










BMJ Open Effect of a patient education video and prehabilitation on the quality of preoperative person-centred coordinated care experience: protocol for a randomised controlled trial

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ABSTRACT

Introduction Multimodal prehabilitation, an emerging field within the Perioperative Medicine specialty, requires close multidisciplinary team coordination. The goal is to optimise the patient's health status in the 4–8 weeks before elective surgery to withstand surgical stress. Most patients are unfamiliar with the concept of prehabilitation but are interested in participating in such a programme after explanation. The objective of this randomised controlled trial is to evaluate the effect of prehabilitation (patient education video and multimodal prehabilitation) on the preoperative patient-centred coordinated care experience.

Method and analysis One hundred patients undergoing major elective surgery (cardiac, colorectal, hepatobiliary-pancreatic and urology) will be recruited into a two-group, parallel, superiority, single-blinded randomised controlled trial. Patients will be randomised to receive either preoperative patient education comprising of a video and prehabilitation programme with standard care (intervention) or standard care (control). The primary outcome measure will be the quality of preoperative patient care experience using the 11-item Chinese version of the Person-Centred Coordinated Care Experience Questionnaire (P3CEQ) before surgery. Secondary outcomes will include the change in Hospital Anxiety and Depression Scale (HADS) score from trial enrolment to before surgery, Quality of Recovery Score (QoR-15) on third day after surgery and Days Alive and At Home within 30 days after surgery (DAH₃₀). Intention-to-treat and per-protocol analyses will be performed.

Ethics and dissemination The Joint CUHK-NTEC Clinical Research Ethics Committee approved the study protocol (CREC Ref. No. 2021.518-T). The findings will be presented at scientific meetings, in peer-reviewed journals and to study participants.

Trial registration number ChiCTR2100053637.

INTRODUCTION

Multimodal prehabilitation is an emerging field within the Perioperative Medicine

STRENGTH AND LIMITATIONS OF THIS STUDY

- ⇒ This is a two-group, parallel, superiority, single-blinded randomised controlled trial to examine the effect of patient education and prehabilitation on the quality of preoperative person-centred coordinated care experience.
- ⇒ As patients are not blinded to treatment allocation, performance bias may occur.
- ⇒ Exact attribution (%) of patient education video, exercise prehabilitation and nutritional prehabilitation to the overall effect on preoperative person-centred coordinated care experience may be difficult to estimate with the proposed sample size.

specialty. It includes individualised structured exercises, nutrition counselling and supplementation and psychological support through standardised multimedia patient education.¹ The goal of multimodal prehabilitation is to optimise the patient's health status in the 4–8 weeks before surgery to withstand surgical stress.¹

Major surgery is associated with a 40% reduction in physiological reserve.² Many 'high risk' surgical patients have low physiological reserves from being older, malnourished or frail with multiple comorbidities.³ These patients also have several modifiable lifestyle factors, such as physical inactivity, obesity, smoking, hazardous alcohol drinking and poor nutrition.³ When all these risk factors are combined, its association with the risk of postoperative complications is higher.³ The interval between diagnosis and hospital admission is an ideal opportunity for promoting behavioural risk modifications for long-term health benefits that goes beyond surgery itself—offering an ideal 'teachable

moment'. Thus, multimodal prehabilitation provides a unique opportunity to optimise the patient's physiological reserve to withstand the surgical stress response.³

In one study, most patients (83%) were unfamiliar with the concept of prehabilitation but were interested in participating in such a programme after explanation.⁴ The primary motivation (62%) for patient participation in prehabilitation programmes was to be physically prepared for surgery and most patients (81%) felt supported by the multidisciplinary healthcare team.⁵ Our systematic review of seven randomised controlled trials (RCTs, 726 cardiac surgical patients) showed that physical prehabilitation may improve postoperative functional capacity and slightly shorten the length of hospital stay (mean difference: -0.66 days, 95% CI -1.29 to -0.03 ; $I^2=45\%$; low-certainty evidence).⁶ However, none of these studies examined the level of patient-centred coordinated care experience associated with multimodal prehabilitation.

Our systematic review (34 trials, 3742 surgical patients) on patient education formats for reducing perioperative anxiety showed that multimedia formats were associated with increased knowledge more than text, which in turn increased knowledge more than verbal formats.⁷ As a component of a cardiac surgical prehabilitation programme, our multifaceted patient education programme (video and intensive care unit tour for patients and their family members) was associated with higher overall patient and family satisfaction scores, and lower patient anxiety scores.⁸

Significance of the present study

Despite previous studies focusing on the effect of prehabilitation education, there are no local 'prehabilitation videos' available for current patients receiving physical and nutritional prehabilitation before elective surgery. Prehabilitation programmes are not widely used in Hong Kong and patient education is usually not standardised across different surgical patients.

Given that multimodal prehabilitation is a complex intervention requiring a high level of coordination between anaesthetists, surgeons, nurses, physiotherapists and dieticians with patients, measurement of the quality of patient-centred coordinated care is essential for quality improvements in Perioperative Medicine. Conceptually, person-centred (patient-centred) coordinated care is when care and support have been guided by and organised effectively around the needs and preferences of individuals.⁹ The five domains of person-centred coordinated care include (1) information and communication processes, (2) care planning, (3) transitions (continuity of care), (4) goals and outcomes, and (5) decision-making.¹⁰

Study objectives and hypotheses

The primary objective of this RCT is to evaluate the effect of prehabilitation (patient education video and multimodal prehabilitation) on the preoperative patient-centred coordinated care experience. The secondary objective is to assess the effect of prehabilitation on

preoperative anxiety and depression levels, quality of recovery and days alive and at home within 30 days after surgery (DAH₃₀).

The primary hypothesis is that prehabilitation (patient education video and multimodal prehabilitation) is associated with a better patient-centred coordinated care experience than standard care. The secondary hypothesis is that prehabilitation is associated with lower preoperative anxiety and depression levels, higher quality of recovery and higher number of days alive and at home within 30 days after surgery.

METHOD AND ANALYSIS

Study design

The study design is a single-centre, two-group, parallel, superiority, single-blinded randomised controlled RCT. Patients will be randomised to receive either preoperative patient education comprising of a video and prehabilitation programme with standard care (intervention) or standard care (control). Block randomisation with 1:1 allocation will be carried out according to a computer-generated sequence to be performed by one of the authors (AL) not involved in the screening, patient recruitment, clinical care or data collection, using 2019 Power Analysis and Sample Size (PASS) Software (NCSS, LLC, Kaysville, Utah, USA). Sequentially numbered, opaque, sealed envelopes will be used to conceal the sequence until the interventions are assigned at an outpatient preoperative clinic. The study has been designed with reference to the CONSolidated Standards Of Reporting Trials statement,¹¹ and reported according to the Standard Protocol Items: Recommendations for Interventional Trials statement.¹² An overview of the study design is provided in figure 1.

Study setting and population

The study will be conducted at the Prince of Wales Hospital in Hong Kong, a 1807-bed teaching hospital. Currently, there are approximately 500 adults undergoing major to ultramajor elective surgical procedures performed per month. Patients meeting the inclusion criteria will be recruited.

Eligibility

Inclusion criteria

- ▶ Adults (>18 years old) undergoing major to ultramajor elective surgery cardiac (coronary artery bypass graft (CABG)±valve/valve only) surgery.
- ▶ Adults (≥50 years) undergoing major colorectal, hepatobiliary-pancreatic or urology surgery
- ▶ Primary language is either English or Cantonese.
- ▶ Prefrail to moderately frail patients with a Clinical Frailty Scale (CFS)¹³ of 4–6 at the time of being accepted for surgery at the outpatient surgical/nurse clinic.
- ▶ Patients with estimated ≥4 weeks of surgical waiting list time.

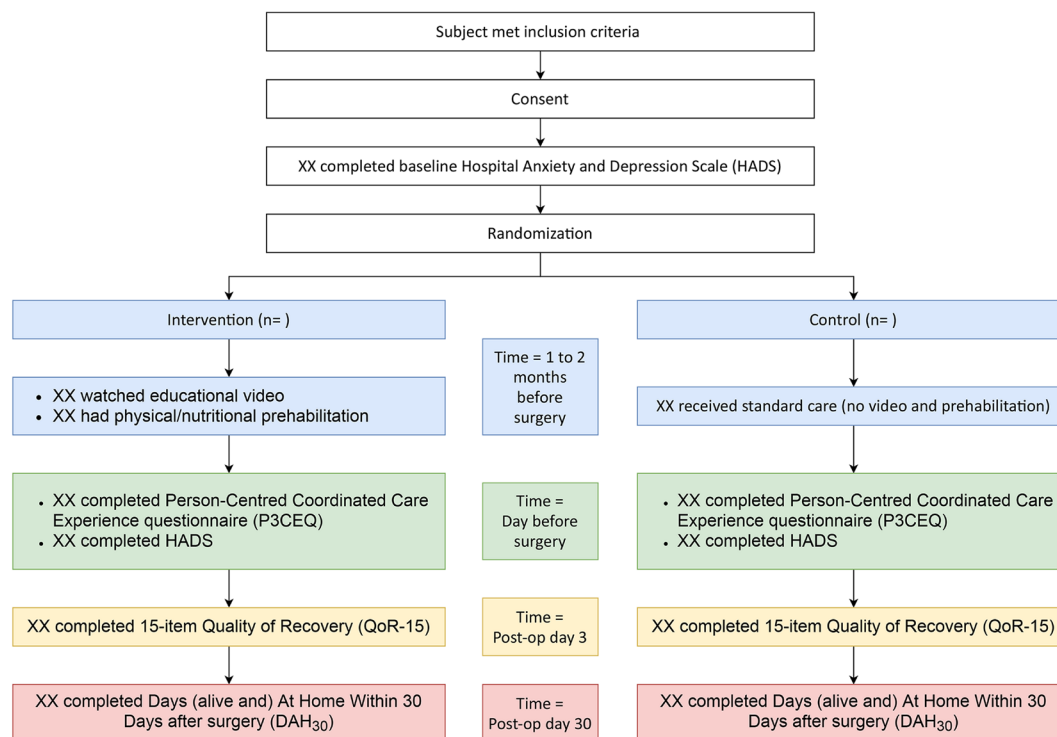


Figure 1 Patient flow. HADS, Hospital Anxiety and Depression Scale.

Exclusion criteria

- ▶ Contraindications for prehabilitation, such as those with cognitive deficits who are unable to comply with study procedures, physical limitations that would preclude prehabilitation and inability to regularly attend prehabilitation sessions, such as those who are severely frail (CFS 7–9).

Blinding

To minimise measurement bias, study research personnel collecting the outcome measures will not be aware (blinding) of the treatment allocation performed by another member of research staff. Due to the nature of the intervention and requirements of informed consent, trial participants will not be blinded to the treatment allocation.

Interventions

Control arm: standard care

Patients in the control group will receive the standard preoperative consultations by surgeons and anaesthesiologists. Unstructured information about life style modifications patients can undertake at home, such as exercise and enhanced nutrition, will be given to patients and family members at the discretion of healthcare staff in the usual manner, often on an ad hoc basis. All patients will receive standardised surgical processes and perioperative care under existing protocols. Anaesthesia techniques, postoperative pain management, early postoperative mobilisation and physiotherapy and postoperative nutrition will follow existing Early Recovery After Surgery protocols where appropriate.

Intervention arm: video and prehabilitation (+standard care)

Patients randomly allocated to the intervention group will receive the same standard care provided in the control group. They will also view a 10 min patient education video about prehabilitation before receiving physical prehabilitation with a registered physiotherapist.¹⁴

All participants undergoing major elective surgery will also receive nutritional assessment/counselling with a registered dietician. The prehabilitation will be conducted in the 4–8 weeks before elective surgery following existing prehabilitation protocols.

The video will describe the concept and benefits of prehabilitation, the flow of current prehabilitation exercise programmes and basic nutritional information. The patient education video will be in Cantonese, the predominant language used in Hong Kong, but with subtitles in English.

The information covered in the 10min video include the following:

- Introduction to prehabilitation
 - Aims of prehabilitation.
 - Benefits of prehabilitation.
 - General ‘generic’ complications and conditions (eg, malnutrition) after surgery.
- Exercise in prehabilitation
 - Aims and benefits of exercise in prehabilitation.
 - Tests of physical fitness (eg, 6 min walk test).
 - Structure, contents and methods of prehabilitation.
 - Safety measures during training.
 - Importance of home exercise.
- Diet in prehabilitation

- Importance of a healthy diet.
- Components of a healthy diet.
- Strategies to eating well.

Components of the physical prehabilitation (1–3 times/week) include the following:

- ▶ Warm up activities (5–10 min).
- ▶ Aerobic exercise in the form of walking/running, stepping, arm cycling and leg cycling (training intensity between 40% and 80% of oxygen uptake reserve for 20–30 min).
- ▶ Resistance training for major muscle groups of upper and lower limbs.
- ▶ Cool down activities (5–10 min).
- ▶ Education on breathing techniques and daily activities.
- ▶ Re-enforcement of advice on nutrition, smoking cessation and positive psychological support.

Outcome measures

Primary outcome

The quality of preoperative healthcare experience from the patient's perspective will be assessed using the Person-Centred Coordinated Care Experience questionnaire (P3CEQ) in both treatment and control groups.¹⁰ The P3CEQ is a valid and reliable measure of patient-centred coordinated care in primary healthcare services in the UK.¹⁰ The English P3CEQ is a 10-item questionnaire that includes two domains of person-centred and care coordination factors, with a total score ranging from 0 to 30 where a higher score represents better experiences of person-centred care. One optional question about the involvement of family member/carer is not included in the final scoring system as the item exceeded the acceptable missing response threshold (>15%).¹⁰ However, as Confucian family values are important in medical decision-making in the Chinese culture,¹⁵ we will include this question in our scoring system. The English P3CEQ has been translated into Hong Kong Chinese for psychometric validation in another study (unpublished). The Hong Kong Chinese version will be used on the day before surgery on hospital admission, which is the common timepoint shared between the control and intervention groups.

Secondary outcomes

Hospital Anxiety and Depression Scale (HADS)

The change in anxiety and depression levels will be measured using the Hong Kong Chinese version of the Hospital Anxiety and Depression Scale (HADS) questionnaire.¹⁶ This is a valid and reliable tool, with seven questions relating to anxiety and seven questions relating to depression.¹⁶ The subscales of anxiety and depression ranges from 0 to 21, with higher scores indicating higher severity of disorder. Patients will be asked to complete the HADS at the time of randomisation. The blinded outcome assessor will ask patients to complete the HADS on the day before surgery on hospital admission.

Quality of Recovery (QoR-15)

The Chinese version of the 15-item Quality of Recovery (QoR-15)¹⁷ will be used on postoperative day 3. The QoR-15 includes the items measuring pain, physical comfort, physical independence, psychological support and emotional state.¹⁷ The QoR-15 score ranges from 0 to 150 and takes about 3 min to complete.¹⁷ The validity (convergent, construct and discriminant), reliability (internal consistency, split-half and test-retest), responsiveness, acceptability and feasibility properties have been well established.¹⁷ A poor symptom state (recovery) after surgery has been defined at a cut-off of <118.¹⁸ Depending on patient's postoperative status, QoR-15 assessment may be deferred if patient is unwell or unavailable when outcome assessor collects the data. QoR-15 assessment will be conducted at a later date after obtaining patient's agreement. The exact date of actual QoR-15 assessment will be recorded by the blinded outcome assessor.

Days (alive and) at home within 30 days after surgery (DAH₃₀)

The DAH₃₀ is a patient-centred, generic outcome measure that will be used to measure the patient's overall recovery profile at 30 days after surgery.¹⁹ DAH₃₀ is a composite measure that incorporates the details on postoperative hospital length of stay, discharge to rehabilitation centre or nursing home, hospital readmissions and postoperative deaths.¹⁹ Half a day difference is considered clinically meaningful.¹⁹ We will extract data from the electronic patient medical record to estimate the DAH₃₀.

Other variables in data collection

Baseline demographic characteristics (age, sex, education level and living at home with family member status) will be recorded at the time of randomisation. From the patient's medical record, we will collect the following data: prehabilitation compliance rate with various elements of prehabilitation and number of sessions attended in the intervention group, CFS at time of randomisation and before elective surgery, American Society of Anesthesiologists Physical Status Classification,²⁰ surgical and anaesthetic details, duration of intensive care unit admission, severity of illness using (APACHE II)²¹ in critically ill patients requiring postoperative care, predicted mortality risk in cardiac surgical patients (logistic EuroScore),²² duration of postoperative stay, hospital readmission, hospital discharge destination and vital status (dead/alive) at 30 days after surgery.

Sample size

Group sample sizes of 45 (intervention) and 45 (control) will achieve 80% power to reject the null hypothesis of zero effect size when the population effect size is 0.60 (medium to large effect size) and the significance level (alpha) is 0.050 using a two-sided two-sample equal-variance t-test. To allow for 10% loss to follow-up, we will recruit 50 patients in each arm; total sample of 100.

Statistical methods

Missing data will be checked and imputed using the most common category value for categorical variables or median for continuous variables if there is <10% missing data. Otherwise, multiple imputation techniques will be used. Shapiro-Wilk's test will be used to check data for normality. Appropriate independent Student's t-test or Mann-Whitney U test will be used appropriately to compared group differences for P3CEQ, QoR-15 and DAH₃₀. The mean difference in HADS scores between groups over time (interaction group*time) will be assessed using the generalised estimating equation with a Gaussian distribution, identify-link function, exchangeable correlation with robust standard errors. Both intention-to-treat and per-protocol analyses will be performed. The two-sided level of significance will be set at $p < 0.05$. SPSS V.27.0 (IBM, Armonk, NY) and Stata V.17.0 (StataCorp, College Station, TX) will be used to performed data analyses.

Monitoring and data management

Study data will be collected and managed using REDCap electronic data capture tools hosted at The Chinese University of Hong Kong.^{23 24} REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for data integration and interoperability with external sources.

No interim analysis has been planned. There will be no formal data monitoring committee. However, the study progress and any unanticipated serious adverse events will be reported as part of an annual renewal application for local research ethics committee approval. Anonymised data set will be available after the publication of the completed study, following the deposition of the data set into The Chinese University Research Data Repository (<https://researchdata.cuhk.edu.hk/>).

Patient and public involvement

Patients and the public were not involved in the development of the research question, the design of the study nor did they contribute to the editing of this document for readability or accuracy. Study participants will receive a one-page plain language summary of the results on completion of the study as part of the knowledge translation approach.

Ethics and dissemination

Before obtaining written informed consent (online supplemental material), the purpose of the study, procedures, risks and benefits of participation and the time commitment involved will be explained to eligible patients by study research staff. The same study research staff will obtain patient's written informed consent to participate at the outpatient preadmission clinics. Patients allocated

to the intervention group will be reimbursed for the number of prehabilitation sessions attended to encourage high compliance with the programme.

Patients may withdraw from the study without prejudice at any time during the study. Data will be kept confidential on password-protected files and computer, and in secure offices of the Department of Anaesthesia and Intensive Care, with access limited to study research staff. Only group data will be published in a peer-reviewed journal publication. Approval for the project (protocol version 2.0, 21 September 2021) was obtained from The Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No. 2021.518-T). Any protocol modifications will be communicated to the local research ethics committee and clinical trials registry in a timely manner. The study will adhere to local laws, Declaration of Helsinki and institutional policies.

DISCUSSION

With Hong Kong's ageing population, the demand for prehabilitation before complex high risk surgical procedures is expected to increase. Our development of a prehabilitation video was based on our previous positive experience with a multifaceted preoperative patient education programme⁸ and recent findings from qualitative studies measuring patients' and caregivers' perspectives of important elements in prehabilitation.^{25 26} Videos taken in real environment with clear explanations about the prehabilitation and expected postoperative recovery processes were common priorities identified in both studies.^{25 26} Prehabilitation could improve patient satisfaction through enhanced and continuous engagement with and support from healthcare providers during the presurgical period.²⁵ As far as we are aware, no studies have measured the quality of patient-centred coordinated care associated with prehabilitation programmes.

The results of this two-group, parallel, superiority, single-blinded RCT will enable us to quantify the incremental level of preoperative patient-centred coordinated care with prehabilitation over standard care in adults undergoing a range of major to ultramajor elective surgery. If favourable results are associated with prehabilitation, the video can be distributed to other public hospitals in Hong Kong with prehabilitation programmes for wider patient education dissemination. However, a limitation of the study is that it may not be generalisable to other surgical specialities outside our inclusion criteria and in settings with vastly different structured multimodal prehabilitation programmes outside Hong Kong. As multimodal prehabilitation is a complex intervention, the exact attribution (%) of patient education video, exercise prehabilitation and nutritional prehabilitation to the overall effect on preoperative person-centred coordinated care experience may be difficult to estimate with the proposed sample size of 100 participants. Nonetheless, the findings will be presented at scientific meetings, in a peer-reviewed



journal and to study participants to address the paucity of preoperative patient-centred coordinated care experience studies.

Trial status

Patient recruitment will start in mid-2023 after the Chinese version of the P3CEQ tool has undergone sufficient psychometrical validations in another study we are currently conducting. We expect patient recruitment and 1 month of follow-up to be completed by the end of 2024.

Contributors The prehabilitation video described in this manuscript was developed and produced by SSW, HHTC, DKWY, MKHW, VNML, WWL and AL. The protocol was jointly written by SSW and AL and was critically reviewed by HHTC, FFN, DKWY, MKHW, VNML, WWL and TWCM. All authors were involved in the study concept and design of the study and approved the final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

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