

Effects of elastic tape associated with pulmonary rehabilitation of patients with Chronic Obstructive Pulmonary Disease (ETRehaCOPD): an RCT protocol, two-arm, assessor blind, randomized trial protocol

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Table of Contents

Original Manuscript..... 7

Supplementary Files..... 26

 Figures 27

 Figure 1..... 28

 Figure 2..... 29

 Figure 3..... 30

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Abstract

Background: (Actigraph) for seven days to assess daily life physical activity (DLPA). Then, the participants will be randomized into the ET or sham groups, and both groups will complete a PR program (2x/week for 8 weeks). The ET group will receive ET, whereas the sham group will receive a non-elastic tape. Data will be presented as the means and standard. Individuals with severe chronic obstructive pulmonary disease (COPD) may exhibit thoracoabdominal asynchrony (TAA), which reduces ventilatory efficiency. A novel intervention using elastic tape (ET) in the chest wall acutely reduces TAA and dyspnea during exercise among individuals with COPD. We hypothesize that ET associated with a pulmonary rehabilitation (PR) program may increase the benefits of PR in this population. Aim: This study aims to evaluate the additional effects of ET on exercise capacity, symptoms of anxiety and depression, and HRQoL among individuals with moderate to very severe COPD who are undergoing PR.

Methods: STUDY DESIGN AND PARTICIPANTS

This is a protocol for a randomized, controlled, two-arm, assessor-blinded clinical trial approved by the Hospital Research Ethics Committee (55617321.2.0000.0068) and registered at [clinicalTrials.gov](https://clinicaltrials.gov) (NCT05939999). Individuals with COPD will be screened and recruited at the Pulmonology outpatient clinic of a tertiary hospital and will be included in the study after signing the informed consent form.

INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria will be as follows: diagnosed with moderate to very severe COPD according to GOLD 2024; clinically stable (i.e., no exacerbations for at least 30 days); male sex; non-obese (BMI ≥ 29.9 kg/m²); no musculoskeletal limitations; no participation in another research protocol or a PR program in the past 6 months. The exclusion criteria will be decompensated cognitive, neurological, and/or cardiological dysfunction and receiving home oxygen therapy.

RANDOMIZATION AND ALLOCATION CONCEALMENT

The randomization will be generated using a computer (www.sealedenvelop.com). An investigator who is not involved in patient recruitment, assessment, or intervention will perform group allocation. Group allocation will be concealed via consecutively numbered, sealed, opaque envelopes.

EXPERIMENTAL DESIGN

Clinical and anthropometric data will be collected during the patient's interview. Subjects will complete questionnaires to assess

health status (COPD Assessment Test, CAT), health-related quality of life (Chronic Respiratory Questionnaire, CRQ), and anxiety and depression symptoms (Hospital Anxiety and Depression Scale, HADS). Then, the complete pulmonary function test (body plethysmography), the Incremental Shuttle Walking Test (ISWT), and the Endurance Shuttle Walking Test (ESWT) will be carried out. Finally, individuals will use a triaxial accelerometer (Actigraph GT9X, Pensacola, FL, EUA) for seven days to assess their PADL. Lastly, individuals will be randomly assigned to one of two groups: the elastic tape (ET) group or the sham group.

At baseline and postintervention, assessments will be performed by a researcher who is not involved in individual recruitment or intervention. After inclusion, individuals will begin an 8-week PR program twice a week (Figure 1). Individuals in the ET group will have the ET placed before the beginning of the PR program, and the ET will be replaced every seven days throughout the 8-week period. The sham group will receive a non-elastic tape of the same color and size at the same position in the chest wall at the beginning of the PR program, and the tape will be replaced every seven days, similar to the ET group. At the end of the PR program, participants will repeat the same assessments except for the ISWT. The ESWT will be performed at the same level established by the ISWT during the initial evaluation (Figure 2).

INTERVENTION

Elastic tape (ET)

The ET (Kinesio® Brand Tape, Tex Gold, Albuquerque, NM, EUA), made of cotton and elastic, skin-colored, and waterproof, will be positioned with the individual relaxed in the supine position. The individual will lie down on a stretcher so that their torso is extended, thus facilitating the application of the ET (Pinto et al., 2020). The ET positioning will be placed in the origin and insertions of the following muscle groups: rectus abdominis, internal oblique, and intercostal (Figure 3). The ET will be placed at the beginning of the session and replaced every seven days.

Sham group

The Sham group will receive a non-elastic tape (3M Micropore TM, Saint Paul, MN, USA) placed using an identical procedure to the ET and replaced every seven days.

PULMONARY REHABILITATION PROGRAM

Both groups will undergo an 8-week PR program, including one-hour sessions twice a week. The program will be divided into 30 minutes of aerobic training on an ergometric treadmill (Technogym Jog 500, Brazil) and 30 minutes of resistance exercises. Aerobic training will be performed with a heart rate (HR) corresponding to 50–80% of the maximum HR according to the formula proposed by Karvonen et al. [$HR_{\text{training}} = HR_{\text{rest}} + (HR_{\text{max}} - HR_{\text{rest}}) * \% \text{ intensity}$]. The intensity will be increased weekly by 5% of the maximum HR until reaching 80% of the maximum HR. HR_{training} = training heart rate; HR_{rest} = resting heart rate; HR_{max} = maximum heart rate and $\% \text{ intensity}$ = percentage of training intensity. Furthermore, this progression of treadmill load will also be guided by the scale of subjective perception of exertion (modified Borg scale) (Borg, 1982). The training will be carried out in such a way that during each session, the participant must remain on the Borg scale between scores 4 and 6 (Spruit, 2014). The increase in intensity by 5% of the maximum HR will be adjusted after two sessions and/or if the score on the Borg scale is less than 4. If the participant reports tiredness beyond six on the Borg scale, the intensity will be reduced, and in the following session, the attempt to increase it will be carried out again in the next session. The participant may interrupt the activity if they feel symptoms or intense respiratory discomfort, resuming it after improvement. Heart rate (HR), peripheral oxygen saturation (SpO₂), and the subjective perception of exertion will be monitored during exercise. Oxygen supplementation will be provided as needed to maintain SpO₂ ≥90% (Spruit, 2014).

Resistance training will consist of exercises for the upper limbs (ULs) through lifting weights with dumbbells and for the lower limbs (LLs) via weight machines. Large muscle groups will be trained, such as the biceps, deltoid, quadriceps, and hamstrings. Training will begin with three sets of eight repetitions of each exercise at a workload of 50% of the one-repetition maximum (1-RM) (Storer, 2001). The number of repetitions will subsequently increase to three sets of 10 and, later, 12 repetitions. Load progression will be carried out when the individual tolerates performing more than 12 repetitions for each set of sets without compensatory movements and/or symptoms of intolerance. The workload will be increased according to individual tolerance.

Resistance training for the upper limbs included 1 - shoulder abduction and 2 - elbow flexion. Resistance training for the lower limbs included 1 - knee extension and 2 - hip extension using "leg press" equipment. Transportation expenses will be subsidized for all individuals to reduce absenteeism. This financial resource will be funded for this research project. To analyze the results, individuals must complete at least 80% (13 sessions) of the program, which will be monitored via the PR monitoring form.

ASSESSMENT TOOLS

PRIMARY OUTCOME MEASURE

FUNCTIONAL EXERCISE CAPACITY

The ISWT will be performed to assess functional exercise capacity. In this test, individuals will be instructed to walk in a 10-m corridor delimited by cones (with a 9-m distance between them), and the speed will be determined by a beep recorded on the sound box, which increases the speed by 0.17 m/s every minute, with a total of up to 15 stages. They will also be instructed to

walk at a speed that allows them to reach the cones when the beep sounds, and at the end of each minute, an additional signal will be given to alert them to the increase in speed (Singh et al., 1992). The test will end when the participant is more than 0.5 m away from the cone, reports chest pain, reports severe dyspnea, reports fatigue, reports exhaustion, or requests to stop. The distance walked at the end of the test will be registered for subsequent analyses (Dourado et al., 2013). Before and after the exercise tests, SpO₂ and heart rate will be assessed via a portable pulse oximeter positioned on the individual's dominant hand (Nonin WristOx2® 3150). Blood pressure (BP) will be assessed via a stethoscope (Littman, Minnesota, United States) and a sphygmomanometer calibrated on the dominant arm (Aneroid Premium - G-Tech, Santa Catarina, Brazil).

The criteria for stopping the test will include diastolic blood pressure (DBP) above 140 mmHg; sustained elevation of systolic blood pressure (SBP) above 240 mmHg; motor incoordination; feelings of imbalance; mental confusion; clinical manifestations of respiratory distress that worsen with increasing load; dyspnea disproportionate to the intensity of the effort; progressive claudication of the lower limb; and limb exhaustion (Holland et al., 2014). Individuals will be instructed not to consume beverages containing caffeine for at least 12 hours before the test and not to perform intense exercise 24 hours before.

The ESWT will be performed 40 minutes after the end of the ISWT, using the same structure; that is, the volunteers will be instructed to walk in a 10-meter corridor limited by cones (with a distance of 9 meters between them), and the speed will be determined by a sound signal recorded by the cell phone. In this case, the speed will be determined using 85% of the maximum speed reached in the ISWT and will be constant throughout the test (Holland et al., 2014). Individuals will be monitored before and after the test, and the interruption criteria will be the same as those used in the ISWT procedure.

SECONDARY OUTCOME MEASURES

HEALTH-RELATED QUALITY OF LIFE (HRQoL)

HRQoL will be assessed via the Chronic Respiratory Questionnaire (CRQ), which was validated and translated into Portuguese (Moreira et al., 2009). The questionnaire consists of 20 questions divided into four domains: fatigue (4 questions), emotional function (7 questions), and self-control (4 questions). The responses will be assessed via a Likert scale with seven alternatives ranging from "never" to "always", whereas the Dyspnea domain (5 questions) includes an individualized assessment in which the patient chooses from a list of 26 daily activities, the five activities that cause the most dyspnea and then rate each one again via a Likert scale with seven alternatives ranging from "Unbearable shortness of breath" to "No shortness of breath". The results will be expressed as the mean score of each domain and the total score, with higher scores indicating better HRQoL.

ANXIETY AND DEPRESSION SYMPTOMS

The Hospital Anxiety and Depression Scale (HADS) will assess anxiety and depression symptoms. The questionnaire was developed to identify symptoms of anxiety and depressive mood and has been translated, validated, and published in Portuguese by Botega et al., 1995. It consists of 14 multiple-choice questions divided into two subscales, anxiety (HADS-A) and depression (HADS-D) symptoms, with 7 questions each. The domains are categorized by the severity of the stress present: 0–7 – none; 8–10 – probable; >11 – present (Cullen, 2017; Trost, 2005).

HEALTH STATUS

Health status will be assessed by the COPD Assessment Test (CAT), a specific questionnaire for COPD that assesses the impact of the disease's symptoms (GOLD, 2020). It consists of eight items related to health conditions and has been applied and validated in several languages, including Portuguese (Spelta, 2018).

SAMPLE CHARACTERIZATION

INITIAL ASSESSMENT

Individuals will undergo an initial interview to provide information on several aspects: identification and contact data, medical history (e.g., depression, osteoarthritis/arthrosis, osteoporosis, diabetes mellitus, and arterial hypertension), and medications in use.

LUNG FUNCTION

Pulmonary function parameters will be obtained from the individual's medical records within the previous six months. The interpretation will be performed according to the standards of the American Thoracic Society and European Respiratory Society (Miller, 2005) and normal values relative to the Brazilian population (SBPT, 2002).

PHYSICAL ACTIVITY IN DAILY LIFE (PADL)

The PADL will be quantified using a triaxial accelerometer (GT9X, Actigraph, USA) for sample characterization. The equipment will be placed on the individual's waist, and the individual will be advised to wear it for seven days and only remove it to sleep and shower. They will be instructed to maintain their lifestyle habits. Seven full days of monitoring will be considered to evaluate the PADL: five weekdays and two weekend days. Zero counting time (considered the period in which the participant did not use the accelerometer) or days with less than eight hours of the device in use will be excluded (Craig, 2003). The results will be expressed as the time of sedentary behavior, steps per day, and time in moderate to vigorous physical activity (MVPA).

STATISTICAL ANALYSIS

Data normality will be assessed via the Shapiro-Wilk test, and homoscedasticity will be assessed using Levene's test. Data will be presented as the mean and standard deviation or as the median and interquartile range [25–75%], according to the data distribution.

Intergroup comparisons will be performed using a two-way repeated measured analysis of variance (ANOVA) followed by the Bonferroni post hoc correction test or the Kruskal-Wallis test, followed by Dunn's post hoc test, depending on the normality of the data. Statistical procedures will be performed based on the intention to treat principle. The threshold for statistical significance will be set at 5% ($p < 0.05$).

SAMPLE CALCULATION

The sample size calculation was based on a previous study showing a mean difference of 65 seconds and a standard deviation of 65 seconds between groups in the ESWT (Pepin, 2013). Thus, considering an alpha equal to 0.05 and a beta equal to 0.80, the estimated sample size will be 17 individuals per group. Considering that the analyses will be carried out with the intention to treat and that for those who eventually do not carry out the final evaluations, the data will be imputed, and the sample size was increased by 20% for each group. Thus, the estimated sample size for this study will be 21 individuals per group.

Results: The São Paulo Research Foundation (FAPESP) will fund the study. The study has already been approved by the Hospital Research Ethics Committee (55617321.2.0000.0068) and registered at clinicalTrials.gov (NCT05939999). Data collection is ongoing and is anticipated to continue until September 2026. A publication of the results is anticipated to be available in late 2026.

Objective: evaluate the additional effects of ET on exercise capacity, symptoms of anxiety and depression, and HRQoL in individuals with moderate to very severe COPD who are undergoing PR.

Conclusions: the use of ET throughout the PR period (16 sessions in 2 months), which may improve the HRQoL of individuals with COPD. Clinical Trial: ClinicalTrials.gov NCT05939999; <https://clinicaltrials.gov/study/NCT05939999>

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Original Manuscript

Effects of elastic tape associated with pulmonary rehabilitation of patients with Chronic Obstructive Pulmonary Disease (ETRehaCOPD): an RCT protocol, two-arm, assessor blind, randomized trial protocol

Number of words = 2,950

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ABSTRACT

Individuals with severe chronic obstructive pulmonary disease (COPD) may exhibit thoracoabdominal asynchrony (TAA), which reduces ventilatory efficiency. A novel intervention using elastic tape (ET) in the chest wall acutely reduces TAA and dyspnea during exercise among individuals with COPD. We hypothesize that ET associated with a pulmonary rehabilitation (PR) program may increase the benefits of PR in this population. **Aim:** This study aims to evaluate the additional effects of ET on exercise capacity, symptoms of anxiety and depression, HRQoL, and daily life physical activity (DPAL) among individuals with moderate to very severe COPD who are undergoing PR. **Methods:** This is a protocol for a randomized, controlled, two-arm, blinded assessor clinical trial. Individuals will be evaluated during regular medical visits. Health status (CAT), HRQoL (CRQ), and psychological distress (HADS) will be assessed before and after the intervention. Then, exercise capacity will be assessed via incremental and endurance walking tests (ISWT and ESWT), and participants will use triaxial accelerometer (Actigraph) for seven days to assess DLPA. Then, the participants will be randomized into the ET or sham groups, and both groups will complete a PR program (2x/week for 8 weeks). The ET group will receive ET, whereas the sham group will receive a non-elastic tape. Data will be presented as the means and standard deviations or medians and interquartile ranges. Intergroup comparisons will be performed using a two-way analysis of variance (ANOVA) followed by the Bonferroni post hoc correction test or the Kruskal–Wallis test, followed by Dunn's post hoc test. The threshold for statistical significance will be set at 5%. **Results:** Data collection is ongoing and will continue until September 2026.

Trial registration

ClinicalTrials.gov NCT05939999; <https://clinicaltrials.gov/study/NCT05939999>

Keywords: COPD, adhesive elastic tape, pulmonary rehabilitation, dyspnea, exercise capacity, physical capacity.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease characterized by persistent and progressive airflow limitations associated with a chronic inflammatory response of the airways¹. Individuals with COPD present destruction of the small airways and decreased elastic recoil, leading to air trapping at rest due to the loss of the intrinsic tendency of the lungs to deflate. Movements of the thoracic and abdominal compartments may be impaired and may become worse with exertion². Therefore, the rib cage and abdomen may move uncoordinatedly; this phenomenon is called thoracoabdominal asynchrony (TAA)³.

TAA occurs in individuals with severe airway obstruction, leading to a mechanical disadvantage, increased breathing work, dyspnea symptoms, limited exercise, and reduced physical activity in daily life (PADL)^{4,5}. To our knowledge, few studies have proposed interventions to minimize TAA. Yamaguti et al. (2009)⁶ proposed that a diaphragmatic breathing retraining program could reduce TAA among individuals with COPD. Recently, Pinto et al. (2020)⁷ proposed a novel intervention using elastic tape (ET) in the chest wall and demonstrated that ET reduces TAA, tidal volume (TV), minute volume (MV), and dyspnea during isoload exercise among individuals with severe to very severe COPD. Participants also improved peak VO_2 during cardiopulmonary exercise testing (CPET) and reduced sedentary time during daily life. More recently, Santos et al. (2024)⁸ used ET for three weeks in patients with moderate to very severe COPD and reported reduced dyspnea symptoms as well as improved health status and health-related quality of life (HRQoL).

Pulmonary rehabilitation (PR) is an effective and successful treatment for individuals with persistent symptoms and/or excessive utilization of healthcare resources⁹. The European Respiratory Society (ERS) and the American Thoracic Society (ATS) define PR as a comprehensive intervention based on a thorough patient assessment followed by patient-tailored therapies, which include but are not

limited to exercise training, education, and behavior changes designed to improve the physical and psychological conditions of people with chronic respiratory disease and to promote long-term adherence to health-enhancing behaviors^{10,11}. The core of PR is exercise training, which directly addresses deconditioning and its association with decreases in symptoms such as dyspnea and fatigue, which are the primary reasons for referral. Exercise training programs also have additional effects on comorbidities, health-related quality of life, and general health¹¹. However, the additional effects of ET associated with PR have not been studied.

Considering that ET has been shown to reduce TAA, we hypothesize that using ET during a PR program may enhance the effects of PR in individuals with moderate to severe COPD. Therefore, this study aims to evaluate the additional effects of ET on exercise capacity, symptoms of anxiety and depression, and HRQoL in individuals with moderate to very severe COPD who are undergoing PR.

METHODS

STUDY DESIGN AND PARTICIPANTS

This is a protocol for a randomized, controlled, two-arm, assessor-blinded clinical trial approved by the Hospital Research Ethics Committee (55617321.2.0000.0068) and registered at clinicalTrials.gov (NCT05939999). Individuals with COPD will be screened and recruited at the Pulmonology outpatient clinic of a tertiary hospital and will be included in the study after signing the informed consent form.

INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria will be as follows: diagnosed with moderate to very severe COPD¹; clinically stable (i.e., no exacerbations for at least 30 days); male sex; non-obese (BMI ≤ 29.9 kg/m²); no

musculoskeletal limitations; no participation in another research protocol or a PR program in the past 6 months. The exclusion criteria will be decompensated cognitive, neurological, and/or cardiological dysfunction and receiving home oxygen therapy.

RANDOMIZATION AND ALLOCATION CONCEALMENT

The randomization will be generated using a computer (www.sealedenvelop.com). An investigator who is not involved in patient recruitment, assessment, or intervention will perform group allocation. Group allocation will be concealed via consecutively numbered, sealed, opaque envelopes.

EXPERIMENTAL DESIGN

Clinical and anthropometric data will be collected during the patient's interview. Subjects will complete questionnaires to assess health status (COPD Assessment Test, CAT), health-related quality of life (Chronic Respiratory Questionnaire, CRQ), and anxiety and depression symptoms (Hospital Anxiety and Depression Scale, HADS). Then, the complete pulmonary function test (body plethysmography), the Incremental Shuttle Walking Test (ISWT), and the Endurance Shuttle Walking Test (ESWT) will be carried out. Finally, individuals will use a triaxial accelerometer (Actigraph GT9X, Pensacola, FL, EUA) for seven days to assess their PADL. Lastly, individuals will be randomly assigned to one of two groups: the elastic tape (ET) group or the sham group.

At baseline and post intervention, assessments will be performed by a researcher who is not involved in individual recruitment or intervention. After inclusion, individuals will begin an 8-week PR program twice a week (Figure 1). Individuals in the ET group will have the ET placed before the beginning of the PR program, and the ET will be replaced every seven days throughout the 8-week period. The sham group will receive a non-elastic tape of the same color and size at the same position in the chest wall at the beginning of the PR program, and the tape will be replaced every seven days, similar to the ET group. At the end of the PR program, participants will repeat the same assessments

except for the ISWT. The ESWT will be performed at the same level established by the ISWT during the initial evaluation (Figure 2).

INTERVENTION

Elastic tape (ET)

The ET (Kinesio® Brand Tape, Tex Gold, Albuquerque, NM, EUA), made of cotton and elastic, skin-colored, and waterproof, will be positioned with the individual relaxed in the supine position. The individual will lie down on a stretcher so that their torso is extended, thus facilitating the application of the ET⁷. The ET positioning will be placed in the origin and insertions of the following muscle groups: rectus abdominis, internal oblique, and intercostal (Figure 3). The ET will be placed at the beginning of the session and replaced every seven days.

Sham group

The Sham group will receive a non-elastic tape (3M Micropore TM, Saint Paul, MN, USA) placed using an identical procedure to the ET and replaced every seven days.

PULMONARY REHABILITATION PROGRAM

Both groups will undergo an 8-week PR program, including one-hour sessions twice a week, supervised by a physiotherapist with experience in PR, carried out in the hospital's outpatient clinic. The program will be individualized and divided into 30 minutes of aerobic training on an ergometric treadmill (Technogym Jog 500, Brazil) and 30 minutes of resistance exercises with free weights (dumbbells and barbells) for the upper and gym machines for lower limbs. Aerobic training will be performed with a heart rate (HR) corresponding to 50–80% of the maximum HR according to the formula proposed by Karvonen et al. [$HR_{\text{training}} = HR_{\text{rest}} + (HR_{\text{max}} - HR_{\text{rest}}) * \% \text{ intensity}$]. The intensity will be increased weekly by 5% of the maximum HR until reaching 80% of the maximum

HR. HR_{training} = training heart rate; HR_{rest} = resting heart rate; HR_{max} = maximum heart rate; and % intensity = percentage of training intensity. Furthermore, this progression of treadmill load will also be guided by the scale of subjective perception of exertion (modified Borg scale)¹². The training will be carried out in such a way that during each session, the participant must remain on the Borg scale between scores 4 and 6¹³. The increase in intensity by 5% of the maximum HR will be adjusted after two sessions and/or if the score on the Borg scale is less than 4. If the participant reports tiredness beyond six on the Borg scale, the intensity will be reduced, and in the following session, the attempt to increase it will be carried out again in the next session. The participant may interrupt the activity if they feel symptoms or intense respiratory discomfort, resuming it after improvement. Heart rate (HR), peripheral oxygen saturation (SpO₂), and the subjective perception of exertion will be monitored during exercise. Oxygen supplementation will be provided as needed to maintain SpO₂ $\geq 90\%$ ¹³.

Resistance training will consist of exercises for the upper limbs (ULs) through lifting weights with dumbbells and for the lower limbs (LLs) via weight machines. Large muscle groups will be trained, such as the biceps, deltoid, quadriceps, and hamstrings. Training will begin with three sets of eight repetitions of each exercise at a workload of 50% of the one-repetition maximum (1-RM)¹⁴. The number of repetitions will subsequently increase to three sets of 10 and, later, 12 repetitions. Load progression will be carried out when the individual tolerates performing more than 12 repetitions for each set without compensatory movements and/or symptoms of intolerance. The workload will be increased according to individual tolerance.

Resistance training for the upper limbs will include 1 - shoulder abduction and 2 - elbow flexion. Resistance training for the lower limbs will include 1 - knee extension and 2 - hip extension using "leg press" equipment.

No written material will be provided to either group. Transportation expenses will be subsidized for all individuals to reduce absenteeism. This financial resource will be funded for this research project.

To analyze the results, individuals must complete at least 80% (13 sessions) of the program, which will be monitored via the PR monitoring form.

ASSESSMENT TOOLS

PRIMARY OUTCOME MEASURE

FUNCTIONAL EXERCISE CAPACITY

The ISWT will be performed to assess functional exercise capacity. In this test, individuals will be instructed to walk in a 10-m corridor delimited by cones (with a 9-m distance between them), and the speed will be determined by a beep recorded on the sound box, which increases the speed by 0.17 m/s every minute, with a total of up to 15 stages. They will also be instructed to walk at a speed that allows them to reach the cones when the beep sounds, and at the end of each minute, an additional signal will be given to alert them to the increase in speed¹⁵. The test will end when the participant is more than 0.5 m away from the cone, reports chest pain, reports severe dyspnea, reports fatigue, reports exhaustion, or requests to stop. The distance walked at the end of the test will be registered for subsequent analyses¹⁶. Before and after the exercise tests, SpO₂ and heart rate will be assessed via a portable pulse oximeter positioned on the individual's dominant hand (Nonin WristOx2® 3150). Blood pressure (BP) will be assessed via a stethoscope (Littman, Minnesota, United States) and a sphygmomanometer calibrated on the dominant arm (Aneroid Premium - G-Tech, Santa Catarina, Brazil).

The criteria for stopping the test will include diastolic blood pressure (DBP) above 140 mmHg; sustained elevation of systolic blood pressure (SBP) above 240 mmHg; motor incoordination; feelings of imbalance; mental confusion; clinical manifestations of respiratory distress that worsen with increasing load; dyspnea disproportionate to the intensity of the effort; progressive claudication of the lower limb; and limb exhaustion¹⁰. Individuals will be instructed not to consume beverages containing caffeine for at least 12 hours before the test and not to perform intense exercise 24 hours

before.

The ESWT will be performed 40 minutes after the end of the ISWT, using the same structure; that is, the volunteers will be instructed to walk in a 10-meter corridor limited by cones (with a distance of 9 meters between them), and the speed will be determined by a sound signal recorded by the cell phone. In this case, the speed will be determined using 85% of the maximum speed reached in the ISWT and will be constant throughout the test¹⁰. Individuals will be monitored before and after the test, and the interruption criteria will be the same as those used in the ISWT procedure.

SECONDARY OUTCOME MEASURES

HEALTH-RELATED QUALITY OF LIFE (HRQoL)

HRQoL will be assessed via the Chronic Respiratory Questionnaire (CRQ), which was validated and translated into Portuguese¹⁷. The questionnaire consists of 20 questions divided into four domains: fatigue (4 questions), emotional function (7 questions), and self-control (4 questions). The responses will be assessed via a Likert scale with seven alternatives ranging from "never" to "always", whereas the Dyspnea domain (5 questions) includes an individualized assessment in which the patient chooses, from a list of 26 daily activities, the five activities that cause the most dyspnea and then rate each one again via a Likert scale with seven alternatives ranging from "Unbearable shortness of breath" to "No shortness of breath". The results will be expressed as the mean score of each domain and the total score, with higher scores indicating better HRQoL.

ANXIETY AND DEPRESSION SYMPTOMS

The Hospital Anxiety and Depression Scale (HADS) will assess anxiety and depression symptoms. The questionnaire was developed to identify symptoms of anxiety and depressive mood and has been translated, validated, and published in Portuguese by Botega et al., 1995¹⁸. It consists of 14 multiple-choice questions divided into two subscales, anxiety (HADS-A) and depression (HADS-D)

symptoms, with 7 questions each. The domains are categorized by the severity of the stress present: 0–7 – none; 8–10 – probable; >11 – present^{19,20}.

HEALTH STATUS

Health status will be assessed by the COPD Assessment Test (CAT), a specific questionnaire for COPD that assesses the impact of the disease's symptoms¹. It consists of eight items related to health conditions and has been applied and validated in several languages, including Portuguese²¹.

SAMPLE CHARACTERIZATION

INITIAL ASSESSMENT

Individuals will undergo an initial interview to provide information on several aspects: identification and contact data, medical history (e.g., depression, osteoarthritis/arthritis, osteoporosis, diabetes mellitus, and arterial hypertension), and medications in use.

LUNG FUNCTION

Pulmonary function parameters will be obtained from the individual's medical records within the previous six months. The interpretation will be performed according to the standards of the American Thoracic Society and European Respiratory Society²² and normal values relative to the Brazilian population²³.

PHYSICAL ACTIVITY IN DAILY LIFE (PADL)

The PADL will be quantified using a triaxial accelerometer (GT9X, Actigraph, USA) for sample characterization. The equipment will be placed on the individual's waist, and the individual will be advised to wear it for seven days and only remove it to sleep and shower. They will be instructed to maintain their lifestyle habits. Seven full days of monitoring will be considered to evaluate the

PADL: five weekdays and two weekend days. Zero counting time (considered the period in which the participant did not use the accelerometer) or days with less than eight hours of the device in use will be excluded²⁴. The results will be expressed as the time of sedentary behavior, steps per day, and time in moderate to vigorous physical activity (MVPA).

STATISTICAL ANALYSIS

Data normality will be assessed via the Shapiro–Wilk test, and homoscedasticity will be assessed using Levene's test. Data will be presented as the mean and standard deviation or as the median and interquartile range [25–75%], according to the data distribution.

Intergroup comparisons will be performed using a two-way repeated measured analysis of variance (ANOVA) followed by the Bonferroni post hoc correction test or the Kruskal–Wallis test, followed by Dunn's post hoc test, depending on the normality of the data. Statistical procedures will be performed based on the intention to treat principle. The threshold for statistical significance will be set at 5% ($p < 0.05$).

SAMPLE CALCULATION

The sample size calculation was based on a previous study showing a mean difference of 65 seconds and a standard deviation of 65 seconds between groups in the ESWT²⁵. Thus, considering an alpha equal to 0.05 and a beta equal to 0.80, the estimated sample size will be 17 individuals per group. Considering that the analyses will be carried out with the intention to treat and that for those who eventually do not carry out the final evaluations, the data will be imputed, and the sample size was increased by 20% for each group. Thus, the estimated sample size for this study will be 21 individuals per group.

RESULTS

The São Paulo Research Foundation (FAPESP) will fund the study. The study has already been approved by the Hospital Research Ethics Committee (55617321.2.0000.0068) and registered at clinicalTrials.gov (NCT05939999). Data collection is ongoing and is anticipated to continue until September 2026. A publication of the results is anticipated to be available in late 2026.

DISCUSSION

The use of ET during rest periods does not alter lung volume; however, during exercise, individuals with COPD under the same workload (isoload) have shown a notable decrease in VT, minute volume (MV), dyspnea, and TAA. Furthermore, individuals with ET have shown a significant increase in VO₂, workload, and maximal exercise duration compared with those without ET. Additionally, ET increased the amount of time spent in moderate and vigorous physical activity, along with a marked reduction in sedentary time. Since the measurements were randomly performed with or without ET, these data strongly suggest that ET attenuated the ventilatory demand required for exercise performance across individuals⁷.

Recently, Santos et al. (2024)⁸ demonstrated that ET use for 21 consecutive days does not alter PADL but reduces dyspnea and improves health status and HRQoL in individuals with moderate to very severe COPD in the short term. Therefore, this new, low-cost intervention also improves COPD symptoms during its continuous use. The use of ET may enhance the already-known effects of the PR program, such as increased exercise capacity and improved quality of life among individuals with COPD.

One of the strengths of the proposed study is the use of ET throughout the PR period (16 sessions in 2 months), which may improve the HRQoL of individuals with COPD. Additionally, this is a randomized, controlled, two-arm, assessor-blinded study, and it is the first study to evaluate the

potential effects of ET during an entire PR program. One possible limitation is the inclusion of only non-obese male individuals from a single center who are not in oxygen use.



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Authors contributions

Substantial contribution to the study concept and design: T.F.P; J.M.B.S; E.C.M.R.; C.C.B.M.S.; C.R.F.C; data acquisition: T.F.P; J.M.B.S; E.C.M.R.; C.C.B.M.S.; data analysis and/or interpretation: T.F.P; J.M.B.S; E.C.M.R.; C.C.B.M.S.; F.F.L.; C.R.F.C; Significant manuscript writing and/or critical revisions for important intellectual content: T.F.P; J.M.B.S; E.C.M.R.; C.C.B.M.S.; F.F.L.; A.C.; R.M.C.P; C.R.F.C;. All the authors have read and approved the final version of the manuscript.

Human Ethics Approval Declaration

This study was approved by the Ethics Committee for Analysis of Research Projects (CAPPesq) of the School of Medicine of the University of São Paulo - Hospital das Clínicas approval: 55617321.2.0000.0068. The study's clinical trial registration number is Clinical Trials.gov Protocol Registration – registered with NCT05939999.

Disclosure statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability Statement

The data supporting this study's findings are available from the corresponding author, C.R.F.C., upon reasonable request.

Legend of the figures

Figure 1: Study flowchart (CONSORT diagram)

Figure 2: Study design. CAT: COPD Assessment Test™; CRQ: Chronic Respiratory Questionnaire;

HADS: Hospital Anxiety and Depression Scale; PFT: pulmonary function test; PAL: physical activity level; ET: elastic tape; V: visit; ISWT: incremental shuttle walking test; ESWT: endurance shuttle walking test; 1RM: 1 repetition maximum test; PR: pulmonary rehabilitation.

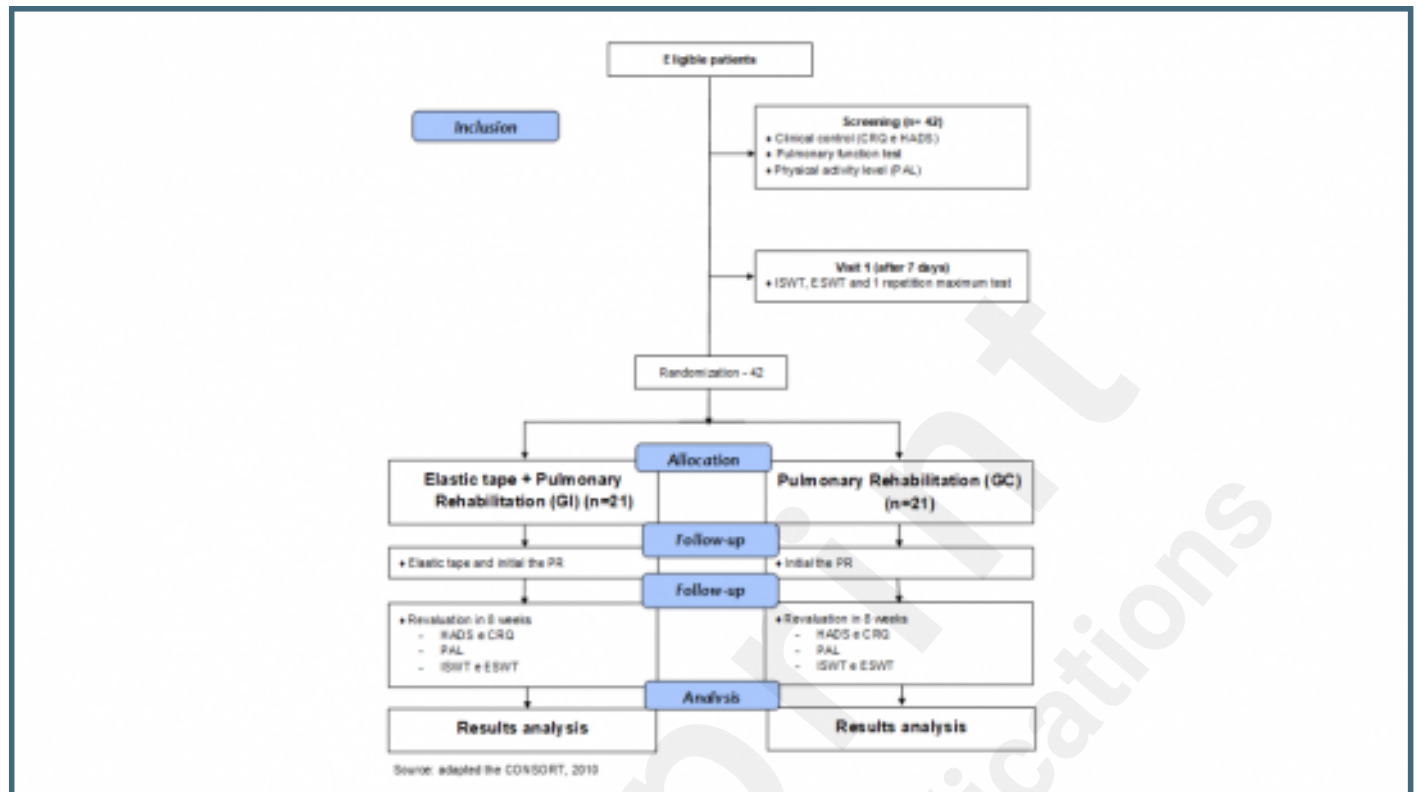
Figure 3: Elastic tape placement



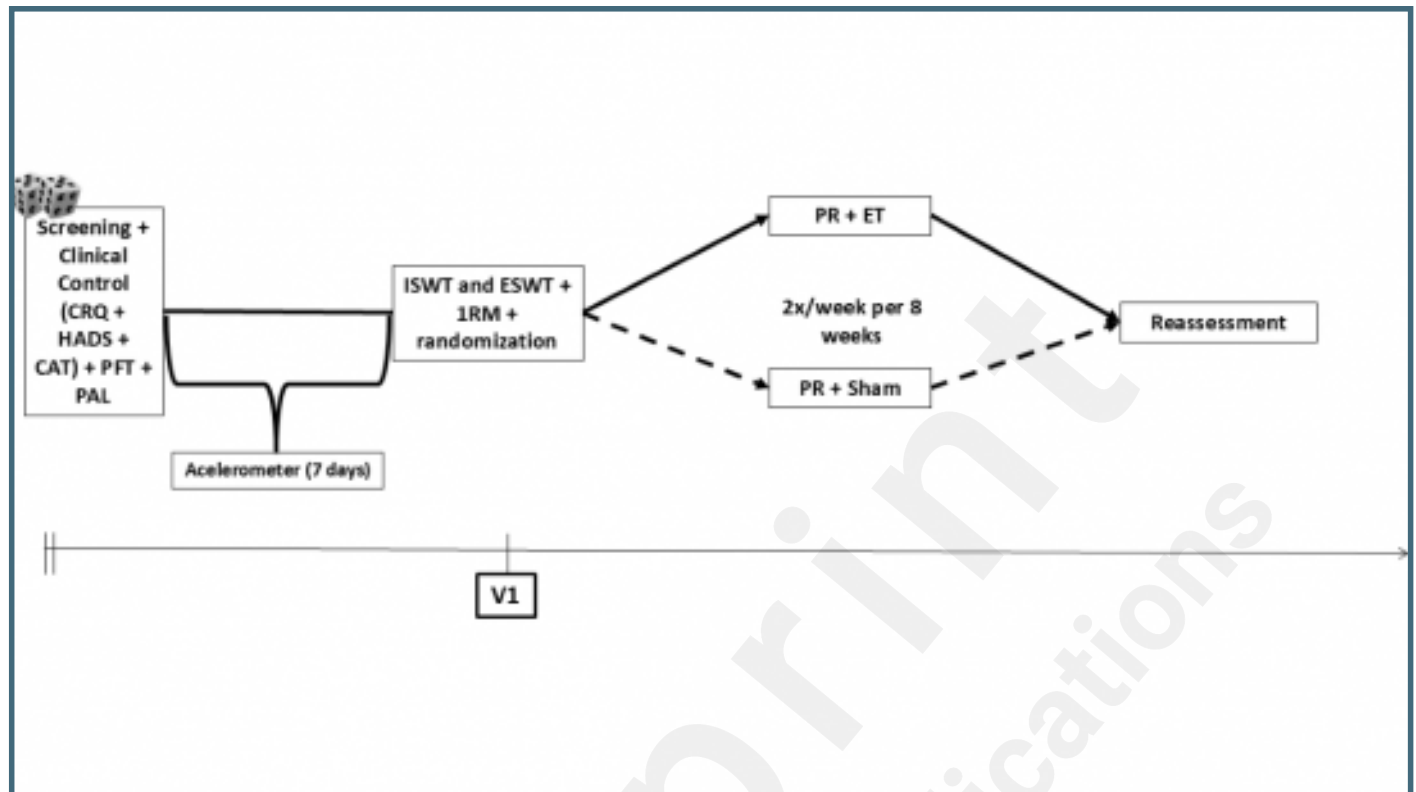
Supplementary Files

Figures

Study Flowchart.



Study Design.



Elastic tape placement.

