

Evaluation of mobile app-based pulmonary telerehabilitation after lung cancer surgery: protocol for a single-blind randomized controlled trial

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Evaluation of mobile app-based pulmonary telerehabilitation after lung cancer surgery: protocol for a single-blind randomized controlled trial

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Abstract

Background: Rehabilitation is well known to improve exercise capacity and pulmonary function in patients with lung cancer surgical resection. We will evaluate the efficacy of smartphone application-based rehabilitation programs in patients with lung cancer after surgical resection.

Objective: The objective of this randomized controlled trial is to evaluate the effectiveness of a mobile app-based pulmonary telerehabilitation program on exercise capacity and pulmonary function in patients after surgical resection for lung cancer.

Methods: A total of 60 participants will be recruited from West China Hospital of Sichuan University of Shangjin Campus for this single-center, single-blind, randomized controlled experiment (30 patients each for pulmonary telerehabilitation group and control group, respectively). A smartphone application and 3-months of application-based therapy will be given to the pulmonary telerehabilitation group. Both groups will complete a 4-week outpatient rehabilitation program (one time per week) at West China Hospital, Sichuan University Shangjin Campus's Department of Rehabilitation Medicine. Both at the beginning and completion of the therapy, participants will undergo evaluations.

Results: Exercise capacity will be the main outcome measure, with both groups' 6MWD. The pulmonary function test (FVC and FEV1), quality of life surveys, and mood disturbances are the secondary outcomes.

Conclusions: This randomized controlled trial will provide evidence on the feasibility and effectiveness of a mobile app-based pulmonary telerehabilitation program for patients after lung cancer surgery. The findings are expected to support the integration of digital health technologies into postoperative rehabilitation, improve patients' exercise capacity and pulmonary recovery, and promote accessible, home-based rehabilitation models for thoracic surgical populations. Clinical Trial: The trial has been registered with the Chinese Clinical Trial Registry, and it has received authorization from the West China Hospital Ethical Committee.

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Original Manuscript

Title

Evaluation of mobile app-based pulmonary telerehabilitation after lung cancer surgery: protocol for a single-blind randomized controlled trial

Abstract

Introduction

Rehabilitation is well known to improve exercise capacity and pulmonary function in patients with lung cancer surgical resection. This study will evaluate the efficacy of smartphone application-based rehabilitation programs in patients with lung cancer after surgical resection.

Methods and analysis

A total of 60 participants will be recruited from West China Hospital of Sichuan University of Shangjin Campus for this single-center, single-blind, randomized controlled experiment (30 patients each for pulmonary telerehabilitation group and control group, respectively). A smartphone application and 3-months of application-based therapy will be given to the pulmonary telerehabilitation group. Both groups will complete a 4-week outpatient rehabilitation program (one time per week) at West China Hospital, Sichuan University Shangjin Campus 's Department of Rehabilitation Medicine. Assessments will be conducted at baseline and at the end of the 12-week intervention. Exercise capacity will be the main outcome measure, with both groups' 6MWD. The pulmonary function test (FVC and FEV1), quality of life surveys, and mood disturbances are the secondary outcomes.

Ethics and dissemination

The trial has been registered with the Chinese Clinical Trial Registry, and it has received authorization from the West China Hospital Ethical Committee. The dissemination of the study's findings will be achieved through peer-reviewed publications and presentations at national and international conferences. Trial Registration: Chinese Clinical Trial Registry (ChiCTR2500100205).

Introduction

According to estimates, about one in five (18.0%) fatalities from cancer are thought to be caused by lung cancer, making it the most common type of cancer-related death worldwide.¹ China has a significantly high rate of lung cancer mortality when compared to other nations.² According to predictions, between 2015 and 2030, lung cancer mortality in China may rise by over 40%.³ As measured by the Chinese standard population (ASMRC), the crude and age- standardized mortality rates for all malignancies were 167.89 per 100,000 and 106.98 per 100,000, respectively.⁴ According to 339 cancer registries data, the ASIR of lung cancer was 36.71 per 100,000⁴. During 2012-2015, the survival rate of lung cancer in men and women were 16.8% and 25% relatively, although the survival rates for all cancers have increased

in recent years⁵. With the development of low dose helical computed tomography (LDCT), the incidence and mortality of lung cancer has been reduced by widespread screening programs^{6 7}. The financial burden of lung cancer incidence and mortality is still growing rapidly around the world. For early-stage lung cancer (stage I, stage II and some stage IIIA), surgical resection is the best choice for cure⁸. Video-assisted thoracoscopic surgery (VATS) has safety, feasibility, and efficacy as a minimally invasive alternative approach.⁹⁻¹²

However, patients will suffer fatigue, cough, and postoperative pain after lung surgical resection¹³⁻¹⁵. And decreased pulmonary function, physical activity level and psychological distress also appeared in lung cancer survivors^{16 17}. Reduced respiratory function caused by pulmonary lobectomy is the major reason for poor postoperative quality of life among wide ranging of complications after surgery.¹⁸

Pulmonary function can be improved by effective postoperative rehabilitation.¹⁹ Recent research shows that perioperative pulmonary rehabilitation (PR) programs including exercise may improve pre- and postoperative exercise capacity, quality of life and functional performance^{20 21}.

Pulmonary rehabilitation is a comprehensive intervention that includes endurance exercise training, resistance exercise training, aerobic exercise training, breathing exercise, education and behavior changes^{22 23}. Pulmonary rehabilitation is a well-established intervention for improving the physical function and quality of life of patients with chronic respiratory diseases such as COPD^{22 24}.

However, access to pulmonary rehabilitation programs can be limited, and patients may face barriers to attending in-person sessions, particularly in the postoperative period after pulmonary lobectomy. Therefore, many patients may lose the chance to improve their physical function and quality of their life. Telerehabilitation, which involves the use of telecommunication technology to deliver rehabilitation services, has emerged as a promising alternative to traditional in-person rehabilitation.

The aim of this study is to evaluate the effectiveness of a pulmonary telerehabilitation program delivered through a mobile app on pulmonary function and exercise for patients after pulmonary lobectomy.

Rationale

The literature review provided sufficient evidence to justify a clinical trial to investigate the effects of postoperative pulmonary telerehabilitation in patients undergoing surgical resection. Pulmonary resection and post-surgery telerehabilitation randomized controlled trial is designed to assess the effect of telerehabilitation after surgery on improving exercise capacity measured with the Six-Minute Walk Test (6MWT) and pulmonary function measure by FVC and FEV1 in such patients. The effects of telerehabilitation on postoperative morbidity, length of hospital stay (LoS), QoL, pain, depression and lung function will also be recorded. The study protocol provides a detailed description of the interventions to accurately interpret results, which will be published on completion.

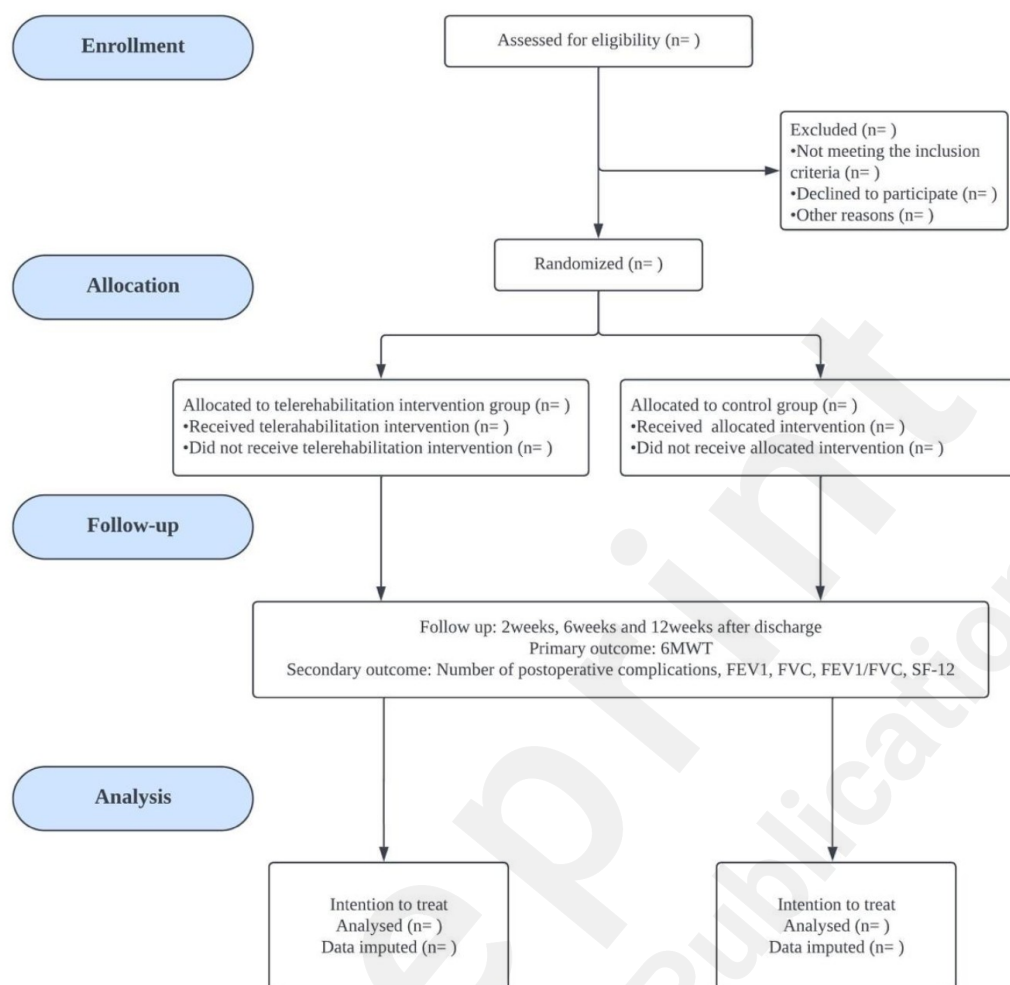
Primary aim

The primary aim of this study is to investigate the effectiveness of a pulmonary telerehabilitation program delivered through a mobile app on pulmonary function and exercise capacity for patients after pneumonectomy.

Methods and analysis

Study design and population

This study will be a single-blind randomized controlled trial. The research will be conducted in compliance with the Declaration of Helsinki and has been planned in line with the Consolidated Standards of Reporting Trials statement²⁵ (Figure 1)



Consolidate Standards of Reporting Trials (CONSORT) flow diagram of trial design. 6MWT, 6 min Walk Test; FEV1, Forced expiratory volume in 1s; FVC, Forced expiratory volume; SF-12, 12-Item Short Form Health Survey.

Patients who have undergone pulmonary lobectomy and meet the eligibility criteria will be recruited from the West China Hospital of Shangjin Campus. Patients will be randomized to either the intervention group or the control group in a 1:1 ratio. The intervention group will receive a telerehabilitation program through a mobile app, while the control group will receive standard care. The investigators will be blinded to the group allocation until the end of the study.



Study participants and randomization

All patients who are scheduled to undergo surgical resection for lung cancer at West China Hospital of Shangjin Campus will be evaluated by attending physicians. The inclusion criteria are as follows: (1) patients aged between 18 and 80 years; (2) patients who will undergo lobectomy and segmentectomy via VATS (video-assisted thoracoscopic surgery); (3) patients with a confirmed postoperative pathological diagnosis of lung cancer; (4) patients without cognitive impairment and with normal communication ability; (5) patients who have signed the informed consent form.

The following are the exclusion criteria: (1) patients who have received preoperative or postoperative chemoradiotherapy; (2) patients who experienced intraoperative hemorrhage exceeding 1500ml; (3) patients who have undergone reoperation or pneumonectomy; (4) patients with preoperative comorbid conditions or postoperative complications that may significantly

affect exercise performance (e.g., musculoskeletal or neurological impairment, severe hypoxemia, myocardial infarction within 30 days, hypertensive crisis, hemoptysis, gastrointestinal hemorrhage within 14 days, etc.).

To ensure the randomization of study participants, a computer-generated random number sequence will be used to assign patients to either the telerehabilitation group or the control group in a 1:1 ratio. An independent investigator, who is not involved in patient recruitment or the intervention procedure, will oversee the computer-generated patient allocation sequence. To maintain balance between the groups, block randomization with a block size of two will be employed. The allocation orders will be concealed within sealed envelopes prepared according to the recruitment order. All assessors will be kept unaware of the group assignments to maintain blinding. However, due to the nature of telerehabilitation, participants cannot be blinded. Therefore, participants will be instructed not to disclose their group affiliation during the evaluation. In the event that the blinding of assessors is compromised, a second assessor, who is unaware of the group allocation, will be available to conduct an additional review on a separate day. Any instances of unblinding will be carefully documented and reported.

Smartphone application development

software tool system serves as a comprehensive health education platform, providing guidance and follow-up for patients undergoing rehabilitation.

The application facilitates rehabilitation exercise training for patients both within and outside the hospital setting. It offers a range of core features, including live exercise training videos, rehabilitation nursing guidance videos, life activity guidance videos, functional evaluation follow-up scales, and dietary guidance. These features collectively support patients in their rehabilitation journey, offering guidance and resources for exercise training, nursing support, daily activities, and dietary considerations.

The collaborative effort between the investigators and Chengdu Xingkang Medical Technology Co., Ltd has resulted in the development of a robust smartphone application that aims to enhance the effectiveness and convenience of rehabilitation for patients.

Intervention

Pulmonary rehabilitation during hospitalization

Preoperative rehabilitation

Before surgery, participants in both the control group and telerehabilitation group receive comprehensive face-to-face education from a multidisciplinary team comprising experienced surgeons, nutritionists, and physiotherapists. This educational session encompasses exercise training and self-management strategies. The self-management component includes the active cycle of breathing techniques, pain control, and physical exercises. The breathing techniques focus on diaphragmatic breathing, deep breathing, and clearance procedures (such as huffing). These techniques are instrumental in eliminating secretions and improving pulmonary function. By providing this pre-surgery education, we aim to equip participants with the necessary knowledge and skills to actively participate in their own recovery and optimize their post-surgical outcomes. The collaboration of the multidisciplinary team ensures a comprehensive approach to address various aspects of pre-operative preparation and self-management.

Warm-up (10-minutes), aerobic training (20 minutes), resistance training (15 minutes), and cool-down (10 minutes) are the four main parts of the exercise training, patients need to perform this training program 3 days before surgery. The intensity of the exercise is moderate, which is measured by the modified Borg rating of perceived exertion (RPE) or heart rate reserve (HRR). The goal is to obtain a moderate training intensity, which corresponds to a modified Borg scale of 4-6 or a %HRR of 40% to 60%. Patients' self-reported modified Borg scale and heart rate will be recorded by physiotherapist before and after each workout (Figure 2.).

Experienced physiotherapy who has been trained in standard procedure will provide advice for patients. Self-management education will be explained and repeated until patients get it very well.

Pulmonary rehabilitation (PR) treatment process record				
Name		Admission number		Therapist
Date	Before PR	During PR process		Post-PR
	Blood pressure: _____ Heart rate: _____ Oxygen saturation: _____ Borg: _____ Vital signs stable: ☐ No ☐ Yes If you had discomfort yesterday, is it relieved now? ☐ No ☐ Yes ☐ No special abnormalities	Duration of cardiopulmonary rehabilitation: _____ minutes During treatment: _____ HRmax: _____ Borg: _____		Blood pressure: _____ Heart rate: _____ Oxygen saturation: _____ Borg: _____ Vital signs stable: ☐ No ☐ Yes The patient has any special discomfort or requirement: ☐ none ☐ Yes:
	Blood pressure: _____ Heart rate: _____ Oxygen saturation: _____ Borg: _____ Vital signs stable: ☐ No ☐ Yes If you had discomfort yesterday, is it relieved now? ☐ No ☐ Yes ☐ No special abnormalities	Duration of cardiopulmonary rehabilitation: _____ minutes During treatment: _____ HRmax: _____ Borg: _____		Blood pressure: _____ Heart rate: _____ Oxygen saturation: _____ Borg: _____ Vital signs stable: ☐ No ☐ Yes The patient has any special discomfort or requirement: ☐ none ☐ Yes:
	Blood pressure: _____ Heart rate: _____ Oxygen saturation: _____ Borg: _____ Vital signs stable: ☐ No ☐ Yes If you had discomfort yesterday, is it relieved now? ☐ No ☐ Yes ☐ No special abnormalities	Duration of cardiopulmonary rehabilitation: _____ minutes During treatment: _____ HRmax: _____ Borg: _____		Blood pressure: _____ Heart rate: _____ Oxygen saturation: _____ Borg: _____ Vital signs stable: ☐ No ☐ Yes The patient has any special discomfort or requirement: ☐ none ☐ Yes:

Pulmonary rehabilitation treatment process record. PR, pulmonary rehabilitation; HR, heart rate

Postoperative rehabilitation

After 2 weeks of surgery, control group and pulmonary telerehabilitation group will complete a 4-week outpatient rehabilitation program (one time per week) at West China Hospital, Sichuan University Shangjin Campus 's Department of Rehabilitation Medicine. The entire rehabilitation program is monitored by experienced physiotherapists. Patients' modified Borg RPE and heart rate will be measured before and after each activity to modify the intensity of training. The intensity and length of each session will be record in a standardized document. For control

group, patients and their family will be given a brochure with training guidance and instructions. Patients were asked to perform the training 45 minutes at home 5 times per week for 12-week after surgery and record each training session in a training log. For pulmonary telerehabilitation group, researchers created a 12-week lung function training program and related instructional videos. Patients will be given a planned exercise program that includes 5 minutes of breathing training, 5 minutes of warm-up, 10 minutes of strength training, 20 minutes of aerobic exercise, and 5 minutes of stretching and cooling activities, as indicated in Table 1. Until 12 weeks following surgery, the workout frequency was 5 times per week, and the intensity was moderate. After each day of training, participants need to record the modified Borg scale score through app. If patients have any questions about training, they can leave the message to the therapist via the app and therapist could give feedback to patients through the therapist port.

For security consideration of training themselves at home, patients will be asked to control their heart rate under 60% of %HRR.

Telerehabilitation program



The telerehabilitation program will consist of a 12-week protocol designed to improve pulmonary function and physical function. The app will have features such as pulmonary rehabilitation exercise videos, educational materials, and a symptom tracker. Patients in the intervention group will be asked to perform exercises and activities according to the program protocol 5 times per week, and will receive weekly feedback and support from a physiotherapist through the app. The control group will receive standard care, which include advice on physical activity and breathing exercises when they been discharged from hospital, the patients were instructed in incentive spirometry exercises by a coaching device and they were asked to repeat the exercises 5 times per week at home, exercise tracker will be given to patient record the exercise. Both group will receive evaluation during baseline and 4 weeks, 8 weeks and 12 weeks after surgery.

Data collection and study outcome

Our clinical researchers will gather information on the participants' baseline characteristics and demographics, such as gender, age, weight, height, body mass index, smoking history, and underlying health issues, at the time of enrollment and end of intervention. The primary outcomes will be exercise capacity, which is measured by the change in 6MWD from baseline to 2 weeks, 6 weeks and 12 weeks after surgery. The secondary aims of this study are to investigate the effectiveness of telerehabilitation on:

- postoperative complications
- forced expiratory volume in 1s (FEV1), forced vital capacity (FVC)
- quality of life (Change in short form 12 questionnaire (SF-12) scores measured six months after surgery and compared to baseline)

Additional assessments

Data regarding patient compliance and treatment-related side effects during both preoperative and postoperative telerehabilitation will also be collected.

Safety

A multidisciplinary team will review all participants to ensure that their enrollment is appropriate. If dizziness, fluster, or nausea develop, the evaluation or exercise training should be stopped immediately, and the patient's vital signs will be monitored by the emergency team. All adverse occurrences will be documented on the case report form (CRF).

Compliance

application, the application will record the practice time when the participants complete each session. For control group, the exercise adherence will be record by the training log and describe each exercise session in detail.

Data management

All collected data will be recorded in an accurate, complete, correct, and timely way using both electronic database and CRF. Based on the initial observation record, the researchers submit data on the CRF. After the monitor has reviewed it and given their signature, the CRF should be delivered to the data manager. All information entered will be verified twice. If problems are discovered, it is necessary to alert the monitor right away and request a response from the researchers. The data manager should offer a check report after it has been confirmed. To maintain confidentiality, all paper CRFs and questionnaires shall be stored in numerical order and locked in the protected file cabinet. The West China Hospital Ethical Committee will closely supervise the data gathering and administration.

Sample size calculation

The sample size was calculated to assess if there was a clinically meaningful improvement in exercise capacity between the baseline and follow-up based on previous reports. In terms of pulmonary rehabilitation, a recent study found that the baseline and follow-up 6MWD were 433.429 ± 65.595 and 448.095 ± 76.421 m, respectively.²⁶ Based on prior studies of 6MWD improvement in comparable trials²⁷, we expected that participants would improve their 6MWD by 30 m on average after 12 weeks. The primary analysis needed 60 patients (30 per group) based on an SD of 60, a 2-sided test at an alpha level of 0.05, power of 80%, and a dropout rate of 20%.

Statistical analysis

Computations were performed using the SPSS for Windows statistical software package (SPSS8 Inc., version 12.0, Chicago, IL). Data are expressed as mean standard deviation (SD). A linear mixed-effects model will be used to compare the changes in 6MWD between the intervention and control groups. In all continuous variables, the distribution was assessed by means of the Kolmogorov—Smirnov test. Normally distributed variables were compared by paired t-test and non-normally distributed variables by Wilcoxon's signed rank test. A p value of less than 0.05 was considered significant.

Ethical considerations

The study protocol has been approved by the Institutional Ethics Committee. Informed consent will be obtained from all participants before enrolment in the study. The study will be conducted in accordance with the Declaration of Helsinki and other applicable guidelines and regulations.

Discussion

This study aims to evaluate the effectiveness of a telerehabilitation program delivered through a mobile app in patients after pneumonectomy. The results of this study will provide valuable information on the feasibility and effectiveness of telerehabilitation in this patient population, and may have implications for the delivery of rehabilitation services in other settings.

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Supplementary Files