usual care (n=67)	Preoperative education (n=68)	
Hours in ICU	48.0 (39.0 to 77.0)	44.0 (23.3 to 67.0)	0.05
Days in hospital after surgery	12.0 (10.0 to 17.0)	14.0 (9.3 to 19.8)	0.17

[a] Mann-Whitney U test

Participants receiving the preoperative education intervention spent four hours less in the ICU than participants receiving the usual care only (median 44 hours versus 48 hours). Borderline statistical significance was noted for the preoperative education group (P=0.05). However, no significant difference was found in length of postoperative hospital stay: the preoperative education group stayed 14 days in hospital after surgery compared with 12 days for the usual care group (P=0.17).

6.9 Summary

Of the 153 participants, 135 (preoperative education group n=68; usual care group n=67) completed all outcome measures. Based on the analyses of these available data, the preoperative education intervention group had a greater decrease in anxiety and depression scores although both groups had lower anxiety and depression scores at the follow-up of seven days after surgery. The intervention had no significant effect on average and current pain intensity as well as pain interference in the domains of general activity, mood and walking ability except sleep. The intervention seemed to affect the time spent in the ICU but not the length of postoperative hospital stay. The findings of the post-trial qualitative interviews are reported in the next chapter.

CHAPTER SEVEN

QUALITATIVE EVALUATION – FINDINGS

7.1 Introduction

Semi-structured interviews were conducted with 20 trial participants. During each interview, the participant was asked to express what they felt they needed to know (retrospectively and in advance of their surgery), to comment on the care they received (whether that be usual care and/or the preoperative education intervention), to explain what worked well for them and what could be improved, and to talk through their experiences of taking part in the trial. This chapter presents the findings generated from the analysis of the interview data. The characteristics of the interview participants are summarised in the next section. The third section outlines the categories and themes generating from the interview data. In the subsequent sections the interview results are reported.

7.2 Characteristics of the interview participants

Twenty participants, ten from each arm of the trial, were purposefully selected to capture variation in age, gender, education level, and types of surgery. Table 7.1 shows a summary of the interview participants' characteristics. Of the 20 interview participants, 12 were male and eight were female. Eleven interview participants were aged 50 years old or younger and nine were over 50 years old. The youngest interview participant was 23 years old and the oldest was 74. Seven of the 20 interview participants had received more than nine years of education. In terms of types of surgery, seven had undergone coronary artery bypass grafting, seven valve surgery, and six congenital or other kinds of cardiac surgery.

Table 7.1 Characteristics of the interview participants

Characteristics	Preoperative Education (n=10)	Usual Care (n=10)
Gender		
Male	8	4
Female	2	6
Age in years		
18-30	2	0
31-50	3	6
51 & older	5	4
Education		
≤9 years	6	7
>9 years	4	3
Surgery type		
Coronary artery bypass grafting	5	2
Valve surgery	3	4
Congenital & Others	2	4

7.3 Categories and themes

A total of eleven main themes were generated from the related codes of the 20 interviews and named according to their content. These were collapsed into three categories: the process of information giving, context of information giving, and trial experience. Table 7.2 provides an overview of the categories and themes. To prevent the interview participants being identifiable, the sources of direct quotations refer to the trial entry number with either PE representing the preoperative education group or UC usual care group. Furthermore, where a quote is used, a brief description of the participant characteristics is included.

Table 7.2 Categories and themes

Categories	Themes
1. Process of information giving	1. Reputation and hierarchy 2. Understanding risk 3. Role models 4. Communication 5. Views on the intervention
2. Context of information giving	1. Illness and help seeking behaviour 2. Strength from knowledge 3. Information as a low priority 4. A perception of paternalism
3. Trial experience	1. Motivations to participate 2. Understanding of randomisation

7.4 Process of information giving

The main findings regarding the process of providing preoperative information were in relation to reputation and hierarchy, understanding risk information, role models, patients' experiences of preoperative communication with health care providers, and views on the intervention. These themes were elicited from the interview participants in both the preoperative education and usual care groups. Views on the intervention were obtained from preoperative education group participants only.

7.4.1 Reputation and hierarchy

Several participants reported that prior to their surgery they were predominantly concerned with who would be performing the surgery and wanted more information about the reputation of their surgeon (e.g., 203PE and 6UC). Having more information related to their surgeon, they explained, would give them a sense of security, give them more confidence in the success of their surgery and ultimately reduce their preoperative anxiety.

Some interview participants explained that many staff tried to minimise the conversation with patients and their families before surgery. They believed that this was in order to avoid taking responsibility,

> *They were afraid of telling you too much before surgery. I guess it may be because they were cautious. They were afraid to say something which might cause disputes or trouble afterwards in case the consequence of surgery was not good. (11PE)*

One participant (6UC) had similar feelings in this regard and said that she preferred to ask the director of the ward - a cardiac surgeon in the hospital

rather than other staff. She believed that the director must have more knowledge, skills, and authority than others and was therefore the most trustworthy person to talk to on the ward. These participants reported that limited information received could be caused partially by some staff members' lack of knowledge about heart disease and surgery or skills of communication. In addition, they found that some junior staff and nurse students were not confident in delivering preoperative information. Some participants also said that they preferred doctors to deliver information rather than nurses (1PE, 18PE and 203PE). Their accounts suggested that position in the perceived hierarchy of hospital staff was important to these patients and information was judged on the basis of its source within the hierarchy and the reputation of the individual conveying the information.

7.4.2 Understanding risk

Although some participants felt that information about possible adverse events and complications from their treatment might make them anxious, others expressed a wish to discuss it with ward staff. A number of participants felt that they received very limited information about such risks prior to surgery giving little knowledge of the nature and likelihood of these problems. This kind of information was available from their doctors if they asked for it but not offered routinely.

Normally staff preferred to discuss this risk related information with family members rather than directly with patients as they thought this information would increase patients' anxiety (6UC, 27UC, 58UC, 11PE and 248PE). However, data from interviews suggested that patients were keen to access this type of information and understood that any surgery entailed some risk (1PE, 248PE and 39UC). One participant (248PE) said that '*Of course, I am also anxious for it but it is just a small part of my concern.*

Sometimes I think there must be the risk no matter what kind of operations…' Another woman, though concerned about risks, appeared keen to be fully informed:

> *The day before surgery when doctors came to ask my husband to sign the consent form for surgery, I was a bit scared. He said theoretically the success rate for this surgery was 98% but after all there were still the risk of 2%. He told us that we should have some preparation for all possible results. I considered that if any problems happened after surgery, how would the whole family stand and go through… Anyway I think I can understand. Such a big operation, it is impossible without risks. (39UC)*

Many participants had a similar understanding of risk information. They considered lack of success as equivalent to death. Thus they had a lot of worries about the threat their heart surgery posed to both their own and their family members' lives. For most of them, surgery was the primary source of anxiety, although other factors contributed to it, such as financial and family concerns. They mentioned that the process of providing information about risk could be improved by checking patients' understanding and reiterating information when necessary.

All open heart procedures carry risks related to the use of cardiopulmonary bypass. More recently, there has been a greater awareness of not only the mortality risk associated with cardiac surgery but also on the incidence of morbidity including renal failure, infection, prolonged ventilation, neurologic deficit and bleeding after surgery. However, the safety of cardiac surgery has improved significantly over the years and major

postoperative complications are now exceedingly rare (Granton and Cheng, 2008).

7.4.3 Role models

Being able to see other patients' improvement and recovery over time was a factor that the participants from both arms of the study cited as a form of helpful encouragement to continue with the process of undergoing surgery. One participant emphasised this by saying that '*… Before surgery I really saw a lot of patients undergoing heart surgery, some were very weak at the beginning, but they all healthily walked out of the hospital after surgery. These real cases also educated me, so that I do not feel the pressure, and really went into the operating room with ease. (248PE)'* In particular, when they witnessed the recovery process of those whose health conditions were considered to be poorer than theirs, they became more confident about their own forthcoming surgery. One 38 year old woman commented,

> *…Not afraid now. At first I was very afraid. After coming here, I saw other patients were experiencing the same as my situation and even worse than mine. You see that little child next room who had congenital heart surgery before. This time he had to do it for the second time… He is so little but has experienced so much. Heart surgery, twice? When thinking about that child and myself, I asked myself 'what I am still afraid of'. I was really not afraid the day before surgery. (273UC)*

Some interview participants found that they did not experience much contact with other patients, so opportunities to gain support from others were limited. They strongly believed that there was a need for mutual

learning and peer encouragement as it helped to develop a sense of shared experience and brought comfort from the feeling that they were not alone. These participants suggested that the hospital could formally invite patients who had experienced cardiac surgery recently to be part of a group discussion with current patients and their families. This form of information sharing was believed to encourage people to actively participate in the discussion and eventually save staff time spent on patients' preoperative education (18PE and 63UC). One participant pointed out,

> *… it can make preoperative patients realise that so many people like themselves suffering the heart problems underwent successful surgery, and recovered so quickly, which can greatly enhance their confidence of overcoming disease and surgery. (254UC)*

Patients wanted to listen to and see the benefit of surgery, know about possible skills of coping with anxiety and pain, and learn ways to overcome any difficulties from previous successful cases. Because the individuals in the group had all been treated with open heart surgery, they could feel some degree of shared experience and communicate easily with each other. Those who did manage to obtain information from others' stories found this peer support very helpful and expressed that they would like to share their own experience with future patients (11PE and 54PE).

7.4.4 Communication

Some participants explained that they gathered information from a range of sources including friends, newspapers, books, television, radio and the internet. However, when they were admitted for surgery, they started to heavily rely on hospital staff to give information or advice as they

considered that information from other sources might be incorrect or misleading and potentially cause harm to them (60UC, 286UC and 54PE). During the interviews, all participants were given the opportunity to reflect on their experiences of preoperative communication between them and the ward staff and to make suggestions for improvements to the delivery of preoperative information for future patients.

7.4.4.1 Communication as a unidirectional and reactive process

Some participants' reflection on preoperative communication was positive though individuals' enthusiasm varied. In particular, they valued the friendliness and courtesy shown by some ward staff, which projected feelings of encouragement, confidence, respect and care in patients (60UC, 214PE, 216PE and 254UC). Some participants mentioned that they appreciated instructional information from the ward staff such as balloon blow training, deep breathing and cough practice (273UC and 286UC). Most of this information could be understood because it was given in plain language and in a straightforward manner (203PE, 254UC and 255PE).

However, other participants noted that information giving was often 'one-way' whereby the information was predominantly from staff to patients and reactive whereby staff only gave the information when patients asked for it. The participants felt a lack of engagement with the way information was given (6UC, 248PE, 27UC and 254UC). Patients often attributed this to the ward staff's heavy workload. As one female participant put it,

> *They always seemed extremely busy. Sometimes I would like to ask something, their response was very short. In fact, I did not quite understand what they said, so felt embarrassed to ask again for clarification. (6UC)*

In the two study hospitals, shortage of staff was a real problem. The staff members were tied up with routine medical tasks. Some participants seemed to accept that the busy working environment did not allow the staff to spend much time on providing patients with information or psychological support. They felt that they could only get information from the staff when asking for it. However, the majority suggested that they were too shy to ask because they thought the staff did not have the time nor assigned responsibility to give them this basic information. One participant described it by saying,

> *They are experts but I am an amateur, so I do not want others to laugh at me. I'll give you an example. I once asked the Director if my body had adjusted to the optimum for operation because I have been here for long time. He told me that all of things look fine but only the EF value was still too low. I did not know what the EF value is and do not dare to ask about it... (248PE)*

7.4.4.2 Limited communication and information giving

There was considerable variability in the amount or level of preoperative information interview participants desired. A few participants were confident that the ward staff would have provided the information they needed to know before surgery, and assumed that whatever information was not provided was unimportant and unnecessary. They were happy to leave it in the hands of experts. However many participants (27UC, 53PE, 216PE and 254UC) expressed that information was insufficient particularly in relation to pain relief and wound care, medications, rehabilitation and living a healthy lifestyle.

A number of interview participants commented on the value of face-to-face communication between patients and ward staff. They believed that it was not only the most direct way to share information and the quickest way to get a response, but could also help enhance patient-staff relationships. One interviewee (1PE) indicated that before surgery she *'just want to have someone to sit with, like friends. If staff could speak to us like this way, I think we would not only get knowledge, but would also receive timely psychological comfort.'*

However eleven out of 20 interview participants indicated that there was very limited contact and communication with the ward staff. One participant (53PE) reported, *'I would say it was nothing. What I mean by that is basically there was no communication and information exchange. I learned a lot by reading the posters on the wall by myself.'* He went on to say, *'I am still not clear about what coronary heart disease is and whether all of coronary heart disease must do bypass surgery etc. etc. I had a lot of questions in my mind…I had such a major operation, what a shame that at the end, I still do not understand why I needed surgery, which blood vessels got a problem...'*

Patients in China are increasingly aware of their rights for information about treatment and care. These participants observed that until discharge, they still had a number of unanswered questions and unresolved concerns. They even argued for the need for a new role of a full time cardiac surgery consultant on the ward with a specific responsibility to spend time talking with patients and their families, and gain a greater understanding. In addition, participants suggested that written or audio-visual materials could be used as complementary tools to facilitate verbal communication (286UC, 27UC, 53PE and 216PE). Some highlighted the need for handbooks or

leaflets focusing on different aspects of care which could be referred to at any time. Two participants (248PE and 255PE) suggested that a combination of different ways of conveying information might be more appropriate, particularly when giving information to those patients from rural areas with often lower levels of education. Both participants explained that different ways could complement each other to achieve a better and more thorough understanding.

7.4.4.3 Preference for individualised information and optimal timing

An issue identified from interview participants was that the information available was not specific enough (58UC and 286UC*)*. One participant (58UC) said that '*staff should select the most appropriate information for different individuals according to their personality. They should pay attention to how much, how deep, and how detailed information to give for each individual. If they could not get it right, it certainly may increase worry*'. General information might not be appropriate in meeting the detailed information needs of all patients. Some tailored and individualised information was also needed.

Half of the twenty interview participants stated 'the sooner, the better' to summarise their views on when best to receive preoperative information. Two participants (286UC and 216PE) noted that it was not considered to be the best time to receive information when getting closer to surgery as they felt that the provision of information when they were at their most anxious could increase their anxiety and fear. They needed enough time not only to digest the information they were given, but also alleviate some of the worry through communication with family members.

7.4.5 Views on the intervention

Each participant in the intervention group received preoperative education including a patient information leaflet and verbal explanation. These participants were asked for their views on the intervention in order to help understand the way the intervention might 'work' as a part of routine care. Analysis of the interview data suggested that participants' feelings about the preoperative education intervention varied considerably.

7.4.5.1 Leaflet

The majority of those who had received the intervention (six out of ten) commented positively on the design of the leaflet. They felt it was clear and straightforward and provided the right amount of information. The leaflet was used as a helpful and handy tool for quick reference (1PE, 11PE, 18PE, 53PE, 54PE and 203PE). Three participants commented that their family had found it helpful to read and that their friends wanted a copy (11PE, 18PE and 53PE). They liked the coloured headings separating sections and the graphics which they found made complex medical procedures simple. One person explicitly stated that the layout of the leaflet helped his understanding,

> *…Every time I read your leaflet, I learned something from it. It is very clear, one point by one point, about what I shall do in this step and what I shall feel the next step. You categorised it into several sections … and also illustrated and explained in a very simple diagram. I like it very much… I often read it through, especially at the preoperative stage… (18PE)*

However, for some interview participants, the amount of information in the leaflet was perceived as insufficient for their needs and they would have

liked more information in areas such as normal range of body temperature after surgery, use of medicine at home and precautions after discharge, although most of the patients mentioned that having this leaflet was better than nothing (203PE, 216PE, 248PE and 255PE). One interviewee (248PE) noted that the leaflet seemed *'so basic'* and he could memorise all the information it contained after his first reading. He implicitly suggested that its design and the limited depth and breadth of its content would be unlikely to motivate some patients to reuse the leaflet.

7.4.5.2 Verbal explanation

The information that the leaflet provided formed the basis of the discussion with those allocated to preoperative education group during the 15-20 minute contacts. Several interview participants reported finding the discussion interesting, enjoyable and rewarding. They expressed that being able to obtain accurate information prior to surgery was something that fulfilled a need unmet by ward staff. As one participant said,

> *In the ICU I always recalled what you told me. I realised you gave the accurate information. What I was experiencing in there was exactly what you explained to me before surgery. I had a tube inserted through mouth and had very dry mouth and lips. I really could not be able to speak like you have told me. (11PE)*

7.4.5.3 Leaflet combined with verbal explanation

When asked to summarise experiences of the leaflet along with verbal explanation and to evaluate its potential impact, eight out of the ten interview participants from the preoperative education group were mostly enthusiastic. This positive reaction to the intervention was related to a sense of control over the situation. They viewed in retrospect that the

intervention improved their understanding about their cardiac surgery and at the same time helped to relieve unnecessary worries and anxiety, highlighted by the following extracts.

> *What you delivered is exactly what I need and desire to get, so when you talked to me about the brochure I listened very carefully. (248PE)*

> *If only giving me the leaflet to read by myself, it would be very intuitive, abstract and boring. I would not take it seriously. After reading it, I still did not know how to breathe and how to cough and so on. But after your thorough explanation, I was pretty sure about it. (53PE)*

They indicated that both the written information and verbal explanation could be effective in improving people's confidence and should be combined to maximise the benefits. A leaflet on its own might be easily ignored without verbal explanation. Another participant (255PE) was concerned about older patients who might not see and understand the leaflet properly. Therefore, the opportunity for a face-to-face explanation was viewed as a helpful alternative way to obtain the information.

However, the reaction of two of the interview participants was less enthusiastic (214PE and 248PE). Although both expressed some surprise at their raised awareness of information needs, they still considered physical health as a priority when they were uncertain about whether they could survive from surgery, as illustrated by the following quote.

The physical aspects of health are the most basic. If physiological needs still could not be guaranteed, what is the point talking about other things? Cardiac surgery patients are just like walking on the boundary of life and death. (214PE)

No one commented that the intervention was too burdensome. All participants in the preoperative education group had consistently completed and followed the intervention. No one reported that the information given in the intervention was a repetition of information that they had already received by other ward staff. One interview participant commented that,

If you did not tell me, I really did not get any information. No other doctors or nurses came to me to talk with me about that… Language is very easy to understand, the entire process is explained very clearly. Your explanation was fantastic and let me know clearly what was going on now and what would the next step… I got very familiar with that procedure, so I was well prepared. (53PE)

A proportion of the interview participants from this group who identified the intervention as a useful tool to get them relaxed commented that they believed it had been too short and would have liked it on more than one occasion (11PE, 53PE, 216PE and 203PE). However, they understood that a one-off preoperative education intervention was part of the trial protocol. They considered it important that in addition to providing accurate information, reinforcement was needed as some patients might have not completely absorbed what they were told or might have forgotten the information they had been given. This was similarly pointed out by some of the interview participants from the usual care group (58UC, 63UC and

282UC). The participants suggested that it would be preferable if patients could be given introductory information on admission and then this information be 're-enforced' at a later point in their hospital stay.

7.5 The context of information giving

The interview participants' accounts provided insight into the context within which the intervention was being delivered. Themes relating to this category were illness and help seeking behaviour, strength from knowledge, information as a low priority, and a perception of paternalism.

7.5.1 Illness and help seeking behaviour

Notwithstanding the considerable variations in patients' experiences of seeking and receiving information relevant to their illness, most interview participants discussed the role of information and their specific information needs in remarkably similar ways. One 44 year old man, who underwent valve replacement, emphasised his inclination toward pharmacological treatment when he was first diagnosed with rheumatic heart disease in 1993.

> *…the symptoms were mild. Doctors did not recommend immediate surgery. They said a bit narrow but my own valve could still be used for eight or ten years. So I tried both western medicine and traditional medicine for two to three months. My symptoms were basically controlled… (282UC)*

This participant further noted that he was not being treated medically since then but his disease had subsequently progressed to the stage where he needed surgery. In fact, acting on the information from doctors did prolong the life of his natural valve for about 17 years. He was satisfied with the

information he received and his decision to not have surgery at that early time.

Many interview participants talked of being reluctant to undergo cardiac surgery unless suggested by a doctor that they had no other choice (e.g., 54PE). Although these interview participants ultimately consented to undergo cardiac surgery, all of them thought about alternative methods of treatment. Information the doctor explained regarding why they believed surgery was necessary helped them make a final decision. As a 67 year old woman recalled:

> *Yes. The same thing happened two years ago. Doctors said to me that I had heart disease and I had to receive a bypass surgery. At that time I only could accept stent placement but not surgery. I understood that surgery was not a small thing. But referring to the result from angiogram, doctor told me that it was not suitable to do stent. The only way was to have an open heart surgery… (254UC)*

In both cases, doctors played an important role in giving accurate information before the surgery actually took place. The participants felt that such honest and straightforward information about treatment alternatives enabled them to weigh risks and benefits of each alternative and helped them make the right decision. Another 41 year old woman explained her story of seeking help in this way:

> *… When it came to winter, the weather was getting cold, I started feeling uncomfortable. The symptoms this time clearly was worse. Chest pain started to bother me a lot… My sister introduced me to see an old traditional Chinese doctor. He gave me some Chinese*

herb medicine to take and acupuncture treatment once a day to go with. These treatments lasted for a month but did not make me feel any better. In December last year, I caught a bad cold and always found rapid breaths. The doctor in a county hospital took X-ray on my chest and then I was diagnosed with heart disease again. He suggested me to come here for further investigation and treatment… (6UC)

The participant 6UC was diagnosed with heart disease by different doctors more than once but still kept a hope that the heart disease could probably be cured by Chinese herb and acupuncture rather than surgery. Once cardiac surgery was considered essential, patients would need to make a decision on which hospital they wished to be treated at. One 42 year old man explained:

… I actually visited several other hospitals. What I was particularly looking at was staff profiles on the wall and health care facilities. I did not ask any doctors and nurses. I regarded myself as an observer from outside. Finally I made decision after having carefully observed every hospital. I think I was very confident about my surgery because of my careful observation, comparison, and evaluation. (286UC)

Throughout his account above, he recalled that his decisions were not based on what he was told or recommended but the information he gathered through his observations. For this patient, seeing was believing. Cardiac surgery, as these interview participants said, is not a small operation. Therefore it is hard to make a decision on whether to have it or not. Patients normally experienced a transition from being reluctant,

hesitant, and frustrated, to making a decision. Their decisions were largely driven by the information they had gathered from various sources before surgery, with doctors having the final influence.

7.5.2 Strength from knowledge

When asked how they felt about cardiac surgery, most interview participants discussed their experience of fears and worries between admission and surgery. One of the most predominant feelings expressed by participants was anxiety. One 52 year old woman talked of her story, after hospital admission,

> *I really started to worry a lot… What if I could not get out of the operating room? Yes, I really could not express myself how scared I got at that time (weeping)… Before surgery I was in bad mood. I had increased pressure when getting closer to surgery. I even started not to sleep a few days before the date of my surgery. (58UC)*

Some interview participants recalled similar preoperative feelings. These emotional feelings were from male and female participants alike. They emphasised that when they thought about how during surgery their chest would be opened and their heart would stop beating, they became extremely scared and anxious (273UC female; 214PE female; 216PE male). They also expressed their worries about family members if they died. This illustrates the potentially considerable psychosocial impact of cardiac surgery.

In contrast, some interview participants pointed out that their psychological state before surgery was relatively stable and they were not that anxious. Their explanations gave insights into the source of their inner strength. One male participant said,

> *… I was not full of worries. First, I believe the world's great progress in medical technology, the second is the belief in the good reputation of the hospital, the third, I trust in the level of health care in our ward… I have experienced everything in my 74 years, and should not have any fear. (248PE)*

Quite a few interview participants specifically commented that having knowledge about the recently rapid improvement of surgical technology, reputation of the hospital and cardiac surgical ward made them feel secure and calm (e.g., 286UC and 54PE). 11PE and 60UC also similarly stated that they did not worry too much about the result of surgery as much as younger patients did. They believed that death was a point everybody would come to at the end, so they should not be scared.

The majority of interview participants stated either explicitly or implicitly that they did experience various degrees of anxiety prior to the surgery. They described how information could to some extent help the gradual building up of their inner strength to mentally cope. A 42 year old man summarised, 'the more I know, the less anxious I feel' (286UC):

> *Yes, I did not have any worries preoperatively… I was equipped myself with the knowledge. By searching relevant information online, I became more confident on my illness and surgery. I think that I will be all right… (286UC)*

This interview participant emphasised the importance of prior knowledge and individual engagement into health care. One 69 year old man without computer skills reported that his children had helped him to search for information on the internet and even went to hospitals to gather information on his behalf (54PE). One woman who felt highly anxious said repeatedly that she wished that she had made every effort to gather all information and knowledge she needed before surgery (58UC). Their different level of prior knowledge may explain why some interview participants felt cardiac surgery to be a source of anxiety while others did not report feeling particularly anxious.

With increasing expectation among Chinese people of a good quality of life, patients and their families become more and more active in seeking health-related information. They are keen to learn more about any aspects of their healthcare. Preoperative information was viewed as very important for them to gain strength and confidence, as most participants stated during the interview. Some articulated what information they particularly wanted and needed before surgery (203PE and 6UC).

> *In the preoperative stage, surgery was the first thing, of course. So I wanted to know all the information relevant to my surgery, such as who would be my surgeon, how long a heart surgery generally lasts, when patients would be awake from anaesthesia etc., followed by the prognosis, for instance, when to get out of bed, how long the patient can be discharged and would the surgery bring a lot of pain?... (6UC)*

Interestingly, there was a tendency for the interview participants to deny experiencing anxiety regarding their surgery in the early stages of their interview, particularly for male participants. As the interview continued, participants were more willing to acknowledge feelings of panic and anxiety. One man (53PE) said *'I did not feel it. No, I never... Well, it is not possible for a person who is not having any fear of the surgery, right?... When the operating room's door was about to close, at that particular time, I was so afraid indeed.'* Those who did experience anxiety might feel it shameful to speak out because it is sometimes seen as an indication of weakness. His account implied that the preoperative education intervention he had received might reduce but not remove anxiety. Of the twelve male participants, six referred to being anxious but only two in the first half of the interview (282UC and 54PE).

7.5.3 Information as a low priority

Three interview participants explained that they felt that in Chinese hospitals, information and emotional support was a generally ignored aspect in patient preoperative care (58UC, 227UC and 53PE). As one 50 year old man put it,

> *Certainly I have learned a lot of knowledge through taking part in your research. I have realised patients' mental health is important and psychological care for patients should be stressed in hospitals. But in our healthcare system, this part is far behind western countries like the UK where provision of patient information and support have been well developed. In China, no one is responsible for giving you information and helping you release anxiety and stress. We definitely lack this aspect of care. (53PE)*

These participants considered themselves vulnerable during the preoperative period. They believed that they should have been equipped with more knowledge about their health and care. However some participants (214PE and 248PE) explained that they placed their attention on physical health rather than information needs and psychological concerns. They doubted the effect of information and psychological care on health outcomes and thought that sometimes information could create anxiety. A participant (214PE) said *'information and psychological care cannot treat my heart disease. I don't want information because getting to know more about my condition can bring more worries to me and my family. I only want to get my surgery successfully done'*. Traditionally in China, provision of information and psychological support has been considered as a lower priority by both hospital staff and patients, compared to other treatment and care.

7.5.4 A perception of paternalism

Some interview participants indicated that ward staff only talked about heart disease and surgery with their family members particularly the severity of their health condition and possible risk of surgery but did not inform them before their surgery took place (6UC, 27UC, 58UC, 11PE and 248PE).

> *To be honest, very few doctors or nurses came to talk with us. Only the day before surgery the doctor and anaesthetist came to ask for some signatures. I think they were related to legal and medical responsibility that sort of thing. No one informed me about things like heart disease, preoperative preparation, and postoperative care and so on. Sometimes when I encountered any doubt I even did not know who to turn to. (27UC)*

The participants were not given full information and others often made decisions for them. In China, hospital staff considered family members to be in the best position to judge whether to pass the information onto patients or not. In fact, family members normally chose to tell patients about the severity of their conditions after surgery rather than prior to surgery. As a result, patients did not know what was going on before surgery in spite of being keen to be informed. It implies that information giving is often based on what health care providers or others perceive are the patients' needs. However this can be quite different to what patients themselves identify as their needs.

When ward staff informed the patient, they tried not to scare patients but convey a feeling of trust, safety and confidence. Sometimes they thought that it would be better for patients not to know, which could be seen as a way of protecting patients. In fact, it is a form of paternalism (Cody, 2003, p288). To be able to help patients make decision and involve them in health care, it is necessary to provide them with full information about disease and treatments.

7.6 Trial experience

Interview participants were encouraged to talk about their own ideas or expectations about any aspect of the study. The majority expressed their motivations and appreciation towards the participation in the study and some of them spoke of their understanding of random allocation.

7.6.1 Motivations to participate

Interview participants found the questionnaires simple to understand and that completing the questionnaires was neither inconvenient nor

burdensome. After knowing what would be required of them in both groups they felt that joining the study was not difficult nor time consuming (203PE and 227UC). Throughout the trial, no one postponed or refused to complete the questionnaires, which was another indicator that the study was not perceived as too burdensome.

More than half of the interview participants spoke about their intention to take part in the study, that is, they expected the study could, to some extent, help them learn more about their surgery and health and think in a positive way (203PE and 58UC). In addition, some participants mentioned that they were keen to help with the study as they hoped that their participation could improve current services, so that other patients and their families would get better treatment and care (203PE, 248PE and 282UC). They showed their care and concerns about others and felt good when they could offer help to others. A 74 year old man told me during his interview that '*I have gone through some tortuous paths, and I do not want other patients to go, like me, again*' (248PE). From their account of motivation, participating in the study, in their view was beneficial to themselves and to others.

Several interview participants emphasised that their motivation was because of curiosity about getting involved in a clinical study. One 63 year old male participant who had his bypass surgery stated,

> *Your study was really good. The first time I heard from you about it, I feel it should be a good study. So I must attend…I know that many things may seem very common in foreign countries, but for our country, are totally new. For example, it is the first time that I had the honour to participate in medical research. This experience*

makes me feel very curious and excited. I had never come across it or even heard of it. (60UC)

For two participants (214PE and 227UC), the study taking place had added to their good impression of the hospital and trust in the overall quality of care of the hospital. A 39 year old man explained that it was his doctor who recommended the study and he found that there would be a need for more clinical studies,

I felt our hospital should have more studies like this. First of all, we can understand more necessary knowledge, and secondly our voices, to a certain extent, can be reflected upward to the management team and eventually it will help improve patient satisfaction and our overall service level of the hospital. (216PE)

7.6.2 Understanding of randomisation

Interview participants had different levels of understanding about the concept of randomisation and what would be involved in the randomisation process, although it had been explained to them before asking for their consent about participation. Some participants had clearly understood that they were randomly assigned to one of the trial arms and the meaning of using this approach. Others were less clear in their understanding of it.

The 52 year old female participant who had nine years of education level reported how she understood randomisation: '*Randomisation is something to be done in random order ... For example input all of patients' names into a computer and ask computer to randomly assign them into groups... It is a bit like gambling or lottery. You have no idea who will be in which group, isn't it?'* She further summarised that, '*Random, in fact, means no law to*

follow and is entirely accidental' (58UC). Although she was in the usual care group and did not get the leaflet she wanted, she believed randomisation could ensure the participants' allocation to be fair because that who was in which group was not decided by someone but a computerised process.

Some participants held similar views about randomisation as something beyond human control (203PE, 214PE and 60UC). They believed that it was arranged by fate as to whether they would be allocated to the preoperative education group or not, and that the possibility of getting into any group for everybody was equal. One 23 year old man (203PE) put his explanation of the randomisation process more simply by saying that, *'I know I have a 50% probability to be assigned to either the control group or leaflet group. I totally understand this is your study requirements.'* Not all patients grasped the concept of randomisation. Several participants explicitly stated that they were not quite clear about what it was. One male participant (60UC) who got a bachelor degree said, '*I knew a little. I was not clear actually. But I knew randomisation must be a good way to do your research.'*

Only two interview participants explicitly stated that they would not mind which group they would be allocated to (60UC and 214PE). The majority of participants described their preference for being allocated to the preoperative education group (254UC and 255PE) as they expected more information and support in this group and desired to see the leaflet. However, they further explained that although they had a preference they would like to keep complying with the study because they understood having two groups was a basic feature of the study design.

All interview participants indicated that they understood what was required of them in the study from the day they signed the consent form. The participants from the preoperative education group stated they had not shared the leaflet with others, while those allocated to the usual care group denied having seen the leaflet. Only one man (53PE) from the preoperative education group mentioned that he was given a leaflet after he had read it from another patient in the same room. From his story, it was apparent there was some contamination between the two groups.

Interview participants felt lucky and pleased to be involved in the study. Most participants, when asked if they would change any decisions they made in relation to the participation, stated that there was nothing they would change and furthermore they would like to recommend joining the study to other patients.

7.7 Summary

The qualitative evaluation provided valuable insights into the content, process and context of the intervention implemented and a deep understanding of patients' experience of taking part in the trial. It helped to answer the questions regarding why and how the preoperative education intervention worked or not and how it could be improved. Regarding the process of information giving, participants spoke about the hierarchy of hospital staff and how information was judged on the basis of the reputation of its source. A number of interview participants expressed their wishes to get more information about possible risks and complications before surgery to enable them to have a better understanding of cardiac surgery. Role models were highlighted by some participants who commented on the need for mutual learning and peer encouragement. This

helped to develop a sense of a shared experience and brought comfort from the feeling that participants were not alone.

Many participants noted that information giving by ward staff was generally one way, reactive rather than proactive, and limited, and patients were not fully engaged. This was often attributed to the staff's heavy workload. The majority of interview participants who had received the intervention felt satisfied with it. Participants believed that the leaflet combined with verbal explanation helped them remain calm, be better prepared for surgery and take an active role in health care.

The context of information giving helped shed a light on possible factors influencing the delivery of preoperative education. Reflecting patients' increasing demand for information about health care, they had gathered from various sources advice and support before surgery to help them make important decisions. A few participants explained that they really have understood the importance of information on building up their inner strength to face surgery. Information giving and psychological support were considered a low priority, compared to other treatment and care in China. Some participants mentioned that they felt lack of knowledge before surgery. As a way of protecting patients, sometimes family members were informed but patients themselves were overlooked. All interview participants appreciated being involved in the study and most showed a level of understanding of the concept of randomisation. These findings are discussed alongside the trial results in the next chapter.

CHAPTER EIGHT

DISCUSSION

8.1 Introduction

The aim of this study was to test the hypothesis that a preoperative education intervention could reduce anxiety among cardiac surgery patients in China. A secondary aim was to examine whether the intervention could reduce depression and perceived pain, as well as length of Intensive Care Unit stay and postoperative hospital stay. The trial was carried out to test this, while a qualitative evaluation was conducted to explore the perceptions and experiences of patients who took part in the trial. In this chapter, the results and methodological strengths and limitations of the study are discussed. The findings from the trial and qualitative evaluation are integrated and discussed in the light of adult learning theory and are critically assessed in comparison with those from other studies.

8.2 Overview of the main findings

Among participants randomised to the preoperative education group, there was a greater reduction in anxiety and depression and less pain interference with sleep compared with those in the usual care group. In the trial, there were no differences observed between the two groups in terms of average pain, current pain, and interference from pain in general activity, mood and walking ability. This suggests the education intervention had a positive effect on patients' psychological health. A lack of difference between randomised groups in postoperative hospital stay and the borderline evidence that the preoperative education intervention can reduce hours spent in Intensive Care Unit suggests that any benefits to physical recovery are likely to occur immediately after surgery rather than in the longer-term.

The three categories emerging from the qualitative evaluation were: the process of information giving, context of information giving, and the process of participating in the trial. Most interview participants commented that preoperative communication between patients and health care providers was limited and reactive and patients were not fully engaged. The overall response to the preoperative education intervention was positive. The participants in the preoperative education group valued both the patient information leaflet and the verbal explanation.

The context of information giving provided insights into possible factors influencing the delivery of preoperative education. There is evidence to support the statement that during the preoperative phase, staff usually intended not to provide full information to patients as a way of protecting patients, especially when discussing the risks and complications of surgery. All interview participants reported enjoying being part of the study and made a number of helpful suggestions concerning preoperative education in future practice.

8.3 Strengths and limitations of the study

8.3.1 Study design

To my knowledge, this was the first randomised controlled trial to assess the effect of preoperative education among Chinese patients undergoing cardiac surgery. The sample size of 153 is larger than most other trials of preoperative education interventions that have been conducted in Norway (Sørlie et al., 2007) and the United Kingdom (McHugh et al., 2001). Most of the larger studies to look at the effect of preoperative information for cardiac surgical patients are non-randomised in design (Ivarsson et al., 2005a). A review of fundamental characteristics of interventional clinical

trials registered in the ClinicalTrials.gov database found that most interventional trials registered between 2007 and 2010 were small in terms of numbers of participants, with 62% enrolling 100 or fewer participants. The median number of participants per trial was 58 for completed trials and 70 for trials that have been registered but not completed (Califf et al., 2012).

The study was conducted in two Chinese public hospitals where protocols for usual care and preoperative education were the same. However environmental factors such as ward staff and ward layout may have had an effect on patients' psychological health. Although randomisation was stratified by hospital the trial was not powered sufficiently to test for an interaction between study group and hospital. Utilisation of health services and social support was not an outcome examined in the present study and therefore it is not possible to draw conclusions about cost effectiveness.

In this study, an understanding of the participants' perspective concerning the cardiac preoperative education intervention and their experiences of involvement in the trial was obtained through a series of individual, face-to-face interviews. This qualitative evaluation provided greater insights into the process of preoperative information giving. The underlying considerations about the context in which preoperative information was delivered for Chinese cardiac patients became clearer. The interview data also helped uncover the possible motivations for the patients to take part in the trial and their understanding of the concept of randomisation. The qualitative evaluation can not only help explain the results of the trial but can also inform the future design of preoperative education interventions for cardiac patients.

Although adding a qualitative perspective into the trial is a strength of this study, there were considerable challenges throughout the research process. Acting as the interviewer may have meant that interview participants might have seen me as a connection or liaison between the patients and hospital administration. Therefore, when they expressed their feelings, concerns or frustrations I sometimes felt they expected me to report to the administration board in order for these to be acted on. However, it is important to acknowledge that the interview participants might attempt to present themselves to the interviewer as playing an appropriate social role, whereby they provided answers that placed them in a positive light or that they believed the interviewer wanted to hear (van Heugten, 2004, Asselin, 2003). For example, they might have been reluctant to criticise the intervention delivered by the interviewer and to talk about their real experience with the interviewer. Consequently their accounts of both the intervention and trial experience could have been influenced by my presence.

It is also recognised that the study participants might have felt uncomfortable in expressing their negative feelings about the surgery or psychological problems. Two case studies of psychosomatic symptoms in China (one from Hong Kong and the other from Nanjing) cited by Helman illustrated that in Chinese culture, the open expression of emotion is not encouraged (Helman, 2007, p262). It is particularly true for males in China, which was supported by the observation that some male interview participants initially denied experiencing any anxiety before surgery but admitted that their anxiety did exist as the interviews went further. This aspect of Chinese culture could also influence patients' response to the Hospital Anxiety and Depression Scales.

8.3.2 Recruitment and follow up

Recruitment to the study was highly successful, with only two patients declining to take part. It was emphasised to patients that participation was voluntary and although there was a relatively small window between admission and surgery in which to inform, recruit and consent patients, all were given at least a day to consider their participation. The successful recruitment in the present study could be attributed to several factors including giving a clear explanation of the study and building up the rapport with patients during the first contact. Additionally, medical support was crucial, in that the doctors on the ward recommended the study to their patients.

The present study had a low attrition rate of 12% (18/153). The main reason for loss to follow-up was being discharged without surgery (n = 14) with the remaining attrition due to reasons of death, and transfer of care to another hospital. In China, it is not unusual for patients to discharge themselves prior to surgery. This may be due to the financial cost incurred by the patient if the procedure is to go ahead. It cannot be ignored that there was a possibility that a patient's decision to discharge themselves before surgery was influenced by the preoperative education intervention. However, this is an unlikely explanation given the similarity of attrition between the two groups (six from the preoperative education group and eight from the usual care group) and that this overall rate is similar to that observed outside the trial period.

The other issue worthy of note is that all participants in the preoperative education intervention group had consistently taken up and completed the intervention. The qualitative evaluation provides a possible explanation. During the interviews, no one reported that the information given in the

intervention was a repetition of information that they had already received from other ward staff. The interview data also suggested that participants' curiosity about the trial may have encouraged those in the two groups to maintain their involvement in the trial, thus contributing to the low attrition rate in the study. Outcomes were observed at seven days following surgery. It is not possible to infer from our study whether the positive effects of the preoperative education intervention would persist beyond this period.

8.3.3 Randomisation, blinding, and contamination

Although randomised controlled trials are the most rigorous type of scientific evaluation, the reliability and validity of the evidence from a trial has to rely on an appropriate procedure of random allocation (Kendall, 2003). Allocation in this study was determined by a stratified block randomisation, with random block size and stratified by the two study hospitals. This prevented too great an imbalance in the number of participants allocated to each arm and avoided the risk of being able to predict the allocation in advance.

Data from the qualitative interviews showed that patients' understandings of the design of the study and what procedures were involved in the study were variable. This has become a widely acknowledged problem in any randomised trial (Kerr et al., 2004, Ellis, 2000, Robinson et al., 2005). Although considerable effort had been made to provide clear and accurate information for patients' consent in this study, doing so could not guarantee their full understanding of it, especially some difficult concepts such as randomisation. It suggests that more discussions and explanations about the purpose of randomisation need to be available for patients in order for investigators to be confident that consent given is fully informed.

To avoid bias, randomised controlled trials should ideally be double blinded, where the participants and those responsible for their treatment or the evaluators are unaware of which treatment the participant is receiving (Pocock, 1983, Schulz and Grimes, 2002). However, due to the nature of the intervention participants could not be blinded to study group allocation. There is the risk therefore that some of the differences observed at follow-up may be due to social desirability bias. To counteract this potential problem it was ensured that the nurse collecting follow-up self-completion measures was unaware as to which group the participant had been allocated and was not the one who delivered the preoperative education intervention. Baseline measures were carried out prior to the random allocation. In conducting the analysis I was blind to study group labels. That some evidence of a difference in hours spent in ICU postoperatively was found also suggests that the difference in outcomes observed were not limited to self-reported outcomes.

Although the leaflet was kept in an envelope and patients allocated to preoperative education were asked not to pass on the leaflet, the possibility of contamination between the two groups cannot be excluded. The resources were not available to cluster randomise so patients allocated to different groups could, in theory, be cared for in the same preoperative ward alongside each other. Even if the participants in the usual care group could have been prevented from seeing the leaflet, it was impossible to avoid those in the preoperative education group sharing the knowledge and skills they had learned from the intervention by talking with those in the usual care group. So the risk of information leakage from the intervention group to the control group leading to contamination of the trial arms can only be minimised but not be avoided. However, the effect of

contamination is likely to have resulted in an underestimation rather than an overestimation of differences between the two groups at follow-up, that is, the point estimate of an intervention's effectiveness can be reduced due to contamination between the two trial arms (Winkens et al., 1997, Torgerson, 2001, Keogh-Brown et al., 2007).

8.3.4 Data analysis

Intention to treat analysis is generally considered the most robust analysis for randomised controlled trials because of the inclusion of patients not receiving intervention despite being randomised to intervention group (Pocock, 1983). However, the use of a strict intention to treat analysis was impossible in cases of missing data such as loss to follow-up (Abraha and Montedori, 2010). Per protocol analysis also did not seem to be an appropriate label to describe data analysis reported in this trial as it implies that any individual receiving a treatment they were not randomised to would be analysed according to the treatment received rather than the treatment randomly allocated (Sedgwick, 2011, Sedgwick, 2010, Shah, 2011).

In this trial, all participants who completed follow-up were analysed as a part of the group to which they were randomised and those lost to follow-up were excluded from analyses. The 14 participants who were lost to follow-up become effectively ineligible for the study by not having the surgery for which the intervention was designed and which would make the outcomes meaningful. Therefore, although these individuals were 'lost to follow-up' in the technical sense, an alternative way of dealing with them would be to have excluded them on the basis of their subsequent 'ineligibility'.

For the trial, independent-samples t-tests were used for anxiety, depression and pain. Differing effects of socio-demographic data such as age, gender and type of cardiac surgery should be taken into account when analysing the data. It seemed more appropriate to also report data analysis from linear regression models, whereby anxiety, symptoms of depression, and pain scores were compared between two groups at follow-up after controlling for baseline score, age, gender, education level, and surgery type.

The qualitative evaluation consisted of the rich descriptive narrative derived from semi-structured interviews with a sample of trial participants. By analysing interview participants' own accounts, patients' voices were heard, and their views on preoperative education and experiences of the intervention and the trial were therefore reflected. With regard to interview data analysis, it is important to ensure that the interpretation of data is as close to the actual meaning of participants' accounts as possible (Silverman, 2001, Green and Thorogood, 2009).

Respondent validation, whereby participants are provided with written transcripts or data analysis to check and confirm whether they reflect participants' own experience, may contribute to the credibility and rigor of findings (Mays and Pope, 2000, Barbour, 2001). However seeking validation from participants can be problematic because views may change over time. Researchers are then faced with dilemma when respondents wish to change data (Johnson and Waterfield, 2004). Through respondent validation, additional data are gathered and require further analysis (Papadopoulos et al., 2002). This may lead to confusion rather than confirmation. So the value of respondent validation may be questionable (Cutcliffe and McKenna, 2002, Horsburgh, 2003). Since the interview

transcripts were not reported back to the participants, it is acknowledged that there may have been some meaning lost through interpretation and translation in this study.

8.4 Comparison with other studies

Many health service activities such as preoperative education should be considered as complex interventions which are built up from a number of various components acting both independently and interdependently (Campbell et al., 2007). The Medical Research Council framework was designed for the development and evaluation of randomised controlled trials for complex interventions to improve health care (Campbell et al., 2000). However, there is no doubt that designing and evaluating preoperative education interventions can pose a considerable challenge and require a substantial investment of time and efforts. A low rate of refusal and attrition in this study to some extent is evidence of the feasibility of delivering the intervention and its acceptability to patients. Previous trials on preoperative education for cardiac patients have provided conflicting evidence. It is also difficult to compare our findings with trials where preoperative education interventions are highly variable or poorly described.

8.4.1 Effect on psychological health outcomes

The participants randomised to the preoperative education group showed a greater decrease in anxiety score (mean difference -3.6 points) and a greater decrease in depression score (mean difference -2.1 points) compared with those in the usual care group after adjustment for baseline differences. The preoperative education intervention appears to be beneficial for these Chinese patients in relation to their psychological health. This finding is consistent with a randomised controlled trial of 98

patients on the waiting list for elective bypass surgery at Glasgow (McHugh et al., 2001). That study concluded that a monthly nurse led programme of shared care for patients consisting of health education and motivational interviews according to individual need could effectively reduce levels of anxiety and depression measured by the HADS. A smaller clinical trial of a preoperative health education program with 70 coronary artery bypass graft patients in Iran observed significant improvements between two groups in emotional reaction as measured by the Nottingham Health Profile (Babaee et al., 2007).

However, some studies have found no evidence of the effects of the provision of preoperative information on postoperative anxiety and depression (Goodman et al., 2008, Ivarsson et al., 2005a, Shuldham et al., 2002). Goodman et al. (2008) replicated the Glasgow study (McHugh et al., 2001) with a larger sample of 188 patients listed for bypass surgery in London and did not observe a difference between groups in anxiety and depression scores. The trial conducted by Shuldham et al. (2002) randomised 356 patients to a day of education from members of a multidisciplinary team before admission for bypass surgery and found no difference between groups in anxiety and depression six months after surgery.

Perhaps these findings relate to the setting of the study. If the study was conducted in a setting where a relatively high standard of preoperative education has been routinely delivered to patients, it would be more difficult to detect the difference between the intervention and routine care. In China, the relative lack of routine information giving in hospitals has led to Chinese patients' eagerness and desire to receive information. It could explain why a structured preoperative education intervention in this trial

had a greater impact on psychological health than similar interventions delivered to cardiac surgery patients in western countries.

8.4.2 Effect on length of stay and other outcomes

A lack of difference between randomised groups in postoperative hospital stay and the borderline evidence that the preoperative education intervention can reduce hours spent in ICU suggests that any benefits to physical recovery are likely to be in the immediate rather than the longer-term. Arthur et al. (2000) in a larger randomised controlled trial of 249 patients in Canada found that patients who received preoperative intervention involving exercise training twice a week, education and monthly nurse-led phone calls spent one less day in the hospital after surgery and two less hours in the ICU. Another study (Shuldham et al., 2002) found that there was no difference between groups in relation to their ICU stay but their preoperative intervention group spent one day longer in hospital after surgery. In this study, there was borderline evidence to show that preoperative education resulted in a reduction of four hours in ICU stay. Although no statistically significant difference in postoperative hospital stay was observed, the median length of stay was two days greater in the preoperative education group compared with those who received usual care only.

There are a number of possible explanations as to why, in this study, the patients allocated to the preoperative education group spent two days longer in the hospital after surgery. The finding could be due to chance. Another possible explanation for this is the slightly higher proportion of preoperative education group patients undergoing bypass surgery (48.7% bypass surgery in the preoperative education group vs. 42.9% in the usual care group). This also can partly be explained by characteristic differences

at baseline whereby the preoperative education group tended to have more patents categorised as single and widowed, separated, or divorced, more patients unemployed, and a relatively higher proportion of patients with co-morbidities and previous hospitalisation and operation experiences. All of these differences can possibly result in the longer postoperative hospital stay for the patients in the preoperative education group due to being less well physically and with less family and social support.

This trial did not observe differences between the two groups in terms of average pain, current pain, and interference from pain in general activity, mood and walking ability. The participants randomised to the preoperative education group showed less pain interference with sleep compared with those in the usual care group. Our finding of relatively little impact on postoperative pain is consistent with previous studies (Shuldham et al., 2002, Watt-Watson et al., 2004). In the Canadian randomised controlled trial (Watt-Watson et al., 2004) with 406 bypass surgery patients to evaluate a preadmission pain education intervention, the patients in the intervention group who received an additional pain booklet did not have better pain management outcomes although they had some reduction in pain-related interference in activities. On the other hand, a clinical trial (Babaee et al., 2007) of a preoperative health education program with 70 Iranian bypass patients observed improvements in pain, sleep and physical mobility as measured by the Nottingham Health Profile. However, the results from Babaee et al.'s small trial are more likely to be biased by less reliable methods, where randomisation was reported but the patients were selected to be in the control group after all of the participants in the intervention group had received the education intervention and been discharged from the hospital.

8.4.3 Factors influencing preoperative education in routine practice

Adult learning theory provided a foundation for the development and delivery of the preoperative education intervention in this study. Adult learning theory helps to understand how adults learn and provide some guidance on how to structure and deliver new information for optimal uptake and mastery (Smith, 2002a, Yannacci et al., 2006, Yang, 2004, Kaufman, 2003). Among various psychological and educational models of adult learning, Malcolm Knowles's notion of andragogy has become the most influential work and widely used as a distinctive conceptual basis for adult education and learning. It emphasises six principles of adult learning: an adult's need to know; readiness to learn; motivation to learn; self-concept; orientation to learning; and the role of the learner's experiences (Knowles et al., 1998, Smith, 2002b). Consideration of these principles of adult learning contributed to the design of this preoperative education intervention for cardiac patients in China in terms of the timing, content, and format of the intervention. When adult learning theory was integrated into the development and implementation of the intervention, the intervention had the potential for not only meeting the information needs of patients but also their special needs and requirements as adult learners.

The goal of the preoperative education intervention was to reduce patients' anxiety and improve recovery by improving patients' knowledge and understanding of their disease process and surgical treatment that they were about to experience and enhancing the level of engagement with their health care. The trial examined the effect of the intervention on patients' psychological health and length of stay. It was also considered important to explore how preoperative education subsequently influenced patients' attitude, behavioural performance and health changes in the qualitative evaluation. As the interview participants who received the preoperative

education intervention recalled, through the accessibility of preoperative information, their anxiety was decreased and their feelings of strength, confidence and control over the situation were improved. They valued both the written and verbal information delivered during the intervention. The interview participants reported that they were motivated by the opportunity to engage with the trial, and made a number of helpful suggestions or recommendations concerning future preoperative education interventions.

The qualitative evaluation revealed that patients' perceptions of the reasons behind not getting sufficient and useful preoperative education fall into three broad areas: the heavy workload of staff; a lack of knowledge and skills among staff; and a scarcity of resources. Some interview participants in this study identified information needs and felt that they needed more or different information and should have been encouraged to ask nurses more questions about unclear issues. The patients' experiences of gaps in cardiac preoperative education from ward nurses is consistent with the findings in a literature review of adult surgical patients' perception of the provision of information by nurses (Suhonen and Leino-Kilpi, 2006) and a study of education of surgical patients by hospital staff members in the Netherlands (Breemhaar et al., 1996).

8.4.3.1 The heavy workload of staff

The inadequacies of preoperative education were mainly attributed to staff nurses' heavy workload. Each cardiac surgery ward in both study hospitals accommodates about 60 patients. There are only five to six nurses on duty in the daytime and one nurse on duty during the night. The low nurse-patient ratio places considerable pressure on ward nurses. The situation becomes even more problematic when extra removable beds are arranged

on the corridor for patients to have a temporary stay if there is no patient room available. Nurses are constantly busy with a large amount of routine care and administration. This may be because in China, the nurse's role has traditionally and culturally been perceived as carrying out doctors' orders and administering medication. Neither doctors nor patients consider health education to be part of a nurse's responsibility (Choi et al., 2010).

The associated lack of time staff nurses can spend with patients resulted in minimal contact with patients and their families and a perceived lack of individualised information and care. This is consistent with the findings from previous studies in China (Wu et al., 2011, Chan et al., 2007), the United States (Barber-Parker, 2002, Chobanian et al., 2003) and the United Kingdom (Casey, 2007). If increasing the numbers of staff is not possible, health care providers need to work together to seek ways to deliver preoperative information more effectively and efficiently.

8.4.3.2 A lack of knowledge and skills among staff

Another commonly mentioned barrier was the perception of staff members' lack of knowledge and skills and a lack of confidence in preoperative information for cardiac patients. Patients in this study noticed that health care providers often provided what they assumed to be important to their patients, with no one taking the time to check that patients and their families were given the information they themselves felt they needed. This is consistent with previous studies describing patients' experiences while waiting for cardiac surgery (Ivarsson et al., 2004) and the experiences of patients' next of kin (Ivarsson et al., 2005b). It is important for health care providers to avoid forms of paternalism wherein a treatment or service is 'carried out intentionally on behalf of a person other than oneself, against

that person's wishes or without consent, with the explicit purpose of doing good for, or avoiding harm to, that person' (Cody, 2003, p288).

In China, more attention needs to be paid to patient-centred care and enabling patients to make decisions on what and how much information they want. Since there is considerable variability in the amount and content of preoperative information that patients desire, providing the same level of information may not meet the needs of a highly diverse group of people (Screeche Powell, 2004). It is unrealistic to expect all cardiac patients to want to receive and discuss the same information. Listening to patients and identifying their individual information needs may be the first step in order to provide appropriate and relevant information (Abela, 2009). Ongoing patient assessment is an important skill for nurses to identify the level of fear and anxiety and its sources, patients' pre-knowledge and understanding level and to individualise education topics according to their specific circumstances (McHugh et al., 2001).

Patients' individual preferences for preoperative information may vary, especially for information regarding potential risks and postoperative complications associated with cardiac surgery. Beresford et al. (2001) demonstrate that it is important for health care providers to routinely discuss with patients about their requirement and preferences. Patients can be distressed by too detailed information about risk (Ivarsson et al., 2007, Tobias and Souhami, 1993) and their preoperative anxiety can be increased by inappropriate information (Gillies and Baldwin, 2001). Previous research has also shown that an inaccurate and sometimes irrational understanding of illness and treatment are frequent among coronary patients, and the overestimation of risk is associated with higher levels of anxiety (Broadbent et al., 2006). Cardiac nurses need to provide

sufficient and accurate information relating to both the benefit of cardiac surgery and risk and possible complications in a way that patients can understand (Oates and Paasche-Orlow, 2009, Cheng et al., 2002). Numerous strategies can be implemented to help patients understand the information conveyed such as clear and simple explanations, interactive communication, use of plain language and visual images, welcoming patients' feedback and questions, and a trusting patient-staff relationship (Weiss, 2007, Rosser and Kasperski, 2001, Hall et al., 2001).

In addition, it was noted by the majority of participants that preoperative communication between nurses and patients appeared to be unidirectional and focused on patient teaching with the patient as a passive recipient of information. More interactive discussion between staff nurses and patients was appreciated. Previous studies have also demonstrated that patient relationships with nurses appear to determine how satisfied patients are with the amount of information they receive (Suhonen and Leino-Kilpi, 2006, Sørlie et al., 2000).

8.4.3.3 A scarcity of resources

There are limited resources for cardiac preoperative education at Chinese hospitals. Most of the resources and guidelines which have been developed in western countries cannot be directly transferred for use in a country like China with such a different socio-cultural context. It is not only because learning needs and preferences are very different from one cultural group to another but also the whole healthcare systems are not comparable (Suhonen and Leino-Kilpi, 2006). The participants described their appreciation of getting specific information about average length of hospital stay, and the tests and procedures likely to be undertaken during their hospital stay. Under the unique characteristics of the Chinese healthcare

system, this kind of information can be considerably different from western countries.

In order to meet the needs of patients undergoing cardiac surgery in China, more creative, and more creative use of teaching materials and practice guidelines are needed, which can facilitate staff in the delivery of preoperative education and eventually improve preoperative education in practice. In cardiac preoperative education, there was an expressed need for the development and use of leaflets or handbooks about rehabilitation and care after hospital discharge. This suggestion was consistent with the findings of a study which identified a need for providing patient specific postoperative care and rehabilitation before patient undergo thoracic surgery (Ong et al., 2009). The period following hospital discharge has been found to be stressful for patients (Utriyaprasit et al., 2010). However, currently in China, only a few hospitals provide patients with cardiac rehabilitation services and in those nurses play a limited role (Thompson and Yu, 2007) and in many Chinese hospitals cardiac rehabilitation programmes do not exist (Wu et al., 2011). Cardiac rehabilitation services are not provided in the two study hospitals. To ensure continuity of care, preoperative information should cover what patients need to know about their care after being discharged from the hospital.

As the impact of digital revolution on modern life is recognised, the production and use of videotapes, audiotapes or computer assisted preoperative education, offer the advantage of being interactive and possibly more engaging to patients. Developing and using health education materials deserves more attention as rapid turnover along with staff shortages make it hard for nurses to deliver sufficient verbal information, (Monsivais and Reynolds, 2003). But these education materials need to be

tailored to match cardiac patients' needs, characteristics and preferences. Although developing these education materials involves the expenditure of time and resources, the significant clinical impact of preoperative education warrants the expenditure of time and resources (Oates and Paasche-Orlow, 2009).

8.5 Summary

This chapter discussed the methodological strengths and limitations of the study in terms of study design, patients' recruitment and follow up, randomisation, blinding and contamination, and data analysis. The trial results and qualitative findings were integrated and examined in comparison with other studies. The trial has demonstrated that the preoperative education intervention is effective in reducing anxiety and depression among Chinese cardiac patients. It supports the importance of preoperative education for the improvement of patients' psychological outcomes. The study was conducted in China where a relative lack of routine information provided to Chinese patients has led to their eagerness and desire to receive preoperative education. This could explain why the structured preoperative education intervention in this trial had a greater impact on psychological health than similar interventions delivered to surgical patients in western countries.

The qualitative evaluation further explained that receiving preoperative information could help decrease patients' anxiety and improve their feelings of strength, confidence and control over the situation. A number of suggestions made by the interview participants helped to reveal several factors influencing preoperative education for cardiac patients in practice in China. The overall findings from this study can inform recommendations for future practice and research, which are presented in the final chapter.

CHAPTER NINE

RECOMMENDATIONS AND CONCLUSIONS

9.1 Introduction

This form of preoperative education has been shown to be effective in reducing anxiety and depression among Chinese cardiac patients. Based upon existing evidence and international practice, preoperative education should be incorporated into routine practice to prepare Chinese cardiac patients for surgery. Improving preoperative education in future may be achievable through changes in nurses' attitudes, values, knowledge and skills. It requires time and commitment, as well as support from individual, professional and organisational levels. This chapter examines the implications for nursing education, practice and policy making in relation to the improvement of cardiac preoperative education in the context of health care in China. Finally, the lessons learnt from carrying out the study and how these can inform future research are presented.

9.2 Implications for nurse training in preoperative education

This preoperative education intervention comprising an information leaflet and verbal advice was relatively simple to design and administer and offered substantial gains for cardiac surgery patients. Despite Chinese patients' increasing demands for preoperative education, nurses focused on medical tasks and collecting factual information and often failed to address the patients' fears and emotional issues, especially when those nurses were facing heavy workloads and limited time. Thus it is recommended that this area of care should receive attention.

The training of nurses in the importance of delivering this form of preoperative education is a key recommendation if evidence from this study is to be incorporated into routine practice. Clinical nurses, apart from

undertaking clinical tasks, should have a role in, or responsibility for, giving general information and supporting patients in relation to the reduction of preoperative anxiety and depression (Sørlie et al., 2007, Bäckström et al., 2006). Preoperative education is a well-recognised strategy by which healthcare providers address patients' fear and worries about their surgery (Mooney et al., 2007). Evidence that clinical nurses are poorly prepared for dealing with psychological health problems demonstrates a need for greater education and training in this area (Bergvik et al., 2008). Perhaps a first step is raising awareness among nurses of the potential for alleviating symptoms of anxiety and depression among the patients in their care.

The knowledge and skills and experience of the individual staff influenced the standard of preoperative information received by patients and patients' confidence in individual members of staff. Nowadays, despite the increasing morbidity and mortality due to cardiovascular disease in China, a survey found that Chinese nurses lacked the knowledge to provide guidance in cardiovascular disease prevention and treatment to patients with, or at risk of, the disease (Wu et al., 2011).

As increasing attention is being paid to the evidence base for practice, nurses need to be equipped with the knowledge and skills in critically appraising and utilising evidence (Soltani, 2008). However, in China, clinical nurses tend to take the view that practice should be underpinned by convention and tradition. A possible reason for the failure of implementing research evidence to inform nursing practice is nurses' lack of research related knowledge and skills. Nurses do not feel they are capable of evaluating the quality of research and have enough authority to make change in health care practice (Eddins et al., 2011, Chien, 2010). There is

a need for a way to educate and empower nurses in order for them to introduce evidence into their practice.

9.3 Implications for preoperative education practice

9.3.1 Multidisciplinary preoperative education

The complex relationship between the physical, psychological, and social health of patients demands that health interventions for anxiety and depression are delivered holistically and coherently (Rosenfeldt et al., 2011, Martin and Turkelson, 2006). The importance of multidisciplinary cooperation in patient education has been noted by others (Deccache and van Ballekom, 2001, Fournier et al., 2001, Bensing et al., 2001), while the role of nurses in patient education cannot be overlooked (Monsivais and Reynolds, 2003).

Although interview data in the present study indicated that doctors played an important role in giving information, providing patients with appropriate preoperative information is not the prerogative of medical staff. As preoperative education includes all aspects of patient health care, to deliver the diverse contents of information may involve a wide range of professionals including not only medical staff, but also nurses, anaesthetists, psychologists, pharmacologists and physiotherapists. The goal of preoperative education to prepare patients for surgery is perhaps best reached through the collaborative efforts of the health care providers involved in the patients' care (Ong et al., 2009, Tse and So, 2008)

There is a need to call for a nurse-coordinated multidisciplinary preoperative education in which different health care providers from across disciplines work closely together to provide a more effective and efficient service. The strength of multidisciplinary interventions lies in the breadth of

skills and expertise that different disciplines bring. On the other hand, inconsistencies, overlaps and gaps can be found when information is supplied by different health workers (Van Weert et al., 2003). The unambiguous delineation of responsibilities and tasks in information provision, such as being clear about who is responsible for what kind of information at what time, can help prevent this (Tromp et al., 2004).

9.3.2 Patient involvement and social support

The participants during the interview valued the involvement of role models in preoperative education and wished they could get more contact with previous patients and learn more from their stories. It is recommended that ward staff help co-ordinate the process whereby patients who have undergone cardiac surgery recently can talk with current patients about their own experiences of surgery. Whyte and Grant (2005) suggested that an eager and well-informed patient could participate in the process of preoperative education. It is considered as a beneficial way to provide peer support and encouragement through shared experience. Additionally, patient feedback on the delivery of preoperative information should be encouraged and taken into account. It can contribute to the development and improvement of preoperative education interventions in the future (Wensing et al., 2003, Kruzik, 2009). Areas in need of improvement can be highlighted by patient feedback (Marshall et al., 2000, Tasa et al., 1996), which often help to inform both practice and policy (Jamtvedt et al., 2006).

Social support not only facilitates recovery after coronary artery bypass surgery (Hämäläinen et al., 2000), but it can also play an important role in patient preoperative education. Family members play an important role in providing social support, although health care providers can provide social support through communication with patients (Rantanen et al., 2004,

Martin and Turkelson, 2006). In the present study, nearly all of the participants in the preoperative education group invited at least one of their family members to attend the intervention. Perhaps this was because the presence of family members enabled them to remember and reinforce what had been discussed. A systematic review of patients' experiences of preoperative communication similarly showed that relatives were found to be needed during the preoperative communication to help the patients prepare better for the surgery (Chan et al., 2011). On the other hand, involving family members in the process of preoperative education to discuss questions they had helped family members become calmer about the surgery (Martin and Turkelson, 2006).

9.4 Implications for policy

The provision of preoperative education has not received sufficient attention in Chinese hospitals. One reason for this is a lack of policy and financial support from the Chinese Department of Health in patient preoperative education. Albada et al.'s research (2007) comparing patient education in hospitals in the Netherlands, Flanders and England suggests that where there is a stable organisation and delivery of patient education in hospitals, it is mainly the result of government policy and subsidy. A lack of national or regional policy of patient preoperative education results in a lack of coherence in preoperative education practice at Chinese hospitals. China having a relatively low total per capita healthcare spend limits financial support which can be provided for patient education.

Evidence based government policies on patient preoperative education are needed. They can trigger every hospital or institution in China to acknowledge the importance of preoperative education in patient health by outlining the minimum service in preoperative education hospitals should

deliver to patients. Financial support from the national and regional government as well as at hospital level is also essential for the development of preoperative education materials to use in practice, cardiac nurse training in the delivery of preoperative education and research in the field of preoperative education.

Although the intervention in this study was designed to be simple, it would take at least ten minutes for each patient from the nurses' limited time if it was to be implemented by clinical nurses on the cardiac surgical wards. It is not impossible to incorporate into routine care but will inevitably increase nurses' workloads. Nurses working in specialist roles were seen to contribute positively to preoperative patient education and their input reduced the workload of ward based nurses (Fitzpatrick and Hyde, 2006). In a qualitative study exploring the perceived role and impact of one nurse consultant in rheumatology (Ryan et al., 2006), seven peers of the consultant and five patients were interviewed and found the nurse consultant role had an impact on service development, leadership and education activities. The advanced nursing roles were found to have a positive impact on patient outcomes and play an important role in improving nursing quality in many areas including cardiac nursing (PEPLAU, 2003). The development of advanced nursing roles in cardiac surgery in China could potentially contribute to optimising preoperative education practice in terms of speed and efficiency.

Since there is a lack of research evaluating preoperative education for cardiac patients in China, policy making in this area is more likely to be based on international literature and international practice. Evidence showed that patient education in one country may function as a mirror for the quality improvement of patient education in other countries (Visser et

al., 2001). Exploring and learning from experience with preoperative education among cardiac patients in other countries can contribute to the development of innovative education interventions and improvement of health care services in China. While it is acknowledged that compared to western countries, there may be different traditions regarding the delivery of information and education in China, patients' desire for information about surgery and suggestions for improving the quality and effectiveness of preoperative education seems fairly consistent (Henderson and Chien, 2004). Findings generated from other countries can enrich the understanding of preoperative education interventions from a cross-cultural perspective (Douglas et al., 2009, Hayman and Hughes, 2005).

However, it is unwise to directly apply preoperative education interventions which have been effective in other countries into practice in China without further investigation. These interventions have to be tailored to suit the social, cultural and economic conditions in China. The intervention designed in this study is likely to be applicable across different countries and cultures by adjusting the method of implementation according to the specific cultural and environmental contexts. As Pettigrew (1990) argued, when any change process takes place, a comprehensive analysis of the cultural and contextual influential factors is important such as exploring and evaluating the underlying obstacles and available resources under the given circumstances.

With the increasing incidence and substantial global burden of cardiovascular disease, nursing care for this group of patients deserves worldwide attention. Health inequalities do exist in prevention, diagnosis, treatment, and follow-up of heart disease. The need for integrating cultural competence into nursing education and practice becomes apparent when

nursing's global consciousness evolves further (de Leon Siantz and Meleis, 2007). In view of this, it is time for nurse leaders in China to acknowledge the importance of engaging Chinese cardiac nurses along with cardiovascular nurses and researchers from other countries to contribute to prevention, treatment and care of people with cardiovascular disease and people at high risk.

9.5 Implications for future research

9.5.1 Effectiveness or efficacy?

More research is needed that evaluates health care interventions applied by health care providers rather than research teams. There has been a tendency for researchers to underestimate both the ability of health services staff, from across professional backgrounds, to work to research protocols and their understanding of the importance of concepts of trial design such as randomisation. However, researchers are often not directly involved in clinical practice. Involving health care providers in research or encourage them to carry out research can become a starting point (Mantzoukas, 2008).

The health care providers in this study were not experienced researchers but they maintained enthusiasm for the project throughout the study period as this was the first time any of them had been involved in a randomised controlled trial. Both the successful recruitment of participants and completion of follow-up measures can be attributed to the significant contribution made by doctors and nurses working at the cardiac surgical wards of the two study hospitals.

Standardising and replicating a non-pharmacological intervention for other settings is sometimes difficult as the intervention in a trial is usually

conducted according to a highly specified protocol which may be impractical when applied in practice (Campbell et al., 2007, Campbell et al., 2000). Therefore, the importance of evaluating these interventions under 'normal' service conditions, or in other words, evaluating interventions as they operate in the 'real world' is emphasised (Arthur et al., 2002, Cheater, 2003). Although in the present study my role was as a cardiac nurse to carry out the preoperative education intervention, it is necessary to test whether a similar effect can be found if the intervention was to be delivered by the nurses on the wards.

9.5.2 Research priorities

Despite some methodological limitations of this study, the results suggest that this simple low cost preoperative education intervention has beneficial effects on cardiac patients' psychological outcomes. This study could serve as a basis for further research regarding preoperative education for cardiac surgery patients. Further trials that deal with these methodological problems should be undertaken, along with ones that replicate the study in other settings such as in primary care and among people with significant anxiety and impaired quality of life.

The preoperative education intervention was feasible and could safely be used among patients who were undergoing various types of cardiac surgery. Exploring possible ways in which the preoperative education intervention could be incorporated into routine practice is a priority for future research. There is a need for more research to determine the optimal time for preoperative education and to examine the long term effects of preoperative education. Future work is also needed to show whether preoperative education interventions like this affect 'hard'

outcomes, such as physiological outcomes, utilisation of health services and costs.

In China, the time from admission to surgery is typically one week although there is an increasing trend toward shortening this period. This is in contrast to cardiac surgery performed in western countries where patients undergoing elective surgery are admitted on the day of the procedure. There is evidence showing that the longer a patient stays on the waiting list for cardiac surgery, the more likely they are to reduce their leisure activities, causing them to experience anxiety, reduced physical and social functioning, poorer vitality, and general health (Sampalis et al., 2001). While longer preoperative hospital stay gives ample time for preoperative intervention, it is possible that this partially accounts for a relatively high level of baseline anxiety which has allowed the trial to demonstrate such a large impact of preoperative education on patient anxiety. The effect of decreasing preoperative hospitalisation on patient anxiety and other postoperative outcomes is a subject suitable for future research.

There is an increasing awareness in western countries of the costs associated with poor health literacy (Eichler et al., 2009) but the concept of health literacy has been given scant attention in China. Health literacy has been defined as 'the ability of individuals to understand and use text, documents, and numbers pertinent to commonly encountered health care situations. These situations included care of illness, dealing with preventive care, and navigating the health care system' (Weiss, 2007, p8). Health literacy is critical to empowerment. Many factors are associated with poor health literacy including an increasingly complex healthcare system, difficulties accessing healthcare, limitations in patient-provider

communication, and the failure of health care providers to promote self-management and recognise patient barriers to communication and comprehension (Oates and Paasche-Orlow, 2009, Hironaka and Paasche-Orlow, 2008). There is a need for observational studies to determine the level and variation of health literacy among Chinese health care users, and qualitative research to gain greater insights into how good health literacy is achieved.

Future research should target the dearth of trials into complex interventions delivered within the context of Chinese healthcare. Cardiac rehabilitation interventions may be a fruitful subject for further exploration, as the period following hospital discharge has been found to be stressful for patients (Utriyaprasit et al., 2010). Complex interventions are context specific (Craig et al., 2008) and it is unwise to assume that evidence from western countries is directly transferable to Chinese healthcare settings without further investigation.

9.6 Conclusions

This study provides empirical support for the hypothesis that a preoperative education intervention involving an information leaflet combined with verbal explanation can be effective in reducing anxiety among Chinese patients undergoing cardiac surgery. The follow-up qualitative evaluation exploring patients' experience provided in depth understanding of the context and process of the intervention implemented and helped answer questions regarding why and how this intervention works and can be improved. The acceptability of both the intervention and the study was supported by the low attrition rate and data from the qualitative evaluation. This type of intervention could be widely implemented both across China and the world.

Cardiovascular diseases are increasing in China and have become one of the leading causes of mortality among Chinese adults. Patients awaiting cardiac surgery experience high levels of anxiety and significant symptoms of depression due to fears, worries and uncertainties about surgery. Findings from this study not only have important implications for hospital staff who are looking for effective strategies to control patients' elevated anxiety in anticipation of cardiac surgery, but also help make recommendations for quality improvement of preoperative education in practice. More research is needed into possible ways to incorporate preoperative education interventions into everyday nursing practice, the optimal time and components of these interventions for sustained effect, and patients' health literacy within the context of Chinese health care.

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APPENDICES

Appendix 1 Participant information sheet

English version

Chinese version

Appendix 2 Consent form

English version

Chinese version

Appendix 3 Patient characteristics form

English version

Chinese version

Appendix 4 Hospital anxiety and depression scale

English version

Chinese version

Appendix 5 Brief pain inventory short form

English version

Chinese version

Appendix 6 Preoperative information leaflet - 'your heart surgery'

English version

Chinese version

Appendix 7 Contact letter

English version

Chinese version

Appendix 8 Leaflet evaluation form

English version

Chinese version

Appendix 9 Interview schedule

English version

Chinese version

Appendix 10 Approval letters

English version

Chinese version

Appendix 11 Publication