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Effectiveness of the self-fatigue assessment in guiding early postoperative ambulation in gynaecological oncology patients: study protocol for a randomised controlled trial

Qian Du,[1] Bo Chen,[2] Shaoyong Xu,[2,3] Hong He,[4] Xiaomin Qin,[1] Tongting Kang,[1] Xu Wang,[1] Xiaojie Huang [1]

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QD and BC contributed equally.

QD and BC are joint first authors.

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For numbered affiliations see end of article.

Correspondence to
Dr Xiaojie Huang;
huangxiaojie1265@163.com

ABSTRACT

Introduction Enhanced recovery after surgery (ERAS) guidelines strongly recommends that patients be in early postoperative ambulation within 24 hours. This study aims to assess the effectiveness and safety of the self-fatigue assessment method to guide patients' early postoperative ambulation.

Methods and analysis This is a single-centre, randomised, open, parallel-controlled trial. Five hundred and fifty-two patients who meet the inclusion criteria for gynaecological oncology surgery are randomly assigned in a 1:1 ratio to either a self-fatigue assessment group (study group) or a fixed activity distance assessment group (control group). The fixed activity distance group adopts a fixed early postoperative ambulation distance to guide the patient's activity, while the self-fatigue assessment group uses the Borg Exercise Scale to assess the patient's fatigue and stops activity when the fatigue level reaches 5–6. The primary outcome measure is the time to first postoperative flatus. Secondary outcome measures are the time to first bowel movement, the incidence of moderate to severe bloating, the incidence of bowel obstruction or venous thromboembolism, the incidence of adverse events (nausea, vomiting, dizziness), patient satisfaction, sleep quality scores, patient compliance with activities, hospital costs and days in hospital.

Ethics and dissemination This study was approved by the Independent Ethics Committee of Xiangyang Central Hospital affiliated with Hubei University of Arts and Sciences and registered with the China Clinical Trials Registry in May 2021. The results of the trial will be disseminated through open access peer-reviewed journals and abstracts will be submitted to relevant national and international conferences.

Trial registration number CTR2100046035.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ All interventions will be instructor-led, patients in both groups are to be assisted to get out of bed in the first 24 hours after surgery, with the aim of decreasing the risk of adverse events.
⇒ One limitation is that the trial is not a double-blind, placebo-controlled trial and implemented in only one hospital, which may limit its generalisability.
⇒ The first flatus status and some secondary outcomes are self-reported by the patient, which may lead to recall or report bias.

INTRODUCTION

Gynaecological tumour surgery is a large and complex surgery consisting of such procedures as expanded radical surgery for malignant tumours and resection for benign tumours. Such surgeries are often characterised by substantial surgical invasions and surgical complications, which lead to slow postoperative recovery, prolonged hospitalisation and increased medical costs, thus increasing the physical, psychological and economic burden on patients.[1]

Reducing surgical complications in gynaecological oncology and promoting early patient recovery are important clinical issues that need to be addressed. The current global quality improvement initiative for surgery is enhanced recovery after surgery (ERAS), which aims to improve perioperative care, shorten hospital stays, reduce surgical stress, reduce complications and accelerate recovery.[2] It provides both clinical improvement[3] and cost–benefits to the healthcare system.[4]

ERAS guidelines for gynaecological oncology surgery encourage patients to have early postoperative ambulation within 24 hours.[2] Having early mobilisation can significantly shorten patients' anal flatus time, promote patients' gastrointestinal motility, reduce the risk of pulmonary infection and thrombosis, and accelerate organism recovery. Advocacy of early mobilisation has

been increasingly used as an effective intervention in the concept of rapid rehabilitation surgery.

However, although ERAS guidelines on gynaecological oncology strongly recommend that patients be in early postoperative ambulation within 24 hours, early ambulation following surgery is substantially impacted by pain management presurgery and postsurgery,[5] postoperative fatigue, as well as orthostatic intolerance.[6 7] Therefore, ERAS has not yet explicit recommendations for directing and quantifying patient activity.[2] Currently, a few studies have evaluated patient strategies for early postoperative ambulation, mainly around patients after thoracoscopic lobectomy,[8 9] laparoscopic hepatectomy,[10 11] prostate cancer[12] and gastric cancer.[13 14] However, all of these studies adopted a fixed daily activity distance to guide postoperative patients, a strategy that undoubtedly did not specifically consider differences in patient fitness, disease severity and comorbidities, and in particular, did not take into account patient fatigue and acceptability.

We hypothesised that a strategy based on self-fatigue assessment rather than a fixed activity distance to guide early postoperative activity would be easy, individualised, safe and have better early recovery outcomes as well as compliance, but would need to be supported by high-quality studies. Therefore, this study aims to investigate the effectiveness and safety of a self-fatigue-based assessment to guide early postoperative activity in patients with gynaecological oncology.

METHODS AND ANALYSIS

Study design

This study is a randomised, open parallel controlled study that consists of a screening period of approximately 2–3 days, an intervention period of approximately 2–7 days, and a follow-up period of several days. The study is being conducted between 01 June 2021 and 30 May 2022 at Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science. Figure 1 shows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram.[15] The SPIRIT checklist is provided in online supplemental appendix 1.

Inclusion criteria

Included in this study are subjects meeting the following inclusion criteria: female with no cognition impairment, aged ≥18 years, 18.5≤body mass index≤ 24.9, undergoing gynaecological oncological elective surgery (open/laparoscopic), with normal preoperative limb movement, stable surgical condition, ability to get out of bed, American Society of Anesthesiologists Physical Status Classification I-III, and who voluntarily participated and signed an informed consent form.

Exclusion criteria

Excluded from the study are those meeting any one of the following exclusion criteria: (1) those with delirium after surgery; (2) those with the cardiac function of grade 3 or higher, which referring to New York Heart Association for cardiac function diagnosis classification criteria[16]; (3) perioperative patients with confirmed lower extremity venous thrombosis; (4) those with reoperation within the last 1 month; (5) those who are pregnant or breast feeding; (6) perioperative patients with persistent fever and temperature is 38.5°C or higher.

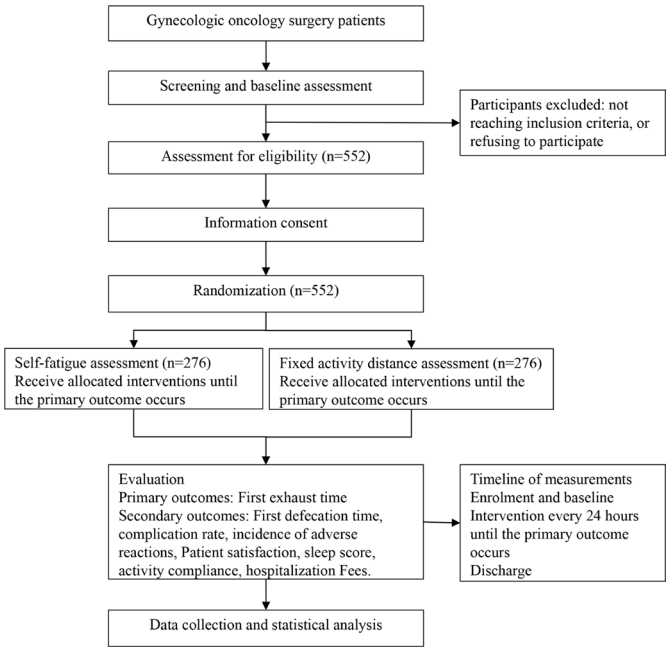

Figure 1 Flowchart of the trial design, based on the Standard Protocol Items: Recommendations for Interventional Trials 2013.

Participant recruitment

All patients with gynaecological oncology who have been admitted to the gynaecology department at Xiangyang Central Hospital and meet the eligibility criteria are invited to participate in this study, and potential participants are then asked to have a face-to-face interview with the professional coordinator to discuss the study and the eligibility criteria. After obtaining the informed consent of eligible and interested patients, information on basic patient demographic characteristics (eg, age, gender, educational background, marital status, type of disease, etc) is collected, and patients are randomised into two groups to receive different interventions.

Informed consent

The general study process is explained to participants at the time of participant recruitment before the start of the study. Participants are informed that participation in the trial is completely voluntary and that they can withdraw from the trial at any time. If they withdraw midway through the study, the data collected about the participant will not be deleted and will be used in the final analysis. Written informed consent is obtained from each participant before they receive any interventions related to the study.

Randomisation and allocation concealment

In this study, block randomisation is used to generate a sufficient number of random sequence numbers using the statistical programme SAS V.9.4 PROC PLAN, which were then randomly divided into two groups according to a 1:1 ratio before the intervention; the group status was sealed in an opaque envelope and assigned a random number based on a random code. The researcher opened the corresponding numbered envelopes to obtain group status according to the order in which the subjects entered the group. An explicit blinded design would be difficult to implement and of little value to the investigator and patients due to the different strategies for quantifying the two activities and the objectification of the main observations. Therefore, an open study was used in this investigation.

Interventions

Subjects who pass the initial screening are reassessed at the end of the procedure, and those confirmed eligible are formally randomly assigned in a 1:1 ratio to two groups: (1) study group: self-fatigue assessment group and (2) control group: fixed activity distance assessment group. Patients in both groups are to be assisted to get out of bed in the first 24 hours after surgery, with 15–20 min of preparation time before each mobilisation, and assisted to walk after completion of the activity assessment by the investigator. If subjects do not meet the intervention volume during each activity intervention, their activity compliance and influencing factors will be assessed. Once adverse events occur during the intervention, the trained nurses will take appropriate nursing actions to mitigate.

Prepare for getting out of bed and moving around

Patients are fed fluids 4–6 hours after surgery, and fully awake patients are instructed to prepare for early mobilisation 30–60 min after feeding. Patients are maintained in a sitting position for 15–20 min before getting out of bed and instructed to do rehabilitation exercises and ankle pump exercises in bed.

Our pain management philosophy revolves around setting appropriate patient-centred expectations. Pain status is assessed based on an inpatient pain dynamic assessment record form: the score ranges from no pain to extreme pain, with the lowest score of 0 and the highest score of 10, for a total of 10 grades. Pain scores 1–3 are classified as mild pain, 4–6 as moderate pain and ≥7 as severe pain. To improve adherence to intervention protocols, patients using an analgesia pump (including hydromorphone, sufentanil and flurbiprofen ester) will receive a double dose of analgesia in the preactivity; patients not using an analgesia pump will receive rectal diclofenac suppositories 30 min before getting out of bed or are given 50 mg of flurbiprofen intravenously 15 min before ambulation. Patients are freed from bed according to the three '30 s' principles and start to mobilise after no discomfort, see online supplemental appendix 2.

Study group: self-fatigue intervention

Postoperative fatigue is assessed by the modified 0–10 category ratio Borg Rating of Perceived Exertion (RPE) scale.[17] The RPE is a widely used psychophysiological assessment tool for assessing subjective perception during exercise, the end points of the scale were anchored such that zero represented 'no discomfort at all' and 10 represented 'the most intense discomfort [they] have every experienced or could ever imagine experiencing'. Patients are instructed to perform the activity until the self-fatigue assessment reaches levels 5–6 (intense discomfort, tiredness and slightly difficult to continue walking), intervening and assessing every 24 hours until the primary outcome occurs. To ensure the reliability of the assessment and to help build the patient's confidence, all key members of the patient's social support network (the 'family', attending physician and nurses) are invited for the patient's psychological intervention, and encourage early ambulation. When using the fatigue assessment intervention, patients are required to wear an electronic bracelet throughout to record the distance (in metres) of early postoperative mobilisation, though this is not the focus for this group.

Control group: fixed activity distance intervention

The fixed activity distance group uses an electronic bracelet (brand: Huawei Honor 5i) to record their postoperative mobilisation distance (in metres). Patients are instructed to mobilise about 1000–1200 m for the first 24 hours postoperatively[18] for about 1–2 hours; thereafter, the daily activity distance is increased by 500 m on top of the previous day's ambulation distance for 1–2 hours until the primary outcome occurs. When assessed using a fixed activity distance, patients are assessed for fatigue at the end of each intervention using the Borg Exercise Scale. There is no mandatory requirement for fatigue status in this group.

Data collection

Data collection is conducted by trained nursing assessors who assess and collect data from patients during the screening and baseline, intervention period, follow-up period, and close-out.

Enrolment and baseline (V_1, V_2)

Patients are screened on admission based on inclusion–exclusion criteria, and subjects who meet the screening criteria provide basic demographic characteristics information (eg, age, gender, educational background, marital status, type of disease, etc). When the patient is further screened at the end of the procedure for their confirmation of inclusion–exclusion criteria, they are enrolled and their vital signs (pulse, respiratory rate, temperature and blood pressure) are measured by the study nurse and assessed using a modified version of the Morse Scale used to measure the risk of falling out of bed in adults,

including 10 items with a score ranging from 0 to 20. The Caprini Risk Assessment Scale is used to assess the occurrence of venous thromboembolism (VTE). This helpful risk quantification tool[19] can effectively screen high-risk patients for VTE.[20] The Caprini Risk Assessment Scale includes 39 risk factors (17 risk factors were assigned 1 point, 7 risk factors were assigned 2 points, 10 risk factors were assigned 3 points and 5 risk factors were assigned 5 points). Caprini scores were 0–1 for low-risk VTE, 2 for medium-risk VTE, 3–4 for high-risk VTE and ≥5 for very high-risk VTE.

Intervention (V_2–V_x)

During the intervention period, one activity intervention is completed within each 24 hours cycle, with the study nurse asking the patient if they had anal flatus before each intervention. The patient's vital signs (pulse, respiratory rate, temperature and blood pressure) are assessed after the intervention and the following indicators.

Bloating is assessed during each visit cycle, and moderate and severe cases are recorded. Bloating is classified into four grades: (1) no bloating; (2) mild: abdominal distension is elevated and slightly higher than the chest, percussion is a low-pitched drum sound, bowel sounds may be diminished, slightly hyperactive or normal, mild abdominal distension may be present; (3) moderate: the abdomen is elevated and significantly higher than the chest with some tension, percussion is a mid-pitched drum sound with increased and pronounced range and intensity, bowel sounds are mostly diminished, and there is significant conscious bloating that interferes with eating or another metabolism; (4) severe: the whole abdomen is bulging in a spherical shape, hard and uncomfortable when pressed, without rebound pain, the percussion is a high-pitched drum sound and may appear as a metallic percussion, without any change in position bowel sounds are markedly diminished or non-existent, and there are obvious gastrointestinal reactions. To assess the possibility of intestinal obstruction during each visit, if highly suspected, an abdominal radiograph should be used.

The Pittsburgh Sleep Quality Index (PSQI) scale is used to assess the sleep quality of patients during each interview period. The scale had high reliability and validity[21 22]; the scale is composed of 19 self-rated items and 5 other items, where the 19th self-rated entry and 5 other-rated entries are not involved in scoring, and the 18 self-rated entries form a total of 7 components, each component is scored on a scale of 0–3. The cumulative component score is the total PSQI score, ranging from 0 to 2 L, with higher scores indicating poorer sleep quality.

The occurrence of adverse events such as nausea, vomiting and vertigo during each visiting period is investigated and the outcome recorded.

Subjects' activity compliance is assessed by the degree to which they meet the intervention volume after each activity intervention.

Follow-up (V_x)

If the patient appears to exhibit anal flatus, the intervention period is over. The exact time when the patient experienced the first anal flatus (hours) is determined. The patient's vital signs at the end of the intervention period are assessed, total compliance with activities throughout the intervention period is calculated, the incidence of bowel obstruction and the moderate and worst degree of abdominal distension is calculated, and the mean sleep quality score and the incidence of adverse patient reactions are calculated.

Close-out (V_{x+1})

After the intervention, follow-up continues until discharge from the hospital, at which time information on the hospitalisation costs and days of hospitalisation, the degree of bloating, the occurrence of intestinal obstruction, the sleep quality score, the satisfaction with the early mobility instructions, and other relevant information is collected. The registration, intervention, assessment and access schedules of participants are shown in table 1.

Outcome measures

The primary and secondary outcomes are shown in table 2.

Quality control

Before the trial, all staff will be required to attend a series of training courses. These courses will ensure that relevant personnel is fully aware of the study protocol and standard operating procedures for the study. To maintain the high quality of the clinical trial, the Xiangyang Central Hospital Clinical Research Centre will regularly monitor study documents, informed consent forms, Case Report Forms (CRFs), serious adverse events and data records.

Data management

The CRFs and adverse event forms will be completed first and then electronically entered into the electronic data capture system by two independent investigators as the first level of control to ensure data accuracy. The second level of data integrity will include data monitoring and validation, which will occur at regular intervals throughout the study. The original CRFs and all other forms (including consent forms) will be kept securely at the Clinical Research Center of Xiangyang Central Hospital, Hubei College of Arts and Sciences for 5 years after the last paper or study report is published.

The safety of this study will be monitored by the Data and Safety Monitoring Board (DSMB) of the Clinical Assessment Center at Xiangyang Central Hospital, Hubei College of Arts and Sciences, which is composed of independent clinical experts and statisticians. The DSMB is independent of competing interests and study sites and will review the performance and safety of the trial every month.

Criteria for discontinuation of the assigned intervention for a given participant include serious complications or a serious adverse event, if any, as described previously.

Table 1 Study plan detailing the procedures

	Study period				
	Enrolment	**Allocation**	**Post-allocation**	**Follow-up**	**Close-out**
Visit	V_1	V_2	……	V_x	V_{x+1}
Timepoint	Hospitalisation	End of surgery	1 intervention in every 24 hours	When the primary outcome occurs	Discharge
Enrolment					
Informed consent	×				
Eligibility screen	×	×			
Demographics	×				
Allocation		×			
Intervention					
Self-fatigue assessment			→		
Fixed activity distance assessment			→		
Assessments					
Vital signs	×	×	×	×	×
Risk of falls	×	×			
First exhaust flatus time			×	×	
Moderate to severe bloating			×	×	×
Intestinal obstruction			×	×	×
Venous thromboembolism		×			×
Pain score		×			
Adverse reactions (nausea, vomiting, dizziness)			×	×	
Sleep quality score	×		×	×	×
Hospitalisation costs					×
Length of hospitalisation					×
Activity compliance			×	×	
Patient satisfaction					×

The DSMB will make the final decision to terminate the trial.

The final trial dataset will be maintained by Xiangyang Central Hospital. The data management staff of the Xiangyang Central Hospital clinical assessment centre will have access to the complete, anonymised final dataset. Access to the final dataset or identifiable data by others will require written request approval by the DSMB of the Xiangyang Central Hospital clinical assessment centre and all investigators.

Patients and public involvement

Patients and the public are not involved in the design or conduct of the study or the outcome measures, and no attempt will be made to assess the burden of the intervention on the patients themselves.

Sample size estimate

The sample size is determined based on the results of a literature review and pretrial,[23 24] and 552 patients will be included in this study. This sample size is based on the following statistical considerations: the primary outcome hypothesis was that patients with gynaecological oncology were non-inferior to patients with self-fatigue assessment in early postoperative ambulation in terms of time to first postoperative flatus compared with patients with fixed activity distance assessment. Based on the literature review and pretrial studies, a conservative estimate of the SD of the change in postoperative time to first anal flatus was

Table 2 Primary and secondary outcomes

	Outcome measure
Primary outcome	
To compare the effect of early bedtime activity in the self-fatigue assessment group with that in the fixed activity distance group on the time to first postoperative flatus in gynaecological oncology patients	Time from the end of the procedure to the patient's first flatus (hours)
Secondary outcomes	
To compare the effects of early bed activity in the self-fatigue assessment group with those in the fixed activity distance group on the time to the first bowel movement, the incidence of moderate to severe bloating, the incidence of bowel obstruction or venous thromboembolism, the incidence of adverse effects (nausea, vomiting, dizziness), patient satisfaction, mean sleep quality score, patient compliance with activities, and hospital costs and days of hospitalisation in gynaecological oncology patients	1. Time from the end of the procedure to the patient's first bowel movement (hours) 2. Incidence of postactivity adverse reactions (nausea, vomiting, dizziness)=number of patients in each group with postactivity adverse reactions (nausea, vomiting, dizziness)/total number of patients in the group×100% 3. Incidence of moderate to severe abdominal distention after patient activity=number of patients in each group with moderate to severe abdominal distention after intervention activity/total number of patients in that group×100% 4. Incidence of postactivity bowel obstruction or venous thromboembolism in patients=number of postactivity bowel obstruction or venous thromboembolism in each group/total number of patients in that group×100% 5. Patient satisfaction rate with bed mobility instruction=number of patients in each group satisfied with early bed mobility instruction/total number of patients in that group×100% 6. Mean postactivity sleep quality score for patients 7. Patient compliance with activity=number of patients in each group who met the standard for early postoperative bed activity/total number of patients in the group×100% 8. The average cost of hospitalisation and the average number of days in the hospital for each group of patients
Safety outcome	
Evaluating the safety of two activity strategies	Incidence of adverse events/serious adverse events. Vital characteristics (including data on the pulse, respiration, temperature, blood pressure, etc)

8 hours, with a non-inferiority cut-off of 2 hours. At a bilateral 0.05 alpha level and 20% dropout rate, 552 patients with a 1:1 allocation rate (276 patients per group) would provide at least 85% validity to detect at least 2 hours difference in change in time to first postoperative anal flatus.

Statistical analysis

All data will be analysed by statisticians using SAS V.9.4 (SAS Institute) at the Xiangyang Central Hospital clinical research centre. Baseline assessments will be performed before randomisation to groups and include patient gender and age, type of disease, vital signs (pulse, respiratory rate, temperature and blood pressure), fall risk level, ability to perform activities of daily living, the primary outcome (time to first flatus) and secondary outcomes (complications, adverse effects, degree of bloating, sleep quality score, activity compliance, cost of hospitalisation and the length of hospitalisation). All patients randomly assigned to each group will be included in the analysis, and data analysis will be performed using a 5% two-sided significance test.

The primary analysis population will be based on the full analysis set of data and all analyses will be based on the intention-to-treat principle using the last observation carried forward principle. Missing values will be filled by multiple imputations. Continuous variables that conform to a normal distribution are expressed as means±SDs and compared by independent samples t-test. For variables that do not conform to a normal distribution, data will be expressed as median (25%–75%) and compared using a non-parametric test. Categorical variables will be expressed as numbers (%) and analysed using the χ^2 test or Fisher's exact test. Descriptive statistics will be used to detail baseline participant demographics and general patient status characteristics such as gender, age, disease type, vital signs, fall risk rating and ability to perform activities of daily living. A χ^2 test will be used to compare the differences in time to first anal flatus, complications,

adverse events, degree of bloating, sleep quality score, activity compliance, cost of hospitalisation, the length of hospitalisation and incidence of adverse events between the two groups. Stratified analysis based patients with or without opioid usage and open/laparoscopic will be performed.

Ethics and dissemination

The trial was approved by the Independent Ethics Committee of Xiangyang Central Hospital affiliated with Hubei University of Arts and Sciences (Project No. 2021C12) and registered with the China Clinical Trials Registry (http://www.chictr.org.cn/index.aspx, registration date: 02 May 2021). The results of the trial will be submitted to peer-reviewed journals and abstracts will be submitted to relevant national and international conferences.

Signed and dated informed consent will be provided by each subject before the conduct of the study. This study is strictly confidential concerning patient information and no public information will reveal the identity of the subjects.

DISCUSSION

ERAS guidelines strongly recommend that patients achieve early ambulation within 24 hours after surgery,[3 25] but these recommendations lack in-depth research on strategies to guide early mobilisation. Early postoperative ambulation can promote gastrointestinal recovery, but it is not possible to determine the level of activity required for gastrointestinal recovery, which can lead to over-activity or under-activity and complications in postoperative recovery. In a survey on the demand for postoperative ambulation health education for patients undergoing abdominal surgery, 47.07% of patients wanted to know 'how to arrange the amount of early ambulation',[26] which shows that patients have a greater demand for precise activity guidance after surgery.

The main factors influencing early postoperative ambulation in patients undergoing abdominal surgery are patient incisional pain,[27–29] postoperative fatigue, orthostatic intolerance,[6 7 30] demographic factors[31] and psychosocial factors. Some studies[6 32] quantified only the distance and duration of activity and did not consider individual differences in surgical patients in terms of age, complications and postoperative fatigue. Therefore, a good early activity guidance strategy should be based on the patient's actual situation to guide early bed activity. Assessing the amount of early mobilisation based on self-fatigue adequately takes into account individual patient differences and appears to be more effective than simply assessing the distance and duration of early bed activity for patients. However, to our knowledge, no studies are examining the validity and safety of assessing patients' early postoperative bed activity based on self-fatigue, and its benefits need to be further confirmed by standardised, transparent, and well-conducted randomised clinical trials.

This study is the first randomised controlled trial of early postoperative mobilisation strategy guidance for gynaecological oncology patients to investigate the effectiveness and safety of early postoperative mobilisation in inpatients undergoing gynaecological oncology surgery based on self-fatigue assessment relative to those based on fixed activity distance assessment, and it may provide support for early postoperative mobilisation strategy guidance for patients undergoing gynaecological oncology surgery, the results of the study may also contribute/influence the patient screening to surgery (inpatient/outpatient) and the development of pain management in outpatient surgery.

Trial status

The first participant was enrolled in June 2021 and the study is expected to end in June 2022.

Author affiliations
[1]Department of Obstetrics and Gynecology, Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science, Xiangyang, Hubei, China
[2]Center for Clinical Evidence-Based and Translational Medicine; Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science, Xiangyang, Hubei, China, Xiangyang Central Hospital, Xiangyang, Hubei, China
[3]Department of Endocrinology, Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science, Xiangyang, Hubei, China
[4]Department of Nursing, Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science, Xiangyang, Hubei, China

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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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ORCID iD
Xiaojie Huang http://orcid.org/0000-0002-5862-1366

REFERENCES

1 Tao N, Chen C, Li L. Application of enhanced recovery after surgery concept in gynecologic oncology surgery. *Chinese Journal of Obstetrics and Gynecology* 2015;8:632–6.
2 Wijk L, Udumyan R, Pache B, *et al*. International validation of enhanced recovery after surgery Society guidelines on enhanced recovery for gynecologic surgery. *Am J Obstet Gynecol* 2019;221:237.e1–237.e11.
3 Ljungqvist O, Scott M, Fearon KC. Enhanced recovery after surgery: a review. *JAMA Surg* 2017;152:292–8.
4 Ljungqvist O, Thanh NX, Nelson G. ERAS-Value based surgery. *J Surg Oncol* 2017;116:608–12.
5 Kutay Yazici K, Kaya M, Aksu B, *et al*. The effect of perioperative lidocaine infusion on postoperative pain and postsurgical recovery parameters in gynecologic cancer surgery. *Clin J Pain* 2021;37:126–32.
6 Bundgaard-Nielsen M, Jørgensen CC, Jørgensen TB, *et al*. Orthostatic intolerance and the cardiovascular response to early postoperative mobilization. *Br J Anaesth* 2009;102:756–62.
7 Jans Ø, Bundgaard-Nielsen M, Solgaard S, *et al*. Orthostatic intolerance during early mobilization after fast-track hip arthroplasty. *Br J Anaesth* 2012;108:436–43.
8 Khandhar SJ, Schatz CL, Collins DT, *et al*. Thoracic enhanced recovery with ambulation after surgery: a 6-year experience. *Eur J Cardiothorac Surg* 2018;53:1192–8.
9 Mayor MA, Khandhar SJ, Chandy J, *et al*. Implementing a thoracic enhanced recovery with ambulation after surgery program: key aspects and challenges. *J Thorac Dis* 2018;10:S3809–14.
10 Zhou L, Ma N, Bu D. Application of early quantitative activity program in accelerated rehabilitation after laparoscopic hepatectomy. *International Journal of Clinical Research* 2019;3:1–5.
11 Xiao-li LIN. Quantitative study and application effect of early getting out of bed of patients after laparoscopic lobectomy. *Smart Healthcare* 2020;6:68–9.
12 Bao Yiping，Liu QingJun，Zhuang Guimin. Effect of quantified early activity on patients undergoing laparoscopic radical prostatectomy. *Journal of Nursing Science* 2020;35:49–50.
13 Bingxin L, Ting G. Implementation of quantitative ambulation schemes in enhanced recovery after surgery for gastric cancer patients. *Journal of Nursing Science* 2018;33:23–6.
14 Cancan X, Zhiwei J, Gang W. Quantitative research and nursing effect of early ambulation in patients with gastrointestinal tumor after the operation. *J Med Postgra* 2016;29:411–5.
15 Schulz KF, Grimes DA. Get in the spirit with spirit 2013: protocol content guideline for clinical trials. *Contraception* 2013;88:676–7.
16 Iung B. NYHA functional class in secondary mitral regurgitation: an old classification to evaluate an innovative technique. *JACC Cardiovasc Interv* 2020;13:2329–30.
17 Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982;14:377???381–81.
18 Xiwang G, Ma Hongna XS. Quantification of daily activity goals in the rapid recovery of patients undergoing gynecologic lumpectomy. *Chinese general practice nursing* 2020;18:3666–8.
19 Al-Ogaili A, Fuentes HE, Tafur AJ, *et al*. Risk assessment as a guide for the prevention of cancer-associated thromboembolism. *Int Angiol* 2018;37:269–76.
20 Krauss ES, Segal A, Cronin M, *et al*. Implementation and validation of the 2013 Caprini score for risk stratification of arthroplasty patients in the prevention of venous thrombosis. *Clin Appl Thromb Hemost* 2019;25:107602961983806.
21 Buysse DJ, Reynolds CF, Monk TH, *et al*. The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989;28:193–213.
22 Chunde Z, Juan X, Jun X. Study on reliability and validity of Pittsburgh sleep quality index in civil servants of Tianjin. *Tianjin Med J* 2012;40:316–9.
23 Zhong S, Zhong X, Zhong X, *et al*. Comparison between the effect of epidural anesthesia combined with epidural analgesia and general anesthesia combined with intravenous analgesia on prognosis of ovarian cancer patients. *Oncol Lett* 2019;17:5662–8.
24 Jiajia Z, Zhang Yi MQ. Analysis of the effect of feeding time on gastrointestinal motility function and adverse effects and blood glucose after open surgery for gynecologic malignancies. *Journal of Advanced Nurse Practitioner Training* 2019;34:1512–5.
25 Ljungqvist O. ERAS--enhanced recovery after surgery: moving evidence-based perioperative care to practice. *JPEN J Parenter Enteral Nutr* 2014;38:559–66.
26 Li Jing CY. Research progress on nursing care of early activity of patients after an abdominal operation. *Chinese Nursing Research* 2014;28:1678–82.
27 Lauwick S, Kim DJ, Mistraletti G, *et al*. Functional walking capacity as an outcome measure of laparoscopic prostatectomy: the effect of lidocaine infusion. *Br J Anaesth* 2009;103:213–9.
28 Lin JH, Whelan RL, Sakellarios NE, *et al*. Prospective study of ambulation after open and laparoscopic colorectal resection. *Surg Innov* 2009;16:16–20.
29 Wu CL, Rowlingson AJ, Partin AW, *et al*. Correlation of postoperative pain to quality of recovery in the immediate postoperative period. *Reg Anesth Pain Med* 2005;30:516–22.
30 Grubb BP. Neurocardiogenic syncope and related disorders of orthostatic intolerance. *Circulation* 2005;111:2997–3006.
31 Taylor AH, Cable NT, Faulkner G, *et al*. Physical activity and older adults: a review of health benefits and the effectiveness of interventions. *J Sports Sci* 2004;22:703–25.
32 Browning L, Denehy L, Scholes RL. The quantity of early upright mobilisation performed following upper abdominal surgery is low: an observational study. *Aust J Physiother* 2007;53:47–52.