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Quantitative analysis of postural control of individuals with COPD during activities of daily living (ATTRACTION) : a study protocol

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a common respiratory disease which is associated with the presence of numerous comorbidities. Among these, impaired postural control has been reported to be common. However, postural control has not been extensively studied in tasks of daily living, in this population. Novel solutions for postural control assessment exist, like the quantitative motion analysis, which has shown to be a robust and accurate tool. **Objective**: The main aim of this study is to characterise the postural control of individuals with COPD during tasks of daily living compared to the postural control of control subjects, using quantitative motion analysis. The secondary aims of this study are to examine the associations between postural control variables of interest and various clinical factors and to investigate the utility of the modified Glittre-ADL for the clinical assessment of postural control in daily tasks. **Method**: A case-control study will be conducted with sixteen individuals with COPD and a control group (n = 16). Quantitative movement analysis will be used to assess postural control during a modified test (incorporating tasks of daily living) and timed-up-and-go test (normal and dual-task conditions). Clinical factors (e.g., dyspnoea, pain, inspiratory muscle strength, falls, fear of falling, etc.) will also be assessed. **Discussion**: ATTRACTION will be the first study to propose the assessment of postural control in various daily living tasks in individuals with COPD using quantitative movement analysis and has the potential to precise the relationship between postural control and several clinical factors.

Trial registration: ATTRACTION study was registered on ClinicalTrials.gov under the number **NCT05211674**

KEYWORDS: chronic obstructive pulmonary disease, physical examination, postural balance, rehabilitation

Background

Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable and treatable condition by persistent respiratory symptoms and airflow limitation due to damage to the airways and/or lung alveoli [1]. According to the World Health Organization (WHO), this disease was the third leading cause of death worldwide in 2019 [2]. COPD therefore represents a major public health problem, and its socio-economic impact is significant [3]. Beyond the presence of respiratory symptoms, the evolution of COPD is also associated with the presence of comorbidities [4]. According to Putcha et al. 86 to 98% of individuals with COPD have at least one comorbidity and about 50% of patients have four or more comorbidities [5]. The presence of these comorbidities is associated with worsened quality of life and increased morbidity and mortality [6]. Among these non-respiratory alterations, previous research has pointed out that postural control could be considered as another comorbidity in

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patients with COPD [7].

Postural control is an essential human system, which allows to manage the body's position in the space for the dual purposes of stability and orientation [8]. During the last fifteen years, important scientific work has been carried out evaluating postural control in individuals with COPD and three systematic reviews have been published on this topic [9, 10, 11]. These systematic reviews highlight several points: the postural control of individuals with COPD is impaired compared to healthy control subjects; this impairment has been demonstrated by laboratory-based tests and through several validated functional tests for postural control assessment [10, 11]. It appears that the severity of the disease is not associated with postural control abilities and that this impairment can be present in individuals regardless of disease severity [11, 12, 13]. The prevalence of impaired postural control also appears to be similar between women and men [11, 12, 13, 14]. Moreover, impairments in postural control also have consequences for the individual by increasing the risk of falls [15] and is associated with greater restrictions in activity and participation according to the International Classification of Health Functioning and Disability [13].

Thus, postural control is a complex system [16] and COPD involves a broad spectrum of pathophysiological impairments [17]. Several domains have been suggested as avenues to better understand the origins of postural control changes in COPD (e.g. morphostatic characteristics, muscular function, cognitive function, pain or dyspnoea) [11, 18, 19, 20, 21]. However, the underlying mechanisms of postural control impairments currently remain unknown [11]. Postural control assessments of individuals with COPD have largely been performed in static situations, and infrequently during tasks of daily living [10]. Yet, these tasks are central to the lives of individuals and are often difficult to perform [22]. An "ecological" assessment (in the sense of being closer to real-life situations) [23] would allow the identification of possible alternative movement strategies used by individuals with COPD and to specify the participation of postural control on the impact in activities of daily living.

Primary aim

The main aim of this study is to objectively characterise the postural control of individuals with COPD during tasks of daily living compared to that of control individuals using quantitative movement analysis.

Secondary aims

The secondary aims of this study are:

- To examine the associations between postural control variables of interest and various clinical factors.
- To investigate the utility of the modified Glittre-ADL for the clinical assessment of postural control in tasks of daily living.

Methods

Study design and settings

ATTRACTION is an observational case-control study comparing individuals with with moderate to severe COPD to healthy control individuals. This study was developed at the Mouvement Sport Santé (M2S) laboratory of the University of Rennes 2, which is also the promotor of the study. The Pontchaillou University Hospital of Rennes is a partner in this research conducted at M2S laboratory facilities (Campus de Kerlann, Bruz, France).

Participants

This study aims to compare individuals with COPD to age and sex-matched control individuals. The eligibility criteria both populations are presented in Tables 1 and 2, respectively.

Recruitment

Recruitment will be carried out prospectively. For individuals with COPD, participation in the study is proposed to individuals followed up by a pulmonologist at the University Hospital of Pontchaillou (Rennes, France) if they meet the inclusion/exclusion criteria established for this study. If the person is interested in participating in the study, they receive oral information, an information letter, and explications from the investigator. After a time of reflection, if they agree to participate, written consent is obtained. The potential participant is then contacted by telephone by an M2S laboratory investigator (RP) and an appointment is made for the experimental part of the protocol. The recruitment of the control individuals will be carried out after the recruitment of the individuals with COPD. Matching of the two groups will be performed according to age and sex ratio. Therefore, a frequency-matching method will be used to recruit the healthy control participants [24]. Briefly, this method consists of identifying the characteristics of interest in the source sample (in this case age and sex) and calculating their frequency of occurrence according to defined classes (e.g. male/female) and recruiting the healthy participants according to the results. This method allows better control of confounding factors [24]. A recruitment campaign will be carried out for recruitment of control participants using posters, mailing lists and social networks. An information sheet, summarizing the main points of the study and indicating the contact details of one of the investigators will be distributed.

Experimental protocol

The experimental part of the study will follow these different parts: reception of the participant, information, and presentation of facilities; general data collection; quantitative analysis of postural control and questionnaires.

Quantitative analysis of postural control

The assessment of postural control can be performed in different ways (with simple or composite functional tests, on force platforms…) but quantitative movement analysis appears to be one of the most accurate and robust techniques in the field [25]. This analysis allows the quantification of biomechanical and physiological parameters to objectively characterize human movements [26]. Quantitative movement analysis has been increasingly employed with success in athletes [27, 28] and in various neurological conditions [29, 30].

The procedure for the quantitative analysis of postural control begins with equipping the participant: 44 reflective markers are placed on the bone landmarks according to the recommendations of the International Society of Biomechanics [31, 32] (Figure 1). A heart rate belt (Polar H9, Kempele, Finland) and a pulse oximeter (Checkme O2, Viatom Technology, Shenzen, China) are placed on the participant. After calibration of the system, the quantified analysis of postural control begins with a thirty-second period where the participant is asked to stand with eyes open. Then, functional tests are carried out by the participant: first, two timed up and go tests (TUG) are performed in two different conditions, in a randomized order (the randomization is performed using Random.org). A TUG will be performed with standard instructions ("perform the test at a normal speed for you, as if you were at home") (normal TUG) and an alternative TUG (cognitive TUG) will be performed with an added cognitive task (counting backwards out loud by 3's starting from 100). These two tests have been validated in healthy and COPD populations [33, 34, 35].

Lastly, the daily living tasks test (a modified and shortened version of the Glittre-ADL test) will be performed. The Glittre-ADL is a field test, developed to assess the functional abilities of individuals with COPD during tasks encountered in their daily lives [36]. It presents clinical assessment validity and its metrological qualities are well documented [37]. For experimental feasibility reasons, we propose here a shortened

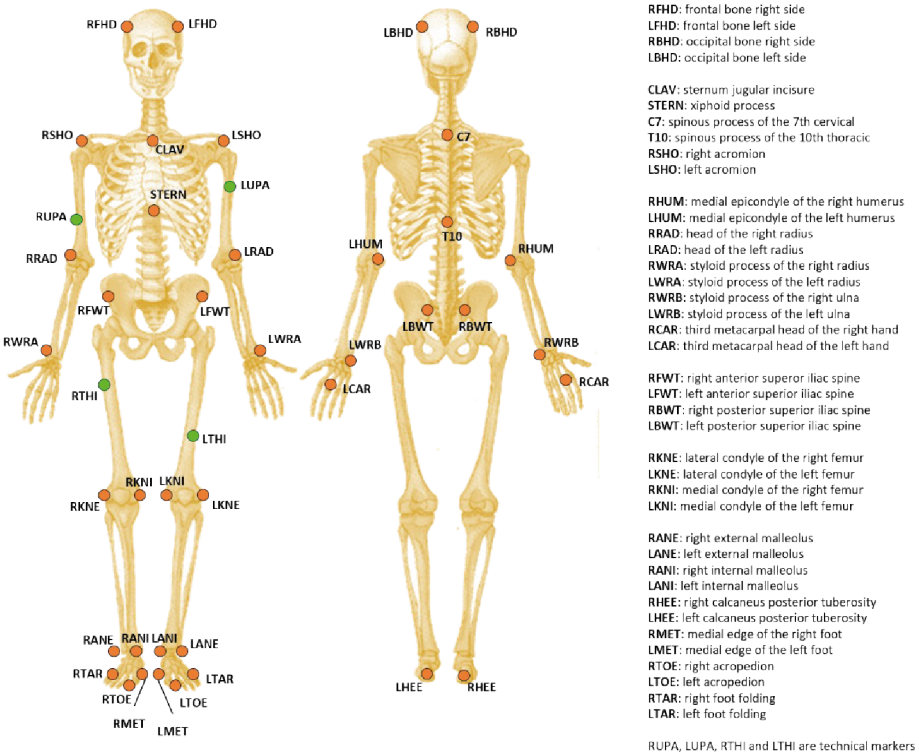

Figure 1 Marker set employed in ATTRACTION study.

version (3 laps instead of 5) and without a backpack. These modifications have been previously validated in individuals with COPD [38, 39]. The test is presented in Figure 2: at the beginning of the test, the participant is sitting on a chair with both feet on the force platform. The individual is asked to get up from the chair, walk in a straight line (10m), go up and down two steps and then stand in front of a shelf. The participant then moves three objects (each weighing 1 kg) from the shelf at shoulder height to a shelf at hip height, then to the floor and then moves the three objects back to the shelf at hip height and then to the shelf at shoulder height. Finally, the participant returns to the chair, taking the same route as before. This circuit is repeated three times. The participants will be instructed to perform the test "at their comfort speed, as if they were at home".

Participants will also be asked to respect a rest time between the two TUGs and between the last TUG and the modified Glittre-ADL. The duration of the rest time is adapted to allow a return of the participant's feeling (perceived intensity of dyspnoea) and vital signs (heart rate, oxygen saturation) to baseline values.

Outcomes

Primary outcomes

The primary outcomes of the study are Centre of Mass-related (CoM) parameters (margins of stability, variability of margins of stability, CoM velocity, CoM displacement) during functional tests (modified Glittre-ADL and Timed up and Go tests (TUG)). These parameters represent valid and reliable postural control variables, already employed in various populations [25] and in individuals with COPD [40].

Secondary outcomes

1. Other postural control-related outcomes

(a) Center of pressure (CoP)-related parameters: CoP area, CoP velocity, CoP variability and coefficient of variation of participant's CoP will be evaluated during the sit-to-stand and stand-to-sit tasks of the modified Glittre-ADL test. CoP parameters have been reported to be valid and reliable in older adults [41] and have been used in COPD in several studies [14, 19, 42].

(b) Evolution of articular angulations: Articular angulations at the ankle, knee, hip, spine, and thoracic level will be assessed during the functional tests.

(c) Gait-related parameters: Gait cadence, gait velocity, gait phases duration, step width, step length, spatio-temporal parameters of gait will be assessed during the walking part of the modified Glittre-ADL test. The reliability of these parameters using three-dimensional quantitative movement analysis is high [25] and has already been successfully carried out with individuals with COPD [43].

(d) Ground force reaction (GRF): The GRF will be assessed during the sit-to-stand task of the modified Glittre-ADL test using the force platform. Assessment of GRF using a force platform has demonstrated its reliability during this task [44]. Previous research has shown that GRF during sit-to-stand reflects lower limb muscle strength [45, 46].

2. Functional performance

(a) Completion time of the Modified Glittre-ADL. While the initial version of the Glittre-ADL has been validated and shows interesting psychometric qualities [36], the version proposed in this study is novel.

(b) Completion time of the normal and the cognitive timed up and go tests (TUGs). The reliability and the validity of the normal TUG has been demonstrated in individuals with COPD [47, 34]. The cognitive TUG has been previously used in individuals with COPD and demonstrated its validity [35, 48].

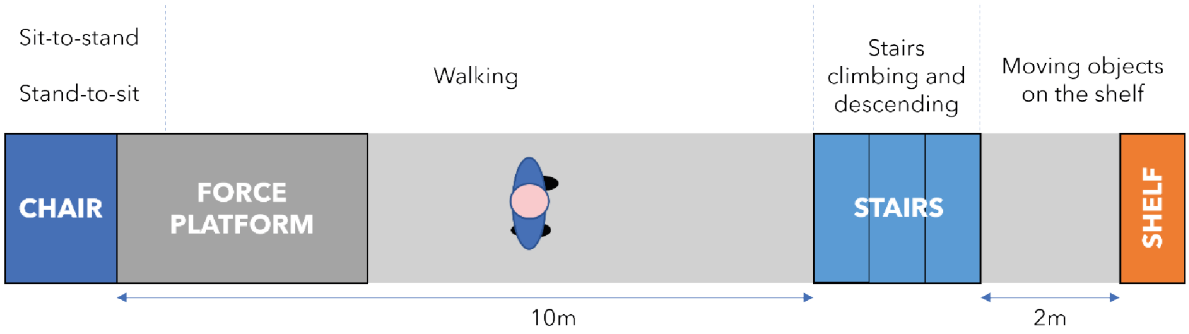

Figure 2 Representation of the modified Glittre-ADL.

3. Dyspnoea

(a) Multi-dimensional dyspnoea profile (MDP): the MDP is a composite tool that assesses the affective and sensory dimension of dyspnoea related to an activity [49]. The MDP is separated into three different scales ("A1" and "A2" focus on the affective dimension of the dyspnoea and "QS", the sensory dimension of the dyspnoea). In this study, participants complete the MDP at the end of the modified Glittre-ADL test. A higher score in the different scales represents a larger impact of their dyspnoea. The MDP has been reported to be a valid and reliable tool in individuals with COPD [50]. The minimal clinically important differences (MCID) are estimated to be 0.8, 2.4 and 4.6 for the A1, A2 and QS scores, respectively [51].

(b) London Chest Activities of Daily Living questionnaire (LCADL): The LCADL is a tool designed to assessed the impact of dyspnoea in fifteen activities of daily living in individuals with COPD [52]. A score from 0 to 5 is given for each activity, 5 representing a higher impact of dyspnoea on the activity. The LCADL is a valid and reliable tool [52, 53], and its minimal detectable change (MDC) is four points [54].

(c) Numeric rating Scale (NRS): the intensity of dyspnoea will be assessed before and after the modified Glittre-ADL test using a NRS. The NRS is a zero to ten scale where zero represents the absence of dyspnoea and ten, the worst imaginable dyspnoea for the participant [55]. The NRS a is valid and reliable tool for assessing dyspnoea in individuals with COPD [55]. The MCID of the NRS for dyspnoea is estimated to be four points [55].

4. Inspiratory muscle strength

Inspiratory muscle strength will be assessed by evaluating maximal inspiratory pressure (MIP). The MIP is obtained by performing 3 to 5 maximal tests, in accordance with current guidelines [56]. The best value of these 3 to 5 tests is selected as the individual's MIP. This assessment has been validated in individuals with COPD and repeatable and reliable measurements can usually be obtained within 5 efforts [56]. The MCID for MIP is estimated to be 17 cmH2O [57].

5. Pain

(a) Visual analogue scale (VAS): the intensity of pain is assessed using the VAS on a 100 mm line scored from 0 to 100 to rate the intensity of pain. Three different measurements will be made to assess: (i) the current intensity of pain, (ii) the average intensity of pain over the preceding eight days and (iii) the most intense pain experienced over the preceding eight days. A VAS is a valid, reliable and widely employed measure for assessing pain intensity across numerous conditions [58, 59].

(b) Pain drawing: participants will be asked to represent their usual pain location on a body chart. Pain drawing is a valid and reliable method for pain assessment [60].

6. Body composition

Bioelectrical-impedance analysis (BIA) will be performed to assess body composition [61]. Body mass-index (BMI) and fat-free mass index (FFMI) will be extracted from the BIA assessment. The assessment of these parameters using BIA has been previously validated, and is recommended by international guidelines on pulmonary rehabilitation [62].

7. Falls and fear of falling

(a) Fall history: Participants are asked to report falls in the twelve month period prior to inclusion in the study. The number of past fall(s) and the context will be recorded.

(b) Fear of falling: The fear of falling will be evaluated using the Fall Efficacy Scale-International (FES-I) [63]. The FES-I is a self-administered questionnaire designed to assess the fear of falling. It consists of 16 items, scored from 1 to 4 by the participant. The total score is therefore between 16 and 64 points. A high score indicates a high fear of falling. The FES-I has shown reliability and validity in various populations with postural control disorders [64].

8. Physical activity and sedentary behaviour

Physical activity and sedentary behaviour will be assessed using the French version of the International Physical Activity Questionnaire (IPAQ) [65, 66]. The IPAQ is a questionnaire exploring four different domains (vigorous physical activities, moderate physical activities, walking and sedentary behaviour). The IPAQ has reasonable measurement properties for monitoring levels of physical activity among adults in diverse settings [67].

9. COPD-related quality of life

The COPD assessment test (CAT) will be used to assess quality of life [68]. The CAT comprises of 8 items, each item is scored on a 1 to 5 point scale. CAT scores range from 0–40 where higher scores correspond to a more severe impact of COPD on an individual's life. The CAT has shown to be reliable and valid and its MCID is estimated to be between two to three points [69, 70].

10. Cognitive abilities

The assessment of cognitive function will be performed using the General Practitioner-Cognitive test (GPCog) [71]. The GPCog is a simple questionnaire developed for the detection of cognitive dysfunction in clinical practice and has been translated and validated in French [72].

Table 1 Eligibility criteria for individuals with COPD and controls

	INTERVENTION GROUP	CONTROLS
	Inclusion criteria	
1	Individuals with a confirmed diagnosis of COPD according to GOLD criteria (Forced Expiratory Volume in one second (FEV1)/Forced Vital Capacity (FVC) < 0.7) and with GOLD stage 2 or 3 (A-D)	Person with no medically diagnosed chronic pathology and corresponding to the age and male-female ratio characteristics of the individuals with COPD group (for further details on frequency-matching see recruitment)
2	In accordance with article L1121-8-1 of the French public health code, participants must be affiliated to a social security scheme or be beneficiaries of such a scheme	
3		Person presenting a certificate of non-contraindication to the practice of physical activity
	Non-Inclusion criteria	
1	Presence of a medically diagnosed pathology resulting in overt balance disorders	
2	Inability to walk 150 m without stopping and inability to climb or descend stairs	
3	Presence of obvious cognitive impairments that prevents adequate understanding of instructions	
4	History of pneumonectomy or lobectomy within the last six months	
5	Person referred to in articles L. 1121-5 to L. 1121-8 and L. 1121-12 of the French public health code[1]	
6	Person under psychiatric care	
7	Body mass index less than 21 or more than 35 kg/m²	
8	Existence of an acute respiratory exacerbation within the last two months	
9	Presence of long-term or exercise-based oxygen therapy	

[1] pregnant woman, woman in labor or nursing mother, person deprived of liberty by judicial or administrative decision, person hospitalized without consent and not subject to a legal protection measure, and person admitted to a health or social establishment for purposes other than research, minor), person subject to a period of exclusion for other research, person of full age subject to a legal protection measure (guardianship, curatorship or safeguard of justice), person of full age unable to express their consent and not subject to a protection measure.

Data collection and processing

Quantitative analysis of postural control

A quantitative biomechanical analysis will be carried out in a gym dedicated to this type of analysis, using twenty-four optoelectronic cameras (Qualisys AB, Gothenburg, Sweden) and two force platforms (Advanced Mechanical Technology Inc, Watertown, USA). These measurement systems are routinely used in the laboratory with various populations (elderly, sportsmen, etc.) [27, 28]. The cameras are associated with reflective markers to obtain the kinematics (displacement of markers placed on bone markers) during movement [25]. The measurement reliability of this system is widely proven in the literature [73]. The force platforms will collect the ground forces (external forces and moments) during the sit-to-stand and stand-to-sit phases. Once the data have been collected, a data processing routine will be developed using Matlab software (Mathworks, Natick, USA) to extract the parameters of interest.

Data collection for secondary endpoints

The time to complete the Timed Up and Go tests and the total time to complete the Glittre-ADL will be recorded during the experimental part of the protocol. The various questionnaires will be completed by the participant in a quiet room in the presence of an investigator. All the tools are self-administered questionnaires with the exception of the GP-Cog, which needs to be administered by an investigator [72]. Nevertheless, an investigator will remain present for all of the questionnaires to be able to respond to any requests for clarification from the participants, without proposing, directly or indirectly, an answer to a specific item.

Statistical Analysis

The normality of each parameter will be tested using the Shapiro-Wilk test and the Levene test for homogeneity of variances. Data will be presented as mean ± standard deviation or median [interquartile range] depending on the type and distribution of the variables. A Student's t test and Wilcoxon test will be used to compare the characteristics of the COPD group and the control group. Effect sizes will also be calculated using Cohen's d or rank biserial correlation.

Primary aim

The characterisation of postural control of individuals with COPD during different tasks and the comparison with the control group will be performed by graphical reading and statistical comparison of the variables of interest via a repeated-measure ANOVA, an independent Student t-test or a Mann-Whitney test according to the distribution of the variables and the conditions analysed. This analysis will be performed for the different parts of the modified Glittre-ADL test (sit-to-stand, walk, stairs, object handling and stand-to-sit).

Secondary aims

Analysis of correlations and independent determinants of postural control: For the postural control variables that best discriminate between the COPD and control groups identified in the primary endpoint, correlations with clinical factors (inspiratory muscle strength, pain, dyspnoea, physical activity, sedentary behaviour, cognitive function…) will be examined via Pearson's or Spearman's tests depending on the type of variable and distribution. Multiple regression analyses will then be

performed to identify independent determinants among different criteria of interest in postural control. These analyses will be carried out using the stepwise forward regression method and the choice of the most relevant model will be made using the Akaike Information Criterion (AIC).

Qualities of the Glittre-ADL test in the clinical assessment of postural control: The correlations between the completion time of the TUGs and the completion time of the modified Glittre-ADL (total time and time for each different task performed during the Glittre-ADL) will be examined using the Pearson or Spearman correlation coefficient depending on the distribution of the data. Their validity will then be analysed by examining the correlations between these clinical variables and the variables related to postural control for each of the tasks proposed in the Glittre-ADL test. The significance level will be set at 0.05 for all statistical analyses performed. Jamovi (version 2.3, The Jamovi Project) with the Rj editor (version 1.1, Jonathan Love) will be used to carry out the statistical analyses. The statistical analysis will be performed by the authors.

Sample size calculation

Due to the exploratory nature of this work and the large number of endpoints present, the calculation of the number of subjects needed for this study was carried out in two different ways. Firstly, the calculation was made in such a way that a difference in the variability of stability margins at comfort speed between the COPD group and the control group could be demonstrated. Based on previous results [40], we expect a standard deviation of 3 mm and a between-group difference of 3 mm for the variability of medio-lateral margin of stability. Assuming an alpha error of 5% and a beta risk of 20%, the required number of participants per group is 16, i.e. 32 participants in total. A second calculation, to highlight a difference between the groups on the stand-sit transfer time variable, was performed. Based on previous results [74], with a standard deviation of 0.6 seconds and an expected between-group difference of 0.7 seconds, 12 subjects are needed per group. Combining these two analyses, we therefore assume a necessary number of 16 subjects per group. The calculations were performed with the Sample size calculator software (ClinCalc LLC, USA).

Discussion

To the best of our knowledge, ATTRACTION will be the first study to propose the assessment of postural control in various daily living tasks in individuals with COPD using quantitative movement analysis. These tasks are performed several times a day and are often difficult for individuals with COPD (22). ATTRACTION has the potential to identify if postural control of individuals with COPD is impaired during these tasks and if so, to describe precisely how postural control is altered. In the ATTRACTION study, numerous clinical factors will be evaluated. Analysis of their potential associations with postural control parameters may provide interesting research perspectives on the underlying mechanisms of postural control impairments in COPD or on the consequences of the latter. Recent studies have highlighted that clinical factors such as pain, dyspnoea or inspiratory muscle strength could be related to postural control impairment in patients with COPD [19, 75]. This study provides an opportunity to improve the scientific understanding of these potential associations. Further, postural control assessment is often performed under conditions that do not represent the challenges encountered by individuals in their daily lives. Our aim is to assess postural control in everyday tasks and to propose simple measures for future clinical assessments, possibly in real-life environment. The incorporation of ecologically-valid assessments is one of the future challenges in the field of rehabilitation [23], and the ATTRACTION study may contribute to this goal.

This study has potential limitations: Firstly, although the aim is to assess postural control in an ecological manner, the study will take place in a laboratory environment, and the equipment of each participant (adapted clothing, presence of markers for quantified movement analysis) is far from representing an everyday situation. However, this proposal can be used as a basis for future studies, and the quantitative movement analysis requires specific facilities and equipment. Secondly, no direct assessment of maximal voluntary strength of lower limbs is planned in our study. Because some authors have suggested that lower limb muscle function may be an underlying mechanism of postural control impairment in COPD, assessment of this function is of interest. However, the assessment of ground reaction force during the sit-to stand task will be performed in ATTRACTION, and two studies have clearly shown its interest for its use in the assessment of muscle function [46, 76]. We believe that the results of ATTRACTION could directly or indirectly enhance assessment and management of postural control impairment in the COPD population. These findings may contribute to assist medical practitioners and physiotherapists to design efficient programs for the diagnosis and management of this alteration.

Trial status

We are currently recruiting participants.

Disclosure of interest

The authors declare they have no conflicting interests with the content of the article.

Ethical approval and considerations

This study complies with the Declaration of Helsinki. The study was registered with the Agence Nationale de Sécurité du Médicament (ANSM) under the number 2021-A00482-39. The Comité de Protection des Personnes (CPP) Sud-Ouest et Outre-Mer 1 (SOOM1) issued a first favourable opinion on 19th of July 2021. Substantial changes to the protocol were presented and the CPP SOOM1 approved these modifications on the 27th of October 2021. This study is in conformation with the General Data Protection Regulation (GDPR) and follows the reference methodology 001 of the Comité National Informatique et Libertés (CNIL). The ATTRACTION study has been registered on ClinicalTrial.gov under the number NCT05211674.

Authors' contribution

Manuscript: *R.Pichon*: Conceptualisation, Methodology, Writing, original, Illustrations; *M.Ménard*: Conceptualization, Methodology, Writing ; *D.Hearing*: Conceptualization, Methodology, Writing; *A. Cretual*: Conceptualisation, Methodology, Writing, Supervision; *G.Brinchault*: Conceptualisation, Writing.

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