Development of a performance-based toolkit of the treatable traits of functioning in hospitalised patients with exacerbation of COPD: a survey-based study protocol

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Shareable abstract (@ERSpublications)
This protocol describes the process of developing a performance-based toolkit to assess the key treatable traits of functioning in hospitalised patients with ECOPD in order to guide the provision of individualised care https://bit.ly/3vy42YS

Cite this article as: Leonardi NT, Kawakami DMO, Cruz J, *et al*. Development of a performance-based toolkit of the treatable traits of functioning in hospitalised patients with exacerbation of COPD: a survey-based study protocol. *ERJ Open Res* 2024; 10: 00809-2023 [DOI: 10.1183/23120541.00809-2023].

Received: 25 Oct 2023
Accepted: 5 Jan 2024

Abstract

Background The management of COPD has been based on the premise of identifying problems that guide personalised treatment based on a multidimensional assessment, known as treatable traits. Exacerbation of COPD (ECOPD) results in physical and functional impairments, limitation of daily activities and negative impact on patients' quality of life and prognosis. In this context, identifying treatable traits in patients with ECOPD is essential to properly guide individualised patient care. There is a need to develop a performance-based toolkit to identify the main treatable traits of functioning in hospitalised patients with ECOPD.

Methods and analysis This is a study protocol of a survey method observational study to develop a performance-based toolkit. The study will include the following steps: 1) definition of treatable traits by both physiotherapists who provide or have provided care to hospitalised patients with ECOPD on a regular basis, and patients who have experienced at least one ECOPD which required hospitalisation; 2) selection of the most appropriate measures (markers) for each treatable trait based on established criteria and a previous systematic review; and 3) implementation of the toolkit in a pilot/feasibility study with hospitalised patients with ECOPD.

Conclusion The development of a feasible performance-based toolkit with the best markers for each key treatable trait of functioning in hospitalised patients with ECOPD will make it possible to create individualised patient care for the specific demands of these patients.

Introduction

Respiratory exacerbations are the major cause of morbidity [1] and mortality in patients with COPD [2]. A severe exacerbation [3] is associated with multifactorial insults, such as immobility, systemic inflammation, corticosteroids, reduced dietary intake, oxidative stress, catabolic/anabolic imbalance, hypoxia and hypercapnia, which may lead to hospital-associated disability [4], such as greater physical and functional impairment [5–9] and reduced quality of life [1, 10, 11].

After discharge, some patients present a natural and complete functional recovery, while others may not fully recover [4]. In this sense, these physical and functional impairments may further lead to activity limitations and participation restriction, perpetuating a vicious cycle that impacts patients' functioning levels [12]. An individualised and multidimensional assessment, identifying issues guiding a personalised

care programme, enables the identification of so-called treatable traits [13]. However, nonpharmacological interventions for extrapulmonary traits, which are included in the concept of functioning, are less clear and not well explored. This may be partially explained by a lack of knowledge of the key extrapulmonary traits in patients with ECOPD, and the best measures to assess them [14, 15].

Although some performance-based measures have been developed to assess functioning of hospitalised patients, such as Physical Function in Intensive Care measure (PFIT) [16], the de Morton Mobility Index (DEMMI) [17] and the Short Physical Performance Balance (SPPB) test [18], these measures do not consider the specific demands of hospitalised patients with ECOPD.

Therefore, there is an evident and important need to define the main treatable traits of functioning in hospitalised patients with ECOPD to support individualised patient care plans [19].

Objectives

The main goal of this study is to develop a performance-based toolkit to assess the main treatable traits of functioning in hospitalised patients with ECOPD and to test its feasibility. To achieve this, we outlined the following specific objectives: 1) define which treatable traits of functioning are most relevant for assessment in hospitalised patients with ECOPD, according to professionals' and patients' perspectives; 2) develop a performance-based toolkit containing measures that assess the previously defined treatable traits; and 3) assess the feasibility of the new performance-based toolkit in hospitalised patients with ECOPD.

Methods

Study design

This is the study protocol of a survey method observational study to develop a performance-based toolkit to assess the main treatable traits of functioning in hospitalised patients with ECOPD. The stages of the process were adapted from De Vet *et al.* [20]: 1) definition of treatable traits to be included in the toolkit, by physiotherapists and patients; 2) selection of markers to assess each treatable trait included in the toolkit; and 3) toolkit feasibility testing. (figure 1) The treatable traits to be evaluated will be based on the functioning categories of Body functions and Activities, according to International Classification of Functioning, Disability and Health (ICF) definitions (table 1) [14]. The study was approved by the Research Ethics Committee of the Federal University of São Carlos (process number 55298722.0.0000.5504).

Stage 1: Definition of treatable traits

Treatable traits will be defined from the perspectives of physiotherapists through an online survey, and by interviewing patients with COPD to guarantee the defined treatable traits are relevant for all end-users of the performance-based assessment toolkit. The design and implementation of the survey will be conducted according to the Consensus-Based Checklist for Reporting of Survey Studies (CROSS) guidelines and is briefly described in the following sections [21].

Stage 1a: Physiotherapists

At this stage, a survey will be answered by physiotherapists who provide or have provided care to hospitalised patients with ECOPD on a regular basis. Eligibility criteria are described in table 2. The survey will be distributed in different countries, in both Portuguese and English, to define the most relevant treatable traits of functioning to be assessed in these patients. The first part of the survey will contain information about the study and the written informed consent request. The second part will consist of data collection for sample characterisation: age, sex, country and professional training, and workplace, without any personal identification. A third part will ask participants to rate the degree of relevance of the treatable traits to be assessed in hospitalised patients with ECOPD, using ICF codes and definitions. Treatable traits were chosen according to the functioning categories of the ICF framework (figure 1) and a systematic review carried out previously by Leonardi *et al.* [22]. Participants will be asked to rate each treatable trait on a scale from 0 to 10, when 0 is "not relevant at all" and 10 is "extremely relevant" (supplementary material box S1). The survey has already been organised in the Research Electronic Data Capture (REDCap) electronic data capture tools hosted at EBSERH (Empresa Brasileira de Serviços Hospitalares), Brazil. It will be maximally distributed among international colleagues, and sent directly to physiotherapists working in clinical practice, research centres and societies related to the area through e-mail and social networks. In consideration of the difficulty of reaching a representative sample of physiotherapists around the world, we will make the survey available for 3 months and collect as many responses as possible.

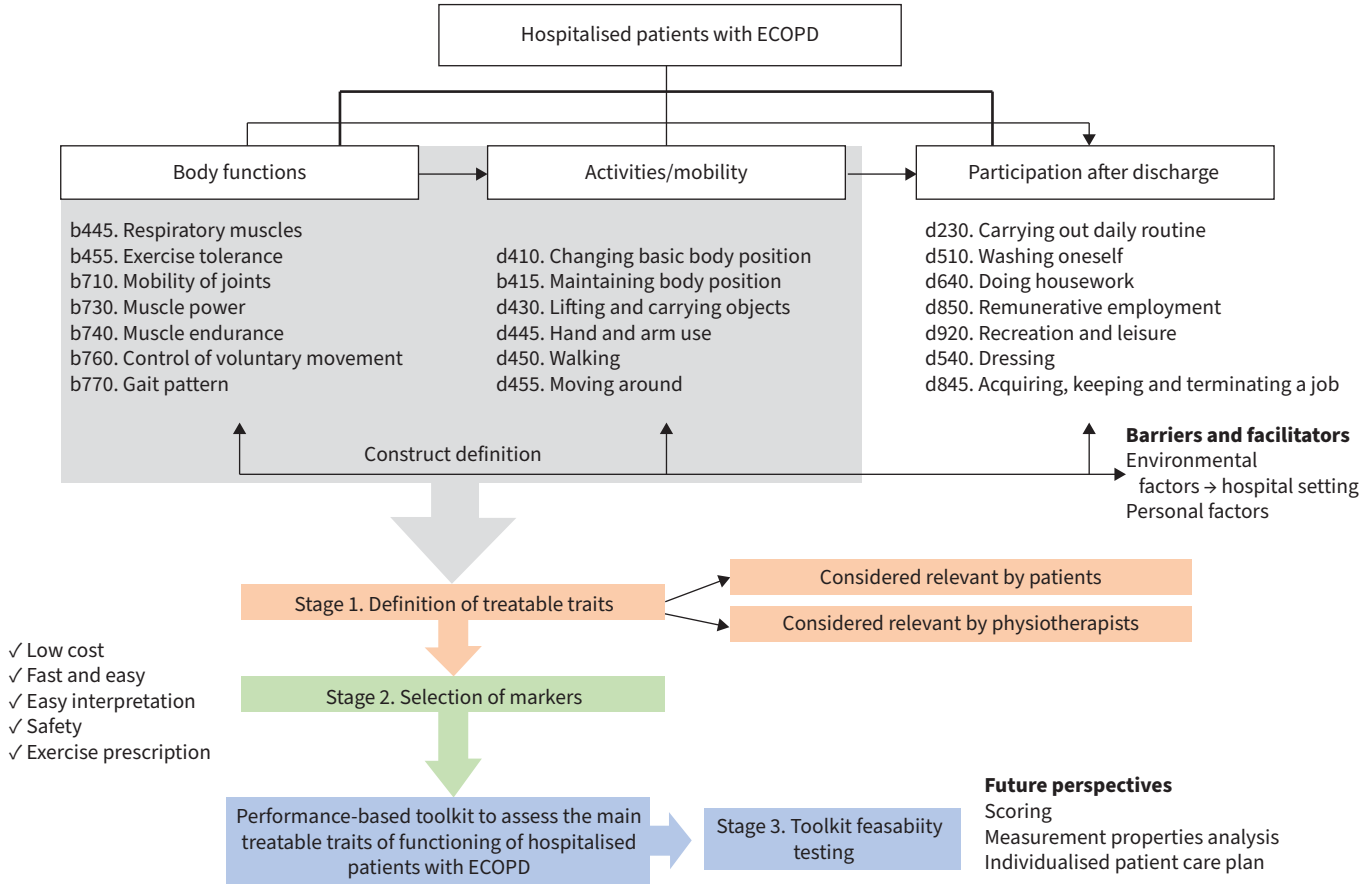

FIGURE 1 Performance-based toolkit development process based on de Vet *et al.* [20], with categories taken from International Classification of Functioning, Disability and Health (ICF) definitions [14] and Leonardi *et al.* [22]. ECOPD: exacerbation of COPD.

Stage 1b: Patients

At this stage, a small interview will be conducted with individuals with COPD who have already experienced at least one hospitalisation for an ECOPD. Patients with severe musculoskeletal or neurological impairments, or with no cognitive capacity to answer the questions, will be excluded. Eligibility criteria are detailed in table 2. Brazilian patients, from the database of the Laboratory of Cardiopulmonary Physical Therapy at the Federal University of São Carlos, Brazil (LACAP – UFSCar), who meet the inclusion and exclusion criteria will be invited to participate. Participants will all sign informed consent forms. The interview will be prepared in Portuguese using closed questions and will be saved in the REDCap electronic data capture tools hosted at EBSERH, Brazil. The interview will elicit data on: characterisation measures; history of previous exacerbations; dyspnoea, using the modified Medical

TABLE 1 Definition of terms used for constructs, components and categories

Construct	Parts and components		Parts and components	
	Functioning	An umbrella term for body function, body structures, activities and participation	Disability	An umbrella term for impairments, activity limitations and participation restrictions
Change in body function	Body function	The physiological functions of the body	Impairment	Problems in body function such as significant deviation or loss
Capacity	Activity	The execution of a task or action by an individual	Limitation	Difficulties an individual may have in executing activities
Performance	Participation	Involvement in a life situation	Restriction	Problems an individual may experience in involvement in life situations

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TABLE 2 Eligibility criteria

Inclusion criteria	Exclusion criteria
Stage 1a	
Physiotherapist who:	Participants who did not:
Provides or has provided care to hospitalised patients with ECOPD on a regular basis	Complete the questionnaire properly
Is age >18 years	Answer personal characteristics
Is able to read and answer questions in English or Portuguese	Judge the relevance of functioning treatable traits
Stage 1b	
Individuals with COPD according to GOLD criteria	Individuals who already have functioning impairments as a result of severe musculoskeletal or neurological diseases
Individuals who had already experienced at least one hospitalisation for an ECOPD	Individuals with no cognitive capacity to answer the questions, according to clinician assessment and presence of reported neurological diseases
Individuals who are aged >18 years	
Individuals who are able to give informed consent for participation	
Stage 3	
Hospitalised patients with ECOPD	Individuals with severe musculoskeletal or neurological diseases
Clinical diagnosis of ECOPD assessed by a physician according to GOLD criteria	Individuals with no cognitive capacity to answer the questions, according to clinician assessment and presence of reported neurological diseases
Aged >18 years	Individuals with respiratory diseases other than COPD
Able to give informed consent for participation	Individuals on mechanical ventilation
24–48 h of admission	Individuals taking vasoactive drugs
Clinically stable:	Individuals with haemodynamic instability
Mean arterial pressure >65 and <110 mmHg	Individuals with unstable angina
Heart rate >40 and <130 bpm	Individuals with a history of myocardial infarction in the last 6 months
S_{pO_2} >88%, and respiratory rate >5 and <40 bpm	Individuals with a FEV_1/FVC ratio >0.70 on spirometry for staging after 1 month
F_{IO_2} <60%	
Dyspnoea and fatigue ⩽5 assessed by the modified Borg scale	

ECOPD: COPD exacerbation; GOLD: Global Initiative for Chronic Obstructive Lung Disease; S_{pO_2}: peripheral oxygen saturation; F_{IO_2}: inspiratory oxygen fraction; FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity.

Research Council (mMRC) Dyspnoea Scale; and functioning, using the Functional Independence Measure (FIM). Interviews will be conducted in person by the research team and responses will be recorded in written form. Patients will judge the relevance of the treatable traits in the same way as described in Stage 1a for physiotherapists. Questions related to the ICF categories in Portuguese will be adapted to facilitate their interpretation, maintaining conceptual equivalence. Prior to data collection, patients will be consulted to evaluate the clarity of the questions (supplementary material box S2). Likewise, as there is no consensus on the ideal number of interviews, we will define a period for data collection of 4 months, with a convenience sample.

Dissemination and recruitment

The survey is organised in the REDCap electronic data capture tool and will be distributed to physiotherapists *via* a link online and disseminated using social networks, such as Instagram, Facebook and Twitter, in snowball sampling around the world. To maximise the dissemination, the survey will also be sent directly by e-mail to the authors' networks of physiotherapists and researchers, and to international research centres and societies. Patients from LACAP – UFSCar will be contacted by phone and invited to participate in Stage 1b. If a patient consents to participate verbally, an in-person interview appointment will be scheduled.

Stage 2: Selection of markers

The systematic review by Leonardi *et al.* [22] conducted following COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) recommendations [23–25], summarises the performance-based measures applied in hospitalised patients with ECOPD, with measurement properties tested to this population. The findings from the review will be used to recommend the markers that have already been tested for this specific population to make up the performance-based toolkit. To generate the

first version of the performance-based toolkit, with the treatable traits and their markers, the authors will reach a consensus based on this systematic review and the following criteria, adapted from DE MORTON *et al.* [26]:

- Low cost and requiring minimal or no equipment
- Fast, and easily administered in a hospital setting
- Easy to interpret
- Administered based on observation of a patient's function and ability
- Safe to use on patients with an acute condition
- Useful for exercise prescription

If there are no markers with sufficient measurement properties for the target population that correspond to the functioning treatable traits included, the authors will achieve a consensus on which measure is most suitable considering the criteria previously mentioned.

Stage 3: Toolkit feasibility testing

The functioning performance-based toolkit will be applied once to 15 hospitalised patients with ECOPD to assess its feasibility [20]. Patients admitted to the University Hospital of São Carlos (HU-UFSCar), São Carlos, Brazil, and Santa Casa Hospital, São Carlos, Brazil, with clinical diagnoses of ECOPD assessed by a physician according to the GOLD (Global Initiative for Chronic Obstructive Lung Disease) criteria will be invited to participate by the researcher. Investigators will ensure they meet the eligibility criteria. Patients with severe musculoskeletal or neurological impairments or no cognitive capacity to answer the questions, respiratory diseases other than COPD, patients on mechanical ventilation or vasoactive drugs, patients with haemodynamic instability, unstable angina, or myocardial infarction history in the last 6 months will be excluded. Eligibility criteria are in detail described in table 2. Those willing to participate will be invited by the research team to sign the informed consent before data collection. Hospital physiotherapists will be asked to deliver the assessments to eligible patients and will receive prior training; data analysis will be performed by the research team. Assessment of functioning using the toolkit will be performed within 24–48 h of hospital admission, when the patient is in a clinically stable condition: mean arterial pressure >65 and <110 mmHg; heart rate >40 and <130 bpm; peripheral oxygen saturation (S_{pO_2}) >88%, respiratory rate >5 and <40 bpm; inspiratory oxygen fraction (F_{IO_2}) <60%, dyspnoea and fatigue ⩽5 assessed by the modified Borg scale [27]. Clinical data will be collected for sample characterisation, including age, sex, body mass index (BMI), oxygen therapy and the mMRC Dyspnoea Scale.

Patients with no recent spirometry data (<1 year prior to inclusion) will be invited to be tested 1 month after discharge at UFSCar cardiopulmonary physiotherapy laboratory, to ensure patients' clinical stability [3], to stage the disease. Three forced, acceptable and reproducible manoeuvres will be performed and repeated 20 min after the inhalation of 400 µg of salbutamol according to the American Thoracic Society/European Respiratory Society guidelines [28] using a previously calibrated spirometer (CPFS/S, Medical Graphics, Saint Paul, MN, United States). Forced expiratory volume in 1 s (FEV_1), forced vital capacity (FVC), and FEV_1/FVC ratio will be obtained and the results compared with those predicted by PEREIRA *et al.* [29]. Patients included will have a clinical or spirometric diagnosis prior inclusion according to the GOLD guideline. However, patients with a FEV_1/FVC ratio >0.70 on spirometry after 1 month will be excluded.

Safety monitoring

Adverse effects such as dizziness, nausea, palpitation, chest pain, dyspnoea greater than or equal to 6 or S_{pO_2} >88% will be monitored and recorded to be used as interruption criteria [30].

Outcome measures

The outcomes identified in Stage 1 by professionals and patients will be considered as the most relevant treatable traits of functioning to be assessed in hospitalised patients with ECOPD. Then, in Stage 2, the outcomes will compose the performance-based toolkit containing measures aimed at assessing the previously defined treatable traits. Lastly, the feasibility of the performance-based toolkit will be assessed by collecting information on its implementation in a hospital-based context, specifically the completion time, patient's and clinician's understanding of the tests, patients' safety requirements (dyspnoea and fatigue, using the modified Borg scale, heart rate, respiratory rate and blood pressure after the tests), number of patients who completed the whole assessment, relevance of the assessment for the physiotherapist, patients' perception of their limitations in a particular trait, and the number of patients who refuse to continue the assessment and the reason for refusal [23–25] (table 3).

TABLE 3 Outcomes and measures included in the feasibility study

Outcome	Contributing	Measure	Acceptability criteria
Comprehensibility	Patient and clinician	Likert scale 0–10 (0: not understandable; 10: easily understandable)	>80% responses 7–10
Ease of administration	Clinician	Likert scale 0–10 (0: not easy; 10: extremely easy)	>80% responses 7–10
Length of toolkit implementation	Clinician	Time (mins) Likert scale (0: unfeasible time for clinical practice; 10: feasible time for clinical practice)	>80% responses 7–10
Patient's safety requirements	Patient and clinician	Dyspnoea and fatigue Borg scale; S_{pO_2}	Borg: >80% of patients with less than or equal to 6; S_{pO_2}: >88% or a drop of <4% during assessment
Relevance of assessments	Clinician	Likert scale 0–10 (0: not relevant; 10: extremely relevant)	>80% responses 7–10
Patient's perception of their limitations	Patient	Likert scale 0–10	Correlate with results of the instrument
Adverse events	Clinician	Dizziness, nausea, palpitation, chest pain	<10% of patients

S_{pO_2}: peripheral oxygen saturation.

Data management

The survey designed for physiotherapists (Stage 1a) has already been organised in the REDCap electronic data capture tools hosted at EBSERH, Brazil. The data will be anonymised by an individual identification number and exported to an Excel spreadsheet for further analysis. Both patient interview data (Stage 1b) and feasibility data (Stage 3) will be collected physically in a specific Case Report Form by a researcher or trained physiotherapist. The patients' data will be exported to an Excel spreadsheet, with double checking for subsequent analysis. The data will be confidential, being identified by an ID number that will be kept confidential in the database of the Federal University of São Carlos under the care of the researcher responsible for the study (R.G. Mendes).

Statistical analysis

Statistical analysis will be performed using Statistical Package for Social Sciences (version 20.0, IBM SPSS, Armonk, NY, United States). Continuous variables will be expressed as mean±SD or median (interquartile range) and categorical variables will be defined in number (percentages). Shapiro-Wilk tests will be applied to verify the normality of data distribution. The judgement of the treatable traits of functioning from physical therapists and patients will be analysed by the percentage of individuals who judged as the traits as relevant. This will be calculated as the number of professionals/patients who judged the category with a relevance greater than or equal to 7 divided by the total number of professionals or patients × 100, according to the following criteria [31]:

- Included: more than 70% of participants assigning a relevance of greater than or equal to 7
- Excluded: fewer than 50% of participants assigning a relevance of greater than or equal to 7
- No consensus: items that do not fit the inclusion or exclusion will be discussed by the authors

The final list of treatable traits of functioning will be reviewed by the authors who will reach a final consensus on the relevant treatable traits to compose the toolkit. Feasibility data will be analysed qualitatively and quantitatively, considering the outcomes proposed and the acceptability criteria (table 3).

Discussion

To our knowledge, this is the first study to develop a performance-based toolkit to assess the main treatable traits of functioning in hospitalised patients with ECOPD. Given the clinical relevance of functioning in these patients, and its ability to be identifiable, measurable and treatable [19], it is essential to develop a toolkit to assess the main functioning traits with good quality and to adequately measure patients' impairments and limitations during and after an ECOPD. To achieve this, it is important to involve patients and the public, which has a potential benefit that the protocol will represents people with lived experiences [32] and will ensure the research is relevant and reflect the needs of those affected.

In this context, a previous systematic review by Oliveira and Marques [33] identified the most frequent outcome measures in patients with ECOPD. The authors outlined measures to assess functional exercise capacity, such as the 6-min walk test and the incremental shuttle walk test, maximal inspiratory pressure and the maximum voluntary contraction of the quadriceps to assess respiratory and lower limb muscle strength. However, the measurement properties of the measures and the heterogeneity of the functioning outcome measures, essential aspects to properly guide the practical decision, are still not clear. Meanwhile, recent studies [34, 35] have established a consensus of measures necessary for patients with ECOPD for a multidimensional assessment, including measures of muscle strength and walking capacity. However, there is no consensus among studies on the inclusion of these functioning outcome measures in this target population.

There are still some questions to be answered and that we intend to answer with this study, including: Which treatable traits of functioning are important to assess in hospitalised patients with ECOPD? and Which markers to use to adequately assess the functioning of these patients? Findings from this study will enable the development of an assessment toolkit which may be useful to define individualised care plans for patients with ECOPD, tailored to their specific functioning needs. If this toolkit proves to be feasible for application in the target population, it will be possible to proceed with the next analyses of measurement and prognostic properties. Otherwise, adjustments to the toolkit and a new feasibility test will be necessary [20].

Conclusion

The development of a feasible performance-based toolkit with the best markers to assess the key treatable traits of functioning in hospitalised patients with ECOPD will be important to identify their impairments and limitations and guide an individualised care plan for these patients.

Provenance: Submitted article, peer reviewed.

Acknowledgements: We would like to express in advance our appreciation to the patients who will participate in the study. We thank the University Hospital of University Federal of São Carlos (HU-UFSCar) Brazilian Company of Hospital Services (EBSERH). J. Cruz acknowledges the support of the Center for Innovative Care and Health Technology (ciTechCare), funded by Portuguese national funds provided by Fundação para a Ciência e Tecnologia (FCT) (UIDB/05704/2020).

Ethics statement: The study was approved by the Research Ethics Committee of the Federal University of São Carlos (process number 55298722.0.0000.5504).

Conflict of interest: N.T. Leonardi reports support for the present manuscript from FAPESP (São Paulo Research Foundation), and support for attending meetings and/or travel from FAPESP outside the submitted work. D.M.O. Kawakami reports support for the present manuscript from FAPESP (São Paulo Research Foundation), and support for attending meetings and/or travel from FAPESP outside the submitted work. J. Cruz reports receiving support to attend the European Respiratory Society Congress 2022 as the representative of the Early Career Members of Assembly 9 and is a member of the editorial board of *ERJ Open Research* (unpaid). C. Burtin has nothing to disclose. A. Borghi-Silva reports support for the present manuscript from FAPESP (São Paulo Research Foundation), and support for attending meetings and/or travel from FAPESP outside the submitted work. R.G. Mendes reports support for the present manuscript from FAPESP (São Paulo Research Foundation), and support for attending meetings and/or travel from FAPESP outside the submitted work.

Support statement: This study is supported by Fundação de Apoio à Pesquisa do Estado de São Paulo (numbers process: 2015/12763-4; 2015/26501-1 (Project grant); 2021/03493-4 (NTL scholarship)). The funding source had no involvement in this analysis or in the writing of this manuscript. Funding information for this article has been deposited with the Crossref Funder Registry.

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