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Complete List of Authors:	Lai, Veronica Ka Wai; The Chinese University of Hong Kong, Anaesthesia and Intensive Care Lee, Anna; The Chinese University of Hong Kong, Anaesthesia and Intensive Care Leung, Patricia; The Chinese University of Hong Kong, Anaesthesia and Intensive Care Chiu, Chun Hung; The Chinese University of Hong Kong, Anaesthesia and Intensive Care Ho, Ka Man; The Chinese University of Hong Kong, Anaesthesia and Intensive Care Gomersall, Charles; The Chinese University of Hong Kong, Anaesthesia and Intensive Care Underwood, Malcolm; The Chinese University of Hong Kong, Division of Cardiothoracic Surgery, Department of Surgery Joynt, Gavin; The Chinese University of Hong Kong, Anaesthesia and Intensive Care
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Patient and family satisfaction levels in the intensive care unit after elective cardiac surgery: study protocol for a randomized controlled trial of a preoperative patient education intervention

Veronica Ka Wai LAI,[1] Anna LEE,[1] Patricia LEUNG,[1] Chun Hung CHIU,[1] Ka Man HO,[1] Charles David GOMERSALL,[1] Malcolm John UNDERWOOD,[2] Gavin Matthew JOYNT[1]

[1] Department of Anaesthesia and Intensive Care, The Chinese University of Hong Kong

[2] Division of Cardiothoracic Surgery, Department of Surgery, The Chinese University of Hong Kong

Address for correspondence: Professor Anna Lee, Department of Anaesthesia and Intensive Care, Prince of Wales Hospital, The Chinese University of Hong Kong, Shatin, New Territories, Hong Kong

Phone: +852 2632 2735 Fax: +852 2637 2422 Email: annalee@cuhk.edu.hk

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ABSTRACT

Introduction: Patients and their families are understandably anxious about the risk of complications and unfamiliar experiences following cardiac surgery. Providing information about postoperative care in the intensive care unit (ICU) to patients and families may lead to lower anxiety levels and increased satisfaction with healthcare. The objectives of this study are to evaluate the effectiveness of preoperative patient education provided for patients undergoing elective cardiac surgery.

Methods and analysis: 100 patients undergoing elective coronary artery bypass graft, with or without valve replacement surgery will be recruited into a two-group, parallel, superiority, double-blinded randomized controlled trial. Participants will be randomized to either preoperative patient education comprising of a video and ICU tour with standard care (intervention) or standard education (control). The primary outcome measures are the satisfaction levels of patients and family members with ICU care and decision-making in the ICU. The secondary outcome measures are patient anxiety and depression levels before and after surgery.

Ethics and dissemination: Ethical approval has been obtained from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (Reference number CREC 2015.308). The findings will be presented at conferences and published in peer-reviewed journals. Study participants will receive a one-page plain language summary of results.

Trial registration: The Chinese University of Hong Kong Centre for Clinical Research and Biostatistics Clinical Trials Registry (CCRBCTR): CUHK_CCT00472

Strengths and limitations of this study:

- Our study was designed to deliver a structured patient education package for cardiac surgical patients that specifically target surgical issues and the ICU stay, as well as to investigate the inter-relationships between patient education, satisfaction with ICU scores and measures of anxiety and depression.
- A weakness may be the shorter time spent in the control group; this could influence the overall satisfaction of patient-family interaction with health care professionals.

INTRODUCTION

Patient satisfaction with health care services is an important outcome that is increasingly used as a marker for quality of care. Poor satisfaction levels reflect a large difference between expectations and fulfilment of perceived needs and may have implications for adherence to treatment that subsequently affects patient outcomes.[1] For example, following cardiac surgery, patients dissatisfied with discharge information were more likely to report a poorer physical recovery and psychological state at home one month after undergoing surgery.[2]

Family satisfaction with care

Severe illness and its potential outcome impacts not only on the patient, but also their close family, defined as those persons with close family, social or emotional relationship to the patient. In addition, many intensive care unit (ICU) patients cannot make decisions for themselves, their family must therefore become surrogate decision-makers for important parts of the care process. Hence, measuring family satisfaction with ICU care has become an important and essential component of quality of care in this setting.[3] Several family satisfaction surveys measuring satisfaction with general ICU care have been developed with sound psychometric properties, and have been reviewed elsewhere.[4] The key domains related to family satisfaction include ICU environment[5, 6] and process of care,[5] sufficient information and quality communication with medical professionals to make important decisions about care.[5, 7] In order to improve the quality of care in ICU, it is essential to examine the perspectives from both patients and their family members[6, 8] and implement strategies to address areas of concern. As an example on the impact of the environment of ICU on patients, both patient and family satisfaction levels increased by 6% with the changes from a ward

with multiple beds to a newly designed ICU with noise-reduced, single rooms with daylight and improved family facilities.[6]

Patient and Family psychological distress

Surgical patients encounter physical trauma and psychological distress after surgery.[9, 10] Psychological distress has been defined as a collective term for anxiety and depression levels.[11] Beyond that, an unfamiliar hospital environment, such as the ICU, is another stressful factor that is associated with high anxiety and depression levels.[12] In coronary artery bypass grafting (CABG) patients, anxiety and depression occurs for several reasons: 1) routine procedures during ICU admission, for instance, oral and nasal tubes are important stressors[13] because they result in an inability to talk, affecting communication with ICU staff and 2) the associated time spent on the waiting list before the surgery. The prevalence of clinically significant anxiety and depression in patients awaiting CABG was 28% and 47% respectively.[14] Results from a systematic review found that higher levels of preoperative anxiety and depression in CABG patients were predictive of psychological distress in the postoperative period.[15] Generally, family members were significantly more anxious than patients themselves towards the cardiac surgery.[16] However, family members of the cardiac surgery patients reported lower level of anxiety and high satisfaction if their informational needs about the surgery and treatment of the patients were fulfilled.[17]

Informational needs

Previous studies have shown that multimedia educational interventions can reduce anxiety and foster an understanding of the processes and risks of cardiac surgery for both patients[18]

and their family members,[17] regardless of the format to convey the patient education: using tape,[19] written leaflets,[18, 20] or verbally during the preoperative visit by ICU or specialist cardiac nurses.[18, 20] Additionally, results from a multicenter study in a non-cardiac ICU [21] showed that disclosing all the available information in a frank, direct, and empathetic way could meet the informational needs of family members about the patients, and thus, they were more satisfied; conversely, families who felt that they had received contradictory information had 21.1% lower satisfaction scores than their counterparts.[21]

Effect of patient education

Having a preoperative patient education programs which provides sufficient information on the risk and process of surgery to patients may help to increase their satisfaction levels and reduce their anxiety levels. A randomized controlled trial[18] of a preoperative educational intervention (usual care plus information leaflet and verbal advice) versus usual care, in patients undergoing cardiac surgery showed a moderate reduction in anxiety levels (adjusted mean difference -3.6, 95% CI: -4.62 to -2.57) and depression levels (adjusted mean difference -2.1, 95% CI: -3.19 to -0.92) using the Hospital Anxiety and Depression Scale (HADS). Another recent study showed that an effective nurse-led preoperative education not only reduced anxiety levels, but also reduced the risk of postoperative complications, such as sternal infection, in cardiac surgical patients.[22]

However, the evidence to support benefits from patient education in the ICU setting is mixed. In a recent multi-centered randomized controlled trial of a structured information program during the ICU stay compared to a non-specific conversation of similar duration, there was

no reduction in patient anxiety levels (mean difference -0.2, 95% CI: -4.5 to 4.1 on a scale from 0 (no anxiety) to 100 (maximum anxiety) in medical and surgical critically ill ICU patients.[23] In a cross-sectional study of family members visiting ICU patients, although there was a moderate correlation between family perception of informational support and satisfaction with care (r=0.74, P<0.001), very little correlation between informational support and anxiety levels (r=-0.13, P=0.50) were found.[24] Neither of the two studies provided information about ICU before the ICU admission.[23, 24] A nonrandomized study examining the effect of a preoperative ICU tour prior to cardiac surgery failed to detect a significant difference in anxiety levels between the control (no ICU tour) and treatment (ICU tour) after adjusting for previous ICU experience (P=0.43).[25] Nevertheless, the authors showed that patients in the treatment group perceived the tour to be beneficial for themselves and for future patients.[25] In addition, other studies found that in order to reduce psychological distress, both ICU nurses and patients believed that preoperative patient education led by ICU nurses explaining the reasons for ICU admission, ICU environment and the expected postoperative care would be beneficial.[26, 27]

Significance of the present study

The previous studies discussed above have focused individually on the separate issues of satisfaction with general ICU care, preoperative psychological distress and informational needs related to surgical aspects of care. However, few have adequately examined the effect of educational interventions specifically targeting surgical issues and the post-operative ICU stay, or investigated the inter-relationships between patient education, patient and family satisfaction scores, and measures of anxiety and depression. This two-group, parallel, superiority, double-blinded randomized controlled trial will examine the effectiveness of a

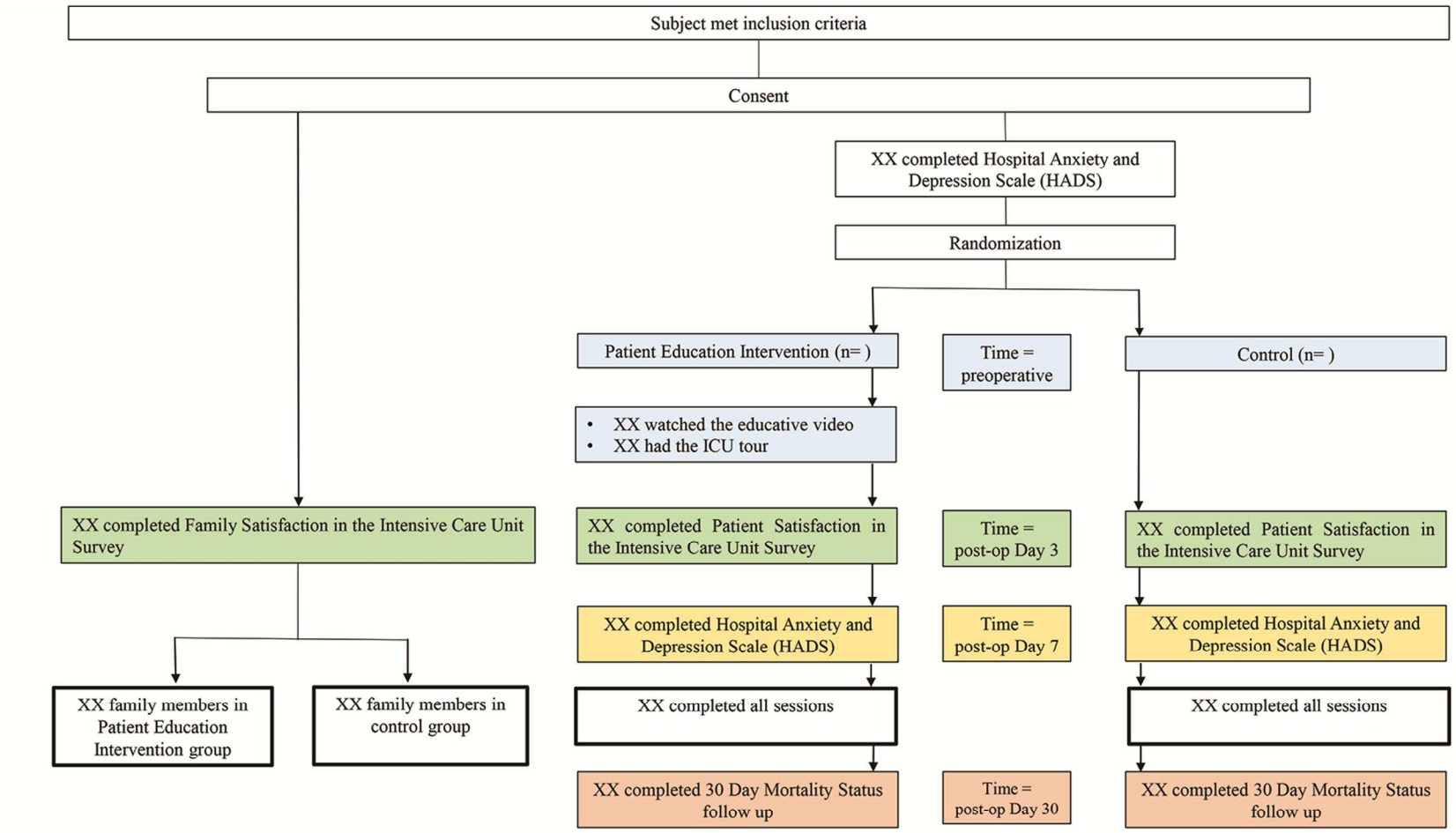
multi-faceted patient education intervention on patient and family satisfaction, and post operative anxiety and depression in patients undergoing cardiac surgery. The primary objective is to determine the effect of the preoperative patient education package (video and ICU tour) for patients undergoing elective cardiac surgery on patient and family satisfaction with care and decision-making in the ICU. The second objective of the study is to determine the effect of preoperative patient education package on anxiety and depression levels in patients after elective cardiac surgery. The primary hypothesis is that preoperative patient education will increase both patient and family satisfaction levels after elective cardiac surgery and the secondary hypothesis is that preoperative patient education will reduce patient anxiety and depression measures after cardiac surgery.

METHODS AND ANALYSIS

Study design

We will conduct a single-centre, double-blinded, two-group, parallel, superiority, randomized controlled trial of 100 adults undergoing general anaesthesia for elective coronary artery bypass graft, with or without valve replacement (CABG ± valve) surgery. Block randomization with a 1:1 allocation has been planned. Family members and patients will be followed up to the third day and to one month after patient's surgery, respectively (Figure 1). The study has been designed with reference to the CONsolidated Standards Of Reporting Trials (CONSORT) statement,[28] and reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.[29]

Figure 1 Flow of participants



Setting and population

The study will be conducted at The Prince of Wales Hospital in Hong Kong, a 1,400-bed university teaching hospital. Currently, there are 12 to 15 adults who undergo elective CABG ± valve surgery per month. All elective CABG ± valve surgery patients are routinely admitted to our 22-bed ICU for early postoperative care and monitoring with 1:1 nursing at all times, and are expected to be discharged from ICU to a high dependency cardiac ward within 24 hours after surgery.

Only adult patients undergoing primary elective CABG ± valve surgery whose primary language is Cantonese will be recruited from the operating theatre list published on the day before cardiac surgery. The patient education intervention includes a video in Cantonese, the predominant language used in Hong Kong. Patients will be excluded if they have a history of dementia, psychosis or neurological disease that would prevent them completing outcome questionnaires and are unable to provide written informed consent. We will also exclude patients undergoing emergency cardiac surgery (no opportunity to apply the intervention), patients who have had a previous cardiac surgery (prior exposure), and those who have received previous care in an ICU (prior exposure).

Family members of the patient will be also invited to join the patient education intervention before the elective cardiac surgery. 'Family' will be defined as persons with close family, social or emotional relationship to the patients;[1] thus next of kin and adult children of the patient will be included in the study. Family members will be excluded if they are unable to understand Cantonese, have previous experience with ICU care, previously underwent any

cardiac surgery or did not visit the patient in ICU. The reasons for exclusion and number of patients or families lost to follow-up will be documented.

Sample size

A sample size of 45 in each group will have 80% power to detect a difference in means of 10 points (the difference between mean control group satisfaction of 70 and a mean intervention group satisfaction of 80) assuming that the common standard deviation is 16.6 (effect size of 0.60) using a two group t-test with a 0.05 two-sided significance level.[6] Given that our fast-track failure rate in cardiac surgery is approximately 10%, we will recruit 100 patients for the study (50 patients in each group). A study of 100 is adequately powered to detect a decrease in anxiety (unadjusted mean difference of 2.7) score at Day 7 after cardiac surgery (using the Chinese-Cantonese version of Hospital Anxiety and Depression Scale[30]) that was associated with a preoperative education intervention.[18] The sample size calculations were performed using nQuery Advisor 7.0 (Statistical Solutions Ltd, Cork, Ireland).

Randomisation and allocation concealment

Block randomization with 1:1 allocation will be carried out according to a computer-generated sequence and will be performed by one of the authors not involved in recruitment or clinical care, using a software program PASS 11 software (NCSS, Kaysville, Utah). The treatment allocation will be concealed in consecutively numbered sealed opaque envelopes and opened after obtaining patient consent before surgery and measuring baseline anxiety and depression levels. Selection bias will be further minimized by restricting access to, and availability of, the video material.

Blinding

Patients in the intervention group are encouraged not to inform clinical staff about their allocation to prevent performance bias. The ICU staff will not be aware of the study objectives and which patients are recruited into the study. The outcome assessor is blinded to treatment allocation and will collect the primary outcome on Day 3, secondary outcome on Day 7 and health status at Day 30 postoperatively (Figure 1).

Interventions

Control arm: Standard education

Patients in the control group will receive the standard preoperative consultations by surgeons and anaesthesiologists, and nursing care in the cardiac surgical wards. Unstructured information about the general process and risk associated with surgery and anaesthesia, postoperative care and the care after discharge from hospital will be given in the usual manner to patients and family members one day before cardiac surgery. All patients will receive standardized surgical processes and perioperative care under existing protocols for postoperative ICU sedation, analgesia and weaning from mechanical ventilation. Also, all patients will be given a standardized anaesthesia described in detail elsewhere[31] with volume controlled ventilation set at a tidal volume of 8ml/kg of ideal body weight with a positive, end-expiratory pressure of 5 cm H_2O.

Intervention arm: Video and ICU tour (+Standard care)

Patients randomly allocated to the treatment group will receive the same standard care provided in the control group, as well as the patient education package conducted in the ward one day before cardiac surgery. The family members will be invited to participate in the patient education session with the patient at the time of consent. First, they will be given a

15-minute education video describing the ICU environment, invasive tubes and lines, pain management, medical management, communication modes and family support (Table 1). Finally, a 5 to 10 minute tour of the ICU, conducted by a dedicated ICU nurse, will be given to patients and their family members after the video intervention.

Table 1. Information covered in the preoperative video and ICU tour

ICU environment (video and ICU tour):
• The standard bedside setting (cardiac monitors, ventilators, pumps, alarms)
• The ICU routine activities – doctor ward rounds, bathing time, etc
Types of invasive tubes and lines for patients after cardiac surgery (video and ICU tour)
• Oral endotracheal tube
• The pacemaker
• Chest drainage tubes
• Urinary catheter
• Various IV lines
Postoperative pain management (video)
• The types of pain experience during the postoperative period
• The pain relieving method
The medical management (video)
• The common weaning strategy from mechanical ventilator
• The duration of the placement of the chest drainage tubes
• What delirium is and how to treat it
• The expected length of stay in the ICU
Communication between patients, relatives and ICU staff (video and ICU tour)
• Role of case nurse (dedicated bedside nurse)
• Communication methods between the patients, family and nurses
• Arrangement of the interview between the family, the ICU doctors and/or surgeons
Family support (video)
• The visiting guidelines – number of visitors per visit, visiting hours
• Demonstration of hand-washing when visiting patient
• The importance of touch to reassure the patient

To help patients and family members retain the information presented, three multiple choice questions will be asked at the conclusion of the video presentation. The research coordinator and ICU nurse will clarify any misconceptions patients may have if the questions are answered incorrectly. A previous study showed that subjects spontaneously recalled less than

a quarter of the preoperative anaesthesia information in a video, but correctly recalled 83% of the information using multiple choice testing format.[32]

Outcome measures

Satisfaction in the Intensive Care Unit Survey

The primary outcome is satisfaction with ICU care and decision-making process, from the perspective of both the patients' family members and the patients themselves. The family satisfaction in the ICU (FS-ICU) survey has been well validated in numerous studies,[4, 33-35] and translated into Chinese[5] and other languages. The Chinese 24-item family satisfaction in the Intensive Care Unit survey[35] and its adapted patient version, will be used on Day 3 after the surgery with help from a blinded outcome assessor. Items in the patient version were semantically modified from addressing perspectives from family to fit the patients' own satisfaction perceptions in the ICU experiences. For example, one of the items in the family version is "the courtesy, respect and compassion your family member was given" was modified to "the courtesy, respect and compassion you were given" in the patient version. In the event that the patient stays longer than 24 hours in the ICU, the questionnaires will be completed on the third day after the time of extubation. Both satisfaction surveys consist of two parts, namely satisfaction with overall care (14 items) and satisfaction with decision-making (10 items). The surveys each take about 10 to 15 minutes to complete for patients and a close family member. All items use a 5-point Likert scale and will be recoded, transformed to a 0 to 100 scale (0 represents poor satisfaction, 100 represent high satisfaction) for both subscales and the total satisfaction score. The reliability of the overall satisfaction score is high (Cronbach's $\alpha = 0.94$) and there are moderate to strong correlations with the Quality and Dying and Death questionnaire and nurse-assessed quality indicators.[35]

Hospital Anxiety and Depression Scale (HADS)

The proposed secondary outcomes will be the change in anxiety and depression scores using the Chinese-Cantonese version of HADS.[30] This is a valid and reliable tool comprising of seven questions relating to anxiety (anxiety subscale) and seven questions rating to depression (depression subscale).[30] Each item is scored according to a four point scale (0-3) and for each subscale, the score ranges from 0 to 21, with higher scores indicating a greater severity of disorder. The incidence of anxiety and depression will be defined as HADS subscale scores of equal to or more than 8.[36] The internal reliability Cronbach's α values for the anxiety and depression were 0.77 and 0.82 respectively and the full scale is 0.86.[30] The Chinese-Cantonese version of the HADS will be used at the time of consent into the study and on the seventh day after cardiac surgery. In the unlikely event that the patient is discharged before postoperative Day 7, the blinded outcome assessor will use the HADS at this point in time by conducting a telephone follow-up.

After obtaining consent, one of the authors will enroll the patients and family members into the trial and collect the following demographic and clinical data: age, gender, education level, American Society of Anesthesiologists Physical Status, predicted mortality using the logistic European System for Cardiac Operative Risk Evaluation (EuroScore) method,[37] patient's comorbidities, details of surgical procedures, duration of anaesthesia, anaesthetic technique, Richmond Agitation-Sedation Scale score[38] during the ICU stay, delirium assessment which was defined by routine bedside Confusion Assessment Method for the Intensive Care Unit (CAM-ICU),[39] severity of illness score on ICU admission (APACHE II),[40] duration of mechanical ventilation, ICU length of stay, duration of the hospital stay and the 30-day

mortality status from the patient's medical record and from the Hospital Authority Clinical Management System electronic database. If the patient has the educational intervention without a family member, this will be noted in the standardized data collection form and will be included in the analyses. Data will be entered into a password protected MS Access database with built-in data integrity checks (valid values, range and primary key checks) and list of valid descriptive code options.

Statistical analysis

Missing data will be checked and imputed to preserve power. The Shapiro-Wilk test will be used to check data for normality. Student's t-test and Mann-Whitney U test will be used for group comparisons of continuous parametric and non-parametric variables at baseline. Chi-square or Fisher's exact tests will be used for group comparison of categorical data at baseline.

Intention to treat and per-protocol analyses will be performed using SPSS software (IBM, New York). The mean and standard deviation of the patient and family satisfaction scores, and HADS anxiety and depression subscale scores will be reported. The mean difference in satisfaction levels between groups will be reported after adjusting for confounders using multiple linear regressions. A generalized estimating equation (GEE) population average regression will be used to examine the mean difference in anxiety and depression subscales between groups over time after adjusting for confounders and patient-family clusters. As some patients and family members may be too apprehensive to join the preoperative ICU tour after the video intervention, we will perform a sensitivity analsyis on the three groups

(control, video only, video plus ICU tour) to examine how robust the results are. The level of significance will be set at $P<0.05$.

DISCUSSION

Ethical considerations

Ethical approval was obtained on July 6 2015 from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (Reference number CREC 2015.308, protocol number 1.0, dated 21 April 2015). Any protocol amendments will be submitted to the local clinical research ethics committee for approval. This trial is registered with the Centre for Clinical Research and Biostatistics, Clinical Trials Registry (CCRBCTR) of The Chinese University of Hong Kong (CUHK_CCT00472). A face-to-face meeting will be scheduled with potential participants to confirm the participants' eligibility. Before obtaining their informed written consent, the purpose of the study, procedures, risks and benefits of joining the study and time commitment of the study will be explained to the participants. Patients may withdraw from the study without prejudice. Data will be kept confidential in secure offices of the Department of Anaesthesia and Intensive Care. The first, fourth and corresponding authors will have access to the final dataset. Only group data will be published. The study will adhere to local laws, Declaration of Helsinki and institutional policies.

Data and monitoring plan

As there are no planned interim analyses and stopping rules for this study, a formal committee for data monitoring is not required. At the start of the trial, the outcome assessor will undergo training in interviewing patients using the satisfaction in ICU questionnaires and

Hospital Anxiety and Depression Scale. Periodic audits on the integrity of the randomization, source data verification against the paper data collection forms, overall quality and completeness of the data will be performed by a senior author. It is anticipated that there are no serious adverse events caused by trial patient education intervention.

Dissemination

We are unaware of any studies examining both patient and family satisfaction levels with ICU care associated with preoperative patient education for major surgery requiring postoperative ICU care. This paper describes a patient education intervention for use within the Hong Kong health service and the video (in Cantonese dialect) will be made available to others after completing the trial upon request to the authors. The results of this study will highlight aspects of ICU care and decision-making process for further quality health services improvement. As part of the knowledge translation approach, study participants will receive a one-page plain language summary of the results. The results will be disseminated at an international critical care medicine conference and in a peer-reviewed journal.

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Competing Interests: None declared.

Contributors: The protocol was jointly written by VKWL and AL and was critically reviewed by PL, CHC, KMH, CDG, MJU, GMJ. All authors were involved in the study concept and design of the study and approved the final version of the manuscript.

Trial Sponsor: The Chinese University of Hong Kong. AL is the study guarantor.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2,17
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	17
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 18
	5b	Name and contact information for the trial sponsor	1, 18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	None
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
	6b	Explanation for choice of comparators	12-13
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8,10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10,11
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12-14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	16-17
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9,14-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9,12-16

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11,15
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-17
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	17
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	18
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2,18
	31b	Authorship eligibility guidelines and any intended use of professional writers	18
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	2,18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not included, in Chinese
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Patient and family satisfaction levels in the intensive care unit after elective cardiac surgery: study protocol for a randomized controlled trial of a preoperative patient education intervention

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Patient and family satisfaction levels in the intensive care unit after elective cardiac surgery: study protocol for a randomized controlled trial of a preoperative patient education intervention

Veronica Ka Wai LAI,[1] Anna LEE,[1] Patricia LEUNG,[1] Chun Hung CHIU,[1] Ka Man HO,[1] Charles David GOMERSALL,[1] Malcolm John UNDERWOOD,[2] Gavin Matthew JOYNT[1]

[1] Department of Anaesthesia and Intensive Care, The Chinese University of Hong Kong

[2] Division of Cardiothoracic Surgery, Department of Surgery, The Chinese University of Hong Kong

Address for correspondence: Professor Anna Lee, Department of Anaesthesia and Intensive Care, Prince of Wales Hospital, The Chinese University of Hong Kong, Shatin, New Territories, Hong Kong

Phone: +852 2632 2735 Fax: +852 2637 2422 Email: annalee@cuhk.edu.hk

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ABSTRACT

Introduction: Patients and their families are understandably anxious about the risk of complications and unfamiliar experiences following cardiac surgery. Providing information about postoperative care in the intensive care unit (ICU) to patients and families may lead to lower anxiety levels and increased satisfaction with healthcare. The objectives of this study are to evaluate the effectiveness of preoperative patient education provided for patients undergoing elective cardiac surgery.

Methods and analysis: 100 patients undergoing elective coronary artery bypass graft, with or without valve replacement surgery will be recruited into a two-group, parallel, superiority, double-blinded randomized controlled trial. Participants will be randomized to either preoperative patient education comprising of a video and ICU tour with standard care (intervention) or standard education (control). The primary outcome measures are the satisfaction levels of patients and family members with ICU care and decision-making in the ICU. The secondary outcome measures are patient anxiety and depression levels before and after surgery.

Ethics and dissemination: Ethical approval has been obtained from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (Reference number CREC 2015.308). The findings will be presented at conferences and published in peer-reviewed journals. Study participants will receive a one-page plain language summary of results.

Trial registration: Chinese Clinical Trial Registry ChiCTR-IOR-15006971.

Strengths and limitations of this study

- This randomized controlled trial will determine the effect of a preoperative patient education on patient anxiety and depression levels, and satisfaction with intensive care unit (ICU) care and decision-making process from the perspectives of both patient and family
- Patient education intervention (15 minute video and an ICU site tour) may help set more achievable recovery goals and expectations
- The overall contact time in the ICU is limited, in most cases to 24 hours after cardiac surgery

INTRODUCTION

Patient satisfaction with health care services is an important outcome that is increasingly used as a marker for quality of care. Poor satisfaction levels reflect a large difference between expectations and fulfilment of perceived needs and may have implications for adherence to treatment that subsequently affects patient outcomes.[1] For example, following cardiac surgery, patients dissatisfied with discharge information were more likely to report a poorer physical recovery and psychological state at home one month after undergoing surgery.[2]

Family satisfaction with care

Severe illness and its potential outcome impacts not only on the patient, but also their close family, defined as those persons with close family, social or emotional relationship to the patient. In addition, many intensive care unit (ICU) patients cannot make decisions for themselves. Their family must therefore become surrogate decision-makers for important parts of the care process. Hence, measuring family satisfaction with ICU care has become an important and essential component of quality of care in this setting.[3]

Several family satisfaction surveys measuring satisfaction with general ICU care have been developed with sound psychometric properties, and have been reviewed elsewhere.[4] The key domains related to family satisfaction include ICU environment[5, 6] and process of care,[5] sufficient information and quality communication with medical professionals to make important decisions about care.[5, 7] In order to improve the quality of care in ICU, it is essential to examine the perspectives from both patients and their family members[6, 8] and implement strategies to address areas of concern. As an example on the impact of the

environment of ICU on patients, both patient and family satisfaction levels increased by 6% with the changes from a ward with multiple beds to a newly designed ICU with noise-reduced, single rooms with daylight and improved family facilities.[6]

Patient and Family psychological distress

Surgical patients encounter physical trauma and psychological distress after surgery.[9, 10] Psychological distress has been defined as a collective term for anxiety and depression levels.[11] Beyond that, an unfamiliar hospital environment, such as the ICU, is another stressful factor that is associated with high anxiety and depression levels.[12] In coronary artery bypass grafting (CABG) patients, anxiety and depression occurs for several reasons: 1) routine procedures during ICU admission, for instance, oral and nasal tubes are important stressors[13] because they result in an inability to talk, affecting communication with ICU staff and 2) the associated time spent on the waiting list before the surgery. The prevalence of clinically significant anxiety and depression in patients awaiting CABG was 28% and 47% respectively.[14] Results from a systematic review found that higher levels of preoperative anxiety and depression in CABG patients were predictive of psychological distress in the postoperative period.[15] Generally, family members were significantly more anxious than patients themselves towards the cardiac surgery.[16] However, family members of the cardiac surgery patients reported lower level of anxiety and high satisfaction if their informational needs about the surgery and treatment of the patients were fulfilled.[17]

Informational needs

Previous studies have shown that multimedia educational interventions can reduce anxiety and foster an understanding of the processes and risks of cardiac surgery for both patients[18] and their family members,[17] regardless of the format to convey the patient education: using tape,[19] written leaflets,[18, 20] or verbally during the preoperative visit by ICU or specialist cardiac nurses.[18, 20] Additionally, results from a multicenter study in a non-cardiac ICU [21] showed that disclosing all the available information in a frank, direct, and empathetic way could meet the informational needs of family members about the patients, and thus, they were more satisfied; conversely, families who felt that they had received contradictory information had 21.1% lower satisfaction scores than their counterparts.[21]

Effect of patient education

Having a preoperative patient education programs which provides sufficient information on the risk and process of surgery to patients may help to increase their satisfaction levels and reduce their anxiety levels. A randomized controlled trial[18] of a preoperative educational intervention (usual care plus information leaflet and verbal advice) versus usual care, in patients undergoing cardiac surgery showed a moderate reduction in anxiety levels (adjusted mean difference -3.6, 95% CI: -4.62 to -2.57) and depression levels (adjusted mean difference -2.1, 95% CI: -3.19 to -0.92) using the Hospital Anxiety and Depression Scale (HADS). Another recent study showed that an effective nurse-led preoperative education not only reduced anxiety levels, but also reduced the risk of postoperative complications, such as sternal infection, in cardiac surgical patients.[22]

However, the evidence to support benefits from patient education in the ICU setting is mixed. In a recent multi-centered randomized controlled trial of a structured information program during the ICU stay compared to a non-specific conversation of similar duration, there was no reduction in patient anxiety levels (mean difference -0.2, 95% CI: -4.5 to 4.1 on a scale from 0 (no anxiety) to 100 (maximum anxiety) in medical and surgical critically ill ICU patients.[23] In a cross-sectional study of family members visiting ICU patients, although there was a moderate correlation between family perception of informational support and satisfaction with care ($r=0.74$, $P<0.001$), very little correlation between informational support and anxiety levels ($r=-0.13$, $P=0.50$) were found.[24] Neither of the two studies provided information about ICU before the ICU admission.[23, 24] A nonrandomized study examining the effect of a preoperative ICU tour prior to cardiac surgery failed to detect a significant difference in anxiety levels between the control (no ICU tour) and treatment (ICU tour) after adjusting for previous ICU experience ($P=0.43$).[25] Nevertheless, the authors showed that patients in the treatment group perceived the tour to be beneficial for themselves and for future patients.[25] In addition, other studies found that in order to reduce psychological distress, both ICU nurses and patients believed that preoperative patient education led by ICU nurses explaining the reasons for ICU admission, ICU environment and the expected postoperative care would be beneficial.[26, 27]

Significance of the present study

The previous studies discussed above have focused individually on the separate issues of satisfaction with general ICU care, preoperative psychological distress and informational needs related to surgical aspects of care. However, few have adequately examined the effect of educational interventions specifically targeting surgical issues and the post-operative ICU

stay, or investigated the inter-relationships between patient education, patient and family satisfaction scores, and measures of anxiety and depression. This two-group, parallel, superiority, double-blinded randomized controlled trial will examine the effectiveness of a multi-faceted patient education intervention on patient and family satisfaction, and post operative anxiety and depression in patients undergoing cardiac surgery. The primary objective is to determine the effect of the preoperative patient education package (video and ICU tour) for patients undergoing elective cardiac surgery on patient and family satisfaction with care and decision-making in the ICU. The second objective of the study is to determine the effect of preoperative patient education package on anxiety and depression levels in patients after elective cardiac surgery. The primary hypothesis is that preoperative patient education will increase both patient and family satisfaction levels after elective cardiac surgery and the secondary hypothesis is that preoperative patient education will reduce patient anxiety and depression measures after cardiac surgery.

METHODS AND ANALYSIS

Study design

We will conduct a single-centre, double-blinded, two-group, parallel, superiority, randomized controlled trial of 100 adults undergoing general anaesthesia for elective coronary artery bypass graft, with or without valve replacement (CABG ± valve) surgery. Block randomization with a 1:1 allocation has been planned. Family members and patients will be followed up to the third day and to one month after patient's surgery, respectively (Figure 1). The study has been designed with reference to the CONsolidated Standards Of Reporting Trials (CONSORT) statement,[28] and reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.[29]

Setting and population

The study will be conducted at The Prince of Wales Hospital in Hong Kong, a 1,400-bed university teaching hospital. Currently, there are 12 to 15 adults who undergo elective CABG ± valve surgery per month. All elective CABG ± valve surgery patients are routinely admitted to our 22-bed ICU for early postoperative care and monitoring with 1:1 nursing at all times, and are expected to be discharged from ICU to a high dependency cardiac ward within 24 hours after surgery.

Only adult patients undergoing primary elective CABG ± valve surgery whose primary language is Cantonese will be recruited from the operating theatre list published on the day before cardiac surgery. A face-to-face meeting will be scheduled with potential participants to confirm their study eligibility. Before obtaining written informed consent, the purpose of the study, procedures, risks and benefits of participation and the time commitment involved will be explained to them. Patients and family members may withdraw from the study without prejudice at any time during the study.

The patient education intervention includes a video in Cantonese, the predominant language used in Hong Kong. Patients will be excluded if they have a history of dementia, psychosis or neurological disease that would prevent them completing outcome questionnaires and are unable to provide written informed consent. We will also exclude patients undergoing emergency cardiac surgery (no opportunity to apply the intervention), patients who have had a previous cardiac surgery (prior exposure), and those who have received previous care in an ICU (prior exposure).

Family members of the patient will be also invited to join the patient education intervention before the elective cardiac surgery. 'Family' will be defined as persons with close family, social or emotional relationship to the patients;[1] thus next of kin and adult children of the patient will be included in the study. One family member per patient will be recruited. Family members will be excluded if they are unable to understand Cantonese, have previous experience with ICU care, previously underwent any cardiac surgery or did not visit the patient in ICU. The reasons for exclusion and number of patients or families lost to follow-up will be documented.

Sample size

A sample size of 45 in each group will have 80% power to detect a difference in means of 10 points (the difference between mean control group satisfaction of 70 and a mean intervention group satisfaction of 80) assuming that the common standard deviation is 16.6 (effect size of 0.60) using a two group t-test with a 0.05 two-sided significance level.[6] We considered this moderate effect size as clinically important. Given that our fast-track failure rate in cardiac surgery is approximately 10%, we will recruit 100 patients for the study (50 patients in each group). A study of 100 is adequately powered to detect a decrease in anxiety (unadjusted mean difference of 2.7) score at Day 7 after cardiac surgery (using the Chinese-Cantonese version of Hospital Anxiety and Depression Scale[30]) that was associated with a preoperative education intervention.[18] The sample size calculations were performed using nQuery Advisor 7.0 (Statistical Solutions Ltd, Cork, Ireland).

Randomisation and allocation concealment

Block randomization with 1:1 allocation will be carried out according to a computer-generated sequence and will be performed by one of the authors (AL) not involved in

screening, patient recruitment, clinical care or data collection, using a software program PASS 11 software (NCSS, Kaysville, Utah). The treatment allocation will be concealed in consecutively numbered sealed opaque envelopes and opened after obtaining patient consent before surgery and measuring baseline anxiety and depression levels. Restricting access to, and availability of, the video material will further minimize the selection bias.

Blinding

To minimize performance bias and a Hawthorne effect, the ICU staff will not be aware of the study objectives and which patients are recruited into the study. We will plan intermittent, ad hoc checks with bedside nurses and ICU physicians to establish whether they remain blinded to the treatment allocation of the patients. The outcome assessor is blinded to treatment allocation and will collect the primary outcome on Day 3, secondary outcome on Day 7 and health status at Day 30 postoperatively (Figure 1).

Interventions

Control arm: Standard education

Patients in the control group will receive the standard preoperative consultations by surgeons and anaesthesiologists, and nursing care in the cardiac surgical wards. Unstructured information about the general process and risk associated with surgery and anaesthesia, postoperative care and the care after discharge from hospital will be given in the usual manner to patients and family members one day before cardiac surgery. All patients will receive standardized surgical processes and perioperative care under existing protocols for postoperative ICU sedation, analgesia and weaning from mechanical ventilation. Also, all patients will be given a standardized anaesthesia described in detail elsewhere[31] with volume

controlled ventilation set at a tidal volume of 8ml/kg of ideal body weight with a positive, end-expiratory pressure of 5 cm H_2O.

Intervention arm: Video and ICU tour (+Standard care)

Patients randomly allocated to the treatment group will receive the same standard care provided in the control group, as well as the patient education package conducted in the ward one day before cardiac surgery. The family members will be invited to participate in the patient education session with the patient at the time of consent. First, they will be given a 15-minute education video describing the ICU environment, invasive tubes and lines, pain management, medical management, communication modes and family support (Table 1). Finally, a 5 to 10 minute tour of the ICU, conducted by a dedicated ICU nurse, will be given to patients and their family members after the video intervention.

Table 1. Information covered in the preoperative video and ICU tour

ICU environment (video and ICU tour):
• The standard bedside setting (cardiac monitors, ventilators, pumps, alarms)
• The ICU routine activities – doctor ward rounds, bathing time, etc
Types of invasive tubes and lines for patients after cardiac surgery (video and ICU tour)
• Oral endotracheal tube
• The pacemaker
• Chest drainage tubes
• Urinary catheter
• Various IV lines
Postoperative pain management (video)
• The types of pain experience during the postoperative period
• The pain relieving method
The medical management (video)
• The common weaning strategy from mechanical ventilator
• The duration of the placement of the chest drainage tubes
• What delirium is and how to treat it
• The expected length of stay in the ICU
Communication between patients, relatives and ICU staff (video and ICU tour)
• Role of case nurse (dedicated bedside nurse)
• Communication methods between the patients, family and nurses
• Arrangement of the interview between the family, the ICU doctors and/or surgeons
Family support (video)
• The visiting guidelines – number of visitors per visit, visiting hours
• Demonstration of hand-washing when visiting patient
• The importance of touch to reassure the patient

To help patients and family members retain the information presented, three multiple choice questions will be asked at the conclusion of the video presentation. The research coordinator and ICU nurse will clarify any misconceptions patients may have if the questions are answered incorrectly. A previous study showed that subjects spontaneously recalled less than a quarter of the preoperative anaesthesia information in a video, but correctly recalled 83% of the information using multiple choice testing format.[32]

Outcome measures

Satisfaction in the Intensive Care Unit Survey

The primary outcome is satisfaction with ICU care and decision-making process, from the perspective of both the patients' family members and the patients themselves. The family satisfaction in the ICU (FS-ICU) survey[33] has been well validated in numerous studies,[4, 34-36] and translated into Chinese[5] and other languages. The original, 34-item English FS-ICU[33] has been shortened to a 24-item English FS-ICU version.[36] However, the 34-item Hong Kong Chinese FS-ICU has not undergone formal psychometric validation except face validity.[5] We used a cross-cultural adaption approach[37] to modify the 24-item English FS-ICU questionnaire and checked for semantic and idiomatic similarities with the 34-item Hong Kong Chinese FS-ICU to establish face and content validity. Items in the patient version were semantically modified from addressing perspectives from family to fit the patients' own satisfaction perceptions in the ICU experiences. For example, one of the items in the family version is "the courtesy, respect and compassion your family member was given" was modified to "the courtesy, respect and compassion you were given" in the patient version.

Both satisfaction surveys consist of two parts, namely satisfaction with overall care (14 items) and satisfaction with decision-making (10 items). The surveys each take about 10 to 15 minutes to complete for patients and a close family member. All items use a 5-point Likert scale and will be recoded, transformed to a 0 to 100 scale (0 represents poor satisfaction, 100 represent high satisfaction) for both subscales and the total satisfaction score. The reliability of the overall satisfaction score is high (Cronbach's $\alpha = 0.94$) and there are moderate to strong correlations with the Quality and Dying and Death questionnaire and nurse-assessed quality indicators.[36]

Both the Chinese 24-item family satisfaction in the Intensive Care Unit survey for family members and its adapted patient version will be used on Day 3 after the surgery. In the event that the patient stays longer than 24 hours in the ICU, the questionnaires will be completed on the third day after the time of extubation. Every effort will be made to collect the family satisfaction data during visiting hours by a blinded outcome assessor. Although the questionnaires are self-reported, a blinded assessor will help participants fill in the questionnaire as some have only primary school education or no formal education at all.

Hospital Anxiety and Depression Scale (HADS)

The proposed secondary outcomes will be the change in anxiety and depression scores using the Chinese-Cantonese version of HADS.[30] This is a valid and reliable tool comprising of seven questions relating to anxiety (anxiety subscale) and seven questions rating to depression (depression subscale).[30] Each item is scored according to a four point scale (0-3) and for each subscale, the score ranges from 0 to 21, with higher scores indicating a greater severity of disorder. The incidence of anxiety and depression will be defined as HADS

subscale scores of equal to or more than 8.[38] The internal reliability Cronbach's α values for the anxiety and depression were 0.77 and 0.82 respectively and the full scale is 0.86.[30] The Chinese-Cantonese version of the HADS will be used at the time of consent into the study and on the seventh day after cardiac surgery. In the unlikely event that the patient is discharged before postoperative Day 7, the blinded outcome assessor will use the HADS at this point in time by conducting a telephone follow-up.

After obtaining consent, one of the authors will enroll the patients and family members into the trial and collect the following demographic and clinical data: age, gender, education level, American Society of Anesthesiologists Physical Status, predicted mortality using the logistic European System for Cardiac Operative Risk Evaluation (EuroScore) method,[39] patient's comorbidities, details of surgical procedures, duration of anaesthesia, anaesthetic technique, Richmond Agitation-Sedation Scale score[40] during the ICU stay, delirium assessment which was defined by routine bedside Confusion Assessment Method for the Intensive Care Unit (CAM-ICU),[41] severity of illness score on ICU admission (APACHE II),[42] duration of mechanical ventilation, ICU length of stay, duration of the hospital stay and the 30-day mortality status from the patient's medical record and from the Hospital Authority Clinical Management System electronic database. If the patient has the educational intervention without a family member, this will be noted in the standardized data collection form and will be included in the analyses. Data will be entered into a password protected MS Access database with built-in data integrity checks (valid values, range and primary key checks) and list of valid descriptive code options.

Statistical analysis

Missing data will be checked and imputed using the median for continuous variables or the most common category value for categorical variables to preserve power, if there is less than 10% missing data. Otherwise multiple imputation techniques will be used. The Shapiro-Wilk test will be used to check data for normality. Student's t-test and Mann-Whitney U test will be used for group comparisons of continuous parametric and non-parametric variables at baseline. Chi-square or Fisher's exact tests will be used for group comparison of categorical data at baseline.

Intention to treat and per-protocol analyses will be performed using SPSS software (IBM, New York). The mean and standard deviation of the patient and family satisfaction scores, and HADS anxiety and depression subscale scores will be reported. The mean differences between groups for satisfaction scores from patients' and family members' perspective will be analyzed using independent t-tests. To address the ceiling effect of the satisfaction questionnaires, we will estimate the change in percentage of overall high satisfaction (score = 100) between groups by using an empirical logit transformation as it is more difficult to improve from 80% to 90% than from 50% to 60%.[43] A generalized estimating equation (GEE) population average regression will be used to examine the mean difference in anxiety and depression subscales between groups over time. As some patients and family members may be too apprehensive to join the preoperative ICU tour after the video intervention, we will perform a sensitivity analysis on the three groups (control, video only, video plus ICU tour) to examine how robust the results are. The level of significance will be set at $P<0.05$.

Data and monitoring plan

As there are no planned interim analyses and stopping rules for this study, a formal committee for data monitoring is not required. At the start of the trial, the outcome assessor will undergo training in interviewing patients using the satisfaction in ICU questionnaires and Hospital Anxiety and Depression Scale. A senior author will periodically audit the integrity of the randomization, source data verification against the paper data collection forms, overall quality and completeness of the data. Data will be kept confidential in secure offices of the Department of Anaesthesia and Intensive Care. Only group data will be published. The first, fourth and corresponding authors will have access to the final dataset. It is anticipated that there are no serious adverse events caused by trial patient education intervention.

Ethical considerations

Ethical approval was obtained on July 6 2015 from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (Reference number CREC 2015.308, protocol number 1.0, dated 21 April 2015). Any protocol amendments will be submitted to the local clinical research ethics committee for approval. This trial is registered with the Chinese Clinical Trial Registry is ChiCTR-IOR-15006971.

DISCUSSION

Development of the present education intervention

To meet the cardiac service expansion at the Prince of Wales Hospital in 2001, we planned a quality improvement exercise and audit. A designated care team was formed, consisting of a group of ICU nurses who were trained in the postoperative care of cardiac surgical patients, as well as conducting preoperative ICU site visits. The aim of the preoperative ICU visit was to decrease patients' anxiety levels due to unfamiliarity with the ICU environment and to

have a better understanding of the immediate postoperative management in the ICU. As the feedback to the site visit by the health care team, patients and family members were positive, a preoperative video was developed in 2002. When Severe Acute Respiratory Syndrome (SARS) outbreak occurred in 2003, the video viewings and ICU tours stopped. We did not reinstitute the ICU education intervention after the outbreak.

Using the literature to establish the factors associated with anxiety and those important to patients and family members regarding ICU care (outlined in the introduction), as well as the experience gained in the brief education intervention before SARS, we developed an updated video. To improve the portrayal accuracy of the video, we employed a professional actor to play the role of a patient for this project. The video aimed to standardize the information content of the visit and included information about the ICU environment, routine care and expected postoperative course of the patient (Table 1).

Strengths and limitations

This study builds upon the work performed in the past. The video provides comprehensive and standardized preoperative information to patients and family members about ICU care to complement preoperative information given by other healthcare professionals working in the cardiac surgical ward. Early informal feedback from patients and family members in the treatment arm is positive, with a common theme that the intervention makes the perioperative pathway processes more transparent to them. This may help set more achievable recovery goals and expectations, and therefore affect satisfaction levels with healthcare provided. However, a limitation of the study is that the overall contact time in ICU is limited, in most cases to 24 hours after cardiac surgery. Also, we did not include family members' anxiety and depression levels due to the time constraints during visiting hours.

Dissemination

We are unaware of any studies examining both patient and family satisfaction levels with ICU care associated with preoperative patient education for major surgery requiring postoperative ICU care. This paper describes a patient education intervention for use within the Hong Kong health service and the video (in Cantonese dialect) will be made available to others after completing the trial upon request to the authors. The results of this study will highlight aspects of ICU care and decision-making process for further quality health services improvement. As part of the knowledge translation approach, study participants will receive a one-page plain language summary of the results. The results will be disseminated at an international critical care medicine conference and in a peer-reviewed journal.

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Competing Interests: None declared.

Contributors: The protocol was jointly written by VKWL and AL and was critically reviewed by PL, CHC, KMH, CDG, MJU, and GMJ. All authors were involved in the study concept and design of the study and approved the final version of the manuscript.

Trial Sponsor: The Chinese University of Hong Kong. AL is the study guarantor.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2,16
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	16
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 18
	5b	Name and contact information for the trial sponsor	1, 18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	None
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-7
	6b	Explanation for choice of comparators	5-6
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7, 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8, 9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	15-16
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10, 12, 16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7,12-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	(Figure 1)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10,13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10,13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14, 16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-14

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2,18
	31b	Authorship eligibility guidelines and any intended use of professional writers	18
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	2,18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not included, in Chinese
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.