Effectiveness and safety of implementing an enhanced patient comfort programme for elective neurosurgical patients: a randomised controlled trial protocol

Bolin Liu,1 Shujuan Liu,2 Binrong Wang,3 Wenjuan Liu,1 Lei Chen,1 Tao Zheng,1 Dan Lu,1 Tao Ma,1 Shiming He 1

ABSTRACT
Introduction Patient comfort is an important quality indicator of healthcare. According to Kolcaba’s comfort theory, enhanced comfort is achieved by meeting the needs in four contexts: physical, psychospiritual, sociocultural and environmental. An enhanced patient comfort (EPC) programme based on this theory has been designed for elective neurosurgical patients. This study aims to assess its feasibility, effectiveness and safety.

Methods and analysis The EPC programme patients will be evaluated in a single institutional randomised controlled trial. A total of 110 patients admitted for elective neurosurgery (including craniotomy, endoscopic trans-sphenoidal surgery and spine surgery) will be randomised in a 1:1 ratio to two groups. Patients in the EPC group are managed under the newly developed EPC programme, which aims to enhance patient experience and includes care coordination since admission (such as appointment of a care support coordinator, personalised setting, and cultural and spiritual support), preoperative management (such as lifestyle intervention, psychological and sleep intervention, and prerhabilitation), intraoperative anaesthetic management (such as nurse coaching, music playing, and pre-emptive warming), postoperative management (such as early extubation, early diet advancement, mood and sleep management, and early ambulation) and optimised discharge planning; while those in the control group receive conventional perioperative care. The primary outcome is patient satisfaction and comfort measured by the Chinese Surgical Inpatient Satisfaction and Comfort Questionnaire. The secondary outcomes include postoperative morbidity and mortality, postoperative pain score, postoperative nausea and vomiting, functional recovery status (Karnofsky performance status and Quality of Recovery-15 score), mental status (anxiety and depression), nutritional status, health-related quality of life, hospital length of stay, reoperation and readmission rates, overall cost and patient experience.

Ethics and dissemination Ethical approval to conduct the study has been obtained from Institutional Review Board of Xi’an International Medical Center (No. 2020282). The results will be presented at scientific meetings and published in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ A multimodal, multidisciplinary, evidence-based enhanced patient comfort (EPC) programme underpinned by Kolcaba’s comfort theory has been designed for elective neurosurgical patients.
⇒ This study includes both subjective and objective outcome measures.
⇒ Blinding is not feasible during the process of patient care but will be used for data collection and analysis.
⇒ To ensure protocol adherence, personnel training, specified care support coordinators and an EPC Record Checklist have been implemented.

Trial registration number Chinese clinical trial registry ChiCTR2000039983.

INTRODUCTION
For the past two decades, enhanced recovery after surgery (ERAS) or fast-track surgery programme has been gaining increasing popularity in multiple surgical disciplines as it has been proven to shorten hospital length of stay (LOS), accelerate functional recovery, and decrease postoperative morbidity and medical costs.1-3 However, the success of such programme seems to emphasise more on the speed of healthcare flow and objective outcomes than the quality of care and subjective outcomes such as patient satisfaction and comfort.1 Indeed, patient-perceived quality of care is believed to have equal importance as clinical effectiveness and patients’ safety.3

Patient comfort, which is a personalised and integral experience, is considered as a source of patient well-being.4 However, there is a lack of universally acknowledged definition on comfort concerning its holistic, transient and multidimensional nature.4-6 The comfort theory, first proposed by Professor
Kolcaba, defined the holistic comfort as an immediate desired outcome of meeting three types of comfort (ie, relief, ease and transcendence) in four contexts (ie, physical, psychospiritual, sociocultural and environmental).5,6 Nevertheless, Wensley et al has recently defined comfort as a transient and dynamic state characterised by four senses: (1) ease from pain, emotional and physical distress; (2) feeling positive, safe and stronger; (3) feeling confident and accepting treatment by choice; and (4) feeling valued, cared for and connecting positively to people and place.7,8 Indeed, the latter definition and (4) feeling valued, cared for and connecting positively to people and place.7,8

Regardless of the varying definitions and perspectives on comfort, earlier studies evaluating the benefits of interventions promoting comfort showed that, in view of the variations in study designs and quality, improvement in patient comfort (in terms of pain relief as well as broader desired outcomes) may be associated with faster recovery, shortened LOS, enhanced functional status, higher patient satisfaction and better cost-effectiveness.5,9-12

Compared with the outcome measures commonly used in ERAS or fast-track surgery programmes, the key distinguishing feature of patient comfort lies in that it involves both physical and psychosocial integrity. Both Kolcaba’s comfort theory and Wensley’s CALM framework support its influencing factors were summarised in the multidimensional Comfort ALways Matters (CALM) framework, which can be used to develop comfort-related care in four integrated layers: (1) patients’ personal strategies, (2) role of family, (3) staff actions and behaviours and (4) factors within the clinical environment.7,8

The aim of this study is to develop and implement a multimodal, multidisciplinary, evidence-based EPC programme underpinned by Kolcaba’s comfort theory for patients undergoing elective neurosurgery and to conduct an RCT to assess the feasibility, effectiveness and safety of this EPC programme. We hypothesise that compared with conventional perioperative care, the EPC programme results in higher patient satisfaction and comfort. To our knowledge, there is no such programme consisting of preoperative, intraoperative and postoperative care that aims to improve patient-perceived quality of care nor is there any RCT that evaluates the feasibility, effectiveness and safety of such an EPC programme.

In addition, patient experience in participating the EPC programme will be assessed in a secondary analysis via a semistructured qualitative interview at 30-day follow-up after discharge.

METHODS AND ANALYSIS

Study design
A single-institutional RCT is being undertaken to assess the feasibility, effectiveness and safety of a novel EPC programme developed for patients undergoing elective neurosurgery.

Participant recruitment

Inclusion criteria
The study has been recruiting patients admitted for elective neurosurgery at the Department of Neurosurgery of Xi’an International Medical Center (Xi’an, People’s Republic of China) from April 2022 to June 2023 if they meet the inclusion criteria: (1) age 18–80 years; (2) indication for elective neurosurgery including craniotomy, endoscopic trans-sphenoidal surgery and spine surgery; and (3) informed consent obtained from the patient or his/her legally authorised representative.

Exclusion criteria
We will exclude patients with intracranial or spinal trauma, pathology requiring emergent surgery, preoperative disturbance of consciousness, significant cognitive impairment who were unable to cooperate and a confounding condition (eg, pregnancy) or disease that could potentially impact postoperative recovery (eg, wheelchair-bound or bed-ridden prior to surgery, autoimmune diseases, myocardial infarction, severe infection, liver and renal malfunction, or severe psychological disorder).
Randomisation

Patients who meet the inclusion criteria will be enrolled by the attending neurosurgeons and randomly allocated, in a 1:1 ratio, into two groups using computer-generated randomisation codes which will be held in sequentially numbered sealed opaque envelopes.

Blinding

Because of the multitude of interventions as well as requirement of active participation of patients, family members and healthcare providers, blinding will not be used in the process of patient care. However, outcome collection and data analysis will be blinded to participants allocation. For primary outcome measure, an interviewer who has not involved in the patient care and blinded to the participants allocation will be appointed to fill in all questionnaires. In addition, the decision for discharge will be made on consensus of two attending physicians who are blinded to participants allocation.

Intervention

EPC protocol

Local institutional review board (IRB) approval has been obtained to conduct the study. First, a multidisciplinary EPC Working Group has been set up, which consists of medical and ancillary staff from neurosurgery, anaesthesia, inpatient and operative nursing, psychosomatic medicine, nutrition, physiotherapy and rehabilitation. An evidence-based strategy has been adopted to develop a comprehensive pathway of perioperative care (online supplemental file 1). Briefly, it consists of (1) care coordination at the time of admission (or preadmission) including patient and family education, appointment of a care support coordinator, personalised setting, and cultural and spiritual support; (2) preoperative evaluation and management including functional status evaluation, prerehabilitation, mental status evaluation and intervention, sleep evaluation and intervention, lifestyle intervention such as abstinence from smoking and alcohol, nutritional assessment and intervention, preanaesthetic evaluation in advance, antithrombotic evaluation and prophylaxis, postoperative nausea and vomiting (PONV) risk score assessment and prophylaxis, preoperative pain assessment and preemptive analgesia, preoperative pain management, preoperative oral carbohydrate loading and preoperative virtual tour of the operation room (OR); (3) intraoperative and anaesthetic management including OR nurse coaching and music playing prior to anaesthesia induction, microinvasive surgery, local incision anaesthesia, absorbable skin suture, pre-emptive warming and hypothermia avoidance, goal-directed fluid balance and restrictive surgical site drains; (4) postoperative management including early extubation, active warming and music playing, shortening of continuous vital sign monitoring, pain management, PONV management, management of other gastrointestinal tract malfunction, early removal of urinary catheter, early oral nutrition, restrictive intravenous fluids, early ambulation, mood and sleep management, etc; and (5) a discharge plan. Types of the comfort measures according to Kolcaba’s four contexts of comfort are outlined in online supplemental file 1.

The EPC Working Group who will take care of the participants are instructed to follow every point outlined in the EPC protocol in a step-by-step manner while trying to implement as many elements as possible. To ensure protocol adherence, the multidisciplinary staff have been trained for several rounds to increase their familiarity with the protocol. In addition, an EPC Record Checklist (online supplemental file 2) will be included in the participant’s medical record once he/she is enrolled in the study. The care providers are responsible to fill out the checklist in a timely fashion. Furthermore, a specified care support coordinator will be appointed to each participant once he/she is enrolled in the study, who will not only coordinate care provision but also check the completeness of the checklist on a daily basis. Minor deviations from the protocol are permitted if deemed necessary or clinically indicated per the judgement of the care providers; however, these deviations must be clearly documented in the checklist as well.

Conventional care

Participants allocated to the control group will receive conventional perioperative care commonly employed in this patient population. Since this may vary according to individual practice patterns of the care providers which may or may not be evidence-based care, the checklist will also be included in the charts of these participants to record the actual care they receive. Notably, as a healthcare quality improvement study, we believe that it is not ethical to purposely prevent the participants in the control group from receiving evidence-based care. Therefore, the actual care they receive will be recorded and compared with the EPC group in results analysis. To minimise similarities between interventions in the two groups, care support coordinators will not be assigned for the control patients, and the EPC Working Group is not actively involved in the routine care, unless a consultation is made as deemed necessary with one or more specialties.

Discharge criteria

Participants in both groups will be discharged according to the same discharge criteria as follows: (1) adequate pain...
control with oral non-opioids, (2) adequate oral nutrition without the need of intravenous fluids, (3) no fever or signs of infection, (4) independent mobility or mobility with minimal assistance and (5) safe disposition home or to rehabilitation centre. The decision for discharge will be made on consensus of two attending physicians who are blinded to participants allocation.

Amendments to the study protocol
Aiming for continuous quality improvement, the EPC protocol will be implemented and refined based on feedbacks from the participants and providers as well as updates in the related fields. Amendments to the study protocol will be made by the EPC Working Group when necessary and approved by the IRB. Time and content of each amendment will be clearly recorded and updated at the registry. All subsequently enrolled participants will be managed according to the latest protocol.

Assessment and data collection
Primary outcome (effectiveness outcome)
The primary outcome is patient satisfaction and comfort, which will be measured by the Chinese Surgical Inpatient Satisfaction and Comfort Questionnaire (CSISCQ) (http://links.lww.com/MD2/A781) at discharge. The CSISCQ is a newly developed multimodal questionnaire in Chinese aiming to evaluate patient perceived quality of care associated with surgical inpatient services, which is shown to have satisfactory acceptability, validity and reliability. The final edition of the CSISCQ consists of two major sections, with one addressing patient satisfaction and the other targeting patient comfort. The patient satisfaction section includes five domains with a total of 50 questions: (1) environment and logistics, (2) inpatient nursing care, (3) OR service, (4) medical care and (5) global assessment. Each question is answered using a 5-point Likert scale, with higher points indicating higher levels of patient satisfaction: 1=completely dissatisfied, 2=moderately dissatisfied, 3=neutral, 4=moderately satisfied and 5=completely satisfied. The patient comfort section includes 2 domains of 15 questions (postoperative and hospitalisation experience and feeling of nervous and fear), which are answered using a different 5-point Likert scale with higher points indicating higher levels of comfort. Score of each dimension is summed and transformed linearly to give a value ranging from 0 to 100, with 100 indicating the highest level of satisfaction/comfort. The CSISCQ also records sociodemographic data including age, sex, marital status, number of children, educational level, professional status, monthly household income, self-perceived personality trait and overall happiness index.

It is noteworthy that though the CSISQ consists of five domains measuring patient satisfaction and two domains measuring patient comfort, aspects measured within the patient satisfaction domains could be linked to Kolcaba’s four contexts of comfort (ie, physical, psychospiritual, sociocultural and environmental), which is also supported by a list of comfort measures in Oliveira’s concept analysis. The consequences of comfort measures may vary based on the individualised comfort needs of patients, including but not limited to symptom relief, creation of a satisfying environment and improved well-being. Therefore, the inclusion of the patient satisfaction domains addresses outcomes related to enhanced comfort under the overall umbrella of quality of care and is suitable for measuring the effectiveness of comfort-related care.

We have recently conducted a multicentre cross-sectional study in China to validate the psychometric properties of the CSISCQ. The results showed satisfactory acceptability, construct validity, convergent validity, discriminant validity and content validity. The internal reliability consistency (Cronbach’s alpha coefficient above 0.70 for all dimensions) and test-retest reliability (intraclass correlation coefficient ranged from 0.77 to 0.96) were satisfying as well.

Secondary outcomes
Safety outcomes
Postoperative morbidity is defined as surgical complications (eg, surgical site infection, intracranial/intraspinal infection, haemorrhage, epilepsy, instrumentation loosening, breakage or displacement) and non-surgical complications (eg, cardiovascular complications, respiratory complications, urinary tract complications, gastrointestinal complications and venous thromboembolism) occurred within 30 days after surgery. All such events will be reported to the data and safety monitoring committee once occur and monitored until they are resolved. The severity and causality will be discussed within the EPC Working Group and documented.

Postoperative mortality is defined as death within 30 days after surgery or death during the hospitalisation in which the primary surgical procedure was performed.

Reoperation is defined as unplanned reoperation for any indication within 30 days of primary surgery.

Readmission is defined as unplanned readmission for any cause and to any hospital within 30 days of discharge.

Effectiveness outcomes
Postoperative pain score is measured on postoperative day (POD) 0–5 and at discharge by Visual Analogue Scales (VASs), which is a 0–10-point numerical scale, with 0 indicating no pain and 10 indicating the worst pain. A composite pain score was calculated as the mean value of four pain severity (least, worst, average and pain right now), regardless of the level of physical activity. Mild pain is defined as having pain VAS score 1–3, moderate pain is defined as having pain VAS score 4–6, and severe pain is defined as having pain VAS score 7–10. The postoperative pain duration in days will also be recorded.

PONV is measured on POD 0–3 by VASs, which is a 0–10-point numerical scale, with 0 indicating no PONV and 10 indicating the worst PONV (mild 1–3, moderate 4–6 and severe 7–10).

Functional recovery status is measured by (1) Karnofsky performance status score at discharge and 30-day follow-up after discharge and (2) Quality of Recovery-15 score daily on POD 0–5 and at discharge.

Mental status is measured by Self-Rating Anxiety Scale (or Hamilton Anxiety Scale), Self-Rating Depression Scale (or Hamilton Depression Scale) and Pittsburgh Sleep Quality Index after surgery and at discharge.

Nutrition status is measured by height, weight, recent weight loss, body mass index, body fat muscle mass, fat mass, grip strength, Nutritional risk screening 2002 and patient-generated subjective global assessment at discharge.

Postoperative LOS is defined as the number of calendar days from the date of surgery to the date of discharge.

Hospital LOS is calculated from the date of admission to the date of discharge.

Overall medical cost is calculated as total cost of hospitalisation in Chinese Yuan Rennminbi.

Patient experience in participating the EPC programme will be evaluated by a semistructured qualitative interview via telephone at 30-day follow-up after discharge. An interpretative phenomenological approach will be used for qualitative analysis.19

Feasibility outcomes
Feasibility outcomes, in terms of eligibility and participation rates as well as patient adherence to the EPC protocol (percentage of implemented elements relative to scheduled elements), will be reported.

Other variables
Demographic variables including age, sex, primary diagnosis for surgery, American Society of Anaesthesiology grades and patient comorbidities (smoking, diabetes, hypertension, hypercholesterolaemia, etc.) will be documented.

Surgery-related variables including length of procedure (anaesthesia/surgery), blood loss, blood transfusion and fluid balance will be recorded.

Sample size calculation
Based on previous results obtained from the multicentre validation study for the CSISCQ,18 the primary outcome of this study (ie, patient satisfaction and comfort) is estimated to be approximately 85. It is notable that 17.9% (283/1582) of the CSISCQ validation cohort were neurosurgical patients and that no significant differences were found between the various surgical specialties in their satisfaction and comfort (data not published). We hypothesise that the EPC programme will increase patient satisfaction and comfort by 10%. A sample size of 88 participants (44 per arm) will provide a power of 80% and a significance level of 0.05. Considering a maximal dropout rate of 20%, the final sample size is calculated as 55 in each group.

Statistical analysis
Categorical data will be presented as number of participants (percentage). To test whether variables differ across groups, the $\chi^2$ test or Fisher exact test will be used according to the testing condition. Continuous data will be presented as mean±SD or median (range) and compared using analysis of variance (ANOVA) or Mann-Whitney U test according to the testing condition. An intention-to-treat analysis will be done for all randomised participants.

An interim analysis is planned to test the effectiveness of the EPC programme with regard to the primary outcome when the minimal number of the predefined sample size is met. Due to the heterogeneity of indications for surgery, subgroup analysis will be performed for elective craniotomy, endoscopic trans-sphenoidal surgery and spine surgery, respectively. Since the aforementioned sample size is calculated for elective neurosurgical patients and will probably be underpowered for subgroup analysis, the analysis for each subgroup will only be performed when one has a minimum of 44 patients per arm. Multinomial logistic regression will be used to identify possible predictors of patient satisfaction and comfort. The reasons of loss to follow-up (including death) will be reported, and their confounding effects on the primary outcome will be analysed. Statistical significance is defined as $p<0.05$. All of the tests are two sided. Statistical analysis will be performed using SPSS software (V.26.0, SPSS).

Qualitative analysis of patient experience will be done using interpretative phenomenological analysis as previously described by Smith et al.19

Patient and public involvement
Patients and/or the public were not directly involved in the development and design of this study. However, during the development and validation of the primary outcome measurement tool of the study (ie, the CSISCQ), patients were consulted and actively involved to identify the factors and measures affecting comfort by exploring and understanding patients’ perspectives and experiences of care.18 The design of the EPC protocol is based on the previous work in the process of literature review on comfort-related factors.

Ethics and dissemination
Ethical approval to conduct the study has been obtained from IRB of Xi’an International Medical Center (No. 202028). The trial has been prospectively registered at the Chinese clinical trial registry: ChiCTR2000039983 (http://www.chictr.org.cn/showproj.aspx?proj=62520) on 16 November 2020. The first patient has been enrolled on 11 April 2022. The protocol adheres to the principles set forth in the US Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects, revised 23 June 2005, and the World Medical Association Declaration of Helsinki. Eligible patients and their family will be fully informed about the study, given sufficient time to read the information and opportunity to ask questions before deciding to participate. Written informed consent will be
obtained from all participants or their legally authorised representatives (online supplemental file 3). Withdrawal from the study is permitted at any time without a reason and will in no way affect the patient care. An independent data and safety monitoring committee consisting of members from the IRB will monitor the conduct and safety of the study to ensure participant safety. All postoperative morbidities including surgical and non-surgical complications will be reported and monitored during the whole process of management. Confidentiality of participants will be protected, and all data will be put in the study dataset in an anonymous way. The principal investigator will be responsible for ensuring secure access to the dataset.

The results will be presented at scientific meetings and published in peer-reviewed journals.

**DISCUSSION**

For the purpose of continuous improvement of healthcare quality, it is imperative to have insight into patients’ perceptions. Patient satisfaction and comfort with communication, physical comfort, pain control, hospital environment, etc. are significant indicators of care quality. The comfort theory proposed by Professor Kolcaba combines four contexts (ie, physical, psychospiritual, sociocultural and environmental) with three kinds of needs (ie, relief, ease and transcendence). The initial comfort theory claimed that ‘in stressful healthcare situations, unmet needs for comfort are met by nurses’. We have broadened this view to incorporate more care providers at various stages of patient care to facilitate a comprehensive and continuous workflow (ie, the EPC protocol for this study). Our EPC protocol includes the basic two types of processes for providing comfort measures (ie, stepping in and stepping back). The process of stepping in involves providing supportive interventions to facilitate comfort such as pain control, PONV prophylaxis and management, anxiety and depression evaluation and intervention; while stepping back involves withdrawing or withholding interventions to prevent discomfort, such as restrictive surgical site drains, early removal of urinary catheter and restrictive intravenous fluids.

Such comfort measures are considered successful when patient comfort is enhanced compared with a previous baseline. The primary outcome will be assessed with a comfort questionnaire which is designed and validated for Chinese patients in our earlier work. Moreover, assessment of secondary outcomes including postoperative morbidity and mortality, postoperative pain score, PONV, functional recovery status, hospital LOS, reoperation and readmission rates, and overall cost will strengthen the applicability of the EPC programme.

In addition, though different definitions of comfort have been made, there is a consensus that comfort is a dynamic and multidimensional state. The needs for psychosocial and sociocultural contexts of comfort are dynamic and essential components of the holistic comfort. Our EPC programme includes several comfort measures to meet the patients’ dynamic needs for comfort, such as appointment of a ‘coaching’ care support coordinator and active involvement of medical staff from the department of psychosomatic medicine (online supplemental file 1).

Antecedent efforts on improving patient comfort are mainly focused on the context of end-of-life care and maternal labour support. To our knowledge, this study will be the first one that focuses on elective neurosurgical patients and incorporates a continuous workflow of preoperative, intraoperative and postoperative care. In addition, along with the evolution and application of the comfort theory, it is further divided into three parts: (1) evaluating and meeting the holistic (physical, psychospiritual, sociocultural and environmental) comfort needs of patients, (2) strengthening patients to participate in health-seeking behaviours and thus enhancing patient well-being (such as decreased blood loss, less complications, faster healing, enhanced mobility and oral nutrition) and (3) achieving Institutional integrity in terms of hospital LOS, medical cost, patient satisfaction, etc.

The design of this RCT addresses all three parts of the comfort theory.

This study will provide preliminary results of the feasibility, effectiveness and safety of a multimodal, multidisciplinary, evidence-based EPC programme for patients undergoing elective neurosurgery. If successful, it will support the potential for broad implementation of the EPC programme to improve patient satisfaction and comfort with hospital surgical service and serve as a stepping stone to promote further research on quality improvement of patient care.

**Author affiliations**

1Department of Neurosurgery, Xi’an International Medical Center, Xi’an, Shaanxi Province, China
2Department of Obstetrics and Gynecology, Xijing Hospital, Fourth Military Medical University, Xi’an, Shaanxi Province, China
3Department of Anesthesiology, Xi’an International Medical Center, Xi’an, Shaanxi Province, China

**Contributors** BL, SL, BW and SH: conceptualisation. BL, SL, BW, WL, LC, TZ, DL, TM and SH: data curation, investigation and writing—original draft. BL, BW and SH: project administration. BL, SL and BW: writing—original draft.

**Funding** This work was supported by Xi’an International Medical Center Research Fund (Key program: No. 20202D004). The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**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.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Institutional Review Board of Xi’an International Medical Center (No. 202026). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request.
REFERENCES