

BMJ Open Effect of preoperative inspiratory muscle training combined with preoperative education on postoperative pulmonary complications in high-risk patients with lung cancer: protocol for a randomised controlled trial

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ABSTRACT

Introduction Preoperative inspiratory muscle training (IMT) is recognised as an important component of the preoperative management of lung cancer, although there is limited evidence for the delivery of a home-based IMT programme combined with preoperative education. We developed a programme combining short-term home-based IMT and preoperative physiotherapy education ('the programme'). This study aims to evaluate the effectiveness of this programme in reducing postoperative pulmonary complications (PPCs) after lung cancer resection compared with standard care.

Methods and analysis In this randomised controlled trial, 114 participants scheduled for lung cancer surgery at the First Affiliated Hospital of Fujian Medical University will be randomly assigned (1:1) to either receive usual care (information booklet) or usual care combined with the programme, which consist of short-term home-based IMT and preoperative physiotherapy education. The primary outcome measure will be PPCs using the Melbourne Group Score. Secondary outcomes will include health-related quality of life, maximal inspiratory pressure, 6 min walk distance, length of hospital stay, anxiety and depression levels, and hospital costs.

Ethics and dissemination The study has received ethics approval from the ethics committee of the first affiliated hospital of Fujian Medical University (approval no: MRCTA, ECFAH of MFU [2021]569). Participants will be required to provide written informed consent. The results of the study will be submitted for publication in peer-reviewed journals.

Trial registration number ChiCTR2300067464.

INTRODUCTION

Currently, lung cancer ranks highest in both incidence and mortality rates among all cancers worldwide.¹ According to epidemiological data, it is estimated that there will be approximately 2.2 million confirmed cases and 1.8 million fatalities in 2020, accounting for 11.4% and 18.0% of cancer incidence

STRENGTH AND LIMITATIONS OF THIS STUDY

- ⇒ The study is based on the Knowledge Attitude Practice Model, considering that once people understand the principles of improving health status, they are more likely to change their attitude and behaviour.
- ⇒ The trial is focused on high-risk patients before lung surgery who are more likely to develop postoperative pulmonary complications.
- ⇒ The intervention is delivered during the preoperative period, and home-based inspiratory muscle training is supervised through WeChat. Evidence of long-term outcomes of preoperative exercise training is lacking.
- ⇒ Participants and physiotherapists delivering the intervention cannot be blinded due to the nature of the intervention.

and mortality rates, respectively.^{1 2} In China, lung cancer also prevails as the most prevalent cancer and the primary cause of cancer-related mortality. The age-standardised mortality rate for lung cancer in the Chinese population is reported as 28.16 cases per 100 000 individuals, representing 30% of all cancer deaths.^{3 4} In contrast to the declining trends observed in Western nations, China has witnessed a steady rise in age-standardised incidence and mortality rates of lung cancer since 1990.⁵ This can be attributed to the escalating number of smokers and the expanding elderly population. Consequently, the incidence of lung cancer is anticipated to continue its upward trajectory in the forthcoming years.⁴

Surgery provides the best chance of survival for early-stage non-small cell lung cancer (NSCLC) patients, resulting in a large



number of patients requiring surgical resection each year. However, preoperative patients with certain high-risk factors, such as lower peak oxygen uptake (VO_2 peak) and poorer performance on physical functional tests like the 6 min walk test (6MWT),^{6,7} are more prone to developing postoperative pulmonary complications (PPCs). In addition to that, age over 75 years, body mass index over 30 kg/m^2 , a diagnosis of chronic obstructive pulmonary disease (COPD) and being a current smoker are also the independent risk factors for the development of PPCs after lung resection,^{8,9} which leads to unnecessary prolongation of hospital stay and increased use of antibiotics. Rehabilitation programmes targeting the respiratory system demonstrate that they can reduce postoperative complications following lung resection surgery,¹⁰ and individuals with marginal function are more likely to benefit from rehabilitation training.¹¹

A recent Cochrane systematic review indicated that preoperative rehabilitation for lung cancer can effectively reduce the occurrence of PPCs¹² (high-certainty evidence). In the preoperative period, studies combining inspiratory muscle training (IMT) with physical exercise for pulmonary rehabilitation (PR) demonstrated a significant improvement in functional capacity and a reduction in hospital stays, yet these are centre-based training programmes.^{13–15} It is also reported that incorporating preoperative exercise training may potentially allow patients with borderline functional parameters to become suitable candidates for surgery, thereby enhancing perioperative and cancer-related outcomes.^{16,17} The short waiting time between lung cancer diagnosis and surgery makes it difficult to implement traditional cardiopulmonary rehabilitation programmes prior to surgery.^{18,19} Evidence suggests that preoperative exercise training reduces the risk to develop PPCs regardless of the type of intervention (respiratory muscles, endurance or combined) and preoperative duration of training.²⁰ Interventions delivered at rehabilitation centres are hindered by factors such as transportation problems, travel costs, considerable distance to the rehabilitation centre and lack of insurance coverage for rehabilitation costs.²¹ Cardiac and pulmonary telerehabilitation are reported to be safe, convenient and cost-effective alternatives to traditional centre-based rehabilitation programmes.²² In addition, evidence has shown that home-based telehealth PR programmes had similar effects to outpatient PR programmes and greater effects than usual care for people with COPD. Therefore, a home-based programme of IMT seems more suitable for preoperative training in patients with lung cancer.

A previous preoperative education programme in Australia for upper abdominal surgery was found to enhance patients' preoperative understanding of the surgery and disease, as well as their ability to self-manage postoperatively, resulting in a nearly 50% reduction in the occurrence of PPCs.²³ Compared with postoperative period, during which opioid analgesia could affect mental clarity,²⁴ preoperative patients are in a relatively good mental state to learn breathing and cough skills

from physiotherapist. Therefore, a face-to-face education session before surgery is reported to leave a deep impression on patients.²⁵ Applying IMT alone could significantly reduce the risk of PPC and length of stay, especially in older and high-risk patients, and in those undergoing pulmonary surgery,²⁶ while there is a lack of studies which integrate IMT and preoperative education in lung cancer patients. This study aims to combine preoperative IMT and preoperative education, an intervention that does not require site requirements, in order to improve its subsequent implementability.

Theoretical framework

The Knowledge Attitude Practice Model²⁷ is used as the theoretical framework in this study. It is a comprehensive procedure covering relevant awareness, attitudes and behaviour change. The core of this model is that once people understand the principles of improving health status, they are more likely to change their attitude and behaviour. In the present study, the intervention is designed to continuously strengthen patients' health education, increase the level of patients' beliefs about controlling their disease, and enhance patients' adherence to preoperative rehabilitation, thereby improving their postoperative outcomes. Before cardiac surgery, patients who had a better understanding of their condition and received more preoperative information in the hospital had a lower incidence of postoperative complications within 30 days of discharge.²⁸ Preoperative cancer education can enhance patients' knowledge, reduce anxiety, improve satisfaction and decrease healthcare costs.^{29,30}

Aims

The aim of this randomised controlled trial is to assess the effectiveness of a preoperative programme integrating home-based IMT with preoperative education on the outcomes of PPCs, pulmonary function and functional performance in lung cancer patients.

METHODS AND ANALYSIS

Design

This is a randomised controlled trial with a 1:1 allocation ratio. The trial will be two-armed and assessor-blinded. The participants will be randomly assigned to either receive a short-term preoperative programme consisting of home-based IMT exercise and rehabilitation education in addition to usual care or receive usual care alone. The design of the trial is illustrated in [figure 1](#).

Setting and participants

Patients at the First Affiliated Hospital of Fujian Medical University who are scheduled to undergo surgical treatment for suspected or confirmed NSCLC and meet the inclusion criteria ([table 1](#)) will be considered eligible for this study. Patients will be approached at the Thoracic Surgery Outpatient Clinic by XW. Potential participants

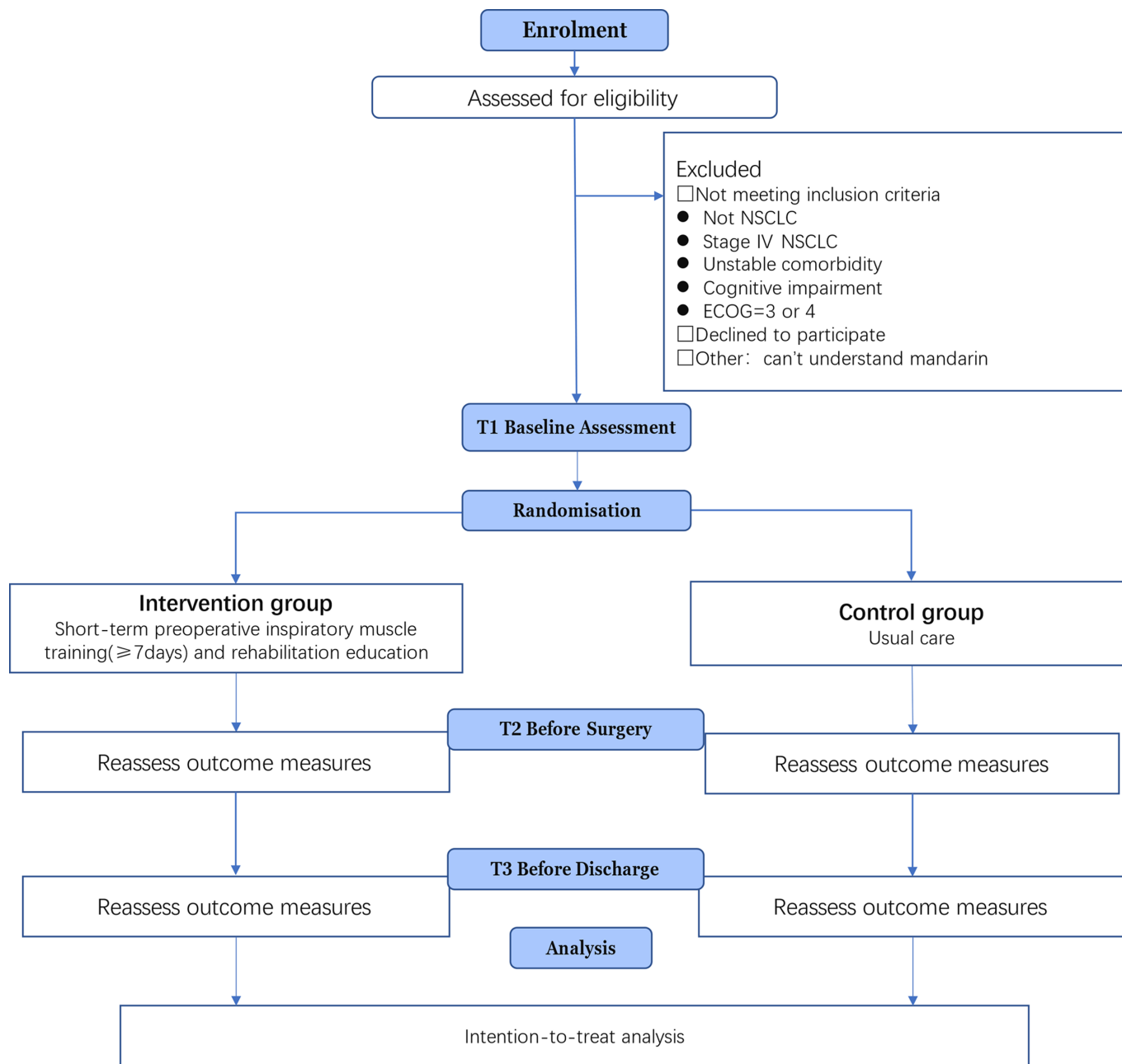


Figure 1 Participant flow diagram. ECOG, Eastern Cooperative Oncology Group; NSCLC, non-small cell lung cancer.

are also offered an appointment to discuss the trial to gauge their interest. Prior to enrolment, participants will receive both written and verbal information about the study. Written informed consent will be obtained from each participant (online supplemental material). Recruitment started on 1 March 2023 and is anticipated to end by 31 December 2024. The protocol for this study follows the guidelines provided by Standard Protocol Items: Recommendations for Interventional Trials³¹ (SPIRIT) and Template for Intervention Description and Replication³² (TIDieR).

Recruitment

Patients who are scheduled for elective hospitalisation and surgery at the thoracic surgery clinic at the First Affiliated

Hospital of Fujian Medical University will be informed about the trial. Once the participants agree to make appointment about the surgery with the surgeon in the outpatient clinic, they will be screened for eligibility prior to enrolment. The researcher will be approaching the potential candidates. Baseline assessment is performed at least 7 days before surgery by ZS at the thoracic surgery ward. Enrolment into the trial and subsequent baseline assessment will be completed in preadmission clinic. The schedule of enrolment and assessments is shown in figure 1.

Randomisation and blinding

The randomisation schedule will be computer generated by an independent statistician and allocation will be

**Table 1** Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> ▶ Aged ≥ 18 years ▶ ≥ 7 days prior to surgery ▶ Suspected or confirmed NSCLC ▶ Planned to have VATs, requiring an overnight hospital stay. ▶ Presence of at least one risk factor for PPCs, including age > 70 years, BMI ≥ 30, history of heavy smoking (smoking index ≥ 400 cigarettes per year or ≤ 2 weeks of preoperative abstinence), FEV₁/FVC $\leq 70\%$ or patients undergoing a second lung cancer surgery. ▶ Require intraoperative general anaesthesia. ▶ Signed informed consent. 	<ul style="list-style-type: none"> ▶ Uncontrolled cardiovascular or respiratory issues such as arrhythmia, acute coronary syndrome, angina. ▶ Cognitive impairment (not being able to provide consent for surgery). ▶ ECOG score of 3 or 4 at the time of inclusion in the study status. ▶ Insufficient Mandarin language skills to complete the questionnaires. ▶ Stage IV NSCLC

BMI, Body Mass Index; ECOG, Eastern Cooperative Oncology Group; FEV₁, first-second expiratory volume; FVC, forced vital capacity; NSCLC, non-small cell lung cancer; PPCs, postoperative pulmonary complications; VATs, video-assisted thoracic surgery.

carried out centrally by the site trial coordinator using the Resman randomisation module. An independent administrator who will have no further involvement in the trial will prepare sequentially numbered sealed opaque envelopes containing allocation cards. Allocation concealment will be achieved as the randomisation code will not be released until the participant has completed the baseline outcome measures. Randomisation will occur when the patient is scheduled to undergo surgery more than 7 days later. If the surgery date is brought forward and the waiting time before surgery does not exceed 7 days, the patients will be retained in the trial, and the final preoperative waiting time will be reported at the end of the trial.

Usual care: intervention and control groups

Usual care (medical, nursing and physiotherapy) will be provided in the perioperative period to participants in both intervention and control groups. On the day of enrolment, patients will receive a hospital-specific information booklet on thoracic surgery, containing information about the surgery and hospital stay, instructions about breathing and coughing, chest and shoulder exercises and advice on the importance of being physically active. Apart from the booklet, no additional education is provided to the control group. After surgery, inpatient physiotherapy will focus on achieving early mobility milestones for discharge home and breathing exercises if required. Inpatient physiotherapists providing usual care will be blinded to group allocation and their inpatient ward treatments will be recorded on the participant's hospital medical record.

Education programme and preoperative inspiratory muscle training: intervention group only

In addition to usual care, participants in the intervention group will receive a detailed education session plus at least 7 day IMT programme before surgery.

Preoperative education programme

The education session is based on the information booklet outlined above. After the baseline assessment and provision of the booklet, participants randomised to the intervention group will receive an additional single 15–30 min education and breathing exercise coaching session with the physiotherapist. In this course, the participants will be informed about the general procedure of the surgery, including the location of the incision, the average duration of the surgery and the effect of anaesthesia on PPCs. They will be educated about the risks associated with the planned surgery and the importance of early mobilisation after surgery to reduce risks. Participants are instructed how to perform deep breathing and coughing while supporting the surgical site after surgery, and are encouraged to perform this once an hour, 10 repetitions of deep breathing, followed by three coughs, starting immediately after waking from anaesthesia.²³ Our intervention physiotherapist will demonstrate the detailed breathing training movements to the participants face-to-face in the outpatient clinic to ensure that the patients are doing the training correctly.

Short-term home-based intensive inspiratory muscle training

In addition to the education programme, the intervention group will be provided with a threshold IMT device (Henan Zhengbei medical equipment Co.). When the baseline maximum inspiratory pressure (MIP) assessment is completed, the participant will be asked to train using the device to perform the IMT training. The physiotherapist will teach the participant how to use the device correctly:

1. There are 0–9 resistance grades on the trainer, and the higher number represents the greater effort spent.
2. Clip the nose and breathe through your mouth.
3. Hold your mouth around the device, close your lips, inhale deeply, when the inhaled air passes through the breathing trainer, the activity switch is opened.

4. Continue to inhale without removing the breathing trainer from your mouth as you exhale. Participants in the intervention group will do IMT with an intensity of 60% of MIP,³³ three times per day and for at least three sets for 10 repetitions while they are waiting for the surgery at home.²⁶ WeChat is broadly used in China. It offers a variety of features such as text messaging, voice calls, video calls and supports group chats. Through WeChat, the therapist will send messages or make voice call to supervise the participants to perform the IMT exercise at home every day until they are admitted to the hospital. The physiotherapist will record the adherence to IMT through WeChat every day. Participants of the intervention group are instructed to rate their fatigue using the Borg Scale and train at an intensity level of somewhat hard (Borg 4/10). If participants experience excessive fatigue or breathing difficulties, resistance and/or time of training will be reduced. An independent data management committee will meet every 3 months to discuss trial progress, and JN, TL, the trial manager and trial personnel will meet weekly to monitor trial progress.

Sample size calculation

The primary outcome of this trial is the incidence of PPCs. According to previous literature,¹⁴ the incidence of PPCs is expected to be 36.7% in the control group and 13.3% in the intervention group. With a $\beta=0.2$, $\alpha=0.05$, two-sided test, 1:1 random entry, PASS 11 software calculated the required sample size of 51 people in each group and 57 subjects in each group are required accounting for an estimated 10% loss to follow-up. Therefore, a total of 114 subjects are required.

Outcome measures

For participants in the intervention and control groups, outcome assessments will be obtained in person at baseline (≥ 7 days before surgery) (T_0), the day before surgery (T_1) and hospital discharge (T_2) by a trained research assistant, who will be blinded to the group allocation. At baseline, a range of objective measures of physical function and patient-reported questionnaires will be assessed. All study outcomes will be collected using validated tools. Table 2 shows the overview of study outcomes and measurement details.

Primary outcome

The primary outcome of this study will be the incidence of a PPC within 7 postoperative days or hospital discharge, whichever occurred first. Participants will be screened using a standardised and validated diagnostic tool Melbourne Group Score developed by an Australian team that consists of eight symptomatic and diagnostic criteria^{34–36} (box 1). Data will be collected by a physiotherapist who is blinded to group allocation before 11 a.m. daily when signs or symptoms of respiratory system deterioration were reported in the medical record until discharge. A PPC will be diagnosed when four or more of these eight criteria were present at any time from midnight to midnight each postoperative day.

Secondary outcomes

Length of hospital stay

Patients are generally admitted to the hospital the day before the operation, and the length of the stay starts from the half day of the hospitalisation, and the assessor will record the length of the patient's stay, accurate to the

Table 2 Study outcomes and measurement details

Variables	Measures	T_0 Baseline	T_1 1 day before surgery	T_2 Day 7 or discharge day
Primary outcome				
PPCs	Melbourne group score			√
Secondary outcomes				
Physical function	Six-Min Walk Test	√		√
Maximal Inspiratory Pressure	The Portable Lung Function Tester	√	√	√
Quality of life	EORTC QLQ-C30&LC13	√		√
Depression	Self-rating Depression Scale	√	√	√
Anxiety	Self-rating Anxiety Scale	√	√	√
Forced expiratory volume in one second/forced vital capacity	The Portable Lung Function Tester	√		√
Length of stay				
				√
PPCs will only be measured to day 7 or discharge. EORTC, European Organisation for the Research and Treatment of Cancer; PPCs, postoperative pulmonary complications.				

**Box 1 MGS PPC diagnostic criteria**

Diagnosis confirmed when four or more of the following are present:

Clinical factors

- ⇒ New abnormal breath sounds on auscultation different to preoperative assessment.
- ⇒ Production of yellow or green sputum different to preoperative assessment.
- ⇒ Pulse oximetry oxygen saturation (SpO₂) <90% on room air on more than one consecutive postoperative day.
- ⇒ Pulse oximetry oxygen saturation (SpO₂) >38°C more than one consecutive day.

Diagnostic factors

- ⇒ Chest radiograph report of collapse/consolidation. When a CXR has been taken but no report is available, a ward medical officer or a senior respiratory physiotherapist with more than 10 years' experience will be asked to report.
- ⇒ An unexplained WCC greater than 11×10⁹/L.
- ⇒ Presence of infection on sputum culture report.
- ⇒ Physician's diagnosis of pneumonia, URTI or an undefined chest infection, or prescription of an antibiotic for a respiratory infection.

MGS, Melbourne Group Score; PPC, postoperative pulmonary complication; CXR, chest radiography report; URTI, upper respiratory tract infection; WCC:white cell count.

first or second half of the day. The total length of hospital stay will be recorded.

Six-Min Walk Test

To assess physical capacity, the 6MWT will be performed according to standardised guidelines.³⁷ The test will be performed indoors, along a long, straight, enclosed corridor with a hard surface. Before the test, a 30-metre walking route is required, necessitating a 100-foot corridor. At each end of the corridor, a cone is placed to mark the turnaround points. Participants undergo the test using the designated 30-metre corridor. Throughout the test, participants' vital signs will be monitored using portable pulse oximetry. Participants will be asked to rate effort and breathlessness before and after the test, as required in the guidelines. If participants have high blood pressure (≥140/90 mm Hg) after 10 min of rest, the test will not commence.

Anxiety and depression

Mood will be measured using the Self-rating Anxiety Scale (SAS) and Self-rating Depression Scale (SDS), which are tools to assess the anxiety and depression levels of participants.^{38, 39} Both scales have 20 items and responses are measured on a 4-point scale (rated 1–4). Higher total scores represent worse status. The distress thermometer will also be used.

Health-related quality of life

European Organisation for the Research and Treatment of Cancer questionnaire and lung cancer module (EORTC QLQ-C30 and LC13) will be used to measure health-related quality of life.⁴⁰ For functional domains

and global health status/quality of life scale, a higher score represents better status, while for symptom domains and single-items, lower scores represent less symptoms.

Maximal Inspiratory Pressure

The Maximal Inspiratory Pressure (MIP) will be tested by the Portable Lung Function Tester E breathe-plus S3 (XEEX (Xiamen) Medical Instrument Co). Before the test, the device will be adjusted to the inspiratory muscle test mode. Participants will be asked to take a seated position, fixed the mouth parts, put on the nose clip and breathe naturally for 1–2 times. After that, participants need to quickly inhale with maximum force and speed and hold the breath for 1–3s. At least three tests are required until the results are within 20% or 10 cm H₂O. The maximum value of the three tests is reported.

Forced expiratory volume in the first second (FEV₁)

The forced expiratory volume in the first second (FEV₁) will be tested by the Portable Lung Function Tester E breathe-plus S3 (XEEX (Xiamen) Medical Instrument Co). The participant holds the nose with a nose clip, breathes normally with the mouth part for 1–2 times, inhales until the lungs cannot hold the gas, and then exhales the gas in the lungs quickly and forcefully and tries to persist for 6s when exhaling. After 6 s, the machine automatically records the data. This step will be repeated at least three times, with the highest performance reported.

Feasibility of the intervention

The feasibility of the study is divided into two aspects—recruitment and adherence to the intervention. The trial recruitment will be considered feasible if the consent rate of patients who meet the enrolment eligibility criteria exceeds 70%. The intervention will be considered feasible if more than 70% of patients in the intervention group completed 70% or more scheduled home IMT.

Total cost

When the patient is discharged, the total cost of the stay will be recorded.

Patient and public involvement

Prior to the commencement of the study, family caregivers, clinical nurses, thoracic surgeons and physiotherapists were invited to attend a focus group to discuss the feasibility of functional assessment, questionnaires and intervention content. We adjusted the assessment location based on the patients' preference and set it up next to the preoperative assessment clinic. After the treatment plan is determined by the thoracic surgeon, the clinical doctors will notify the study team of patients for inclusion in the study based on the eligibility criteria. The timing of the three patient assessments was chosen when they had relatively ample time, including after scheduling the outpatient examinations, the afternoon before the surgery and the day of discharge. Therefore, the patients expressed that they had sufficient time for the assessments.

At the end of the study, we will notify the patients of the results according to their preference, either through text messages or WeChat.

Data management and analysis

All data will be analysed based on intention to treat principals using SPSS Windows V.26.0 (SPSS, Chicago, IL, USA). First, Shapiro-Wilk statistics will be used to test the normality of the data. Mean and SD will be reported for parametric data, and median and IQR will be reported for non-parametric data. Descriptive statistics will be used to summarise the participants' characteristics and the feasibility and safety results. For analysis of results over time, a paired sample t-test will be used if the data conform to a normal distribution. Wilcoxon sign rank test will be used for data that do not conform to normal distribution. One-way analysis of variance (ANOVA) will be used to analyse differences over the three time points. By comparing the changes in anxiety, depression and MIP at the three time points, the difference between the two groups will be obtained by subtracting the baseline standard scores before surgery and discharge. Interim results multiple imputation will be applied to handle missing data. Positive differences indicate an increase in score, while a negative difference in symptom subscale indicates a decrease in score. For all analyses, a p value < 0.05 will be considered statistically significant. If the enrolled participants fail to meet the anticipated numbers, a mid-term analysis will be initiated. JN will have access to these interim results and make the final decision to terminate the trial.

ETHICS AND DISSEMINATION

The study was approved by the Ethics Committee of the first affiliated hospital of Fujian Medical University (approval no: MRCTA, ECFAH of MFU [2021]569). All study participants will receive written and verbal information about the study and sign written informed consent before study participation. They will be informed they can withdraw from the study for any reason at any moment and with no consequences for continued treatment. Participants will not be restricted from any activities or treatments outside the study. All details regarding patients who are screened, consent and being monitored are kept in a secure Resman database. We expect to release the original data in February 2025 on the ResMan original data sharing platform (IPD sharing platform) of the China clinical trial registry, which can be viewed at the following website: <http://www.medresman.org.cn/pub/cn/proj/projectshow.aspx?proj=9949>.

The results of the study will be submitted for publication in peer-reviewed journals. All papers related to the study will be reported in accordance to the Consolidated Standards of Reporting Trials statement.

DISCUSSION

Our research aims to reduce the incidence of PPCs and hospital stay in lung cancer patients through a combination of short-term home-based IMT and preoperative education. This approach can be carried out during the period when patients await surgery notification, eliminating the need for them to come to the hospital for rehabilitation training and addressing the issue of patient commuting. Additionally, the study also reduces the requirements for rehabilitation centre facilities, which are limited in number in some counties and townships in China.

We hope to achieve significant benefits using limited resources through this method. Previous studies have shown that preoperative education can bring substantial postoperative benefits in a short period of time. Therefore, we believe that combining home-based moderate-intensity IMT can further enhance the outcomes. If our research can demonstrate the effectiveness and feasibility of this approach, it can be widely implemented in real-world clinical practice. This will provide timely and effective preoperative rehabilitation measures for lung cancer patients, further improving their surgical outcomes and recovery process.

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Contributors TL and JN contributed to the study conception and design, attaining the funding to support the project and preparing documents for ethical approval. TL developed the intervention together with ZS, XW and SH, KM is supervising statistician and provided statistical support, while LL provided overall advice and content for the study protocol. TL and JN contributed content to the original manuscript and have assisted with revisions. All authors provided critical revisions and approved the final manuscript.

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Competing interests None declared.

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