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Impact of graded nursing interventions based on

Submission date 18/04/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/04/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/04/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
Background and study aims
Liver cancer is one of the malignancies with high incidence and mortality rates worldwide. This study aims to explore the impact of quantitative graded nursing interventions on psychological stress and postoperative recovery in patients undergoing primary liver cancer resection by constructing a grading assessment system centered on Child-Pugh scores and HAMA/HAMD scales, combined with dynamic nursing resource allocation.

Who can participate?
Patients preparing for liver cancer surgery.

What does the study involve?
Health education and nursing before and after liver cancer surgery.

What are the possible benefits and risks of participating?
Helps liver cancer patients recover after surgery. No potential risks.

Where is the study run from?
The study was conducted at the First Affiliated Hospital of Ningbo University (China)

When is the study starting and how long is it expected to run for?
January 2023 to February 2024

Who is funding the study?
Provincial Medical Project (No.2025KY249) (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The impact of graded nursing interventions based on quantitative risk assessment on psychologica

Study objectives
Graded nursing interventions based on quantitative assessment may reduce postoperative psychological stress levels and negative emotions in patients undergoing primary liver cancer surgery, promoting postoperative recovery

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/07/2023, Ethics Committee of The First Affiliated Hospital of Ningbo University (59 Liu Ting Street, Haishu District, Ningbo, 315000, China; +86 0574 87085233; sychenjy@163.com), ref: 2023Y-095RS

Study design
Single-center interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Nursing care for patients undergoing resection of primary hepatic cancer

Interventions
Random number sequences are generated using SPSS 26.0, stratified by Child-Pugh score (A/B grade), with a block size of 4 for each stratum. Sealed opaque envelopes are used to store allocation results, managed by an independent statistician. After enrollment, research nurses assign patients to groups according to the envelope instructions, dividing them into an observation group and a control group, each with 40 patients.

The control group receive routine nursing care, which included:
Preoperative health education: Nursing staff provided patients with knowledge about liver cancer through oral communication; Postoperative pain management (VAS score ≤ 3): Close monitoring of patients' pain, bowel movements, and drainage tube conditions after surgery; Early ambulation (within 24 hours postoperatively): Guidance on early ambulation to actively prevent complications. A targeted assessment of the condition of enrolled liver cancer patients is conducted. Treatment risk was categorized based on the comprehensive score: low risk medium risk and high risk.

Based on the quantitative assessment results, clinical nursing staff from various departments were allocated appropriately, and stratified nursing measures were implemented. Low-risk patients: Assigned N0–N1 nursing staff to provide routine ERAS care + psychological support (10 minutes of mindfulness training daily). Medium-risk patients: Assigned N2 or higher nursing staff to implement low-risk measures + personalized exercise plans (bed activities starting 6 hours postoperatively). High-risk patients: Assigned N3 or higher nursing staff, team leaders, or specialist nurses to implement medium-risk measures + multidisciplinary team interventions (joint daily rounds by psychiatric nurses and nutritionists) .

Intervention Type
Behavioural

Primary outcome measure
1. Psychological stress response is measured using Psychological Stress Response Questionnaire (SRQ) at one day before surgery, three days after surgery , and at discharge.
2. Depressive state is measured using Hamilton Depression Scale (HAMD) at one day before surgery, three days after surgery , and at discharge.
3. Anxiety level is measured using Hamilton Anxiety Scale (HAMA) at one day before surgery, three days after surgery , and at discharge.

Secondary outcome measures
Measured using patient records:
1. Recorded the time to tolerate semi-liquid diet (time from surgery to first intake of ≥200 mL semi-liquid food)
2. Time to first out-of-bed activity (time from surgery to independent standing and walking ≥5 meters)
3. Time to first postoperative anal exhaust, and length of hospital stay

Overall study start date
05/01/2023

Completion date
06/02/2024

Eligibility

Key inclusion criteria
1. Meeting the surgical indications outlined in the "Guidelines for the Diagnosis and Treatment of Primary Liver Cancer (2022 Edition)" (single tumor diameter ≤ 5 cm, no portal vein trunk tumor thrombus, Child-Pugh A/B grade)
2. Age 18-75 years
3. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. Severe cardiovascular disease (NYHA III-IV grade)
2. Immune system disease or coagulation dysfunction (INR > 1.5, PLT < 50 × 10^9/L)
3. Malignant tumors in other locations
4. History of cognitive impairment or mental illness.

Date of first enrolment
06/01/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Ningbo University
59 Liu Ting Street, Haishu District
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Sponsor information

Organisation
The First Affiliated Hospital of Ningbo University

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Provincial Medical Project

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy and ethical restrictions.

IPD sharing plan summary
Not expected to be made available