

# Impact of graded nursing interventions based on

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<b>Registration date</b> 25/04/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/04/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

Dr Qinhong Xu, xuqinhong\_xqh03@126.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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**Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

**Study information**

**Scientific Title**

The impact of graded nursing interventions based on quantitative risk assessment on psychological

**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; sychenjoy@163.com), ref: 2023Y-095RS

**Study design**

Single-center interventional double-blind randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Other

## **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  $\leq 3$ ): 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(s)**

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.

## **Key secondary outcome(s)**

Measured using patient records:

1. Recorded the time to tolerate semi-liquid diet (time from surgery to first intake of  $\geq 200$  mL semi-liquid food)
2. Time to first out-of-bed activity (time from surgery to independent standing and walking  $\geq 5$  meters)
3. Time to first postoperative anal exhaust, and length of hospital stay

## **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  $\leq$  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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

75 years

## Sex

All

## 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  $<$   $50 \times 10^9/L$ )
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  
Ningbo  
China  
315000

## Sponsor information

### Organisation

The First Affiliated Hospital of Ningbo University

## Funder(s)

### Funder type

Government

### Funder Name

Provincial Medical Project

## Results and Publications

### 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes