Trials

STUDY PROTOCOL

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The effectiveness of dual-task exercises in individuals with chronic obstructive pulmonary disease: a study protocol for a randomized controlled trial

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Abstract

Background Central nervous system dysfunction is an extrapulmonary complication of chronic obstructive pulmonary disease (COPD), and brain function, particularly frontal lobe function, has been shown to deteriorate. It has also been reported that the time taken to complete a functional test involving a cognitive task is prolonged in patients with COPD. The aim of this study is to evaluate the effect of dual-task performance on motor and cognitive function in COPD and to determine the effect of dual-task exercises delivered in a pulmonary rehabilitation program on cardiopulmonary and musculoskeletal parameters.

Methods COPD patients who are admitted to pulmonary rehabilitation, meet the inclusion criteria, and volunteer to participate will be randomly divided into the pulmonary rehabilitation group (control group) and dual-task exercise group. The Dual Task Exercise Group will continue the established rehabilitation programs. During the walking and balance exercises in the program, they will also do cognitive exercises, which are different from those in the pulmonary rehabilitation control group. The COPD Assessment Questionnaire will be applied, and dyspnea assessment will be done with the Modified Medical Research Council Dyspnea Scale. Mini-Mental State Examination and Frontal Assessment Battery will be used to assess cognitive status. Mini-BESTest: Balance Evaluation Systems Test will be used to assess balance. Functional balance and mobility assessment will be performed with the Timed Up and Go Test and the 10-m Walk Test. The tests will be applied twice, as a single task (normal walking) and a dual task (walking and cognitive task). The 6-min walk test will be used to assess functional capacity. Quality of life will be assessed using the St. George Respiratory Questionnaire. Results of pulmonary function tests performed at routine check-ups will be obtained. Assessments will be repeated at the end of the 8-week exercise program.

Discussion Extrapulmonary clinical problems may affect the treatment process in COPD. Studies examining the effect of cognitive dysfunction evaluated dual-task performance in COPD and compared it with healthy controls. Despite the differences in the results, it emphasized that the effects of adding dual-task training to pulmonary rehabilitation should be investigated. Our study may contribute to the literature at this point.

Trial registration ClinicalTrials.gov ID: NCT05930158 (Date: 14.06.2023).

Keywords Chronic obstructive pulmonary disease, Cognitive, Dual-task, Walking, Balance, Randomized controlled clinical trial

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	The effectiveness of dual-task exercises in individuals with chronic obstructive pulmonary disease: a study protocol for a randomized controlled trial
Trial registration {2a and 2b}.	This trial has been registered at ClinicalTrials.gov (ID: NCT05930158; Date: 14.06.2023), and all required items from the WHO Trial Registration Data Set are available in the public registry entry and also in this protocol.
Protocol version {3}	Version 3 of 25.09.2024
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Name and contact information for the trial sponsor {5b}	Investigator-initiated clinical trial; Begüm Ünlü begum.unlu@marmara.edu.tr Supervisor: Aysel Yıldız Özer aysel.yildiz@marmara.edu.tr
Role of sponsor {5c}	There is no funding sponsor for this doctoral thesis research. Therefore, no funders played a role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Introduction

Background and rationale {6a}

Airflow restriction is a hallmark of COPD, which is caused by a complicated interplay between lung parenchymal deterioration and inflammation of the small airways. We know that COPD has wide-ranging effects on multiple systems. It is common to describe gait abnormalities as one of these consequences. Walking test results indicate a decline in walking cadence and distance. Increased oxygen consumption and increased muscle fatigue are linked to these modifications in walking patterns. It has been proposed that impaired walking ability could be associated with extrapulmonary issues as well as respiratory issues that result in aerobic deconditioning [1].

One extrapulmonary complication of COPD is central nervous system dysfunction [2]. In the context of decreased motor cortex activity, studies have shown that people with COPD have limited muscular force production [3]. It has been demonstrated that COPD impairs brain functioning, notably frontal lobe functions [4]. Additionally, research indicates that completing a functional test alongside a cognitive activity takes longer [5]. Because many daily activities require doing dual or multiple tasks simultaneously, such as conversing while walking or avoiding obstacles, this discovery is particularly crucial for managing COPD. The simultaneous performance of two tasks—motor-motor or cognitive-motor—is referred to as dual tasks. But the ability of the human mind to process information is finite. Simultaneous execution of cognitive and physical tasks results in competition for attentional resources and information-processing brain networks. This conflict, known as "dual-task interference (DTI), may cause a decline in performance on one or both activities [6, 7]. The literature emphasizes how people with COPD lose the capacity to do complex multitasking, such as walking or driving alongside a cognitive task [5, 8]. For many activities of daily life, it is crucial for people with COPD to do multiple tasks at once (e.g., maintaining balance while performing a cognitive activity). Any issues completing one or both tasks could result in an inability to complete the activity as a whole as well as major health issues like falling [5]. Because COPD patients typically struggle with balance on their own, successful dual-tasking is considerably more challenging for them [9]. There is an increased risk of falls, disability, and death with higher DTI during muscular force production and functional balance [10, 11].

Although COPD patients are likely to exhibit a motor and/or cognitive disadvantage during muscle force production with a cognitive task, to our knowledge, research has not focused on this issue in depth to date. In addition, studies investigating functional balance in dual tasks are also quite limited in COPD patients [1, 12].

To the best of our knowledge, research has not yet done a thorough investigation into this matter, although individuals with COPD are likely to show signs of a motor and/or cognitive disadvantage while producing

muscle force during a cognitive activity. Furthermore, there are not many studies looking into functional balance in dual tasks among COPD patients [1, 12].

Objectives {7}

When the literature in this field is examined, it seems very likely that COPD patients will exhibit gait deficits during dual-task walking. However, studies conducted to date are limited [1, 5, 12]. Investigating the reversibility of this situation is crucial, given its importance as a clinical problem. Considering the positive effects of pulmonary rehabilitation, which is one of the main steps of COPD treatment, on cognitive functions such as planning, selective attention, and verbal memory, additionally, given dual-task exercises may be a suitable treatment method. The success of this new pulmonary rehabilitation protocol may not only improve the patients' clinical condition but also their participation, independence, and quality of life.

Examining the research in this area suggests that gait abnormalities during dual-task walking are highly likely to occur in COPD patients. There have only been a few studies done thus far, albeit [1, 5, 12]. Given the significance of this clinical issue, further research into the situation's reversibility is warranted. Given that one of the primary components of treating COPD is pulmonary rehabilitation, which has been shown to improve cognitive abilities, including verbal memory, planning, and selective attention, dual-task activities may also be an appropriate course of treatment. If this new pulmonary rehabilitation program is successful, patients' participation, independence, and quality of life may all improve, in addition to their clinical condition.

The aim of this study is to evaluate the effects of dual task exercises given together with cognitive exercises in addition to the pulmonary rehabilitation program on performance, balance, walking and cognitive functions, as compared control group of patients who continued the classical pulmonary rehabilitation program.

Trial design {8}

This study is a prospective, parallel-group, randomized controlled clinical trial. The patient allocation ratio is 1:1. The framework of the study is superiority.

Methods: participants, interventions, and outcomes

Study setting {9}

This study was conducted at the University of Health Sciences, Süreyyapaşa Chest Diseases and Chest Surgery Training and Research Hospital, in coordination with Marmara University Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation in Istanbul, Türkiye. COPD patients who are admitted to pulmonary rehabilitation meet the inclusion criteria, and voluntarily agree to participate will be included in the study. Patients will be informed about the study and asked to sign an informed consent form. Two study groups will be randomly assigned to patients. Patients in the Dual Task Exercises group, which is the study group, will also perform cognitive exercises determined differently from patients in the Pulmonary Rehabilitation group during walking and balance exercises. The Pulmonary Rehabilitation Group will continue with the classic rehabilitation programs determined for the control group.

Eligibility criteria {10}

Inclusion, exclusion, and study withdrawal criteria are listed below.

Inclusion criteria

- Diagnosis of COPD (by a physician specializing in chest diseases)
- COPD patients between the ages of 40 and 75
- Being in a stable period of COPD
- Absence of abnormal laboratory findings
- Not having a mental problem that prevents filling out the questionnaires to be used in the study.

Exclusion criteria

- COPD exacerbation
- Being pregnant
- Being of advanced age
- Having ischemic heart disease
- Having kyphoscoliosis, an advanced postural disorder
- Having orthopedic disability and amputation surgery
- Having a neurological condition causing balance problems
- Having an additional respiratory condition that affects respiratory functions
- Pulmonary embolism
- Pleural effusion
- Heart failure

Study withdrawal criteria

- Patient's desire to leave the study
- Not participating in the specified exercise program for more than five sessions
- Hospitalization due to COPD exacerbation
- Diagnosis of cardiac or neurological disease after starting the study

Who will take informed consent? {26a}

COPD patients referred to the pulmonary rehabilitation will be informed about the study by the researchers at the Pulmonary Rehabilitation Unit with verbal explanation and written information (purpose of the study, evaluations, procedures, potential harms and benefits). Those who volunteer to participate in the study and meet the inclusion criteria will be asked to sign a written informed consent form approved by the ethics committee.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

The initial assessment data obtained within the scope of the study will be used for an ancillary study. The ancillary study was approved by the ethics committee and the Provincial Health Directorate. The information was also included in the participant consent form.

Interventions

Explanation for the choice of comparators {6b}

Within the scope of the study, patients who are referred to pulmonary rehabilitation after the clinician's evaluation will be randomly divided into intervention and control groups. The control group will receive routine pulmonary rehabilitation. They will participate in a standard pulmonary rehabilitation program (twice a week for 8 weeks) including endurance, strength, balance, and breathing exercises. Cognitive exercises will not be applied to this group. Pulmonary rehabilitation includes evidence-based practices that have proven therapeutic and preventive benefits for COPD patients. The Intervention Group (Dual Task Exercises Group) will participate in a standard pulmonary rehabilitation program (twice a week for 8 weeks). Patients will also perform dual-task exercises that include cognitive tasks during walking and balance exercises. These cognitive tasks will be structured according to individual performance and will be gradually modified and performed individually (one-on-one). All sessions will be supervised by a physiotherapist trained in pulmonary rehabilitation.

Intervention description {11a}

Pulmonary Rehabilitation Group: Patients in this group will persist with the traditional rehabilitation programs established within the Pulmonary Rehabilitation Unit. There will be two sessions a week throughout the full 8-week program. Pulmonary rehabilitation will consist of relaxation, stretching, strengthening, balance exercises, walking, and cycling. The targeted level of exercise intensity will be moderate. There will be warm-up and cool-down periods for walking and cycling exercises.

Dual Task Exercises Group: In contrast to the patients in the Pulmonary Rehabilitation group, members of this group will also do determined cognitive exercises while performing the walking and balance exercises as part of their rehabilitation program. There will be two sessions a week throughout the full eight-week program. Exercises involving walking and balance will each last 15 min. The 6-min walk test findings will be used to determine the moderate intensity of the exercise, which will consist of a warm-up and cool-down phase. The workout will be done on a treadmill.

The balance exercise program will consist of walking in different directions, walking in a straight line, walking in tandem (walking by tapping the toe of the other foot with the heel), standing on one leg (eyes open-closed), standing on soft ground with eyes open-closed, and sit-to-stand exercises.

Walking and balancing exercises will be combined with cognitive exercises that are presented as dual tasks. Exercises for memory, executive functions, calculation, and information processing speed (reaction time) will be included in the cognitive program. Cognitive exercises include grouping words, explaining proper responses to basic circumstances, performing simple addition, subtraction, and multiplication operations, and having the patient recall terms they are asked to remember before beginning an exercise. Walking and balancing exercises will be done concurrently with cognitive activities.

Criteria for discontinuing or modifying allocated interventions {11b}

If the patient desires to withdraw from the study, misses more than 5 sessions, is hospitalized due to COPD exacerbation, or gets a diagnosis of cardiac or neurological disease after starting the study, they will withdraw from the study with their doctor's decision. In addition, in extraordinary circumstances, various institutions, such as the hospital directorate or the Istanbul Provincial Health Directorate, may decide to stop the research. The thesis monitoring board and the Health Sciences Institute may follow their recommendations in this case.

If the patient withdraws from the study, the following procedure will apply to the data collected:

1. If the participant has attended 80% of the study, they will receive an invitation to participate in the final evaluation. If the evaluation is completed, the data will be used.
2. If the patient misses 80% of the study, declines the evaluation invitation, or is unreachable, the data will not be analyzed.
3. With the patient's consent, the ancillary study can use the first assessment data.

Strategies to improve adherence to interventions {11c}

Patients will be informed about participation in rehabilitation sessions and the value of regular attendance at rehabilitation sessions to increase adherence. Throughout the program, participants will get individual performance reviews to help keep them motivated. Standardized session tracking forms will be used by researchers to track attendance. The research team will get in touch with participants who miss sessions to offer support and determine the cause of their absence.

Relevant concomitant care permitted or prohibited during the trial {11 d}

N/A There is no permitted or prohibited concomitant care and interventions.

Provisions for post-trial care {30}

The clinic's routine pulmonary rehabilitation program provides indefinite service, regardless of the project. Patients come for follow-up according to their doctors' recommendations. Dual-task exercises may be included in the program at the discretion of the clinic management. If the beneficial effects of dual-task training are determined after the data analysis of the project, the inclusion of this training in the routine pulmonary rehabilitation program will be reported to the clinic management and the provincial health directorate with a report. Patients who experience adverse events can return to the routine pulmonary rehabilitation program with the approval of the doctor, according to the clinic's own operating protocol. However, they will not be included in the project again.

Outcomes {12}

Primary outcome measures are improved cognitive function and dual-task performance. The cognitive status will be assessed with the Frontal Assessment Battery and the Mini-Mental State Examination (MMSE). The dual-task performance will be assessed with the Timed Up and Go Test (TUG) and the 10-m Walk Test. The tests will be administered once as a single task (regular walking) and once as a dual task (walking and cognitive task).

The health status, dyspnea severity, balance, mobility, functional capacity, and quality of life are secondary outcomes. The COPD Assessment Test (CAT) will be applied to determine the health status. The Modified Medical Research Council Dyspnea Scale (mMRC) will be used to assess dyspnea. Mini-BESTest: Balance Evaluation The Systems Test will be used to evaluate balance. The Timed Up and Go Test (TUG) and the 10-m Walk Test will be used to assess functional balance and mobility. The functional capacity assessment will make use of the 6-min walk test. The St. George's Respiratory Questionnaire will be used to evaluate quality of life. We will also acquire the results of the respiratory function test, which was part of the patients' regular checkups.

All of the outcome measures will be done at baseline, 8 weeks later from the baseline, and at the end of 6 months from the baseline. The primary endpoint is the change in outcomes at 8 weeks from the baseline. Six months after baseline, the change in results is one of the secondary endpoints. The same physiotherapist will perform all assessments at the relevant time.

Tests including all primary and secondary outcome measures will be administered at baseline (week 0), at the end of the program (week 8), and at the follow-up visit (month 6). Measurement results will be analyzed as the change from baseline.

Frontal Assessment Battery, MMSE, TUG, 10-m Walk Test, Mini-BESTest, 6-min walk test, respiratory function tests, and the St. George's Respiratory Questionnaire total score results will be given as mean and standard deviation. CAT, mMRC, and the St. George's Respiratory Questionnaire sub-parameter scores will be given as median, minimum, and maximum. Data regarding unexpected/adverse events and the clinical and social status of patients during the clinical trial period will be summarized in the table as numbers, percentages, and categorical data.

Measurements

Mini-Mental State Examination (MMSE) The MMSE is a quick, useful, and standardized technique for figuring out someone's global cognitive level. It has eleven items altogether, divided into five primary categories: language, recall, attention and computation, recording memory, and orientation. The test is graded out of a possible thirty. Scores in the range of 24 to 30 are often regarded

as normal. Cognitive impairment is indicated by a score lower than 24. The scale employed was the Turkish version, for which validity and reliability analyses were carried out. [13, 14].

Frontal Assessment Battery (FAB) FAB is a short-term, straightforward examination designed to assess frontal lobe functions. Each of the six components in FAB has a score ranging from 0 to 3. Better performance is indicated by a higher score. The study applied the Turkish version of the test [15, 16].

FAB consists of 6 subtests.

1. Similarities (conceptualization)
2. Lexical fluency (mental flexibility)
3. Motor Series Test (programming)
4. Conflicting instructions (sensitivity to interference)
5. Go-no-go (inhibitory control)
6. Prehension behavior (environmental autonomy)

Timed Up and Go Test-Dual Task (TUG-DT) In our study, a cognitive task will be added during the TUG test. As a cognitive task, participants will be asked to say the sequence of letters and numbers (A1-B2-C3…) during the test. The test will be repeated twice and the time will be recorded.

10-m Walk Test-Dual Task The standard 10-m walking test is performed on individuals while they simultaneously perform a second task. There are many additional task suggestions that can be given during walking. One of these suggestions is the cognitive task of counting backwards. For the test, volunteers will be asked to count backwards from 100 by three. The test will be repeated twice, and the walking time and walking speed averages (m/s) will be recorded [1, 5, 17].

COPD Assessment Test (CAT) The CAT is an eight-item, unidimensional, COPD health status evaluation tool. It has a score range of 0 to 40. A higher score indicates a more severe COPD-related impact on an individual's life. The Turkish version, which has been proven to be valid and reliable, was used [18, 19].

Modified Medical Research Council (mMRC) Dyspnea Scale The patient uses a score ranging from 0 to 4 to indicate the severity of their dyspnea. Using a scale from 0 to 4, the mMRC scale allows users to self-rate how much disability dyspnea causes for daily activities: 0, no breathlessness except on strenuous exercise; 4, too breathless to leave the house, or breathless when dressing or undressing [20].

Mini-BESTest: Balance Evaluation Systems Test It is a clinical test used to assess balance and walking. It has 14 components altogether and is divided into 4 sub-parameters: anticipatory, reactive postural control, sensory orientation, and dynamic gait. The Turkish version of the exam was utilized for the study, and it is assessed over a total of 28 points and takes an average of 10 to 15 min [21].

Timed Up and Go Test (TUG) TUG is a useful technique for measuring functional mobility that does not require any special equipment. The test involves the participant sitting in a chair for the first part of it, standing up when instructed to do so, walking to a location marked 3 m ahead, and then walking back to the chair. The time spent doing this is then recorded. Scores of 10 s or less are considered normal, while scores between 11 and 20 s are considered normal for working elderly and disabled people. A score of more than 20 s suggests the need for walking assistance and training, while a score of more than 30 s suggests a fall-prone individual [22–24]. The time will be recorded, and the exam will be administered twice.

10-m Walk Test It is a test for determining walking speed. The test requires participants to walk a distance of 14 m. The first 2 m of the walking path to be applied are acceleration, and the last 2 m are deceleration. The tape is attached to the end and beginning parts of the acceleration and deceleration sections and the 10-m distance in the middle section is determined. After the participant starts walking, the chronometer starts when his foot passes over the tape at the beginning of the determined 10-m section, and the chronometer is stopped when he passes over the tape at the end of this section. This reduces the effects of acceleration and deceleration. The test will be repeated 2 times, and the walking time and walking speed averages (m/s) will be recorded [25].

6-min walk test (6-MWT) Patients can walk at their pace during the 6-min walk test, which measures walking capacity. In 6 min, patients are required to walk as far as they can along a straight corridor. The exam will involve the use of encouraging statements and standardized orders. Exercise performance and physical activity scales are substantially linked with the 6-MWT, a test that assesses functional exercise ability and has high construct validity. The 6-min walk distance (6-MWD) is the total distance the patient walks in 6 min and it is the test's main outcome [26].

St. George's Respiratory Questionnaire (SGRQ) SGRQ is one of the measures of health-related quality of life that is particular to respiratory conditions. The SGRQ consists of 50 items divided into three areas in the patient: symptoms (8 items), activity (16 items), and impacts (26 items). The test's three components are scored independently, and a final score is determined. The possible scores are 0 to 100. Maximum disability is indicated by a score of 100, whereas normality is indicated by a score of zero. Four treatment-related change units are deemed significant in the SGRQ questionnaire. The Turkish translation, which has been shown to be accurate and dependable, was applied [27, 28].

Participant timeline {13}

Patient recruitment for the study began in October 2023 and is planned to last approximately one and half years. The evaluations and their timing are summarized in the table (Table 1: Summary of the study schedule).

Sample size {14}

The sample size was calculated by using the GPower 3.1.9.7 program. Since no study was found in the previous literature that was conducted with the same parameters (dual-task exercises combined with pulmonary rehabilitation in COPD patients), consequently, we used Cohen's medium effect size (f= 0.25), which is widely accepted in the literature for similar intervention studies, to base our effect size estimate. The 0.25 effect size indicates a moderate expected difference between the study groups for cognitive performance change; thus the choice of 0.25 [29]. In the test performed, when the effect size was calculated with 0.25, an alpha error rate of 0.05 and 80% power, it was found to be 17 for each group. In line with these results, it was planned to continue with 21 people for the groups, considering the 20% loss that could occur in the number of participants.

Recruitment {15}

The chest diseases clinic will primarily refer cases for this study. The chest diseases clinic is a regional hospital in this area and has a large patient list. However, if the number of cases is not sufficient, other hospitals in the vicinity will be contacted, and appropriate cases will be referred to the chest diseases clinic. After all of the accessed patients are evaluated in the Chest Diseases

Table 1 Summary of the study schedule

	Baseline	Weeks 1–8	Week 9	6thmonth follow-up
Enrollment:				
Inclusion in the study	X			
Informed consent form	X			
Demographic information form	X			
Allocation	X			
Assessments:				
Mini-Mental State Examination (MMSE)	X		X	X
Frontal Assessment Battery (FAB)	X		X	X
Timed Up and Go Test-Dual Task (TUG-DT)	X		X	X
10-m Walk Test-Dual Task	X		X	X
COPD Assessment Test (CAT)	X		X	X
Modified Medical Research Council (mMRC) Dyspnea Scale	X		X	X
Mini-BESTest: Balance Evaluation Systems Test	X		X	X
Timed Up and Go Test (TUG)	X		X	X
10-m Walk Test	X		X	X
6-min walk test (6-MWT)	X		X	X
St. George's Respiratory Questionnaire (SGRQ)	X		X	X
Interventions:				
Dual Task Exercises Group:		X		
Pulmonary Rehabilitation Group		X		
Session Monitoring:				
Vital signs		X		
Session participation statuses		X		

Clinic and referred to pulmonary rehabilitation, they will be included in the study.

Assignment of interventions: allocation

Sequence generation {16a}

Individuals with COPD included in the study were divided into 2 groups, 21–21, with a total of 42 individuals, using the single-block randomization method using the "Random Allocation Software" program by an independent researcher not included in the study [30].

Concealment mechanism {16b}

The independent researcher, who is not involved in this study, will handle the randomization sequence to maintain allocation concealment. The researchers who do the enrollment and assessment won't view future assignments or the full sequence, thus preventing prediction or manipulation of group assignments.

Implementation {16c}

The independent researcher will generate the allocation sequence using a computer-based program, as previously noted. Participants will be enrolled by the physician. Once eligibility is confirmed, informed consent is obtained, and assessments are completed, the patient will learn his/her study number and with that will also receive information about their assigned group from the independent researcher; then the study researcher will plan the sessions according to protocol.

Assignment of interventions: blinding

Who will be blinded {17a}

Considering the exercise program in the study plan, it is not possible to conduct the study blindly. However, the researcher who will perform the statistical analysis will be blinded to the study group in which the patients are included.

Procedure for unblinding if needed {17b}

There is no unblinding procedure because the trial design lacks blinding.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Evaluations will be conducted by the same researchers who are experts in their fields. The data of primary and secondary outcomes will be collected at baseline, 8 weeks after baseline, and 6 months after baseline. All of the tests, questionnaires, and scales used in this study have been valid and reliable. The research team has created paper patient report forms especially for this study, and they will be used to gather data initially. Following data collection, the information will be entered into an electronic database after being cross-checked by two separate researchers to guarantee correctness and completeness. Signed paper consent forms will be collected.

Plans to promote participant retention and complete follow-up {18b}

Participants are free to withdraw from the study at any time without any consequences. If the participants attended enough pulmonary rehabilitation sessions (80%), they will be asked if they are willing to complete a final (last-visit) assessment at the time of withdrawal. If the participant agrees, the data collected up to that point, including the final assessment, will be retained and included in the analysis. If a participant declines the final assessment or cannot be contacted, their data will not be included in this study's analyses. Finally, the first assessment data can be used for the ancillary study with the patient's consent.

Data management {19}

The data recorded on paper in the evaluations will then be recorded on a PC. The information will be entered into an electronic database after being cross-checked by two separate researchers to guarantee correctness and completeness. Signed paper consent forms will be collected. All study data will be input into a Microsoft Excel database that is password-protected and kept on a safe institutional computer with restricted access. A backup copy will also be kept by the researcher, a PhD student. Both the paper forms and the computer data will only be accessible to approved research personnel. We use codes in files instead of names. According to institutional data retention standards, paper forms for case reports will be kept for five years following the conclusion of the study in locked cabinets in a secure location. Additionally, the electronic data will be safely kept for the same amount of time.

Confidentiality {27}

Research data will be stored using a patient's ID for each participant. The codes will be accessible only to researchers. No patient name or identification information will be used in publications. After the study is completed, all data will be securely stored for 5 years. All data will be deleted permanently after this period.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/D There is no biological data in the study.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The SPSS (Statistical Package for Social Sciences) (SPSS Inc., IBM Corp., Armonk, NY) statistics program will be utilized in both qualitative and quantitative statistical methods for the classification of the data to be acquired in the research. The values will be assessed at $p < 0.05$ for significance and with a 95% confidence range. Normal distribution graphs and the Kolmogorov–Smirnov test will be used to assess the variables' conformance to a normal distribution, provided there are enough cases. Depending on the availability of parametric test conditions, the relevant statistical tests will be used in the variable analysis. A paired *t*-test or Wilcoxon test will be used to compare the values in the groups before and after the program, while a student *t*-test or Mann–Whitney *U* test will be used to compare the groups based on the parametric circumstances. In the analysis of the difference of evaluations within and between the groups, ANOVA tests will be used.

Interim analyses {21b}

No interim analysis is planned.

Methods for additional analyses (e.g., subgroup analyses) {20b}

No subgroup analyses planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

If any statistical method is needed to account for missing data in the secondary outcomes, multiple imputations will be used. If necessary, professional help will be sought for statistical analysis.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

The study database is only available by the corresponding author upon reasonable request.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5 d}

This study is carried out in cooperation with the Pulmonary Rehabilitation Unit of the Department of Chest Diseases of the Hospital and in coordination with the Department of Physiotherapy and Rehabilitation of the Faculty of Health Sciences. Ethics committee approval and a study permit have been obtained from the hospital where the study was conducted, and information about the conditions for continuing the study is provided. Study results will be shared upon completion of the trial.

All assessments of patients and pulmonary rehabilitation sessions are performed in the hospital. The principal investigator (PhD student) participates in pulmonary rehabilitation sessions and is responsible for implementing dual-task exercises and pre- and post-program evaluation. The study coordinator coordinates the study and plans timelines, checks reports, and also assists in the evaluation and interpretation of study data. The study physician finds, directs, and evaluates patients who may be included in the study and monitors the patient's condition, ensuring follow-up according to protocol. In addition, unit healthcare personnel who are not part of the work team monitor the safety of patients.

The assessment results are recorded on paper. Data entry is made into the computer under the control of two researchers and backups are taken. The final data analysis will be done by an expert blinded to the study.

The thesis advisor and the PhD student discuss the progression with weekly meetings. The thesis monitoring committee checks the study with 6-month meetings. In this meeting, developments in the study over the 6-month period, patients included or excluded, special situations that occur, or changes that need to be made are discussed, and the committee offers feedback or recommendations for improvement. The institute to which the doctoral student is affiliated evaluates and approves the decisions of the Thesis Monitoring Board.

Composition of the data monitoring committee, its role and reporting structure {21a}

The research unit and ethics committee of the hospital where the study was conducted are monitoring the study. In this study, data monitoring will be conducted by the thesis advisor, thesis monitoring committee, supervisor, and clinic research manager.

Adverse event reporting and harms {22}

There is no expected harm directly from the study; patients will be monitored during the sessions. Within the scope of the study, firstly, patients are evaluated in detail (balance and functional mobility). Previous fall history is checked in the patient's file. As a result of the evaluations, those with a high risk of falling or a history of falling are not included in the study. The applications within the scope of the study are carried out as one-on-one applications in the hospital clinic. The vital signs will be monitored during the sessions. The researchers will also ask the participants if there are any unexpected or new symptoms at each session. There are necessary facilities and specialists for emergency intervention in case of any incident.

All adverse events will be monitored and recorded by the researchers during the study period. Regardless of perceived severity, all reported harms will be documented. However, for the sake of research and reporting, events will be grouped according to their seriousness and potential relationship to the intervention. In case of any adverse event, the situation will be reported to the specialist doctor, and the necessary intervention will be carried out. All unfavorable incidents will also be routinely reported to the thesis monitoring board, advisor and the institute. If any incident occurs within the scope of the study, the health expenses related to this will be covered by the researchers.

Frequency and plans for auditing trial conduct {23}

Clinicians and physiotherapists who are not involved in the research monitor the ongoing pulmonary rehabilitation protocol in the clinic and evaluate it every two months.

The student's monitoring and evaluations for the doctoral thesis are also carried out every 2 months, and these evaluations are supervised by the thesis advisor.

In addition, the thesis monitoring board, which includes the student, advisor, chest diseases specialist working in the clinic, and head of the doctoral program, meets every 6 months to discuss whether there are any problems experienced during the research process, the data obtained and their comments, and designing the next monitoring period, and if necessary, program revisions are made.

The report prepared after this meeting is discussed (supervised) by the Institute Board of Directors, which is completely independent of the project; the board's decision on whether it is sufficient and appropriate is made.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

The institute, the ethical committee, and the appropriate authority will be informed of any substantial modifications. Any minor modifications will be noted and discussed with the research team. Patients will be informed of any modifications that may have an impact on them. Further permissions and consents will be asked for if needed. Additionally, the clinical trial records will be updated.

Dissemination plans {31a}

This study is a doctoral thesis, and the results will be presented at the university as a PhD dissertation. After the thesis is concluded, the results will be submitted for publication in peer-reviewed international journals related to research. Abstracts can also be sent to be presented at relevant congresses. Ethical rules will be adhered to in all of these publications.

Discussion

COPD is one of the major non-communicable public health problems. Clinical and non-clinical research focuses on solving the problems intertwined in the variable, multisystemic structure of COPD. With modern medicine, the extrapulmonary effects of the disease are becoming clear. New treatment applications specific to extrapulmonary problems that may develop due to COPD can reverse the clinical process related to these problems and help manage the disease. This study aims to investigate the effectiveness of applications that will increase cognitive performance when added to the pulmonary rehabilitation program. Thus, it is aimed to reduce cognitive dysfunction, which is one of the extrapulmonary problems, and to improve the clinical and non-clinical patient status related to this problem.

Dual task performance losses associated with frontal lobe involvement in COPD negatively affect activities of daily living, participation, and maintaining individual control of the disease in normal life routine [4, 5, 12]. The foundation of dual-tasking is the ability to execute two tasks at once (two motor-motor or cognitive-motor). Activities that we frequently do in daily life, such as observing traffic, chatting, talking on a mobile phone, and carrying things while walking, can be given as examples of dual tasks. People with limited dual-task ability also have very limited daily life functions [31, 32]. In fact, it is reported in the literature that fall injuries in geriatric individuals are most common when performing motor or cognitive dual tasks [31].

DTI is the term used to describe the situation where attention is divided between two simultaneous tasks, leading to the failure of one or both. [33, 34]. The neurological basis of DTI is believed to be frontal lobe dysfunction, which results in an associated decrease in attentional capacity [35]. In COPD, the frontal lobe is known to be impacted as well. In several neurological illnesses and older individuals, higher DTI levels have been linked to frontal lobe impairment [31, 36, 37].

The assessment and comparison of COPD patients' dual-task performance with that of a healthy group was conducted. In a study published by Özsoy et al. in 2020, the dual-task performances of 35 COPD patients during TUG and muscle force production were compared with 27 healthy individuals with similar demographic characteristics. Although there was a statistically significant difference between single- and dual-task tests in terms of TUG duration in both groups, no difference was found between the groups. In addition, in the assessment of muscle force production, it was observed that the rate of

correct responses per second was statistically higher in COPD patients than in the control group [12]. In another study, the dual-task performances of COPD patients during the walking test were evaluated and compared with a healthy control group, including 21 COPD patients and 20 healthy controls. Walking parameters were evaluated during the 15-m walking test, and in the dual-task performance assessment, a task of counting backwards from 100 by threes was given during the walking test. There was no difference between the two groups in terms of walking speed, while the duration of dual-task walking was statistically increased when compared to single-task walking. In terms of the step time variable, the COPD group was found to be statistically higher during the dual-task. In the same study, COPD patients were included in a 5-week pulmonary rehabilitation program, and the evaluations were repeated after the program, and no difference was found in the duration of both single- and dual-task performance in terms of walking speed, but it decreased [5]. They pointed out the necessity of investigating the effects of adding dual-task training to pulmonary rehabilitation.

As seen in a recently published review, the number of studies on dual-task in COPD is extremely limited [38].

We anticipate that our study will clarify this important point in the literature. One of the strengths of this study is that long-term results, such as 6 months after eight weeks of training, will also be analyzed.

The limitation of the study is that clinician and patient blinding could not be done. Since the study is a doctoral thesis and the nature of the exercise program, blinding was not possible, but the researcher who will do the statistical analysis will be blind to the groups in which the patients are included.

Trial status

The application was made on 14.06.2023 to ClinicalTrials.gov (ID: NCT05930158).

(https://clinicaltrials.gov/study/NCT05930158?cond=copd%20dual%20task&rank=1).

This is the third and definitive protocol version. Participants started recruiting on October 13rd 2023. Study completion is expected to be in May 2025. The study protocol has been submitted before the end of the recruitment.

Abbreviations

COPD	Chronic obstructive pulmonary disease
DTI	Dual-task interference
CAT	COPD assessment test
mMRC	Modified medical research council dyspnea scale
TUG	Timed Up and Go Test
MMSE	Mini-Mental State Examination
FAB	Frontal Assessment Battery
TUG-DT	Timed Up and Go Test-Dual Task
6-MWT	6-Min walk test
6-MWD	6-Min walk distance
SGRQ	St. George's Respiratory Questionnaire

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Authors' contributions {31b}

Authorship of future publications resulting from this study will be according to the guidelines of the International Committee of Medical Journal Editors (ICMJE). All authors who fulfill the requirements will be included. Others who contribute but do not fulfil all criteria will be acknowledged as appropriate. Additionally, author roles for other future publications and the thesis have been determined. Conceptualization and methodology: BU, AYÖ, İÖ, MGP Recruitment: BU, İÖ Enrollment: BU, İÖ Clinic intervention: BU Supervision: AYÖ, MGP Writing—original draft: BU, AYÖ Writing—review and editing: İÖ, AYÖ, MGP Data monitoring and discussion: BU, AYÖ, İÖ, MGP All authors have read and approved the final manuscript of this protocol.

Funding {4}

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Data availability {29}

The study database is only available by the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate {24}

Ethics committee approval has been received from the University of Health Sciences Süreyyapaşa Chest Diseases and Chest Surgery Training and Research Hospital Clinical Research Ethics Committee (Protocol No: 136). Written informed consent to participate will be obtained from all participants. The study was registered with ClinicalTrials.gov (ID: NCT05930158; Date: 14.06.2023).

Consent for publication {32}

An informed consent form was prepared in compliance with the committee's rules and structure, and it received ethics committee approval. Volunteer participants are given a copy of the written consent form and requested to sign it before the research protocol begins. They are also given written and verbal explanations. Using the formal format authorized by the hospital's ethics committee, the written informed consent form was created in Turkish. Because of the format and language requirements, the form is not shared here.

Competing interests {28}

The authors declare that they have no competing interests.

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