ISRCTN53815807 https://doi.org/10.1186/ISRCTN53815807

Comprehensive maintenance program: a health haven for chronic obstructive pulmonary disease in Lleida, Spain

Submission date 10/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/10/2025	**Overall study status** Ongoing	
Last Edited 13/10/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
People with chronic obstructive pulmonary disease (COPD) often experience breathlessness, tiredness, and reduced ability to exercise. Pulmonary rehabilitation programs (PRPs) — which combine exercise, education, and support — are known to improve symptoms, fitness, and quality of life. However, these benefits usually fade within a few months after the program ends. This study aims to test whether a supervised maintenance PRP can help people with COPD keep the benefits of their initial PRP for longer. The study will also look at mental health, physical activity, sleep patterns, and the use of healthcare services.

Who can participate?
Adults diagnosed with COPD who have already completed an 8-week pulmonary rehabilitation program can take part. Participants need to be stable in their condition and able to attend the supervised sessions. People with other severe illnesses that could limit exercise participation will not be included.

What does the study involve?
The study will run for 12 months and include two groups:
The intervention group will take part in a 3-month supervised maintenance program at a physiotherapy centre. This includes two weekly exercise sessions led by a physiotherapist and monthly education sessions on COPD, healthy lifestyles, and how to recognize early signs of flare-ups.

The control group will receive the usual clinical advice about staying active but will not attend the supervised sessions.

All participants will have four assessments: before starting (T0), and then at 3 months (T1), 6 months (T2), and 12 months (T3). These assessments will include questionnaires about symptoms and quality of life, walking and strength tests, mental health questionnaires, and sleep monitoring using a wrist device. Lung function tests and body measurements will be done at the start and end of the study.

What are the possible benefits and risks of participating?
Participants in the supervised program may experience better control of breathlessness, improved fitness and mood, and a higher quality of life. The findings could also help design better long-term care strategies for people with COPD.
Risks are minimal. Some people may feel tired or short of breath during exercise, but all sessions will be supervised by trained physiotherapists, and oxygen will be available if needed. Any health problems or COPD flare-ups will be promptly referred to the hospital clinic.

Where is the study run from?
The study is run from a public healthcare hospital, Hospital Universitari Arnau de Vilanova i Santa Maria de Lleida, in coordination with a physiotherapy centre that provides pulmonary rehabilitation services.

When is the study starting and how long is it expected to run for?
The study is expected to start enrolling in November 2025 and will last for 12 months per participant, including 3 months of supervised maintenance sessions and 9 months of follow-up and evaluations.
With an estimated 12-month recruitment period, the total study duration is expected to be approximately 2 years.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Jessica González, jegonzalez.lleida.ics@gencat.cat, jgonzalezgutierrez88@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CEIC-3295

Study information

Scientific Title
Comprehensive maintenance program: a health haven for COPD in Lleida.The NAPOLEON Project.

Acronym
NAPOLEON

Study objectives
1-To compare general and COPD-specific health-related quality of life between intervention and control groups at T0, T1, T2, and T3 using the EuroQol-5 Dimensions questionnaire (EQ-5D) and the COPD Assessment Test (CAT).
2-To assess the impact of the intervention on mental health by comparing anxiety and depression levels between groups at T0, T1, T2, and T3, measured with the Hospital Anxiety and Depression Scale (HADS).
3-To compare functional and exercise capacity between groups at T0, T1, T2, and T3, based on spirometry values, the six-minute walk test (6MWT), and handgrip strength.
4-To compare self-reported physical activity levels using the short version of the International Physical Activity Questionnaire (IPAQ) across time points.
5-To evaluate the sleep-wake pattern and determine the intervention's effect on its modulation, through analysis of sleep-wake pattern and activity variables (total sleep time, sleep latency, wake after sleep onset, light and deep sleep stages) recorded by wearable devices throughout

the follow-up.
6-To compare healthcare utilization at T3, including non-hospitalized exacerbations, hospital admissions, and total hospitalization days between groups.
7-To assess the cost-effectiveness of the intervention from the healthcare system perspective, considering direct healthcare-related costs and the clinical benefits achieved.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/05/2025, Comité de Ética de Investigación con Medicamentos del Hospital Universitari Arnau de Vilanova de la Gerència Territorial de Lleida – GSS (Av. Alcalde Rovira Roure 80, Lleida, 25198, Spain; +34 663840328; ceim.lleida.ics@gencat.cat), ref: CEIC-3295

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Maintenance pulmonary rehabilitation program (PRP) in patients with chronic obstructive pulmonary disease who completed an initial PRP.

Interventions
Methods summary:
A 12-month randomized controlled trial (RCT) with two parallel groups will be conducted in adults with COPD who have completed an initial 8-week PRP. Participants will be randomly assigned in a 1:1 ratio to either the intervention or control group. The randomization model to be used is computer-based through the REDCap platform (v.15.0.39). The intervention group will undergo a maintenance PRP consisting of two weekly supervised exercise sessions and monthly educational sessions on COPD at a comprehensive health centre over 3 months. The control group will receive standard clinical care recommendations regarding physical activity. Clinical evaluations will be conducted at four time points throughout the study: baseline (T0), 3 months (T1), 6 months (T2), and 12 months (T3). Full pulmonary function tests and anthropometric assessments will be performed at T0 and T3. Other variables, including symptom burden, quality of life, functional capacity, mental health, physical activity, sleep-wake pattern, and healthcare utilization, will be systematically collected at all four time points.

Study arms:
Experimental: Supervised multidimensional pulmonary rehabilitation maintenance program
Participants assigned to the intervention group will engage in a supervised, multidimensional pulmonary rehabilitation maintenance program over a period of three months. This program will consist of two weekly sessions of supervised exercise and a total of six educational sessions, each lasting approximately 20 minutes, delivered twice per month. The educational sessions will address key topics such as the prevention and management of chronic obstructive pulmonary disease (COPD) exacerbations and the adoption of healthy lifestyle behaviors. All sessions will be conducted at a comprehensive healthcare center by a physiotherapist who serves as both the

program facilitator and case manager. This intervention aims to sustain the clinical benefits achieved during the initial 8-week pulmonary rehabilitation program and to promote long-term self-management and functional capacity.
No Intervention: Standard physical activity recommendations and unsupervised home exercise
The control group will receive general recommendations for physical activity and a table of exercises to be performed at home, as established in standard clinical practice. They will not receive supervised interventions; however, they will be followed during the 12 months of the study and evaluated at the same times and with the same variables as the intervention group (baseline (T0), 3 months (T1), 6 months (T2), and 12 months (T3)).

Assigned Intervention:
Behavioral: Interdisciplinary intervention.
This intervention integrates a structured, interdisciplinary educational and physical activity approach specifically designed for individuals with COPD who have completed a standard pulmonary rehabilitation program. The program is distinguished by its incorporation of six monthly educational sessions addressing key lifestyle-related topics, including sleep hygiene, nutrition based on the Mediterranean diet, smoking cessation, alcohol reduction, and clinical self-management.
In parallel, participants engage in twice-weekly exercise sessions tailored to their individual capacity, combining aerobic, strength, and functional training. Exercise intensity is prescribed based on initial functional assessments, at 50-80% of the average speed achieved in the six-minute walk test or the workload reached in an incremental cycle ergometer test. All sessions are supervised by physiotherapists and emphasize patient empowerment, behavioral change, and long-term disease management.

Intervention Type
Behavioural

Primary outcome(s)
Dyspnea will be measured using the Dyspnea-12 (D-12) questionnaire at month 12 post-baseline

Key secondary outcome(s))
1. Adherence (% attendance): Treatment adherence will be measured as the percentage of attended supervised rehabilitation sessions out of the total prescribed, using study data from baseline to month 12
2. Disease-specific Health-related Quality of Life will be measured using the COPD Assessment Test (CAT total score) at baseline, month 3, 6, and 12
3. General Health-related Quality of Life will be measured using the EQ-5D-5L index and a visual analog scale (VAS) at baseline, month 3, 6, and 12
4. Exercise Capacity will be measured using the 6-minute walk test distance (meters) at baseline, month 3, 6, and 12
5. Respiratory Function (FEV1, FVC, DLCO, % predicted) will be measured using spirometry, with results expressed as % predicted based on international reference values at baseline and month 12
6. Direct Healthcare Costs will be calculated from the healthcare provider's perspective, based on hospitalizations, unscheduled visits, and medication use. Costs will be expressed in euros (€) for 2025, measured using hospital data, from baseline to month 12
7. Quality-adjusted Life Years (QALYs) will be estimated using EQ-5D-5L utility scores and area-under-the-curve methods from baseline to month 12

8. Cost-utility Ratio: Incremental cost-utility ratios (ICURs) will be calculated by dividing incremental costs (€) by incremental QALYs gained between intervention and control groups. Bootstrapping methods will be used to account for uncertainty from baseline to month 12

Completion date
30/10/2027

Eligibility

Key inclusion criteria
1. Adults aged 40 to 75 years
2. Confirmed medical diagnosis of chronic obstructive pulmonary disease (COPD) of moderate to severe severity, based on clinical evaluation and pulmonary function testing
3. Clinically stable for at least 4 weeks following the last severe exacerbation, as confirmed by the treating pulmonologist
4. Referred to an outpatient pulmonary rehabilitation program due to persistent symptoms and a history of exacerbations, with moderate to severe dyspnea (Medical Research Council [MRC] dyspnea scale score > 2), according to physician assessment
5. Completed at least 6 out of 8 sessions of a standard 8-week initial pulmonary rehabilitation program

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Presence of medical contraindications to physical exercise, including unstable cardiovascular conditions (e.g., recent myocardial infarction, uncontrolled arrhythmias), severe musculoskeletal or neurological disorders, recent surgery, or acute medical conditions (e.g., recent stroke) that impair participation
2. Severe cognitive impairment that limits the ability to understand instructions or participate actively in the program
3. Unstable psychiatric disorders that may compromise adherence to or continuity with the exercise regimen
4. Lack of availability or refusal to attend the scheduled sessions of the community-based exercise program

5. Participation in another pulmonary rehabilitation program within the 6 months before study enrollment

Date of first enrolment
01/11/2025

Date of final enrolment
30/10/2026

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari Arnau de Vilanova i Santa Maria de Lleida
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Sponsor information

Organisation
Biomedical Research Institute of Lleida

ROR
https://ror.org/03mfyme49

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The details of the data to be shared are not yet fully defined, but we can provide the following statement:
Individual participant data (IPD) underlying published results, including de-identified data on primary and secondary outcomes, will be made available upon reasonable request from Jessica González, jegonzalez.lleida.ics@gencat.cat, jgonzalezgutierrez88@gmail.com. Data will be shared after publication of the main results, for non-commercial academic use, and upon approval of a data-sharing agreement. Supporting documents, such as the study protocol and statistical analysis plan, will also be available.

IPD sharing plan summary

Available on request