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Study of the effect of bridge symptom intervention in symptom management of colorectal cancer patients undergoing postoperative chemotherapy

Submission date 25/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/01/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 06/01/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration.

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
The study on the effect of bridge symptom intervention in symptom management of colorectal cancer patients undergoing postoperative chemotherapy

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/08/2025, Ethics Committee of Soochow University (Room 1312, Comprehensive Building, First Affiliated Hospital of Soochow University, No. 899 Pinghai Road, Gusu District, Suzhou City, Jiangsu Province, 215006, China; +86 512 6797 2861; sdfyec@163.com), ref: SUDA20250108H13

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Parallel

Purpose
1. Develop a bridging symptom intervention program for patients undergoing adjuvant chemotherapy after colorectal cancer (CRC) surgery 2. Evaluate the efficacy of bridging symptom intervention in symptom management for patients undergoing adjuvant chemotherapy after CRC surgery.

Study type(s)

Health condition(s) or problem(s) studied
Symptom management in patients undergoing adjuvant chemotherapy after colorectal cancer surgery

Interventions
Randomization Grouping Method: Block randomization method is adopted. The specific operation process is as follows: First, patients are sorted according to their enrollment time, and different block lengths (i.e., each block includes a different number of patients) are set to divide all patients into several blocks; subsequently, the simple randomization method is used to number the patients in each block sequentially (1, 2, 3...); starting from any position in the random number table, a corresponding number of random numbers are continuously selected and assigned to each patient in the block; then, the random numbers are ranked and numbered

according to their values. It is pre-specified that patients whose random number ranking falls within a certain range in each block are included in Group A (control group), and those whose ranking falls within another range are included in Group B (intervention group).

Interventional Measure
1. Vomiting: Knowledge Education + PMR Guidance and Practice + Problem-Solving.

PMR guidance:
1. Clench fists - relax; stretch all five fingers - relax
2. Clench fists and bend arms upward - relax; straighten fingers and stretch arms forcefully - relax
3. Furrow the forehead tightly - relax; frown deeply - relax
4. Close eyes tightly - relax
5. Press the tongue firmly against the upper palate - relax
6. Close lips tightly - relax
7. Tilt the head back as far as possible in sequence - bend to the right - bend to the left - finally lower the head to press against the chest - relax
8. Shrug shoulders upward - relax; shrug shoulders forward - relax
9. Take a deep breath - relax
10. Push the abdomen out forcefully - relax; tighten the abdomen forcefully - relax
11. Bend the waist forward - relax
12. Lift the lower legs to tense the buttocks and thighs - lower the lower legs to relax
13. Press the heels down hard to tense the calf and thigh muscles - relax
14. Press the toes down hard to tense the calf muscles - relax
15. Curl the soles of the feet outward to both sides to tense the calves - relax

2. Fatigue: Pre-Exercise Assessment Individualized Prescription (50-65% HRmax, 10-45 mins, ≥3 days/week).
Pre-exercise Assessment:
1. Fatigue level: The Numerical Rating Scale (NRS) is used for screening and recording, where 0 points indicate no fatigue, 1-3 points indicate mild fatigue, 4-6 points indicate moderate fatigue, and 7-10 points indicate severe fatigue. For patients with no or mild (0-3 points) fatigue, continuous monitoring is conducted; for patients with moderate to severe (4-10 points) fatigue, exercise management is implemented
2. Presence of contraindications (such as extensive osteolytic bone metastasis, extreme thrombocytopenia, anemia, fever or active infection; restrictions secondary to cancer metastasis or other comorbidities; safety issues, such as high risk of falls assessed)
3. Develop a personalized exercise plan based on the patient's basic conditions such as age, gender, treatment status and physical condition

Individualized Prescription:
1. Exercise form: Aerobic exercise. According to the patient’s daily exercise habits, guide the patient to choose exercise forms such as walking, going up and down stairs, jogging, Baduanjin, cycling, etc. Considering the age and safety of CRC patients undergoing adjuvant chemotherapy, strenuous exercise is not suitable, so walking, going up and down stairs and other exercise methods are recommended first
2. Exercise intensity: Start from low intensity to moderate intensity exercise (the exercise intensity is when the heart rate reaches 50%-65% of the maximum heart rate; the maximum heart rate for women = 210 - age, and the maximum heart rate for men = 220 - age)
3. Duration: Start from a low duration. Perform 5-10 minutes of stretching warm-up exercises before and after exercise, move the limbs to avoid limb injuries during exercise, and exercise for 10-45 minutes every day
4. Exercise frequency: At least 3 days a week

Intervention Type
Behavioural

Primary outcome(s)
1. symptom clusters score measured using the Chinese version of the Memorial Symptom Assessment Scale (MSAS-C) at the day before chemotherapy (T0), the end of the 2nd chemotherapy cycle (T1), the end of the 4th chemotherapy cycle (T2), the end of the 6th chemotherapy cycle (T3)

Key secondary outcome(s))

Completion date
25/06/2026

Eligibility

Key inclusion criteria
1. Age ≥ 18 years old
2. Confirmed as CRC by pathological report and receiving adjuvant chemotherapy after surgery for the first time
3. Receiving the combined chemotherapy regimen XELOX (oxaliplatin and capecitabine)
4. Undergoing laparoscopic surgery as the surgical approach
5. Clinical Stage II and Stage III
6. Voluntary participation

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
106

Key exclusion criteria
1. Patients with severe physical diseases, such as other malignant tumors
2. Patients with organic brain diseases or complicated with other mental disorders
3. Patients with a previous history of ostomy surgery
4. Patients who need to have their condition concealed

Date of first enrolment
21/08/2025

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Government of Jiangsu Province

ROR
https://ror.org/004svx814

Funder(s)

Funder type

Funder Name
Government of Jiangsu Province

Alternative Name(s)
Jiangsu Province, Jiangsu Provincial People's Government,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jingjing Hou, 20235231053@stu.suda.edu.cn. Expected sharing date: August 1, 2026.

IPD sharing plan summary

Available on request