

# Perioperative respiratory therapy hierarchical management in enhanced recovery after surgery

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>12/05/2025   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>16/05/2025 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>17/09/2025       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

This study focuses on improving recovery after surgery, especially for patients having chest or upper abdominal operations. After surgery, some patients develop breathing problems like lung infections or difficulty getting enough oxygen, which can slow recovery and increase hospital stays. The study tests a new approach called "graded respiratory care management," which includes breathing exercises before surgery, special lung-protecting techniques during surgery and guided breathing exercises after surgery. This study aims to see if this approach helps patients recover faster, reduces breathing problems, and shortens hospital stays.

### Who can participate?

Adults (18 years or older) scheduled for chest or upper abdominal surgery can join.

### What does the study involve?

All control group participants were enrolled in one period, and all treatment group participants were enrolled in a later, separate period:

1. Standard care group (control): Receives usual medical treatment.
2. Graded respiratory care group (treatment): Receives extra breathing exercises before surgery, lung-protecting techniques during surgery, and guided exercises after surgery.

Doctors will check lung function (using simple breathing tests), blood oxygen levels, and track recovery progress.

### What are the possible benefits and risks of participating?

#### Possible benefits:

- Better lung recovery after surgery.
- Lower chance of breathing problems.
- Possibly shorter hospital stay.

#### Possible risks:

- Breathing exercises may feel tiring.

- Minor discomfort from tests (e.g., blood draws).
- No extra physical harm—all methods are safe and proven.

Where is the study run from?

The Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, China

When is the study starting and how long is it expected to run for?

January 2022 to June 2025

Who is funding the study?

This study receives no external funding.

Who is the main contact?

Dr. Ge Huiqing, Gehq@zju.edu.cn

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Huiqing Ge

### ORCID ID

<https://orcid.org/0000-0002-5822-2998>

### Contact details

Sir Run Run Shaw Hospital

3 East Qinchun Rd

Hangzhou

China

310016

+86 13588706787

gehq@zju.edu.cn

### Type(s)

Scientific

### Contact name

Miss Yiqing Xu

### ORCID ID

<https://orcid.org/0000-0002-4730-9633>

### Contact details

Sir Run Run Shaw Hospital

3 East Qinchun Rd

Hangzhou

China

310016  
+86 13634115344  
xuyiqing@srrsh.com

### **Type(s)**

Public

### **Contact name**

Mr Runze He

### **Contact details**

Sir Run Run Shaw Hospital  
3 East Qinchun Rd  
Hangzhou  
China  
310016  
+86 19883130216  
2259784284@qq.com

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Protocol serial number**

2022021530

## **Study information**

### **Scientific Title**

Respiratory stratification for perioperative optimization in enhanced recovery after surgery: a multicenter study

### **Acronym**

RESPRO-ERAS

### **Study objectives**

Graded perioperative respiratory management reduces length of stay

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 15/02/2022, Ethics Committee of Sir Run Run Shaw Hospital Zhejiang University School of Medicine (3 East Qinchun Rd, Sir Run Run Shaw Hospital, Hangzhou, 310016, China; +86 571 86006811; 594961420@qq.com), ref: 20250323

### **Study design**

Multicenter non-randomized intervention trial with a non-concurrent enrollment design

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Recovery after surgery

## Interventions

Current interventions:

This study is now a non-randomized intervention trial with a non-concurrent enrollment design, with control group participants enrolled in one period, and all treatment group participants enrolled in a later, separate period.

Four aspects of the patient's condition were assessed: aerosol therapy, bronchial hygiene, lung expansion, and aerobic exercise.

### -Control Group

Guided deep breathing exercises, to achieve the pre-operative assessment's FVC (forced vital capacity)

### -Experimental Group

#### 1. Aerosol Therapy AT

Score 0-2: Continue previous treatment

Score 3-4: Bronchodilator inhalation (Salbutamol 2.5 mg, three times daily)

Score 5-6: Bronchodilator inhalation (Salbutamol 2.5 mg + Ipratropium Bromide 0.5 mg, three times daily)

Score >7: Bronchodilator inhalation (Salbutamol 2.5 mg + Ipratropium Bromide 0.5 mg, three times daily) + combination therapy, three times daily

#### 2. Bronchial Hygiene (BH)

Score 0-2: Deep breathing, 3-5 times per hour

Score 3-4: Coughing guidance 3-5 times per hour + Flutter 3-5 times per hour for 6-8 hours

Score 5-6: Metaneb or High Frequency Chest Wall Oscillation twice daily

Score >7: Same as 5-6, with possible bronchoscopy if necessary

#### 3. Lung Expansion (LE)

Score 3-4: Inhalation device (IS) 5-10 times per hour for 6-8 hours

Score >5: If ineffective, PEP (Positive Expiratory Pressure) with a three-ball resistance device, set to maximum resistance

FVC < 15 ml/kg: Non-invasive ventilation 12/6 cmH<sub>2</sub>O for 2 hours twice daily

#### 4. Aerobic Exercise (AE)

Daily walking distance and time: 6-minute walk distance / 6 \* 20 minutes \* 0.8 meter

Previous Interventions:

Participants are randomized using a simple randomization method at the time of recruitment into an intervention group and a control group.

Four aspects of the patient's condition were assessed: aerosol therapy, bronchial hygiene, lung expansion, and aerobic exercise.

**-Control Group**

Guided deep breathing exercises, to achieve the pre-operative assessment's FVC (forced vital capacity)

**-Experimental Group**

**1. Aerosol Therapy AT**

Score 0-2: Continue previous treatment

Score 3-4: Bronchodilator inhalation (Salbutamol 2.5 mg, three times daily)

Score 5-6: Bronchodilator inhalation (Salbutamol 2.5 mg + Ipratropium Bromide 0.5 mg, three times daily)

Score >7: Bronchodilator inhalation (Salbutamol 2.5 mg + Ipratropium Bromide 0.5 mg, three times daily) + combination therapy, three times daily

**2. Bronchial Hygiene (BH)**

Score 0-2: Deep breathing, 3-5 times per hour

Score 3-4: Coughing guidance 3-5 times per hour + Flutter 3-5 times per hour for 6-8 hours

Score 5-6: Metaneb or High Frequency Chest Wall Oscillation twice daily

Score >7: Same as 5-6, with possible bronchoscopy if necessary

**3. Lung Expansion (LE)**

Score 3-4: Inhalation device (IS) 5-10 times per hour for 6-8 hours

Score >5: If ineffective, PEP (Positive Expiratory Pressure) with a three-ball resistance device, set to maximum resistance

FVC < 15 ml/kg: Non-invasive ventilation 12/6 cmH<sub>2</sub>O for 2 hours twice daily

**4. Aerobic Exercise (AE)**

Daily walking distance and time: 6-minute walk distance / 6 \* 20 minutes \* 0.8 meter

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Length of stay measured using data collected from the hospital record at one time point

**Key secondary outcome(s)**

Maximum Inspiratory Pressure and Forced Vital Capacity, measured using pulmonary function testing, post-operatively at day 2

**Completion date**

30/06/2025

**Eligibility**

**Key inclusion criteria**

1. Peri-operative patient
2. Age over 18 years old

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Key exclusion criteria**

1. Age less than 18 years old
2. Pregnant
3. Neuromuscular disease
4. Other systemic diseases induced ineligibility for surgery
5. Impaired cognitive functions
6. Refuse to enroll

**Date of first enrolment**

15/02/2022

**Date of final enrolment**

05/06/2025

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**Sir Run Run Shaw Hospital, Zhejiang University, School of Medicine**

3 East Qinchun Rd, Sir Run Run Shaw Hospital

Hangzhou

China

310016

**Study participating centre**

**Yongkang First People's Hospital**

No. 599, Jinshan West Road

Yongkang

China  
321399

**Study participating centre**  
**Shaoxing People's Hospital**  
No. 123, Baiyutan Road, Yuecheng District  
Shaoxing  
China  
312035

**Study participating centre**  
**Wuyi County First People's Hospital**  
No. 1, Wanlongcheng South Gate Street, Shuxi Subdistrict  
Jinhua  
China  
321299

**Study participating centre**  
**Zhejiang Putuo Hospital**  
No. 19, Wenkang Street, Donggang Subdistrict, Putuo District  
Zhoushan  
China  
316199

**Study participating centre**  
**Lanxi People's Hospital**  
No. 896, Huancheng West Road  
Lanxi  
China  
321102

**Study participating centre**  
**Jiaxing First Hospital**  
No. 1882, Zhonghuan South Road  
Jiaxing  
China  
314001

**Study participating centre**

**Ningbo Yinzhou No. 2 Hospital**  
No. 998, Qianhe North Road  
Ningbo  
China  
315192

**Study participating centre**  
**The First Affiliated Hospital of Wenzhou Medical University**  
No. 2, Fuxue Lane  
Wenzhou  
China  
325000

**Study participating centre**  
**Ningbo No. 1 Hospital**  
No. 59, Liuting Street  
Ningbo  
China  
315010

**Study participating centre**  
**Taizhou Hospital**  
150, Ximen Street  
Linhai  
China  
318000

## **Sponsor information**

**Organisation**  
Sir Run Run Shaw Hospital

**ROR**  
<https://ror.org/00ka6rp58>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**

Investigator initiated and funded

**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

**IPD sharing plan summary**

Not expected to be made available