GRANTS FOR FUNDING R&D;&I; IN BIOMEDICINE AND HEALTH SCIENCES IN ANDALUSIA

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Strategic Research Projects in Emerging Groups

Strategic Research Projects in Public Health and One Health

Strategic Research Projects in Rare Diseases

Strategic Research Projects with CAR-T Cells

Strategic Research Projects in Personalised Medicine and Advanced Therapies

Strategic Research Projects in Digital Health, Artificial Intelligence (AI) and Real-World Evidence (iRWD)

Strategic Research Projects in Chronicity and Multi-Morbid Patients

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PRINCIPAL INVESTIGATOR(S)

NAME AND SURNAME: María Jesús Viñolo Gil

NAME AND SURNAME: Carlos Manuel Pérez Pérez

PROJECT TITLE

PulmoSalud: Multimodal Prehabilitation and Early Home-Based Rehabilitation Programme in Lung Cancer Patients

KEYWORDS

Lung cancer, prehabilitation, rehabilitation, physical exercise, respiratory physiotherapy, multidisciplinary programme, oncological treatment, mobile application, treatment adherence.

1. ABSTRACT (Maximum 500 words)

Lung cancer remains one of the leading causes of morbidity and mortality. Resective surgery is the treatment of choice in operable stages. However, a significant proportion of patients present functional impairment prior to the intervention and develop postoperative complications, especially respiratory ones. Prehabilitation has become established as a strategy capable of optimising physical condition before surgery, while early rehabilitation contributes to accelerating recovery after discharge. However, its routine implementation is limited by logistical barriers, reduced waiting times and difficulties with in-person access.

The PulmoSalud project proposes a multimodal programme consisting of 8 weeks of prehabilitation (strength exercise, endurance and respiratory physiotherapy) and 4 weeks of early home-based rehabilitation, supported by a specific digital application, in order to facilitate care continuity without the need for additional travel. The content includes progressive strength training, structured respiratory exercises (including inspiratory muscle training), educational guidelines and digital recording of activity and symptoms. Patients will receive initial in-person training to ensure correct exercise execution, and will subsequently continue autonomously with telematic supervision.

A controlled study will be conducted comparing this programme with standard care at the centre. Functional variables (aerobic capacity, muscle strength), respiratory parameters, postoperative complications, quality of life, self-efficacy and use of healthcare resources will be assessed. Measurements will be carried out at three time points: baseline (T0), immediate pre-surgical (T1) and one month after surgery (T2).

PulmoSalud aims to improve preoperative preparation, accelerate post-surgical recovery and reduce the healthcare burden, safely integrating a home-based intervention supported by digital technology.

2. RESEARCH TEAM

2.1. RESEARCH TEAM DATA

Please verify that the researchers listed in this document match those entered in the application software, as they are the ones who will be considered members of the research team.

Name and Surname	Degree	Speciality	Role (PI/CI)	Dedication (h/week)
Mª Jesús Viñolo Gil	PhD in Health and Sport; BSc Psychology; BSc Physiotherapy	Physiotherapy	PI	20
Carlos Manuel Pérez-Pérez	PhD in Health and Sport; BSc Physical Activity and Sport Sciences; Diploma Physical Education	Physical Activity and Sport	Co-PI	30
Amparo Valverde Martínez	BSc Medicine & Surgery; PhD Medicine & Surgery	Medicine & Surgery	CI	10
Dionisio Espinosa Jiménez	BSc Medicine & Surgery	Medicine & Surgery	CI	5
Ángel León Valenzuela	BSc Medicine; PhD UCA	Physical Medicine & Rehabilitation	CI	5
Jesús Baltasar González Rubiño	PhD Health Sciences; BSc Physiotherapy	Physiotherapy	CI	10

Name and Surname	Degree	Speciality	Role (PI/CI)	Dedication (h/week)
Ismael García Campanario	PhD Health and Sport; BSc Physical Activity and Sport Sciences; Diploma Physiotherapy	Physiotherapy & Physical Activity	CI	10
Francisco Martín Vega	PhD Health Sciences UCA; BSc Physiotherapy	Physiotherapy	CI	10
Francisco José Vera Serrano	BSc Physiotherapy	Physiotherapy	CI	10
Pedro Alfonso Domínguez Vera	BSc Physiotherapy (2 Masters; PhD student, University of Seville)	Physiotherapy	CI	10
Juliana Pardo Campoy	BSc Physiotherapy	Physiotherapy	CI	10
Francisco Javier González Espinosa de los Monteros	PhD Health Sciences UCA; BSc Physiotherapy	Physiotherapy	CI	10
María José Crisóstomo Acevedo	PhD University of Murcia; Diploma Physiotherapy	Physiotherapy	CI	10
Eduardo Sánchez Sánchez	PhD UCA; Diploma Nursing	Nursing	CI	5
José Manuel Romero Castro	PhD UCA; Diploma Nursing	Nursing	CI	10
Rosa María Campos Carmona	BSc Psychology	Psychology	CI	5
Santiago Jacobo Díaz Hurtado	BSc Psychology	Psychology	CI	5

2.2. EXPERIENCE OF THE PRINCIPAL INVESTIGATORS AND RESEARCH TEAM ON THE PROJECT TOPIC

The PulmoSalud team constitutes an innovative model that effectively integrates Primary Care and Specialist Care to globally address the needs of the lung cancer patient. This coordination between care levels ensures a smooth transition and real continuity of care, from the initial phase in primary care centres to high-specialisation hospital care. Within this framework, the joint participation of the Primary Care physiotherapist and the Specialist Care physiotherapist makes it possible to develop respiratory, functional and preventive interventions adapted to each phase of the disease, optimising clinical outcomes and recovery.

The multidisciplinary PulmoSalud team comprises thoracic surgeons, a rehabilitation physician, physiotherapists, graduates in Physical Activity and Sport Sciences, nursing professionals — one of them an expert in clinical nutrition — and clinical psychologists, thus providing comprehensive, evidence-based accompaniment. Added to this is the university connection: several physiotherapists and nurses on the team, as well as the rehabilitation physician, are university professors, allowing for the incorporation of up-to-date knowledge and innovative teaching approaches within the project.

In keeping with this educational dimension, PulmoSalud will develop audiovisual educational content, produced by the team's lecturers, which will be integrated into a mobile application aimed at promoting health education, self-care and therapeutic adherence among oncology patients. This combination of clinical experience, coordination between care levels and teaching capacity provides a solid and transformative framework for improving the quality of life and health outcomes of people with lung cancer.

Brief Curriculum Vitae of the Principal Investigator(s)

The capacity and experience of the principal investigator(s) will be assessed through competitively funded projects, publications resulting from their own and collaborative projects, publications and their qualitative impact, intellectual protection, patents, participation in stable research structures, the impact of previous projects, and dissemination/outreach to society. Additionally, the training capacity of the Principal Investigator(s) and the team will be assessed (supervision of Doctoral Theses, Master's supervision, residents or rotating students under their charge).

Principal Investigator: Dr. María Jesús Viñolo Gil

BSc in Psychology and Diploma in Physiotherapy. PhD in the 'Health and Sport' programme (2009). More than 29 years of clinical experience in hospitals and primary care centres, combining clinical practice with university teaching (more than 4,000 hours) and research activity.

Her career includes competitively funded projects, both as principal investigator and collaborator, including:

- "Effects of a manual therapy programme to reduce the time course of axillary web syndrome in women affected by breast cancer" (Competitive grant call for research and innovation projects in Primary Care and District Hospitals and High-Resolution Hospital Centres of the Andalusian Public Health System (SSPA) for 2024) (€13,340) (PI).
- "Manual therapy for recovery of axillary web syndrome in women after mastectomy", LINE 1 — Funding for research and innovation projects for INIBICA research groups, Modality 3: Strengthening research activity in primary care and health care, reference PP13-001-2023, 2023 call (€4,000) (PI).
- "Development and effectiveness of an mHealth intervention for health literacy and self-management of multi-morbid patients with heart failure", funded by the Biomedical Research and Innovation Institute of Cádiz (INiBICA), LINE 1 call, reference LI19/04IN-CO13, 2019 (€20,000).
- "Effectiveness of an m-Health intervention, based on rehabilitation and personalised nutrition plan, in the recovery and improvement of dysphagia in patients diagnosed with stroke", funded in the competitive FPS 2020 call — R&I; projects in primary care, district hospitals and CHAREs (€19,926.51).
- "Effects of an educational intervention on adherence to therapeutic exercise programmes in patients with fibromyalgia". Ref. PU/PP-PROY-UCA/PR/2016-014. University of Cádiz (€1,000).

She has contributed to intellectual protection, including:

- "Physiotherapy technique to reduce the time course of axillary web syndrome in post-mastectomy women". Safe Creative: Registration no. 2504091404443, registered on 09/04/2025 (IPR granted 2025).
- "mICardiApp", software registered in Safe Creative (Registration no. 2309265413814, 26/09/2023). Tool for monitoring and self-management of multi-morbid patients.

With regard to her scientific output: Author of 40 publications in indexed journals, of which 6 are directly related to cancer and others relevant in respiratory pathology, 8 book chapters and numerous conference presentations. Among the most notable:

- Physiotherapy protocol to reduce the evolution time of axillary web syndrome in women post-breast cancer surgery. Supportive Care in Cancer, 2025.
- Effectiveness of physical therapy in axillary web syndrome after breast cancer: systematic review. Supportive Care in Cancer, 2024.
- Blood Flow Restriction in Oncological Patients: Advantages and Safety Considerations. Healthcare (Switzerland), 2024.
- Digital physiotherapy in Long COVID. Digital Health, 2024.
- Pulmonary rehabilitation programmes and respiratory muscle training: systematic review. Respiratory Research, 2024.
- Tele-rehabilitation in COPD: systematic review. Anales del Sistema Sanitario de Navarra, 2022.

Training capacity: Supervisor of more than 30 undergraduate final projects (TFG), 9 Master's final projects (TFM) and 1 doctoral thesis in breast cancer. Training of students in clinical placements.

Dissemination: Invited speaker at international congresses (International Congress of FUDEN 'City of Granada'). Active participation in scientific outreach initiatives including the 2024 European Researchers' Night, Applied Classes 2025 and the Women, Science and Future programme for 11th February. She also carries out outreach activities focused on raising awareness about the harmful effects of electronic cigarettes and vaping devices. She collaborates with the Andalusian Physiotherapy in Oncology Plan (PAFO) and participates in actions linked to the National Physiotherapy in Oncology Plan (PLANFO).

Summary of contribution to the project: Dr. Viñolo brings a combination of clinical, teaching and scientific career with a track record of funded research, high-impact publications, technological innovation and intellectual protection, ensuring efficient project planning, implementation and monitoring. Her experience in cancer, respiratory pathology and in accompanying patients from diagnosis to post-treatment recovery guarantees the success of the PulmoSalud project.

Co-Principal Investigator: Dr. Carlos Manuel Pérez Pérez

Assistant Professor with PhD, Department of Medicine and Surgery, University of Cádiz. Diploma in Physical Education, BSc in Physical Activity and Sport Sciences, and PhD in Health and Sport.

Lecturer and researcher with 17 years of educational experience and specialised training in physical exercise applied to health and clinical settings. His career integrates biomedical research, therapeutic exercise, educational innovation and knowledge transfer, with particular interest in the application of exercise in oncology patients and populations at cardiovascular risk.

Competitive research projects:

- Update on the management of the dyslipidaemic patient. Positioning of iPCSK-9: Evolocumab Dyslipemia Circle (2020–2022). Principal Investigator.
- INNOVA-UCA Teaching Innovation Project: Gamification applied to learning in Medicine degree subjects. Funding: €1,300. PI.
- Participation in other research initiatives related to therapeutic exercise, cardiovascular health and applied teaching.

Scientific output — among the most relevant contributions to the project (therapeutic exercise and oncology):

- Chapter: Benefits of Nordic walking as a complementary intervention in breast cancer (2025).
- Chapter: Aquatic interventions and Dragon Boat in oncological rehabilitation.
- Article: Gender Differences Regarding Self-Perceived Physical and Mental Health… Healthcare (2025).
- Biomedical research in cardiology and genetics (Atherosclerosis, 2023): Next-generation sequencing reveals genetic differences between two distinct etiologies of dilated cardiomyopathy.

Teaching activity: Assistant Professor with PhD in the Department of Medicine and Surgery (UCA), teaching Medicine of Sport, Underwater and Hyperbaric Medicine, Biochemistry and Molecular Biology of Exercise, Advanced Exercise Prescription, and Physical Activity for Health in the Aquatic Environment. Teaching evaluations above 4.5 points in most subjects. Extensive continuing education participation (more than 180 hours).

Training capacity: Supervision of 5 Final Degree Projects in Medicine, including two systematic reviews in breast cancer (Nordic Walking, Dragon Boat). Tutoring of students in clinical and sports placements.

Summary of contribution to the project: Dr. Pérez brings a unique combination of teaching experience in health sciences, scientific output in therapeutic exercise and cardiovascular genetics, leadership in competitive projects and a solid track record in teaching innovation. His contributions in oncological rehabilitation, together with his membership of group CTS1152, consolidate his capacity to design, implement and evaluate exercise-based interventions in oncological and respiratory pathology populations.

2.3. DEVELOPMENT OF COOPERATIVE PROJECTS WITHIN ANDALUSIA

Multi-centre projects (different centres), inter-level projects (different care levels) and projects including both consolidated and emerging groups will be assessed. To this end, there must be two PIs in the project.

Group Code	Group Name	Centre / Care Level	Type (CG/EG)	Team Investigators
CTS-1079	Bariatric surgery: Diabetes: hepatic and pancreatic involvement	PAIDI Group / AH	CG	Amparo Valverde Martínez (Specialised Care – Hospital Puerta del Mar, Cádiz)
CTS1019	Transformative research and empowerment in healthcare	PAIDI Group / University of Cádiz	CG	José Manuel Romero Sánchez (University of Cádiz)
CTS391	Multidisciplinary group for the advancement of mental health	PAIDI Group / Primary Care / University of Cádiz	CG	Ismael García Campanario (University of Cádiz)
CTS1152	Physiotherapy, physical activity and sport	PAIDI Group / Primary Care / Specialised Care / University of Cádiz	EG	María Jesús Viñolo Gil (PC Chiclana); Carlos Pérez Pérez (UCA); María José Crisóstomo (SC Jerez Hospital); Pedro Alfonso Domínguez (PC San Fernando); Juliana Pardo Campoy (PC Early Intervention); Francisco Martín Mora (UCA); Francisco Javier Serrano (SC Puerto Real Hospital); Carlos Pérez Pérez (UCA)

*CG: consolidated group; EG: emerging group

2.4. PARTICIPATION OF THE TEAM IN PUBLIC-PRIVATE COLLABORATION PROJECTS

It will be assessed whether the PI has participated in public-private collaboration projects, including clinical trials sponsored by pharmaceutical or biotechnology companies or other company collaborations.

PI Name	Project Code	Funding Entity	Collaborating Company	Role	Budget
Ángel León Valenzuela	INCOTOBA-CA-2015	Hospital Universitario Puerta del Mar	Merz Pharmaceuticals	Merz financed translation and assisted in manuscript preparation	€1,200
Arturo Morgado Estévez (CI: Ángel León Valenzuela)	PROBOTHAND: Advanced Multimodal Systems for Upper-Limb Robotic Prosthetics	Consejería de Economía y Conocimiento – Junta de Andalucía	Ortopedia Garo	Technical assistance in orthopaedic material design	€74,054.64
Eduardo Sánchez Sánchez	DYSPHAGIA: Professional satisfaction with an m-health application for oropharyngeal dysphagia	Fresenius Kabi	Fresenius Kabi	Logistics, funding, marketing, expert recruitment, graphic design	€24,846.76

PI Name	Project Code	Funding Entity	Collaborating Company	Role	Budget
Luis López Molina (CI: José Manuel Romero Sánchez)	OT2024/158 – Technical, research and advisory services for IoT products, electronic prototypes (LET'S PROT OTYPE)	SAN JUAN INGENIEROS S.L.	SAN JUAN INGENIEROS S.L.	Public-private contract	€60,500
Manuel Rosety Plaza (CI: Ismael García Campanario)	CTD2003-062 /01: Design and validation of an adapted physical activity programme for young people with Down syndrome	Consejería de Turismo y Deporte – Junta de Andalucía	Down Syndrome Association of Cádiz	Logistics	—

3. RESEARCH PROJECT AND RESULTS

3.1. BACKGROUND AND CURRENT STATE OF THE ART

BACKGROUND AND CURRENT STATE OF KNOWLEDGE

Cancer is one of the leading causes of morbidity and mortality worldwide. In 2020, 19.3 million new cases and 10 million deaths were recorded, according to the GLOBOCAN report [1]. In Spain, it remains the second cause of death, with more than 280,000 new diagnoses per year and a notable impact from tumours of thoracic location [2]. This scenario reinforces the need to complement conventional medical treatments with strategies capable of improving functional reserve, therapeutic tolerance and recovery, especially in diseases with high physiological repercussions such as lung cancer.

Lung cancer is one of the tumours with the greatest epidemiological impact. In 2022, 2.48 million new cases and 1.8 million deaths were estimated, making it the leading cause of cancer mortality globally [3]. In Spain it exceeds 30,000 diagnoses per year, with a notable increase in women associated with historical changes in tobacco consumption [2].

Non-small cell lung cancer (NSCLC) represents 85% of cases, with adenocarcinoma as the predominant subtype [4]. These patients typically present a high symptom burden: dyspnoea, fatigue, loss of muscle mass, frailty and functional impairment, which conditions treatment tolerance and prognosis [5].

Deconditioning prior to thoracic surgeries or systemic treatments has been associated with a greater risk of complications and less favourable clinical outcomes [6], which underscores the importance of preventive and rehabilitative strategies.

In this context, oncological prehabilitation is defined as the set of interventions applied between diagnosis and the start of treatment in order to increase functional reserve. Available evidence shows that, in lung cancer, prehabilitation improves functional capacity with increments greater than 30 metres in the 6MWT [7], reduces postoperative complications and hospital stay [8], and promotes greater physical and psychological preparation for surgery or aggressive therapies. Likewise, rehabilitation after treatment has been associated with improvements in functional recovery, dyspnoea, muscle strength, lean mass and quality of life [6]. Complementarily [9], it is noted that the integration of supervised exercise, respiratory education and nutritional support can optimise clinical evolution both in the pre- and post-surgical period.

At the national level, various groups have contributed to the development of exercise oncology, generating robust evidence on the feasibility and benefits of supervised exercise programmes in oncology patients.

Initial pilot studies in breast cancer already demonstrated that a structured exercise programme improves strength, functional capacity, quality of life and psychological variables such as depression and self-esteem [10]. Subsequently, integrated exercise and lifestyle counselling interventions confirmed that it is possible to induce sustained behavioural changes, significantly increasing leisure-time physical activity and improving functional capacity and psychological wellbeing in cancer survivors [11]. Randomised clinical trials have shown that supervised combined aerobic and strength exercise, low-cost, can reverse the loss of cardiorespiratory capacity, improve body composition and quality of life in women with breast cancer after primary treatment, with maintenance of benefits at medium term and high adherence [12]. These studies, together with subsequent observational studies such as Women in Motion 2.0, have reinforced that the level of physical activity decisively conditions cardiorespiratory capacity and cardiovascular health of survivors, to the point that physically active patients can reach levels similar to those of women without cancer [13].

At a conceptual level, the role of exercise as a safe and effective therapeutic intervention in different phases of the oncological process has been consolidated [14]. They have synthesised how exercise can modulate the side effects of treatments (fatigue, cardiovascular toxicity, loss of muscle mass, psychological alterations), and have proposed practical guidelines for individualised prescription, underscoring the need for supervised, multidisciplinary programmes coordinated from the clinical environment. In parallel, the position document of the Spanish Society of Medical Oncology (SEOM) on exercise and cancer formally recognises physical exercise as an important part of the therapeutic approach, recommends its integration into clinical practice and points to the need to develop standardised oncological exercise programmes in hospitals and reference centres [15].

In addition to external evidence, the project draws on the prior experience of two members of the research team, whose scientific output has significantly contributed to the advancement of oncological rehabilitation through exercise and physiotherapy. Among their works, a systematic review and meta-analysis demonstrates that Nordic walking improves functional capacity, upper limb mobility, fatigue and quality of life through safe interventions with high adherence [16]. These findings are complemented by an academic review on exercise modalities in oncology, which deepens the physiological and functional mechanisms that explain these benefits [17].

Likewise, their output includes another systematic review and meta-analysis identifying therapeutic exercise as the most effective intervention for treating axillary web syndrome, with significant improvements in pain, mobility and function [18]. This line is reinforced by a randomised clinical trial evaluating an intensive physiotherapy protocol, resolving AWS in more than 90% of patients and demonstrating the team's capacity to implement complex clinical programmes with relevant functional results [19].

Finally, this trajectory is completed with evidence generated on specific therapeutic exercise interventions in oncology patients, such as the review on the benefits of Nordic walking that underscores its role in functional improvement and management of musculoskeletal sequelae common in this population [20]. Taken together, this recent and specialised scientific output evidences the team's high level of knowledge on the subject of the project, reinforcing their capacity to lead advanced research in oncological rehabilitation.

A recent scoping review, which analysed 31 studies published between 2016 and 2023, confirms that prehabilitation is feasible, safe and effective, with more than 95% of programmes incorporating physical exercise as a central component [21]. Programmes aimed at people receiving neoadjuvant treatment or systemic therapy remain scarce, despite the fact that they also present significant functional impairment and could benefit from early and sustained interventions [21].

There is also a growing need for prehabilitation and rehabilitation models that can be implemented in a multi-centre and decentralised fashion in the public health system, enabling a greater number of patients to be reached and ensuring care continuity beyond the reference hospital. This lack of technological and organisational integration reinforces the need and originality of the present project, which combines prehabilitation, rehabilitation and digital monitoring through the PulmoSalud project, integrating as a central axis a structured and supervised in-person programme of physical exercise and respiratory physiotherapy, carried out by specialised professionals in district healthcare facilities.

The PulmoSalud digital platform acts as a complement aimed at reinforcing adherence, recording activity and monitoring symptoms between sessions, but does not replace the in-person intervention, which constitutes the core of the therapeutic strategy.

Telehealth and tele-rehabilitation are emerging as key tools to overcome frequent barriers in lung cancer patients, such as distance from hospital, fatigue or functional limitations. Various remotely supervised exercise programmes have shown improvements in fatigue, anxiety, physical function and sleep [22]. Clinical trials have demonstrated that digitally supervised walking interventions improve circadian rhythms and sleep quality [23], while the use of digital platforms promotes adherence and allows real-time monitoring of symptoms and physical activity [24]. Additionally, projects such as OACCUs demonstrate how specific apps improve motivation, participation and continuity in physical activity programmes in the oncology population [25]. Despite these advances, interventions integrating prehabilitation and rehabilitation in a single process with structured digital monitoring, continuous monitoring and multimodal content including respiratory exercise, strength and aerobic training remain very scarce. This scarcity of integrated interventions underscores the need to evaluate not only the preliminary clinical effect of these programmes, but also their feasibility, safety and adherence in a real healthcare system context — aspects essential for their future large-scale implementation.

The current project proposes accompanying the patient through the PulmoSalud app, designed to provide education through videos on respiratory exercises, dyspnoea control, effective coughing techniques and sleep hygiene [23]. It also allows scheduling home support sessions in both the prehabilitation and subsequent rehabilitation phases. The platform facilitates daily recording of exercises performed, minutes of activity [26], dyspnoea, fatigue, sleep and adherence [24], and incorporates a bidirectional communication system enabling the clinical team to monitor progress, adjust loads and respond to possible incidents. Thus, PulmoSalud

becomes a comprehensive support tool before and after treatment, promoting continuity, personalisation and patient engagement.

3.2. BIBLIOGRAPHY

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3.3. HYPOTHESIS, RESEARCH QUESTION OR DESCRIPTIVE STUDY

HYPOTHESIS

The PulmoSalud programme, which integrates adapted physical exercise, respiratory physiotherapy and digital monitoring through an app to monitor adherence and provide health education, will improve respiratory recovery and functional capacity in lung cancer patients compared to conventional treatment.

RESEARCH QUESTIONS

The main research questions, from which the general objective of the study derives and which are subsequently broken down into specific objectives, are:

- Does the PulmoSalud programme improve functional capacity (6MWT, strength, functional tests) compared to standard care in patients operated on for lung cancer?
- Does the PulmoSalud programme improve respiratory function (spirometric volumes and flows, cough flow, vital capacity) after surgery versus the control group?
- Does the health education included in the application improve knowledge of the postoperative process and patient self-management?
- Does the PulmoSalud programme reduce perceived dyspnoea during the recovery process (measured with validated scales such as mMRC or Borg)?
- Does the PulmoSalud programme reduce postoperative complications, re-consultations or prolonged recovery, compared to the control group?
- Is patient satisfaction with the care received greater in those included in the PulmoSalud programme than in those receiving conventional care?

3.4. OBJECTIVES

GENERAL OBJECTIVE

To evaluate the efficacy of an intervention integrating individualised physical exercise, respiratory physiotherapy and a mobile application with exercise videos and health education content, as a complement to standard clinical practice, to improve functional and respiratory recovery in patients operated on for lung cancer.

SPECIFIC OBJECTIVES

- Evaluate the efficacy of the PulmoSalud programme in improving pulmonary function (FEV1, FVC, respiratory strength parameters and cough flow) in patients operated on for lung cancer.
- Determine the impact of the intervention on functional capacity using standardised tests (6MWT and complementary physical tests) throughout the 8 weeks.
- Assess the evolution of dyspnoea and perceived exertion during the rehabilitation period using validated scales (mMRC and Borg).
- Analyse whether the intervention reduces postoperative respiratory complications, hospital stay and readmissions, compared to standard clinical practice.
- Evaluate adherence to the programme, recording compliance with planned sessions.
- Measure the improvement in health-related quality of life after the intervention using standardised instruments.
- Evaluate the effect of the health education integrated into the application on health literacy, knowledge of the post-surgical process and patient self-management.
- Analyse satisfaction and usability of the mHealth tool among patients undergoing surgery for lung cancer.
- Identify possible predictors of better response to the intervention, considering clinical, functional and adherence variables.

3.5. METHODOLOGY

STUDY DESIGN

The present study will be developed as a randomised controlled trial (RCT) with 1:1 allocation, two parallel arms (intervention group and control group) and blinded outcome evaluation through external evaluators and masked analysts.

POPULATION AND RECRUITMENT CENTRES

The study population will consist of adult patients with a recent diagnosis of lung cancer (de novo diagnosis), with any histology amenable to surgical treatment, who have been selected and scheduled for curative resection. Both those receiving neoadjuvant treatment (preoperative chemotherapy and/or radiotherapy) and those who do not will be included, provided they meet the eligibility criteria of the study and clinical recommendations for surgical intervention.

Participant referral will be made from Primary Care physicians at health centres belonging to the Bahía de Cádiz–La Janda District, as well as from preoperative thoracic surgery consultations at the Hospital Universitario Puerta del Mar.

Various healthcare institutions in the provincial area will participate in the study, including health centres of the Bahía de Cádiz–La Janda District and the Hospital Universitario Puerta del Mar. All these institutions will collaborate both in identifying potential participants and in implementing study procedures.

Participants will be recruited exclusively by physicians at the mentioned centres, who will conduct the initial clinical assessment, determine functional status using the ECOG scale and carry out screening of inclusion criteria. Research team members may collaborate in information and logistical support tasks during the recruitment process, but clinical evaluation and ECOG confirmation will be the exclusive responsibility of medical staff (Primary Care physicians and the rehabilitation physician and two thoracic surgeons from the research team).

Once a potentially eligible person has been identified, the research team will provide detailed information about the study and answer any questions. Those who agree to participate must sign an informed consent in writing before any specific research procedure is performed.

Persons assigned to the intervention group will be scheduled for initial assessments in spaces previously set up within the participating health centres.

Inclusion Criteria

- Age ≥ 18 years.
- Histological or cytological diagnosis of lung cancer (resectable stage according to the multidisciplinary team).
- Patients scheduled for pulmonary surgery with curative intent (lobectomy, segmentectomy, pneumonectomy, etc.).
- Capacity to understand and sign informed consent.
- Clinical condition that allows participation in a supervised exercise programme, according to medical evaluation, with ECOG functional status 0–2 (Eastern Cooperative Oncology Group Performance Status).
- Availability to carry out scheduled measurements and follow-ups (preoperative and postoperative).
- Ability to use the mobile application or to have family support to do so.

Exclusion Criteria

- Absolute medical contraindications for supervised physical exercise, such as unstable angina, recently decompensated heart failure, uncontrolled arrhythmias or acute cardiovascular events in the last 3 months.
- Very advanced chronic lung disease that prevents participation in the programme (e.g., severe COPD with FEV1 <30% predicted, if determined by the clinical team).

- Distant metastases or metastatic cancer contraindicating surgery with curative intent.
- Planned palliative surgery or life expectancy <3 months.
- Home oxygen therapy with severe uncorrectable hypoxaemia, according to clinical criteria.
- Moderate-severe cognitive, neurological or psychiatric incapacity that prevents understanding of the study or adequate use of the mobile application.
- Insurmountable language barrier preventing understanding of study information or use of the mobile application.
- Pregnancy.
- Participation in another interventional clinical trial that may interfere with the study objectives or its primary variable.
- Any other condition that, in the judgement of the research team, compromises participant safety or protocol adherence.

Withdrawal Criteria

- Revocation of consent.
- Adverse events contraindicating continued exercise (clinical decision).
- Non-compliance >30% of planned sessions (for per-protocol analysis; continue in ITT).

SAMPLE SIZE AND SAMPLING PROCEDURE

Sample size calculation: The sample size estimate is based on the primary variable, which underpins our hypothesis and general objective: functional capacity, evaluated by the change in distance covered in the 6-minute walk test (6MWD), between the preoperative baseline assessment (T0) and the final assessment at 8 weeks (T2). This parameter is considered a robust indicator of functional capacity and is widely used in clinical trials of rehabilitation in patients with lung cancer and chronic respiratory diseases [27,28].

The minimal clinically important difference (MCID) for 6MWD in this type of population has been estimated at between 30 and 50 metres in previous studies of perioperative rehabilitation and exercise programmes in patients with thoracic cancer [29,30]. Thus, for our study we estimate a conservative MCID of 40 metres with an expected standard deviation of change in 6MWD, in accordance with equivalent studies in exercise programmes for thoracic surgery [31,32].

Therefore, assuming an MCID of 40 m and $\sigma = 60$ m, $\alpha = 0.05$ and a power of 80%, approximately 36 patients per group are required according to the formula for two independent means. Considering a 15% attrition rate, 42 participants per group are planned (84 in total).

Based on these estimates, a sample size of 42 participants per group will be taken, sufficient to detect the clinically relevant difference defined for the primary variable. An intention-to-treat analysis will be performed and measures will be implemented to minimise losses during follow-up.

Sampling and Allocation

Recruitment will be conducted by consecutive sampling from thoracic surgery consultations and from Primary Care centre consultations, inviting all candidate patients for pulmonary surgery who meet the inclusion criteria. This method is consistent with previous preoperative rehabilitation studies in lung cancer [33,34].

Random allocation will be 1:1 to the two trial arms (Standard Care vs. PulmoSalud Programme). It will be carried out by block randomisation, stratified by centre and by baseline functional capacity according to the 6-minute walk test distance (6MWD) (<350 m vs. ≥350 m), following recommendations of previous trials using 6MWD as the primary functional indicator [27,28].

Blocks will be of variable size (4–6) to minimise predictability of the sequence. Generation of the random sequence will be performed by an independent researcher using an electronic system, and allocation will be carried out through a centralised platform to ensure concealment of the sequence [35].

The study will be open to patients and clinicians due to the nature of the intervention, but will have blinded evaluators for functional and respiratory measurements.

INTERVENTION

The study is structured in two phases: prehabilitation and postoperative rehabilitation. The prehabilitation phase, lasting 8 weeks, includes a supervised in-person programme of individualised, progressive physical exercise (strength, endurance and neuromuscular training), together with specific respiratory training aimed at preparing the patient for the postoperative period. During this stage, physiotherapists teach and practise with the patient all the respiratory, ventilatory and secretion management techniques that they will subsequently perform autonomously. After surgery, the rehabilitation phase begins, lasting 4 weeks and carried out entirely at home to facilitate early intervention and avoid travel. In this stage, the patient applies the respiratory exercises previously learned, adapted to their clinical evolution, while receiving non-in-person monitoring and adjustments from the research team.

PREHABILITATION

Control group (Standard care): Participants will receive conventional care provided by the centre, which includes the usual clinical recommendations from the thoracic surgery and oncology team. They will remain on the waiting list for lung cancer surgery according to the standard care pathway, without a structured exercise programme, without scheduled respiratory physiotherapy and without use of the mobile application.

Intervention Group: Individualised Exercise Programme + Respiratory Physiotherapy + Mobile Application Support

The experimental group will receive a preoperative multimodal programme comprising:

- 1. Individualised physical exercise
- 2. Respiratory physiotherapy
- 3. Telematic support through a mobile application with brief educational sessions on preoperative self-care

1. Individualised Physical Exercise (supervised by graduates in Physical Activity and Sport Sciences)

The intervention consists of 16 sessions divided into 8 weeks, with two sessions per week. Each session is pre-planned and organised according to the progression patients should follow and the intensities at which they should work.

Programme Design: The physical exercise programme is conceived as a progressive, adaptable intervention centred on the specific needs of the lung cancer patient in the preoperative and postoperative phase. Its objective is to improve exercise tolerance, functional strength and aerobic capacity before surgery, as well as to promote faster and safer recovery after the surgical procedure. The intervention combines supervised in-person sessions, autonomous home sessions and telematic monitoring through the PulmoSalud mobile application.

The programme is developed in two phases:

- Prehabilitation (8 weeks): Two supervised in-person weekly sessions supervised by Physical Activity and Sport Sciences professionals; one home session per week, recorded via PulmoSalud.
- Postoperative rehabilitation (4 weeks): Carried out entirely at home with digital monitoring; adapted to clinical status and post-surgical progress.

Phase 1 — PREHABILITATION (8 weeks): Structure of in-person sessions (45–60 minutes)

Each in-person session includes four components:

a) Warm-up and mobility (8–10 minutes)

- Global mobility of spine, shoulder girdle and hip.

- Walking or gentle cycling.
- Progressive muscle activation.
- Intensity: RPE 2–3.

b) Aerobic training (12–20 minutes) — Two modalities according to tolerance and individual progression:

Continuous moderate aerobic: Walking, treadmill, cycle ergometer. Intensity: RPE 4–5. Duration: 8–10 minutes initially, progressing to 15–20 minutes.

Moderate intervals (gentle HIIT): Introduced when the patient tolerates continuous exercise without exacerbation of dyspnoea. Format: 1 min brisk walking / 2 min gentle walking. 4–6 repetitions. Intensity in intervals: RPE 6–7, not exceeding dyspnoea 5/10. Objective: improve ventilatory efficiency without overloading.

c) Strength training (15–25 minutes) — With elastic bands, light dumbbells and bodyweight, with special emphasis on lower limbs and scapular musculature relevant after thoracic surgery.

Main exercises (adaptable according to functional capacity): Assisted squat or sit-to-stand; low and high row with band; chest press with band or light dumbbells; hip raises; lateral walk with band; scapular work (retraction, Y-T-W).

Structure: 2–3 sets per exercise; 8–12 repetitions; intensity based on RIR (Repetitions in Reserve): 2–3 RIR; gradual progression of volume (repetitions/sets) rather than abrupt load increases.

Planned progression: Weeks 1–4: familiarisation and technique; very light loads. Weeks 5–8: increased time under tension and range of motion. Weeks 9–12: increased repetitions or sets, maintaining safe loads.

d) Cool-down (5–8 minutes): Thoracic and scapular mobility; controlled breathing (coordinated with respiratory physiotherapy).

Home autonomous session (1/week)

Carried out with support of the PulmoSalud application. Indicative content: 10–12 min walking at tolerated pace (RPE 3–4); strength circuit of 3 exercises (assisted squat + row with band + hip raise) × 2 sets; 5 min scapular and thoracic mobility. Patient records in the app: final RPE, dyspnoea (0–10 scale), total duration, exercises performed, unexpected symptoms.

Phase 2 — POSTOPERATIVE REHABILITATION (4 weeks)

Weeks 1–2 (initial recovery): Gentle walking 10–15 min/day, RPE 2–3. Very basic strength exercises (1 set): sit-to-stand with support; lateral walk; gentle scapular retraction. Reinforcement of thoracic mobility and respiratory exercises from the clinical protocol.

Weeks 3–4 (progressive functional recovery): Walking 15–25 min/day, RPE 4–5. Introduction of light intervals (30" fast / 90" slow). Strength circuit (2 sets): assisted squat, row with band, hip raise; add scapular work according to tolerance.

Weekly telematic follow-up to adapt loads, frequency and intensity according to progress.

Training Monitoring

Monitoring combines perceptive indicators, clinical signals and digital recording to ensure safety, adherence and progression.

RPE Scale (Rate of Perceived Exertion) — used as the main tool to regulate intensity: Warm-up RPE 2–3; Continuous aerobic RPE 4–5; Moderate intervals RPE 6–7; Strength: 2–3 RIR (safe submaximal effort).

Clinical safety signals: Dyspnoea ≤ 5/10 during effort; Recovery in <2 minutes after intervals; Absence of chest pain, dizziness, syncope or exercise intolerance; Control of ventilatory pattern and pauses when necessary. In patients with home pulse oximeter (optional): maintain $SpO_2 \geq 90\%$.

Digital recording via PulmoSalud app: Record home sessions; enter final RPE and dyspnoea; note symptoms or perceived barriers; view reference videos; receive personalised recommendations. The research team reviews data weekly and adjusts sessions, progression and exercise dose.

Programme progression principles: Gradual increase in time before intensity; undulating (non-linear) progression to avoid overload; individualisation based on symptoms, RPE and dyspnoea; constant adaptation according to pre- and post-surgical evolution.

2. Respiratory Physiotherapy

PREHABILITATION: The respiratory physiotherapy programme will be applied by physiotherapists specialised in respiratory therapy. The intervention will consist of two supervised in-person sessions per week (during 8 weeks) of 15–20 minutes, which will be complemented by structured home practice. This home practice will be performed autonomously by the participant, guided and supervised through the mobile application, which will provide instructions, reminders and feedback on exercise execution.

The following components will be included:

Breathing pattern re-education and control: Specific training aimed at optimising ventilatory efficiency, including diaphragmatic breathing in sitting and recumbent positions, de-automatisation of thoraco-apical breathing patterns and work on ventilatory coordination through learning respiratory timings and rhythm control.

Pulmonary expansion exercises (EDIC) and segmental ventilation: Directed ventilation techniques towards lung bases, middle fields and apices, complemented by external manual facilitations according to tolerance and combined with prolonged inspiratory times, with the objective of improving alveolar recruitment and costal mobility.

Basic secretion management techniques: Strategies to optimise bronchial hygiene safely, including adapted ACBT (Active Cycle of Breathing Techniques), slow prolonged expiration manoeuvres with open glottis (ELTGOL) according to tolerance and effective ventilation techniques without abrupt coughing using huff (a forced expiration manoeuvre with the open glottis that generates a controlled expiratory flow to mobilise secretions without the impact and pain associated with coughing). The objective is to facilitate mobilisation of secretions without compromising the future surgical wound.

Protective education of the scar and effective coughing strategies without pain: These techniques are taught preoperatively so that patients can apply them autonomously in the postoperative period, optimising pain control, wound protection and cough effectiveness. They include: cough training assisted or directed with protective manual support ('splinting', placing hands or a pillow over the surgical area to reduce pain and protect the wound during coughing); no-cough strategies when not needed (suppression techniques, to avoid painful gestures or those that increase pressure on the scar); effective coughing strategies with minimal pain, learning to coordinate breathing, muscle activation and manual protection; training in the use of positive pressure devices to reduce the impact on the surgical wound and facilitate bronchial hygiene.

Inspiratory muscle training (IMT): Performed using adjustable resistance devices, such as PowerBreathe®, starting with a load of 30–40% of maximum inspiratory pressure (MIP) and progressively increasing by 5–10% every 2–3 days, according to tolerance. Sessions will be conducted twice a day, lasting 15–20 minutes. The programme will be complemented by controlled abdominal breathing (2–3 times/day) and assisted costal breathing with a volumetric incentive spirometer (such as Voldyne or other equivalent device), performed 3–4 times/day to optimise thoracic expansion and ventilatory efficiency.

Whole-body ventilatory training: Includes global exercises integrating the ventilatory pattern with trunk and upper limb mobility, such as costal elevation and opening assisted with elastic bands, thoracic mobilisation in sitting with directed breathing and 'breathing + movement' sequences in complete kinetic chain. The objective is to promote a more efficient ventilatory pattern during physical activity and improve coordination between breathing and movement.

Respiratory physiotherapy interventions will be carried out in person twice a week, coinciding with the scheduled physical exercise sessions. Physiotherapy will be performed immediately before training, lasting approximately 15–25 minutes, enabling optimisation of the ventilatory pattern, secretion mobilisation and pulmonary expansion before the exercise session. This sequence facilitates better exercise tolerance, reduces dyspnoea during training and avoids subsequent respiratory overloading. Complementarily, participants will perform guided home practice through the mobile application (IMT, diaphragmatic breathing, expansion exercises, huff techniques, etc.), reinforcing the work done in in-person sessions.

3. Mobile Application (App) Support

The application will be used as an educational and autonomous follow-up tool by the patient, allowing daily recording of basic parameters such as dyspnoea (Borg scale), pain, sleep quality and compliance with exercise sessions, IMT (Inspiratory Muscle Training) and respiratory exercises. The App includes demonstration videos of respiratory techniques, education on scar protection and preoperative preparation content, as well as scheduled notifications for IMT, thoracic expansion exercises and physical activity, plus brief self-assessment tests.

The use of the application will have an exclusively educational and self-monitoring purpose, without remote monitoring or transmission of clinical data to the healthcare team.

Basic technical description (initial proposal): The application is planned as a hybrid mobile app developed in a multi-platform environment (Android/iOS), with a simple and intuitive graphic interface based on iconographic menus and guided navigation. In its initial version, data is expected to be stored locally on the device, without access to external servers or exchange of personally identifiable information. It does not initially incorporate artificial intelligence or clinical chatbot; notifications and exercise sequences are managed through internal simple logic rules.

Possibility of technological expansion: These characteristics may be adjusted after the meeting with the IT team responsible for development. Depending on the available budget and technical assessment, additional functionalities could be incorporated, such as low-complexity AI modules, conversational assistants (clinical chatbot) or more advanced monitoring systems, always guaranteeing ethical and data protection requirements.

EARLY REHABILITATION — Control group (Standard care)

After surgery, participants assigned to the control group will receive standard care provided by the thoracic surgery service, following the standard clinical protocols of the centre. They will not participate in a structured respiratory physiotherapy programme nor in a supervised exercise plan, and will not have telematic support or mobile application monitoring. Their recovery will proceed according to conventional recommendations from the healthcare team, including pain control, early mobilisation according to tolerance and basic respiratory guidelines indicated routinely, without additional specific intervention within the study framework.

Intervention Group: Home-Based and Tele-assisted Programme

After hospital discharge, participants assigned to the experimental group will start a structured 4-week home-based early rehabilitation programme. The programme start will be individualised for each patient, activated when the responsible medical team confirms that the patient meets the minimum clinical criteria to begin rehabilitation (adequate pain control, respiratory stability and absence of relevant complications). This information will be documented in the clinical record and communicated to the research team via a surgical discharge and rehabilitation aptitude record, which will serve as the starting point for the patient's schedule.

Once clinical aptitude is verified, the responsible researcher will activate week 1 of the programme in the mobile application, so that each participant begins in the same phase regardless of their specific discharge date.

The programme is designed to continue the work learned in prehabilitation, facilitating safe, early respiratory recovery without the need for travel. The intervention is carried out entirely at home through respiratory exercises, progressive mobility and health education, guided through educational videos accessible from the mobile application. The load is organised by weeks, being lighter in the initial phases and slightly increasing in weeks 3 and 4, always without impact or excessive effort.

1. Breathing pattern re-education and control (Weeks 1–4): Objective: promote efficient ventilation, prevent hypoventilation and reduce respiratory pain. Interventions (2–3 times/day): gentle diaphragmatic breathing in sitting or semi-sitting; progressive non-forced inspirations with rhythm control; correction of thoraco-apical patterns associated with pain; relaxed breathing to decrease dyspnoea and thoracic tension. Progression: Weeks 1–2: 5–7 min sessions; Weeks 3–4: 8–10 min sessions with greater respiratory continuity.

2. Pulmonary expansion exercises and directed ventilation (Weeks 1–4): Objective: maintain adequate pulmonary expansion and prevent atelectasis. Interventions (3 times/day): directed ventilation to bases and middle fields; gentle inspirations with slightly prolonged inspiratory times; pre-surgical costal expansion exercises learned in prehabilitation. Progression: Weeks 1–2: small–moderate respiratory amplitude; Weeks 3–4: greater amplitude within comfortable range.

3. Safe bronchial hygiene techniques (As needed, weeks 1–4): Objective: facilitate secretion elimination without compromising the scar. Interventions: modified ACBT (controlled breathing + thoracic expansion + gentle huff); gentle low-pressure huff; gentle autogenic drainage, avoiding high-flow manoeuvres, intense forced expiration and ELTGOL in the entire early period.

4. Protective scar education and cough management (videos + daily practice): Objective: protect the incision, decrease pain and improve cough effectiveness. Includes: splinting with pillow; assisted or directed coughing techniques; cough suppression when not needed; postural education and safe movements (getting up, walking, sleeping).

5. Thoracic mobility and gentle physical activity without impact (weekly progression): Weeks 1–2: gentle scapula and shoulder mobility; thoracic mobility in sitting (small rotation, gentle opening); light walks at home: 5–10 min/day in short intervals. Weeks 3–4: greater range of thoracic and scapular mobility; low-load 'breathing + movement' exercises; progressive walking 10–20 min/day outdoors if safe.

6. Inspiratory muscle training (IMT) — progressive introduction: IMT will be incorporated from week 2 (or when authorised by the surgeon), once pain and baseline ventilation are stabilised. Interventions: use of adjustable resistance device with PowerBreathe; initial load: 15–20% of MIP; progression: +5% per week according to tolerance; duration: 10–15 min/day, 1–2 sessions/day.

7. Mobile Application (App) support during postoperative rehabilitation: During the 4 weeks of home rehabilitation, participants in the intervention group will use a mobile application designed to support continuity of the respiratory physiotherapy and physical activity programme, previously trained in the prehabilitation phase. The App does not perform advanced clinical monitoring, but facilitates self-registration, structured delivery of educational content, and a weekly communication channel with the team. The patient can record basic symptoms (pain VAS, dyspnoea using Borg scale, sleep hours and perceived fatigue), as well as daily compliance with the incentive spirometer, bronchial hygiene techniques (including ACBT and huff), and respiratory exercises. The team will provide a weekly phone call to review progression, resolve doubts and reinforce adherence, plus an asynchronous messaging system within the App for non-urgent queries. The platform includes a library of educational videos produced by physiotherapists (respiratory exercises, pulmonary expansion, directed ventilation, thoracic mobility, safe walking), nursing (wound care, device management and basic recovery guidelines), psychology (coping strategies and stress management) and thoracic surgery (general information on the postoperative process and self-care recommendations). The application also sends scheduled notifications to remind patients to perform respiratory exercises, use the incentive spirometer, daily walks and brief self-assessment.

SOURCES, CLINICAL DATA COLLECTION AND DATA ACCESS

Clinical information for the study will be obtained from the electronic clinical record (in Diraya), scheduled in-person assessments and data generated by the programme's mobile application. From the clinical record, only data necessary for the study will be collected (lung function, comorbidities, surgical data, complications and relevant tests), while in-person visits will collect functional measurements (6MWT), respiratory measurements (spirometry, MIP/MEP, PCF), body composition (BIA) and validated questionnaires (EORTC QLQ-C30/LC13, EQ-5D, PAM-13 and dyspnoea scales). The app will provide structured information on session adherence, viewing of educational videos, questionnaires and user experience (SUS). All data will be stored on secure, encrypted servers, with access limited to the research team and processed in pseudonymised form in accordance with current regulations (GDPR, LOPDGDD and Law 14/2007). Documentation and the correspondence key will remain kept in separate, restricted-access locations, guaranteeing confidentiality and traceability of the study.

VARIABLES, OUTCOME CRITERIA AND MEASUREMENT INSTRUMENTS

Sociodemographic, anthropometric, clinical and functional variables will be collected in this research, together with primary and secondary outcome variables. All of these will allow evaluation of the impact of the PulmoSalud programme on functional and respiratory recovery of patients operated on for lung cancer.

A broad set of physiological, functional, psychometric and training control measures will also be included, in order to analyse the efficacy of the combined supervised physical exercise and specialised physiotherapy programme in patients who are candidates for lung cancer surgery.

The selection of the set of variables linked to training has been defined following the methodological recommendations derived from existing scientific evidence in exercise oncology, including work developed by members of the research team.

1. Independent Variables

1.1. Sociodemographic variables: Age (continuous quantitative, years); Sex (dichotomous qualitative, male/female); Educational level (ordinal qualitative: none/primary/secondary/university); Family situation (nominal qualitative: lives with partner/lives alone/extended family); Place of residence (dichotomous qualitative: urban/rural); Employment situation (polychotomous qualitative: active/retired/sick leave/unemployed); Smoking (dichotomous qualitative yes/no and quantitative pack-years).

1.2. Anthropometric variables: Weight (kg); Height (cm); Body mass index (BMI, kg/m²); Body composition by bioimpedance (TANITA BC-545 HR): muscle mass (kg and %), fat mass (%), total body water (%).

1.3. Clinical and surgical variables: Type of lung cancer (nominal qualitative: NSCLC/SCLC/histological subtype); Tumour stage (TNM, ordinal qualitative); Type of pulmonary resection (nominal qualitative: lobectomy/segmentectomy/pneumonectomy/other); Surgical approach (dichotomous qualitative: VATS/thoracoscopy vs thoracotomy); Baseline pulmonary function (FEV1, FVC, FEV1/FVC, % predicted); Comorbidities (Charlson index, discrete quantitative); Adjuvant treatments (dichotomous qualitative: chemotherapy yes/no; radiotherapy yes/no); Time from diagnosis to surgery (discrete quantitative, months); Preoperative complications prior to programme start (nominal qualitative).

2. Dependent Variables (Primary)

2.1. Functional capacity: 6-Minute Walk Test (6MWT), continuous quantitative (metres), protocol of the American Thoracic Society (ATS) [37]; 30-Second Sit-to-Stand Test, discrete quantitative (repetitions), protocol of Jones et al. [38]; Functional strength-endurance test, discrete quantitative (number of repetitions).

2.2. Pulmonary function: FEV1 (L and % predicted), FVC (L and % predicted), FEV1/FVC — spirometry following ATS/ERS criteria [39].

3. Dependent Variables (Secondary)

3.1. Respiratory strength: MIP and MEP using a digital manovacuometer following ATS/ERS recommendations [40].

3.2. Cough function: Peak Cough Flow (PCF), continuous quantitative (L/min), per ATS/ERS recommendations [40].

3.3. Dyspnoea and perceived exertion: mMRC scale (ordinal qualitative, 0–4) [41]; modified Borg scale (0–10) [42].

3.4. Peripheral strength: Hand-grip dynamometry (kg), following standardisation recommendations of Roberts et al. [43], with normative values from Mathiowetz [44] and Dodds et al. [45].

3.5. Muscle function/Strength: Estimated 1RM (Brzycki equation): shoulder press, leg press (kg, continuous).

3.6. Cardiovascular capacity: Bruce ramp test (minutes or loads); submaximal heart rate reached (80%, heart rate monitor).

3.7. Nutritional status: FAACT–A/CS questionnaire (anorexia-cachexia); PREDIMED diet quality (ordinal qualitative scores).

3.8. Habitual physical activity: IPAQ (International Physical Activity Questionnaire) [46] — classified as low/sedentary, moderate and high. Godin questionnaire [47] as a complementary leisure-time exercise measure. Subjective perceived exertion (RPE, 0–10 scale): discrete quantitative variable, target values 4–6/10 in continuous work and 7–9/10 during intensive intervals.

3.9. Adherence and compliance: Number of sessions performed (% adherence relative to total planned); compliance with additional recommended physical activity day; compliance with prescribed intensities (aerobic: RPE; strength: RIR); documented training progression (weekly changes in volume, load, intensity and exercise tolerance); compliance with PulmoSalud application use (number of weekly records, data entries and audio-visual content queries).

Training progression documentation: recorded via a self-registration card integrated into the mobile application, after each session: dyspnoea level (Borg), muscle fatigue (modified Borg), session duration, sets and repetitions, resistance used in strength exercises, respiratory training parameters (time, resistance and number of inspirations in IMT), global perceived exertion (RPE). Data stored locally with timestamps.

3.10. Knowledge and self-management: Patient Activation Measure (PAM-13) (Annex 4), 0–100 continuous score [48]; ad hoc postoperative knowledge questionnaire.

3.11. Quality of life: EORTC QLQ-C30 and lung cancer module QLQ-LC13 [49,50].

3.12. Clinical safety: Postoperative respiratory complications (nominal qualitative: atelectasis, infection, prolonged air leak…); Hospital stay (discrete quantitative, days); Readmissions (dichotomous yes/no).

3.13. Satisfaction and application usability: Specific patient satisfaction questionnaire; System Usability Scale (SUS), continuous quantitative [51].

3.14. Patient-Reported Outcomes (PROs): Cancer-related fatigue (FACT-F subscale) [52]; Depression (HADS-D subscale) [53]; Anxiety (HADS-A subscale) [53].

MEASUREMENT TIME POINTS

Measurement Time Point	Clinical Phase	Description
T0 – Baseline	Start of study	Initial assessment before beginning prehabilitation.
T1 – Pre-surgery	End of prehabilitation	Measurement after 8 weeks of prehabilitation and immediately before surgery.
T2 – End of protocol	4 weeks post-surgery	Final measurement upon completion of postoperative home rehabilitation.

Additionally, and subject to sample availability and temporal resources, a follow-up measurement at 3 months post-surgery (T3) is contemplated to evaluate the persistence of effects on functional capacity, respiratory parameters, quality of life and healthcare resource use. If recruitment and logistics allow, an extended follow-up (6–12 months) as an extension study will also be assessed.

SOURCES AND SAMPLING/RECRUITMENT PROCEDURE

Recruitment will be carried out from thoracic surgery surgical lists, preoperative hospital consultations and referrals from Primary Care of the Cádiz Bahía–La Janda Health District. Healthcare professionals will identify potential candidates and refer them to the research team, who will contact patients and perform screening and signed informed consent during the preoperative consultation. The planned recruitment period will be 18 to 24 months, depending on the flow of candidates for pulmonary surgery expected at participating centres.

STATISTICAL ANALYSIS

The data collected will be analysed using IBM SPSS Statistics version 31.0.1.0. Demographic data will be analysed using descriptive statistics and presented as mean and standard deviation, as well as in the form of frequencies.

Homogeneity of the sample will be assessed using the Shapiro-Wilk test, expecting a normal distribution of the data.

For initial comparisons between groups, the t-test for independent samples will be applied, or the Mann-Whitney test if normality is not met. For comparisons within the same group (paired data) the paired t-test will be performed, or the Wilcoxon test when normality is not met. For qualitative variables, the Chi-squared test will be applied, and if the necessary conditions for its application are not met, Fisher's exact test will be used.

Final comparisons between groups will be performed using an ANCOVA model, adjusting results for baseline values of each variable.

Finally, effect size will be calculated using Cohen's d to interpret the magnitude of intergroup differences.

CITIZEN PARTICIPATION: Patient and Public Involvement (PPI) in Digital Intervention Development

Participatory activities will be carried out with the objective of integrating the perspective of people who have undergone surgery for lung cancer in the design and validation of educational content and the digital application. These activities will follow the international standards of Patient and Public Involvement (PPI), according to the UK INVOLVE and EUPATI guidelines, ensuring non-clinical participation centred solely on accessibility, comprehension and usability.

Planned actions: Active listening meeting with patients operated on in the last 24 months; brief group session to identify needs, barriers and preferences related to the use of digital tools during recovery; basic usability testing of the App (non-clinical interface) — participants will review navigation, icon clarity, comprehension of texts and educational videos (no clinical exercises or therapeutic instructions); review of educational content — evaluation of language, clarity, tone and adequacy of information.

All activities will be consultative in nature, without transmission of health data or involvement in the clinical trial. Methodology: activities coordinated by a team member with experience in health education and patient materials design. Participants: patients operated on for pulmonary surgery in the last 24 months and, where relevant, primary carers. Duration: active listening meeting: 45–60 minutes; app usability test: 20–30 minutes; materials review: same session. Data: qualitative, anonymous, used only to improve clarity and accessibility of materials.

3.6. INCORPORATION OF THE GENDER PERSPECTIVE IN RESEARCH

The gender perspective is integrated transversally in this project, in line with the methodological recommendations of the Andalusian School of Public Health (García-Calvente et al., 2015; García, Jiménez & Martínez, 2010) and the evaluation criteria proposed by Gaceta Sanitaria (Ariño et al., 2011). This approach is not conceived as an add-on, but as a structural component guiding the definition of the problem, the methodological design, the intervention, the digital monitoring and the interpretation of results. Furthermore, the research team maintains an explicit commitment to gender equity, reflected in mixed leadership: the Principal Investigator is a woman and the Co-PI is a man, guaranteeing a balanced and inclusive perspective in decision-making.

The relevance of the gender approach in this study is particularly important given that lung cancer presents epidemiological and clinical differences between women and men. Incidence continues to be higher in men, but the accelerated growth in women is modifying the epidemiological profile (Bade & Dela Cruz, 2020). Likewise, women tend to present a greater symptom burden such as dyspnoea, anxiety, fatigue or sleep disturbances, which directly influence the effectiveness of and adherence to exercise programmes and self-care interventions. There are also documented gender inequalities in care roles, time availability, mental load and use of health services (García-Calvente et al., 2015), factors that may condition participation in prehabilitation and rehabilitation programmes.

The study design incorporates this approach from the recruitment process, ensuring proportional representation of women and men based on the actual distribution of cases and monitoring possible recruitment biases. In addition to biological sex, key indicators recommended by the EASP will be collected to interpret health inequalities: care responsibilities, employment status and scheduling flexibility, perceived barriers to physical activity, social support, digital divide and technological familiarity.

The design of the digital intervention also incorporates gender sensitivity criteria. PulmoSalud content will use inclusive language and materials accessible at different literacy and digital experience levels. Educational videos on respiratory exercises, dyspnoea control techniques and health education are formulated to ensure equal comprehension and applicability for both sexes.

In the analysis of results, the project will apply a gender-sensitive approach. Stratified analyses by sex will be performed to evaluate differences in functional capacity, dyspnoea, fatigue, sleep, adherence and use of the PulmoSalud app. Interaction models will also be developed to study whether the effect of the intervention varies by sex, following the recommendations of Ariño et al. (2011). This approach is complemented by explanatory analyses using the gender variables collected (care burden, social support, digital divide, perceived barriers), allowing identification of structural inequalities and not only biological differences.

In the interpretation and knowledge transfer phase, the project will present gender-disaggregated results in reports, scientific communications and conferences, following EASP and SSPA guidelines. Specific recommendations will also be generated to reduce detected inequalities — for example, adapting the programme structure to facilitate adherence in women with high domestic workload or promoting motivational strategies oriented towards improving male participation, traditionally lower in self-care interventions.

3.7. WORK PLAN

The project will be developed between September 2026 and June 2029 (3 years) and will include four main phases: preparatory phase, digital programme development, implementation of the Randomised Clinical Trial (RCT) with prehabilitation-rehabilitation and final analysis and dissemination phase. Work will be carried out through a multidisciplinary approach integrating respiratory physiotherapy, therapeutic exercise, thoracic surgery, nursing, psychology and technological development. Recruitment will be continuous throughout the intervention phase.

Phase 1. Preparation (September 2026 – March 2027)

Tasks: Final adjustment of protocol and methodological documentation; logistical preparation: materials, flowcharts, registration templates and documentation for the Research Ethics Committee (REC); training of the research team in data collection, standardisation of functional tests, questionnaire management and clinical

safety criteria; final definition of the educational content of the PulmoSalud programme; design of functional requirements for the app and contracting of the technical development team.

Main responsible: MJVG (PI), CMPP (Co-PI), clinical physiotherapists (FJ Vera, MJ Crisóstomo, FJ Martín Vega, FM Rodríguez Vera, FJ González Espinosa, J. Baltasar, J. Pardo), with support from Ismael García Campanario. Collaborating: Nurses (E. Sánchez and J. Romero), psychologists (Rosa María Campos Carmona and Santiago Jacobo Díaz Hurtado).

Phase 2. Development of the PulmoSalud Application (April 2027 – December 2027)

Tasks: Technical development of the app (exercise modules, monitoring, videos and messaging); recording and editing of educational videos on respiratory exercise, wound care, psychological aspects and postoperative recommendations; clinical review of content and integration into the application; pilot test with a focus group of 10 patients to evaluate comprehension and usability; final adjustments and incorporation of improvements; intellectual property registration.

Responsible: External technical team (to be specifically contracted within the project); supervision of MJVG and CMPP. Clinical content: physiotherapy and sport science graduates + nurses + psychologists + rehabilitation physician + thoracic surgeons.

Phase 3. Recruitment and Implementation of the RCT (January 2028 – December 2028)

Tasks: Continuous recruitment of candidates from thoracic surgery and primary care; random allocation and participant registration; baseline assessments (T0) by blinded evaluators; prehabilitation (8 weeks): exercise programme and respiratory physiotherapy with app support; surgery according to standard care pathway; early home rehabilitation (4 weeks) supervised via app, messaging and a weekly call; digital follow-up of adherence and collection of app data; T1 (pre-surgery) and T2 (end of rehabilitation) assessments.

Responsible: Recruitment: thoracic surgeons, MJVG, CMPP, team physiotherapists; Blinded evaluation: specifically contracted evaluator; Intervention: clinical physiotherapists + CMPP + support from Ismael G. Campanario; Educational support: entire team.

Phase 4. Analysis and Dissemination (January 2029 – June 2029)

Tasks: Database cleaning and statistical analysis; interpretation of results and comparison between groups; preparation of scientific articles (JCR journals), conference presentations and knowledge transfer documentation; preparation of final report for REC and funding body.

Responsible: MJVG, CMPP, thoracic surgeons and nurses.

WORK SCHEDULE (By Quarters)

Year / Quarter	Main Activities
2026 – Q3	Final protocol adjustment, logistical planning, REC preparation.
2026 – Q4	Team training, test standardisation, content definition and app functional requirements.
2027 – Q1	App functional design, technical documentation, start development.
2027 – Q2	App development; recording of respiratory, psychological and care videos.
2027 – Q3	Content integration, internal testing, focus group of 10 patients.
2027 – Q4	Final adjustments, intellectual property registration.
2028 – Q1	Start of continuous recruitment; T0 assessments; prehabilitation begins.
2028 – Q2	Recruitment + prehabilitation + T1 assessments.
2028 – Q3	Surgery + start of early rehabilitation + T2 assessment.
2028 – Q4	Continuation recruitment + rehabilitation monitoring.
2029 – Q1	Database closure; statistical analysis.

Year / Quarter	Main Activities
2029 – Q2	Articles, conferences, dissemination and final report.

3.8. ETHICAL ASPECTS OF THE RESEARCH

The present study will be developed following the fundamental ethical principles established in the Declaration of Helsinki, the international recommendations of Good Clinical Practice (ICH-GCP) and the current Spanish and European regulations on data protection and research with human beings. In particular, compliance with Regulation (EU) 2016/679 (GDPR), Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD) and Law 14/2007 on Biomedical Research will be ensured.

1. Ethical Approval

Before the start of recruitment and data collection, the complete study protocol has been submitted for evaluation to the competent Research Ethics Committee. Currently, ethical approval is in process, and the submission and application justification is included as Annex 7. The study will not begin until express authorisation from the corresponding Ethics Committee has been obtained.

2. Informed Consent and Voluntariness

All participants will be informed in detail about the study objectives, procedures, expected benefits, potential risks and their rights as participants.

- Participation will be entirely voluntary.
- Subjects may withdraw at any time, without need to justify their decision and without this causing any prejudice to their healthcare or care process.
- Informed Consent will be signed by each participant before any study procedure is performed.
- A clear and comprehensible Patient Information Sheet will be provided (included in Annex X).

3. Data Protection and Confidentiality

The processing of personal data will strictly follow the principles of legality, loyalty, transparency, minimisation and purpose limitation established in the GDPR and LOPDGDD. Measures applied: Minimisation: only data strictly necessary for the scientific objectives of the study will be collected; Pseudonymisation: each participant will be assigned an alphanumeric code; Confidentiality: only the research team will have access to the data; Security: data will be stored on institutional servers with necessary technical and organisational measures; ARCO-POL rights: the exercise of rights of Access, Rectification, Cancellation, Opposition, Portability and Processing Limitation will be facilitated.

4. Regulatory Compliance

The present study complies with: Declaration of Helsinki (latest revision); Law 14/2007, Biomedical Research; Regulation (EU) 2016/679 (GDPR); Organic Law 3/2018 (LOPDGDD); Good Clinical Practice Standards (ICH-GCP); CONSORT recommendations for clinical trials.

5. Data Access and Publication

Data generated in this research will be used exclusively for scientific purposes. Results will be presented in completely anonymised form and will not allow individual participant identification. The research team undertakes to comply with institutional standards on data custody and publication, guaranteeing the rights of subjects as established by current legislation.

3.9. IMPACT ON PATIENT SAFETY

The PulmoSalud programme integrates individualised physical exercise, respiratory physiotherapy and digital monitoring — elements that, applied in a protocolised manner, reduce the risk of respiratory and functional complications after lung cancer surgery, directly improving patient safety.

Firstly, the inclusion of respiratory training (pulmonary expansion, directed ventilation and inspiratory muscle training) contributes to reducing the occurrence of atelectasis, respiratory infections and early pulmonary deterioration — frequent complications in the postoperative period. Improvement of inspiratory strength and effective cough promotes more efficient secretion management, reducing the risk of bronchial obstruction and hospital readmissions.

The programme also incorporates safe intensity and progressive exercise protocols, adapted to the patient's clinical status, minimising the risk of overexertion, desaturations or adverse events associated with physical activity. Sessions are supervised by specialised professionals, adding constant clinical monitoring of symptoms, saturation and tolerance.

The digital component of the project acts as an additional safety mechanism: the application monitors adherence, records relevant symptoms (dyspnoea, pain, saturation) and issues automated alerts at warning signs, allowing early action and avoiding potential complications.

Finally, the health education included in the app improves self-management and understanding of the postoperative process, decreasing risk behaviours, promoting correct protection of the surgical wound and improving informed decision-making.

Overall, the PulmoSalud programme contributes significantly to reducing the potential damage associated with the postoperative period, through early detection of complications, safe training, continuous supervision and patient empowerment, thus reinforcing a safer and more efficient clinical environment.

3.10. APPLICABILITY OF RESULTS

YES — results are applicable and incorporate improvements in routine clinical practice of the Health System.

Scope of application: Both in Specialist Care (thoracic surgery, hospital physiotherapy, postoperative consultations) and in Primary Care, facilitating longitudinal monitoring, respiratory education, exercise supervision and self-care support, reinforcing care continuity.

Estimated timeframe: 3–6 months after project completion, given that: the techniques used are known and already partially used in clinical practice, though not in a structured or protocolised manner; the training required for professionals is minimal; the App can be integrated without generating relevant organisational changes; the protocol is easily standardisable and transferable.

Potential population who could benefit: All candidates for lung cancer surgery in the SSPA, as well as patients undergoing bariatric surgery, major abdominal surgery, cardiac surgery, patients with chronic respiratory diseases (COPD, severe asthma, bronchiectasis), patients with respiratory muscle weakness secondary to neuromuscular conditions, and pre- and post-lung or cardiac transplant patients.

3.11. IMPACT OF RESULTS

3.11.1. Transferable Assets

YES — the project has potential to generate various assets of value for the SSPA, including: transferable Know-How (exercise protocols, telematic monitoring algorithms, respiratory education content and self-management clinical flows); the developed m-Health application constitutes an asset susceptible to registration as intellectual property (health software); structured clinical materials (guides, educational content, adherence tools) that can be integrated into SSPA care protocols; and if some app modules incorporate innovative algorithms, these could be evaluated for protection as a utility model or own health technology.

3.11.2. Positive Health Impact

YES — a positive impact on the health of the population is expected, especially in people affected by lung cancer undergoing thoracic surgery. The proposed intervention — based on respiratory physiotherapy, supervised physical exercise and health education via an m-Health application — has the potential to: (1) reduce post-surgical complications; (2) improve pulmonary function, physical capacity and autonomy; (3) promote self-management through greater health literacy; (4) increase clinical safety through early detection of warning signs; (5) improve quality of life in recovery; and (6) optimise the use of healthcare resources by reducing readmissions and hospital stays.

3.11.3. Population in Andalusia

Current situation: Approximately 7,000–7,500 new cases of lung cancer per year are diagnosed in Andalusia, with an incidence of 80–85 cases/100,000 inhabitants. Of these, approximately 20–25% are candidates for

surgical treatment, representing approximately 1,400–1,800 patients operated on each year.

Situation after implementation: If the PulmoSalud programme proves effective and is incorporated into clinical practice, it could directly benefit all patients operated on for lung cancer in Andalusia (1,400–1,800 people/year). Additionally, due to the transversal nature of the intervention, it could be extended to other populations, with the total potential population easily exceeding 4,000–5,000 patients/year if integrated into various care pathways.

3.11.4. Economic Impact on the SSPA

YES — MEDIUM-LONG TERM: The implementation of the proposed protocol has high potential to generate sustained savings for the SSPA at medium and long term. Resources needed for implementation: initial professional training in protocol and digital platform (low, one-time cost); m-Health application maintenance (moderate, easily absorbable); basic low-cost material; professional time for physiotherapy and telematic monitoring, optimised through the hybrid model; possible minimal integration with clinical record systems.

Resources that could be saved: reduction of postoperative respiratory complications; decrease in hospital stay (1–3 days per patient described in literature); reduction of readmissions in the first 30 days; lower care burden in Primary and Specialist Care through improved self-management and early detection; optimisation of professional time. Even modest reductions of 10–20% in complications or readmissions would represent very significant savings for the Andalusian health system.

3.12. DISSEMINATION AND EXPLOITATION PLAN

3.12.1. Publication in High-Impact Indexed Journals

YES — the project results are clearly susceptible to publication in JCR-indexed journals, as they address a highly relevant clinical problem — improving pulmonary function and functional capacity in patients operated on for lung cancer — through an innovative protocol combining respiratory physiotherapy, supervised physical exercise and m-Health support. The study design meets the methodological requirements for publication in high-impact journals such as Journal of Thoracic and Cardiovascular Surgery, Chest, European Respiratory Journal, Journal of Medical Internet Research, Clinical Rehabilitation or Physiotherapy Theory and Practice.

3.12.2. Consensus Documents and Clinical Guidelines

YES — project results have high transfer potential and can directly contribute to the preparation and updating of consensus documents and clinical practice guidelines in the areas of lung cancer, thoracic surgery and rehabilitation. If effective, the project could: update or support the creation of clinical practice guidelines (prehabilitation and rehabilitation in thoracic surgery; perioperative management of lung cancer; physical exercise programmes in oncology; use of digital technologies for self-management); generate standardised clinical protocols for primary and hospital care; promote multidisciplinary consensus documents; develop or validate clinical instruments such as adherence questionnaires and self-management assessment tools; contribute directly to the SSPA Integrated Care Process (PAI) for Lung Cancer.

3.12.3. Dissemination Plan with Timelines

During project implementation (Years 1–3): Presentation of preliminary results, programme methodology and intermediate analyses at national (SEOM, AEF, SECA, SEPAR) and international (ACSM, ERS, IASLC) conferences; innovation and knowledge transfer activities; collaboration with patient associations (AECC, AEACaP).

After project completion (Year 3 onwards): Publication of 2–3 articles in high-impact journals including Journal of Thoracic Oncology, Supportive Care in Cancer, Medicine & Science in Sports & Exercise, Journal of Cancer Survivorship, Clinical Rehabilitation. Manuscripts planned: (1) Main RCT results; (2) Adherence, safety and efficacy analysis of the hybrid intervention; (3) Cost-effectiveness and clinical applicability in the SSPA.

Collaboration with companies: Two expert referees in exercise oncology will facilitate knowledge transfer to specialised private centres and collaborations with technology companies for digital tool development.

Total estimated dissemination timeline: 4 years (3 years of execution + 1 additional year for publication, transfer and adoption).

3.12.4. Exploitation Plan

Immediate users of results: SSPA thoracic surgery, pulmonology, rehabilitation, respiratory physiotherapy and sport science services; primary care professionals; patients operated on for lung cancer; private centres specialised in exercise oncology.

Implementation contexts: Direct care implementation as an integral perioperative prehabilitation and rehabilitation programme; updating of clinical pathways including thoracic surgery itineraries, patient safety programmes and the SSPA Lung Cancer Integrated Care Process (PAI).

Transfer and commercial exploitation potential: In the public sector (SSPA): integration into corporate telemonitoring and digital health platforms. In the private sector: specialised centres in exercise oncology and rehabilitation; digital health and tele-rehabilitation companies could commercially exploit the digital part of the programme (app, interactive materials, monitoring algorithms); potential evolution of the software towards a medical device (software as a medical device) if sufficiently validated. Intellectual protection through the SSPA Office of Technology Transfer (OTT-SSPA), contemplating: registration of digital and educational content; protection of programme methodological design; licensing for free clinical use in the public sector; possibility of commercial exploitation in the private sector through licences or transfer agreements.

4. AVAILABLE RESOURCES AND REQUESTED BUDGET

4.1. RESOURCES AND MEANS AVAILABLE FOR THE PROJECT

INVENTORIABLE MATERIAL: The research team and participating centres currently have: Appropriate care spaces for the development of interventions; Institutional desktop and laptop computers for data recording and analysis; Access to the Diraya corporate platform and clinical databases necessary for pre- and post-surgical monitoring; Institutional statistical software licences (SPSS, R, STATA); Wi-Fi connectivity and secure network to host research tools.

BIBLIOGRAPHIC MATERIAL: Institutional access to: Virtual Library of the Andalusian Public Health System (BV-SSPA); Scientific databases (PubMed/MEDLINE, Scopus, Web of Science, Cochrane Library); Indexed journals in rehabilitation, thoracic surgery, physiotherapy and exercise sciences.

SERVICES/PLATFORMS: The team has corporate communication devices (institutional mobile phones) that allow clinical calls, telematic monitoring and direct contact with patients throughout the prehabilitation and rehabilitation process. Additionally, there is a Research Support Unit at the centre for methodological advice.

4.2. REQUESTED BUDGET AND JUSTIFICATION

Budget Category	Amount Requested (€)
1. Goods and Services — Consumable Material	10,430
Mats (10 units) for respiratory physiotherapy and exercise sessions	
Disposable mouthpieces for spirometry and PowerBreathe	
Disposable turbines for clinical spirometer	
Disinfectant wipes, hand gel and individual towels	
Cones, elastic bands, Theraband, medicine ball	
External services and research equipment rental	44,470
App technical development (architecture, frontend/backend, database, dashboard, QA, security, documentation, 6-month maintenance): €18,000	
Additional ICT services (secure server, audit, UX/UI design): €4,800	
Scientific translation and editing (2 articles): €1,000	
Statistical services: €4,000	
TOTAL GOODS AND SERVICES	54,900
2. Personnel costs (salaries, social security contributions)	33,000
Scientific-technical activities contract	33,000
TOTAL PERSONNEL	33,000
3. Travel, accommodation and subsistence	2,000
National congress travel (SEPAR, etc., 2 people × 2 congresses)	2,000
4. International congresses and team meetings	2,000
5. Congress registration fees	1,600
6. Publication costs (Open Access, maximum €2,000/year)	6,000
7. Equipment (maximum 20% of direct costs)	—
8. Other expenses — Clinical trial insurance (mandatory policy)	2,500
TOTAL DIRECT COSTS	100,000
Indirect costs (max. 7%)	7,000

Budget Category	Amount Requested (€)
TOTAL PROJECT BUDGET	107,000

Physical Exercise Programme — Equipment Detail

A. Intensity Monitoring

Item	Units	Unit Price	Total	Justification
Heart rate monitors with chest band (Polar H10)	2	90 €	180 €	Precise %HRR control
Compatible sports watches	2	170 €	340 €	Continuous HR recording
Tablet for session recording	1	250 €	250 €	Digital adherence/progression recording
SUBTOTAL A			770 €	

B. Cardiovascular Equipment

Item	Units	Unit Price	Total	Justification
Professional cycle ergometer	1	900 €	900 €	Structured aerobic work
Adjustable step	2	40 €	80 €	Aerobic intervals, technique, warm-up
Cones / markers	1 pack	25 €	25 €	Space marking and 6MWT
SUBTOTAL B			1,005 €	

C. Strength Training Equipment

Item	Units	Unit Price	Total	Justification
Dumbbell set (1–10 kg)	2	120 €	240 €	Progressive strength per %1RM
Kettlebells (4, 6, 8 kg)	3	35 €	105 €	Power and functional strength
Theraband elastic bands	6	8 €	48 €	Progressive load adaptation
Medicine ball (2–3 kg)	2	20 €	40 €	Core and power work
Multi-purpose bench	1	110 €	110 €	Press and support exercises
SUBTOTAL C			543 €	

D. Stability and Proprioception

Item	Units	Unit Price	Total	Justification
Unstable platform (Bosu)	1	140 €	140 €	Proprioceptive and motor control work
Fitball	2	20 €	40 €	Stability and technique
Exercise mats	2	25 €	50 €	Mobility and stretching
SUBTOTAL D			230 €	

E. Functional Assessment Equipment

Item	Units	Unit Price	Total	Justification
Stable armless chair	1	40 €	40 €	30-second Sit-to-Stand Test
Digital stopwatch	1	15 €	15 €	Time control
Distance measure (metric wheel)	1	40 €	40 €	6MWT delimitation
SUBTOTAL E			95 €	

F. Storage

Item	Units	Unit Price	Total	Justification
Storage trolley	1	70 €	70 €	Equipment organisation and hygiene
SUBTOTAL F			70 €	

G. PPE and Hygiene

Item	Units	Unit Price	Total	Justification
Disinfectant wipes	6 packs	8 €	48 €	Equipment disinfection after each use
Hand sanitiser gel	4 units	6 €	24 €	Hand hygiene before/after sessions
Individual microfibre towels	6	5 €	30 €	Personal hygiene for patient
SUBTOTAL G			102 €	

TOTAL PHYSICAL EXERCISE EQUIPMENT: 2,815 €

Respiratory Physiotherapy Programme — Equipment Detail

Item	Budget (€)
Portable clinical spirometer (including turbines, basic software and calibration)	2,000
Tablet for data recording	900
Computer for development and analysis	1,500
Non-inventoriable material (spirometry mouthpieces, PowerBreathe)	230
Mats (10 units)	95
PowerBreathe devices (100 units)	7,000
Pulse oximeters (10 per room, €30/unit)	300
Static bicycle or cycle ergometer	900
Peak flow meters (2 units)	60
MIP/MEP manometer (respiratory pressure measurement device)	1,100
Acapella devices (60 units, €100/unit)	6,000
PowerBreathe (60 units, €70/unit)	4,200
TOTAL ESTIMATED	24,825

Health Education Programme with Digital Application — Budget

App development (external team): €18,000. This includes: architecture; frontend + backend programming; database; professional dashboard; patient interface; secure access control; QA testing; corrections; technical documentation; basic 6-month maintenance.

Additional ICT costs: Secure platform/server for clinical data: €1,500; Software licences (forms, data management, analysis): €1,000; Technical audit / cybersecurity: €1,500; Additional UX/UI design services (if iterations required): €800. Subtotal ICT: €4,800.

Total for the digital application section: €22,800.

Scientific translation and editing of manuscripts (2 articles): €1,000. Professional translation and scientific editing service in English of two manuscripts resulting from the clinical trial, to ensure linguistic quality and 'journal-ready' format before submission to international journals.

Statistical services: €4,000. Contracting of a statistician with experience in clinical trials to carry out statistical design (sample size calculation), statistical plan drafting, database cleaning and validation, intermediate and final analyses, table and figure generation, methodological advice and support in responding to reviewers. This

amount covers approximately 120–160 hours of specialised work.

Total goods and services: €54,900.

4.3. JUSTIFICATION OF THE NEED FOR PERSONNEL RECRUITMENT

The recruitment of a research support technician is essential for the adequate implementation of this randomised clinical trial, which requires intensive activity of care coordination, structured participant monitoring and advanced data management. This professional will be responsible for organising appointments, coordinating logistics between the various services involved, collecting and verifying clinical, functional and questionnaire data, entering them into secure databases (REDCap or SSPA platforms), performing quality controls, debugging inconsistencies and ensuring traceability in accordance with current regulations and the GDPR.

They will also support study monitoring, preparation of interim and final reports, and provide methodological support to the research team through variable coding and table preparation for statistical analysis. Since the healthcare team does not have the time or resources to assume this workload without affecting their clinical activity, the incorporation of this specialised professional profile is essential to guarantee protocol compliance, scientific data validity, follow-up continuity and, ultimately, the operational feasibility of the project.

Version Control

Version	Date	Modification
00	12/12/2025	Initial version — English translation. Document date corrected to MM/DD/YYYY format (12/12/2025) for consistency with ClinicalTrials.gov requirements.

ANNEXES

ANNEX 1: ECOG Scale

Grade	Description
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light house work, office work).
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
5	Death.

ANNEX 2: mMRC Dyspnoea Scale

Grade	Description
0	Breathless only with strenuous exercise.
1	Short of breath when hurrying on level ground or walking up a slight hill.
2	Walks slower than people of the same age on level ground because of breathlessness, or has to stop to catch breath when walking at own pace on level ground.
3	Stops for breath after walking about 100 metres or after a few minutes on level ground.
4	Too breathless to leave the house, or breathless when dressing.

ANNEX 3: Modified Borg Scale (Perceived Exertion / Dyspnoea)

Score	Description
0	Nothing at all
0.5	Very, very slight (just noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Very, very severe (almost maximal)

Score	Description
10	Maximal

ANNEX 4: Patient Activation Measure (PAM-13)

The Patient Activation Measure (PAM-13) is a validated instrument to assess the degree to which patients feel confident and able to manage their own health and healthcare. The scale consists of 13 items scored from 1 to 4 (disagree strongly to agree strongly), yielding a total score from 0 to 100. Higher scores indicate greater patient activation and self-management capacity.

The four levels of activation are: Level 1 (score <47.0): Patient may not yet believe that their active role is important; Level 2 (score 47.1–55.1): Patient lacks confidence and knowledge to take action; Level 3 (score 55.2–67.0): Patient beginning to take action but may lack confidence; Level 4 (score ≥67.1): Patient has adopted many proactive self-management behaviours.

Reference: Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res. 2005 Dec;40(6 Pt 1):1918–30.

ANNEX 5: System Usability Scale (SUS)

The System Usability Scale (SUS) is a reliable tool for measuring the usability of a system or application. It consists of 10 statements, each rated on a 5-point Likert scale from 'Strongly disagree' to 'Strongly agree'. The score ranges from 0 to 100, with higher scores indicating greater usability.

Scoring interpretation: ≥90: Excellent (A+); 80–89: Good (B); 70–79: Average (C); 60–69: Poor (D); <60: Unacceptable (F).

The 10 SUS items are: (1) I think that I would like to use this system frequently; (2) I found the system unnecessarily complex; (3) I thought the system was easy to use; (4) I think that I would need the support of a technical person to be able to use this system; (5) I found the various functions in this system were well integrated; (6) I thought there was too much inconsistency in this system; (7) I would imagine that most people would learn to use this system very quickly; (8) I found the system very cumbersome to use; (9) I felt very confident using the system; (10) I needed to learn a lot of things before I could get going with this system.

Reference: Brooke J. SUS: A 'Quick and Dirty' Usability Scale. In: Usability Evaluation In Industry. Taylor and Francis Group; 1996. pp. 207–12.

ANNEX 7: JUSTIFICATION OF SUBMISSION TO THE PROVINCIAL RESEARCH ETHICS COMMITTEE OF CÁDIZ

PROVINCIAL RESEARCH ETHICS COMMITTEE FOR MEDICINES (CEIm) OF CÁDIZ

Ms. Mónica Saldaña Valderas, Secretary of the Provincial CEIm of Cádiz, accredited and constituted in accordance with Decree 8/2020, of 30 January, regulating bodies for care ethics and biomedical research in Andalusia,

HEREBY CERTIFIES

That the study entitled MULTIMODAL PREHABILITATION AND EARLY HOME-BASED REHABILITATION PROGRAMME IN LUNG CANCER PATIENTS (code 1PULMOSALUD; SICEIA-2025-003794 no.) in which Ms. María Jesús Viñolo Gil participates as principal investigator, is currently under evaluation by this Committee.

For the record and to produce the relevant effects and at the request of the interested party, this document is signed in Cádiz, on the date of signature.

Signed by SALDAÑA VALDERAS MONICA – 31663449Q on 11/12/2025 with a certificate issued by CA FNMT Users

ANNEX 8: PATIENT INFORMATION SHEET

PATIENT INFORMATION SHEET (PIS)

Study title: Multimodal Prehabilitation and Early Home-Based Rehabilitation Programme in Lung Cancer Patients

Principal Investigator: _____

Centre: _____

Contact telephone: _____

Why is this study being conducted?

Surgery is an important treatment for lung cancer, but many people come to the operation with low strength or respiratory capacity, which may slow recovery. Preparing before surgery and receiving support after discharge can help improve physical capacity, reduce complications and facilitate the return to daily life.

What does the PulmoSalud programme involve?

PulmoSalud is a programme that combines 8 weeks of in-person exercise and respiratory physiotherapy before surgery, and 4 weeks of home rehabilitation after discharge. To facilitate monitoring, a mobile application (APP) is used that offers videos, reminders and health advice.

The programme includes:

- Adapted strength and endurance exercises.
- Respiratory exercises and breathing management.
- Advice on physical activity and post-surgical care.
- Recording of symptoms and progress through the APP.

What is the purpose of this study?

We will compare this programme with standard care to find out if it helps to:

- Improve preparation before surgery.
- Accelerate recovery after discharge.
- Reduce complications.
- Improve breathing, strength and quality of life.

Assessments will be carried out at the beginning, before surgery and one month after.

What will I have to do?

During the study you will be asked to:

- Complete questionnaires on health literacy, knowledge of the postoperative process, and self-management/self-efficacy.
- Undergo assessments of your respiratory function (FEV1) according to standard clinical practice.
- Use the APP (if assigned) for _____ weeks.
- Allow recording of clinical events and post-surgical complications.

The total duration of follow-up will be: _____.

What risks or inconveniences are there?

The study does not involve additional clinical risks. Use of the APP does not replace healthcare or communication with your medical team. There may be some time investment to answer questionnaires or use the APP.

Voluntary participation

Your participation is voluntary. You may withdraw at any time without giving reasons and without this affecting your current or future healthcare.

Confidentiality

Your data will be treated confidentially, in accordance with Regulation (EU) 2016/679 (GDPR) and Organic Law 3/2018. A code will be assigned to your data to avoid direct identification. Only the authorised research team will have access to the information. Results will be analysed and published in aggregate form, without your identity being recognisable.

Participation does not involve any cost to you. No financial compensation is contemplated for participation.

If you have questions or would like more information, please contact:

Telephone: _____

Patient Declaration

I have read and understood this information. I have had the opportunity to ask questions and have received satisfactory answers. I understand that my participation is voluntary.

ANNEX 9: INFORMED CONSENT

Study title: Multimodal Prehabilitation and Early Home-Based Rehabilitation Programme in Lung Cancer Patients (PulmoSalud)

Principal Investigator: _____

Centre: _____

Contact telephone: _____

INFORMED CONSENT

I have read (or have had read to me) the Patient Information Sheet for the above-mentioned study. I have been able to ask questions and all have been answered satisfactorily.

I declare that I have been informed of the following:

1. The purpose of the study is to evaluate whether an exercise and health education programme, combined with a mobile application, can improve preparation before lung cancer surgery and promote recovery after discharge.

2. My participation includes:

- Completing 8 weeks of in-person exercises and respiratory physiotherapy before surgery.
- Completing 4 weeks of home rehabilitation supported by a mobile application.
- Answering questionnaires and undergoing physical and respiratory assessments at three time points in the study.
- Allowing my clinical data related to the surgical intervention to be recorded.

3. My participation is voluntary. I can withdraw from the study at any time and without needing to give reasons, without this affecting my usual medical care.

4. The risks are minimal, related only to the practice of physical exercise, which will be carried out safely, supervised and adapted to my health status.

5. Benefits are not guaranteed, although I may improve my physical condition before surgery and my subsequent recovery.

6. The information collected will be treated confidentially and anonymously, complying with current data protection legislation.

7. Should I have doubts or any problem during the study, I can contact the research team using the provided telephone numbers.

PATIENT DECLARATION

■ I agree to participate in this study

■ I do not agree to participate

Patient name and surname: _____

Signature: _____ Date: ___ / ___ / _____

INVESTIGATOR DECLARATION

I, _____, have explained to the patient the nature of the study, its objectives, expected benefits and possible risks. I consider that they have correctly understood the information provided.

Signature: _____ Date: ___ / ___ / _____

DECLARATION OF THE PERSON DELIVERING THE INFORMATION (if different from principal investigator)

Name: _____

Position: _____

Signature: _____ Date: ___ / ___ / _____