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Effect of Breather Trainer Versus Pulmonary Rehabilitation on Cardiopulmonary Efficiency in Patients with COPD Post Covid-19

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Abstract

A growing body of evidence indicates that SARS-CoV-2 infection can cause long-term problems in the lungs and various other organ systems, such as a higher risk of cardiovascular diseases, neurological disorders, as well as mental health problems. These complications are referred to as long-COVID or post-acute syndrome or sequelae of SARS-CoV-2 infection (PASC). Excruciating dyspnea, hypoxia, dry cough, reduced exercise capacity and extreme exhaustion, with or without sputum production, cardiopulmonary endurance dependency on daily tasks, and lower quality of life were all long-term impacts of COVID-19 infection in chronic obstructive pulmonary disease (COPD) patients. This study was carried-out to examine the impact of combining the breather respiratory muscle trainer with traditional pulmonary rehabilitation in COPD patients with post-COVID-19 pneumonia on the symptoms, pulmonary function, and physical and cardiopulmonary fitness compared to traditional pulmonary rehabilitation alone. In this study, 80 COPD patients, with GOLD1 and GOLD2 (FEV1/FVC 50-79%), dyspnea, and with post COVID-19 pneumonia among 3 and 6 months ago, were recruited, aged from 30 to 40 years old. Assessment measures were initially assessed for all patients before starting the treatment (Pre) following 6 weeks (Post I) and following 12 weeks (Post II) by measuring forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1/FVC, maximum voluntary ventilation (MVV), Oxygen Saturation (SPO2), rate pressure product (RPP) and physical fitness index (FFI). The patients were randomized into two equivalent groups at random. Group (A): Forty patients who were given the breather respiratory muscle trainer added to mild interval aerobic of 30- 45 minutes treadmill walking exercises with intensity at 30-50 % of max HR and respiratory training on the treadmill; and Group (B): Forty patients who were given the diaphragmatic along with segmental breathing exercises added to mild interval aerobic as well as respiratory training on the treadmill. For both groups, the treatment session was carried-out for an average duration of 45 to 60 minutes, three times per week for 12 weeks for both groups based on the described techniques for every group. Data obtained from both groups regarding FEV1, FVC, FEV1/FVC, MVV, RPP, in addition to FFI were subjected to statistical analysis and comparison. Through comparing the statistical findings after-treatment within and between both groups, Group (A) showed significant improvements regarding FEV1, FVC, FEV1/FVC, MVV, RPP, in addition to FFI compared to before-treatment and Group (B). Statistical analysis revealed a significant increase after 12 weeks of treatment in FEV1, FVC, FEV1/FVC, MVV, oxygen saturation, and RPP improvement by improvement percentages of 25.18%, 12.24%, 11.69%, 25.26%, 5.57%, and 26.47%, respectively, in group (A), and of 16.73%, 8.70%, 7.50%, 16.93%, 5.23%, and 25.25%, respectively, in group (B). The net findings revealed the superiority of the intervention provided to the study group. In COPD patients with post-COVID-19 syndrome, combining the breather respiratory muscle trainer with traditional pulmonary rehabilitation may be more advantageous than traditional pulmonary rehabilitation alone for managing symptoms and enhancing quality of life through increased physical and cardiopulmonary fitness.

Keywords: Post COVID-19 sequelae, COPD, breather trainer, pulmonary rehabilitation, pulmonary function.

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1. Introduction

Multiple groups have reported persistent parenchymal problems after COVID-19 pneumonia; these have been identified as post-COVID interstitial lung disease [1]. There are a variety of long-term consequences that can arise from a SARS-CoV-2 infection. These include pulmonary and extrapulmonary organic systems, as well as a higher risk and burden related to cardiovascular problems, neurological and mental health problems, metabolic diseases (diabetes along with dyslipidemia), kidney disease, and gastrointestinal conditions [2].

Deterioration in exercise capacity, dyspnea, as well as cardiovascular endurance, dependency on ADLs, and overall quality of life are some of the long-term consequences [3]. greater than nearly a third of adult COVID-19 hospitalized individuals experienced an airway-related disorder, namely COPD, according to a new report from center of Disease Control [4]. Patients with COPD are at increased risk for acute pulmonary infections due to the disease's long duration, severe decrease in lung function, and associated inflammation. Before vaccines were available, individuals with COPD who had COVID-19 sometimes developed unbearable dyspnea, hypoxia, dry cough, as well as high levels of fatigue, with or without sputum generation if treatment was not quickly and appropriately administered. Pneumonia was a serious medical condition that required hospitalization, intensive care unit admission, and in some cases, death for some people [5]. Patients after COVID-19 should be particularly concerned for potential respiratory as well as cardiovascular system involvement leading to dyspnea, decreased oxygen saturation in the blood, and reduced cardiopulmonary performance [6]. The ability of both the circulatory as well as respiratory systems to deliver oxygen towards the mitochondria of skeletal muscles for the synthesis of energy required throughout physical activity is called cardiopulmonary efficiency (CPE). Cardiovascular disease (CVD) in addition to overall mortality in adulthood is strongly predicted by low or poor CPE [7]. An indirect measure of myocardial utilization of oxygen, the rate pressure product (RPP) anticipates cardiac performance, mortality, as well as morbidity in individuals with CVD [8]. However, RPP, a non-invasive basic assessment, may give helpful information for risk stratification and prognosis for patients [9]. Patients with C0OPD who experienced symptoms after the COVID-19 pandemic were more likely to be in a severely deconditioned and unstable condition than usual, with research suggesting that addressing these cases within the first three to six months after the pandemic could prevent the symptoms from turning chronic [10]. By decreasing the impact and death caused by viral infections, interval training may alleviate chronic inflammation and reinforce the immune response [11]. Since COVID-19 impacted both the respiratory and immunological systems, increasing aerobic capacity can lead to better overall health [12]. Neither the benefits nor the drawbacks of combining inspiratory muscle training (IMT) with expiratory muscle training (EMT) have been extensively documented. The potentially underestimated potential of combining IMT and EMT has been brought to light, however, by a limited number of significant research. Combining the IMT and EMT at the same time resulted in a 33% improvement in maximal inspiratory as well as expiratory pressure in patients having COPD [13]. The Breather is a device which effectively provides Resistive Breathing Training (RBT), which involves breathing against resistance to improve breath support by activating and rebuilding strength in the throat's inspiratory and expiratory muscles. This improves cough effort, speech training, and swallow safety [14].

2. Materials and methods

2.1. Study Design and Participants

2.1.1. Subjects

Eighty COPD patients with post-COVID pneumonia, after 3 - 6 months, from both sexes were chosen in this study from the Chest outpatient clinics of Al-Mansoura Hospital. The demographic details of the patients are represented in Table 1. After a careful evaluation, the chest physician and physiotherapy specialist referred all patients based on criteria for inclusion as well as exclusion. Patients were selected according to the established inclusion criteria, which included being between the ages of 30 and 40, having COPD, having (FEV1/FVC) of 50 to 79%, dyspnea, along with a history of post-COVID-19 pneumonia within the past three to six months as confirmed by a computed tomography (CT) scan as well as polymerase chain reaction (PCR) test; their BMI varied from 20 to 29.9 kg/m^2, they were hemodynamically and medically stable with SPO2 ≥ 93%, cooperative, competent, and able to comply with treatment. Patients were excluded if they had orthopedic problems or a neurological impairment that led to bulbar affection, or with visual or/and auditory problems or mental impairment that resulted in difficult communication, if they complained of unstable hemodynamics or cardiac instability, or arrhythmias e.g., atrial fibrillation, left bundle-branch block, or heart failure, pericardial effusion, mitral or aortic valvular disease, congestive heart failure, or recent myocardial infarction, if they had uncontrolled severe COPD (FEV1/FVC < 50%) or bronchospasm, and unmanaged asthma, if they had originally inadequate training performance of the respiratory muscle such as neuromuscular disease (NMD), i.e., myopathy or neuropathy, or if they weren't indicated for physiotherapy such as suffering from a recent pulmonary embolism.

2.1.2. Design

This randomized controlled trial ran from December 2021 to June 2023. No. P.T.REC/012/003659 was the approval number given to the study by the ethical committee of faculty of the physical therapy at Cairo University in Egypt. Following the explanation of the study's objective and the obtaining of informed consent, the participants who were chosen for the study were divided into two equivalent groups using the envelope approach: group (A) and group (B). When patients gave their consent, a blinded physiotherapist or assistant nurse took one of two envelopes containing cards labeled "group (A)" or "group (B)" and opened it. Subjects were grouped into their respective categories based on the cards they were given. Documentation: A recording data sheet was used to document all relevant information regarding every participant in this study. This included their name, age, sex, spirometry measurements, oxygen saturation, FFI, as well as rate pressure product. During the course of treatment, patients were instructed to report any adverse effects. Forty patients were divided into two groups: group A was given respiratory muscle trainers utilizing a breather in addition to mild interval aerobics on the treadmill for 30–45 minutes within an intensity level of 30–50% of maximum heart rate (HR), while group B was given diaphragmatic along with segmental breathing exercises in addition to the

previously mentioned mild interval aerobics along with respiratory training on the treadmill.

2.2. Procedures of the study

To make sure that the study would not be hindered or impacted by any underlying conditions, the following items were checked off the list: a thorough medical history free of chronic respiratory conditions, kyphosis or additional musculoskeletal problems, neurological disorders affecting the respiratory muscles (NMD), as well as any major or active hemoptysis. Every patient underwent a comprehensive clinical evaluation that included taking their temperature, heart rate, blood pressure, oxygen saturation, as well as respiratory rate prior to, during, and following each session. This was done to rule out potential issues that could compromise the study's integrity. Safety measures include keeping track of vital signs prior to as well as during treatment procedures (heart rate > 140 or < 60 b/m, oxygen saturation < 85%, blood pressure > 140/90 or < 90/60 mmHg), along with reporting any negative effects that occur during the study. No large meals for at least two hours prior to the session are recommended for patients.

2.3. Measurement equipment and methods

Measuring the variables of assessment and the outcomes groups for all participants of both groups prior to starting the treatment (Pre) following 6 weeks (Post I) and following 12 weeks (Post II).

2.3.1. Pulmonary function measures

Pulmonary function measures (FVC, FEV1, FEV1/FVC, and MVV) have been assessed by using Spirometry (smartSOFTmee version 2.14.21) [15]. After preparing the device and the patient and delivering instructions, each patient assumed the sitting position with a nose clip on the nose, they were told to take a deep breath in quickly, with a hold of more than one second at TLC, next, firmly seal the mouthpiece with the lips, then execute the FVC technique. Lastly, forcefully exhale for as long as you can and as quickly as feasible while loudly asking for more, more, more. This process should last for at least six seconds. The maximum volume of air that an individual can breathe in a given time frame (often 12 seconds) is called the maximum voluntary ventilation (MVV). The potential output in one minute, measured in liters per minute, is then calculated by multiplying the 12-second volume by 5 [16].

2.3.2. Oxygen Saturation

Additionally, the finger pulse oximeter was used to measure all participants while they were seated [17].

2.3.3. Physical Fitness Index (PFI)

Each patient was allowed five minutes of chair rest. This is the position in which the resting pulse rate was recorded [18]. Once the instruction was complete, participants were instructed to rhythmically complete the modified Harvard step test, which involves stepping onto a 33 cm height step at a rate of two seconds thirty per minute) for 5 minutes, for an overall of 150 steps. The test includes three intervals of one minute following exercise (PR1), 3 minutes following exercise (PR2), and 5 minutes following exercise (PR3), where the pulse rate is measured as (a), PR1, (b), and PR3, respectively. To determine PFI, the subsequent formula was used:

$$\text{PFI }\% = \frac{100 \times \text{Duration of exercise in seconds}}{2\ (\text{pulse } 1 + 2 + 3)}$$

2.3.4. Rate Pressure Product (RPP)

Rate Pressure Product (RPP) is equal to the sum of the systolic blood pressure readings (SBP) and the heart rate taken at rest (RHR), then basal measures of S.B.P, and heart rate (H.R.) were recorded by using an automatic BP monitor (OMRON). it is expressed as:

The rate-pressure product (RPP) = HR X SBP [19].

2.4. Therapeutic procedures

The treatment procedures were carried out three times weekly over 12 weeks in both groups using the specified approaches. A mean treatment session lasted between forty-five and sixty minutes. The procedures of treatment approaches were achieved under the following steps: for group “A”, each treatment session consisted of the breather device for respiratory muscles training added to the traditional pulmonary rehabilitation methods, while for group “B”, each treatment session consisted of the traditional pulmonary rehabilitation methods only.

2.4.1. The Traditional Pulmonary Rehabilitation methods

This technique was performed by both the groups (A) and (B) and was involved.

2.4.1.1. Mild intensity interval aerobic training (MIIT)

- The **submaximal treadmill exercise test** was utilized to establish the maximum heart rate for the intensity of aerobic exercise. Patients were directed through a series of three-minute stages on a motorized treadmill, each with a progressively increasing speed along with grade [20]: the first stage: 1.7 mph, grade = 0%; the second stage: 1.7 mph, grade = 5%; the third stage: 1.7 mph, grade = 10%; the fourth stage: 2.5 mph, grade = 12%; the fifth stage: 3.4 mph, grade = 14%; the sixth stage: 4.2 mph, grade = 15%; and the seventh Stage: 5.0 mph, grade = 15%. After each three-minute stage, heart rate data was recorded. Tests were stopped when individuals reached 85% of their peak heart rate, when patients asked to stop, or when the exercise consultant thought it was unsafe for the patient to continue exercising.
- **Treadmill walking exercise** consisted of 5 sets of 3-minute bouts at 50% of MHR interspersed by 3-minute bouts at 30% of MHR (totaling 30 min) (1-3 METS) [21]**.** The exercise training will be 3 times/week for 12 weeks. 5–10 minutes of warming up at 25% of MHR, 30 minutes of minimal interval aerobic exercise (treadmill walking), with an intensity of 30–50% of maximum HR (1-3 METS), as well as 5–10 minutes of cooling down at 25% of MHR.
- **Warm-up and cool-down** included exercise at low intensity (at 25 % of MHR) for five to ten minutes in the form of either a treadmill or stretching exercise and ROM exercises of the upper extremity (elbow extensors, shoulder flexors, as

well as extensors) and trunk muscles (for lateral side bending both sides, trunk extensors combined with breathing exercise [20].

2.4.1.2. Breathing training

- **Diaphragmatic breathing exercises:** Patients were asked to place their hands on their abdomen and expand their abdomen to lift their hands during inhalation. The exercises were done for 5 to 10 minutes, three to four sessions a day, as suggested by the clinical practice guidelines (CPG) [22].
- **Localized Breathing for lower, middle, and upper segments:** As directed by the CPG, exercise was done for 5 to 10 minutes three to four times per day [22].

2.4.2. The Breather Respiratory Muscle Trainer device (PN Medical, BD12438, USA)

The technique was only used with the study group (A), which had 40 patients who got both standard pulmonary rehabilitation as well as the breather trainer device. There are two stages to this part of the process [23]:

2.4.2.1. Preparatory phase

Patients were asked to patient get rid of candy, gum, as well as dentures from the mouth and to empty their bladder before begging the session to be relaxed. Instructions were given to each patient regarding the procedure and sufficient time was provided to practice the maneuvers. Patients had assumed a comfortable sitting position on a chair, and all limbs rested and supported. The training began with the easiest inhalation and exhalation resistances by rotating both dials to number one. Each patient was taught and trained to use the diaphragmatic breathing technique and to secure the mouthpiece with lips making sure not to bite down on the mouthpiece. For the infection control of the breather the device was sterilized by plasma gas sterilization or autoclaves after each patient session, and disposable mouthpieces were used to minimize cross-infection.

2.4.2.2. Application phase

A soft nose clip was put on the nose to occlude the nostrils and prevent patient leaks. Each patient was asked to rapidly inhale, maintain a slight pause, and then quickly forcefully exhale. After exhaling slowly through pursed lips, the device was secured in the patient hand and the patient was asked to inhale deeply and forcefully for approximately two to three seconds and had a pause of slightly under a second. The patient's stomach, rib cage, and neck muscles were noticed and monitored during breathing in against resistance to make sure to relax the upper chest and shoulders. The patient was ordered to exhale forcefully for two to three seconds while preventing puffing from the cheeks. The previous steps were done for 2 sets of ten breaths two times per day, 6 days a week.

2.5. Data collection and Statistical analysis

The data were checked for the normality assumption test as well as the homogeneity of variance. A Shapiro-Wilk test was employed to see if the data had a normal distribution (P>0.05). then, box and whiskers plots were utilized to find outliers. Levene's test for checking the homogeneity of variance also showed that there wasn't a significant change (P>0.05). Parametric testing was done on the data. The Statistical Package for Social Studies (SPSS Package) tool version 25 for Windows (SPSS, Inc., Chicago, IL) was used to do the statistical analysis. An independent t-test was used to compare the features of the subjects in the two groups. The Chi-squared test was used to see how gender and PFI were distributed among groups. We used a mixed MANOVA to look at how time (before and after treatment) and treatment (between groups) affected the average values of FEV1, FVC, FEV1/FVC, MVV, SPO2, as well as RPP. We additionally examined at how time and treatment affected each other. For later multiple comparisons, post-hoc tests with the Bonferroni correction were run. A p value of less than 0.05 was used for all statistical tests.

3. Results and Discussion

3.1. Subject characteristics

An overall of 80 patients took part in this study. They were divided at random into two groups of 40 patients each. There were no substantial differences among groups (A) and (B) in terms of age (P=0.54; P>0.05), sex (P=0.82; P>0.05), or BMI (P=0.77; P>0.05) (Table 1). Utilizing a mixed design MANOVA, the results shown in Table 2 showed that there were statistically substantial differences (F-value=5.05; P=0.0001; P<0.05) between the tested groups (the 1st independent variable) upon all of the dependent variables, such as FEV1, FVC, FEV1/FVC, MVV, SaO2, RPP, as well as oxygen saturation. Also, the measurement periods (the 2nd independent variable) had a substantial impact on the factors that were being tested (F-value=1812.47; P=0.0001; P<0.05). Also, there was a substantial association among the two outcome measures (groups x time) (F-value=16.26; P=0.0001; P<0.05). This meant that the measurement periods (2nd independent variable) affected the impact of the tested group (1st independent variable) on the dependent variables. The purpose of this prospective study was to compare the effectiveness of pulmonary rehabilitation with that of a breather trainer in improving cardiopulmonary performance in individuals diagnosed with post-COVID-19. Research has shown that treating COPD patients within the first three to six months after the virus has cleared the airways can keep their symptoms from getting worse or even going away altogether. This is especially true for patients whose conditions worsened after the COVID-19 pandemic [10]. This study aimed to compare the effectiveness of pulmonary rehabilitation with that of a breather trainer in improving cardiopulmonary performance in patients with post-COVID-19. The primary outcomes were measured using the following parameters: PFI, RPP, oxygen saturation (SPO2), MVV), FEV1, FVC, as well as FEV1/FVC. Pairwise comparison tests (Post hoc test) for FEV1, FVC, FEV1/FVC, MVV, oxygen saturation, and RPP within each group (Table 3) revealed that there was a substantial increase in FEV1 (P=0.001; P<0.05), FVC (P=0.0001; P<0.05), FEV1/FVC (P=0.0001; P<0.05), MVV (P=0.0001; P<0.05), oxygen saturation (P=0.0001; P<0.05), and RPP (P=0.0001; P<0.05) post-treatment in comparison with pre-treatment within group A and group B. Group (A) enhanced

FEV1, FVC, FEV1/FVC, MVV, oxygen saturation, and RPP improvement by 25.18%, 12.24%, 11.69%, 25.26%, 5.57%, and 26.47%, respectively) than group (B) (16.73%, 8.70%, 7.50%, 16.93%, 5.23%, and 25.25%, respectively).

Furthermore, pairwise comparison tests (Post hoc test) for FEV1, FVC, FEV1/FVC, MVV, oxygen saturation, as well as RPP among both groups (Table 3) revealed no substantial differences (P>0.05) pre-treatment of FEV1, FVC, FEV1/FVC, MVV, oxygen saturation, and RPP. Whereas post-treatment, there were substantial differences in FEV1 (MD= 0.25; P=0.001; P<0.05), FVC (MD=0.15; P=0.0001; P<0.05), FEV1/FVC (MD=3.04; P=0.0001; P<0.05), MVV (MD=8.56; P=0.0001; P<0.05), oxygen saturation (MD= 0.02; P=0.0001; P<0.05), as well as RPP (MD=149.1; P=0.0001; P<0.05), among-group (A) as well as group (B). Both groups had all of these variables assessed prior to treatment began (Pre), again after six weeks (Post I), and again after twelve weeks (Post II). As for the pulmonary function variables (FEV1, FVC, FEV1/FVC, and MVV), and the oxygen saturation variable adding to the rate pressure product and the physical fitness index variables, our study showed that there was a substantial improvement of FEV1/FVC, as well as MVV with an improvement percentage after 12 weeks about 25.18% and 16.73%, 12.24% and 8.70%, 11.69% and 7.50%, and 25.26% and 16.93% for both groups (A) and (B) correspondingly in comparison with pre-treatment (P value=0.0001; P<0.05). In addition, group (A) had a substantial improvement in oxygen saturation of approximately 5.57% and group (B) of around 5.23% in comparison with the pre-treatment (P value=0.0001; P<0.05) (Table 3). At last, group (A) showed a substantial rise in RPP, with a percent of around 26.47%, while group (B) showed an enhancement of about 25.25%, in comparison to the pre-treatment (P value=0.0001; P<0.05). This substantial rise in all variables post-treatment favored the study group (A). A possible explanation is that, similar to other skeletal muscles, the respiratory muscle experiences structural and functional adaptation in response to training stimuli. also, Respiratory muscles can be strengthened and endurance trained. Strengthening exercises for the inspiratory muscles increases respiratory muscular strength for reasons that have to do with the anatomy of the skeletal muscle as well as the resistance that is used during training. In response to brain signals, the inspiratory muscles generate more mechanical power, which the body uses to meet the higher respiratory demands caused by exercise [24]. Hence, it is possible to increase total exercise tolerance by creating new performance-enhancing training approaches that target specific respiratory mechanisms. This would enhance neuromuscular reactions and respiratory performance. One of these techniques is IMT, which involves repeatedly putting a heavy strain on the inspiratory muscles in order to build their strength and improve their respiratory power and endurance. Reducing the impression of dyspnea and improving exercise capacity are two benefits of respiratory muscle workouts. These exercises work by strengthening the inspiratory muscle, which is weak for individuals suffering cardiopulmonary disease [25]. One tool for strengthening the respiratory muscles is the Breather, which allows the user to breathe through holes of varying sizes while subjected to resistance training. In order to enhance respiratory physiology and ease symptoms, breathing techniques are used as a therapeutic modality [14]. In generally, high-intensity exercise improves aerobic performance as well as maximum oxygen uptake (VO2 max) in healthy adults using pressure-resistive IMT devices. Further, PR-IMT devices which utilize high intensities of MIP (80% to 90%) enhance lung volumes, power output, pulmonary muscle strength, as well as working capacity [26]. Numerous studies supported our results. Researchers Al-Najar et al., (2022) used the Functional Evaluation of Chronic Illness Therapy (Dyspnea-10 item "FACIT-Dyspnea" Questionnaire), chest expansion, as well as ventilatory function measures (FEV1, FVC, FEV1/FVC, MVV) to examine the impact of respiratory muscle training utilizing the Breather on pulmonary functions in women aged 40–50 who had undergone unilateral mastectomy [27]. Consistent with previous research, this study found that respiratory muscle training (The Breather) significantly improved ventilatory functioning and dyspnea following mastectomies, particularly when coupled with physiotherapy treatment. A quasi-experimental study was carried out by Chang et al. (2023) involving twenty-three individuals who were 40 years of age or older and had moderate COPD (FEV1/FVC < 0.7) [28]. The purpose of the study was to examine the impact of IMT performed at home on smaller airway function along with symptoms in COPD patients. The clinical efficacy of the training was measured by the variations in forced expiratory flow (FEF25-75%), FEF50%, FVC, FEV1, and FEV1/FVC. Based on their findings, IMT has the potential to enhance post-bronchodilator airflow within the small airways, and pulmonary functions, and alleviate symptoms caused by COPD) in individuals with moderate to severe disease severity who are stable. Pulmonary rehabilitation programs conducted in the comfort of one's own home may benefit from this type of training. Within the same framework, a randomized controlled clinical trial was carried out by De Farias et al., (2019) involving 60 patients suffering from COPD [29]. The purpose of the trial was to evaluate the efficacy of various IMT modalities when added to standard treatment for COPD. The trial measured factors such as pulmonary function, breathing muscle strength, functional capacity, as well as sniff nasal inspiratory pressure (SNIP), maximal respiratory pressure (MRP), along with sustained maximum inspiratory pressure (SPImax). When they combined conventional pulmonary rehabilitation with threshold inspiratory training, they discovered a statistically significant improvement across all participants. Abodonya et al., (2021) evaluated 42 patients who had recovered from COVID-19 [30]. The patients' ages ranged from 48.05 to 48.85 years. The purpose of the study was to determine how effective resistive IMT was for these patients. The researchers measured variables such as FVC, FEV1, dyspnea severity index (DSI), QOL, as well as six-minute walk test (6-MWT). They discovered that in patients who had recovered from COVID-19 in the intensive care unit, IMT enhances respiratory functions, dyspnea, functional performance, and quality of life following successive weaning from mechanical ventilation. It is recommended that the COVID-19 treatment protocol incorporate the IMT program, particularly for patients in the intensive care unit. In their study, Elmarakby et al., (2021) examined 80

lacrosse players to determine the effects of an inspiratory pressure threshold loading (IPTL) device on variables such as MIP, MVV, FVC, and aerobic capacity (VO2max) [31].

Their research led them to the conclusion that an IPTL device can be effectively used to train the respiratory muscles. This device should be utilized to its maximum capacity in order to improve aerobic capacity as well as exercise performance. Enhance exercise performance and reduce respiratory fatigue by incorporating IPTL high-intensity training routines into sports training regimens. A total of thirty female patients suffering from interstitial lung diseases (ILD) and an average age of ±48.57 were studied by Mahmoud et al., (2020) to determine the impact of IMT on their functional capacity as well as ventilatory function [32]. The participants were measured using metrics such as FVC, FEV1), FEV1/FVC ratio, MVV, as well as the distance proceeded in 2 minutes. The results showed that IMT could be an additional component to the rehabilitation strategy for patients with ILD, with the goal of enhancing their functional capacity as well as ventilatory function. The purpose of the pilot RCT carried out by Lamberti et al., (2023) was to assess the practicality and efficacy of low-intensity RMT that patients with end-stage kidney disease (ESKD) who were 18 years old or older, receiving hemodialysis from two to four times weekly, and able to walk at least 10 meters [33]. The trial measured lung capacity (FEV1, FVC, MVV), maximal inspiratory and expiratory pressure (MIP, MEP), as well as the participants' ability to practice the breathing exercises at home. Using a basic device that engages the inspiratory as well as expiratory muscles, they found that low-intensity RMT performed at home might substantially improve respiratory muscle strength. El-Refay et al., (2014) carried-out a cross-sectional study with thirty-four diabetic participants having maximal inspiratory pressure (Pimax) <70% of anticipated, their ages were between 50-60, to examine the impact of the threshold resistive inspiratory muscle trainer on ventilatory function, inspiratory muscle strength as well as exercise tolerance by measuring Pulmonary function measures (FEV1, FVC, MVV, and FEF 25-75%), Maximum Inspiratory Pressure (Pimax) and predicted peak oxygen consumption (VO2 peak) [34]. Researchers concluded that pulmonary dysfunction is one of the first non-metabolic changes in diabetes that can be measured with relatively simple techniques, hence it is recommended that patients with diabetes have pulmonary function testing in addition to other examinations. Patients with diabetes who have poor inspiratory muscles can regain their strength with training, which also improves their pulmonary function as well as functional capacity. 30 male and female patients, ranging in age from 45 to 65, with COPD grades I and II were the subjects of a cross-sectional study by Shaikh et al. (2019) [14]. The purpose of the study was to examine the impact of the Breather device on inspiratory muscle strength as well as functional capacity as measured by Pimax and 6MWD. Researchers discovered that patients with COPD who used the breather device had significantly higher inspiratory muscle strength as well as 6MWD compared to those who used diaphragmatic breathing alone. They also discovered that patients with COPD who added IMT had higher inspiratory muscle strength in addition to functional capacity. The current study is in agreement with a RCT that Langer et al. (2018) performed with 20 patients who had COPD and a Pimax [35].

Table 1: Comparison of age, sex, and BMI among both groups.

Items	**Groups**		***P*-value**
	Group (A) (n=40)	**Group (B) (n=40)**	
Age (year)	35.47 ±2.87	35.07 ±2.98	0.54
Gender (males: females)	22 (55%): 18 (45%)	23 (57.5%): 17 (42.5%)	0.82
BMI (Kg/m²)	25.45 ±2.32	25.30 ±2.31	0.77

Mean ± standard deviation is used to express quantitative data (age & BMI), which are then compared using an unpaired test. The chi-square test is used to compare qualitative data, specifically gender, which is expressed as a percentage. Probability value, or P-value.

Table 2: Main impacts of independent variables by Mixed MANOVA test for dependent measuring variables.

Source of variation	**F-value**	**P-value**
Treatment effect	5.05	0.001*
Time effect	1812.47	0.001*
Treatment x time (Interaction effect)	16.26	0.001*

P-value: probability value, * Significant (P-value <0.05).

Table 3: Mixed MANOVA within and between group comparison for outcomes variables.

Outcomes variables	Items	Groups (Mean ±SD)		Mean difference	*P*-value
		Group A (n=40)	Group B (n=40)		
FEV1 (L)	Pre-treatment	2.82 ±0.33	2.81 ±0.38	0.01	0.91
	Post-treatment I	3.20 ±0.35	3.07 ±0.39	0.13	0.12
	Post-treatment II	3.53 ±0.37	3.28 ±0.38	0.25	0.005*
	Mean difference (Pre vs. Post II)	0.71	0.47		
	Improvement %	25.18%	16.73%		
	P-value	0.001*	0.001*		
FVC (L)	Pre-treatment	3.92 ±0.38	3.91 ±0.46	0.01	0.91
	Post-treatment I	4.14 ±0.40	4.07 ±0.46	0.07	0.46
	Post-treatment II	4.40 ±0.42	4.25 ±0.47	0.15	0.16
	Mean difference (Pre vs. Post II)	0.48	0.34		
	Improvement %	12.24%	8.70%		
	P-value	0.001*	0.001*		
FEV1/FVC (%)	Pre-treatment	71.78 ±2.01	71.75 ±2.07	0.03	0.93
	Post-treatment I	77.07 ±1.77	75.27 ±1.73	1.8	0.001*
	Post-treatment II	80.14 ±1.44	77.13 ±2.08	3.04	0.001*
	Mean difference (Pre vs. Post II)	8.39	5.38		
	Improvement %	11.69%	7.50%		
	P-value	0.001*	0.001*		
MVV (L/min)	Pre-treatment	98.55 ±11.62	98.25 ±13.17	0.03	0.92
	Post-treatment I	111.89 ±12.21	107.42 ±13.52	4.47	0.13
	Post-treatment II	123.44 ±12.88	114.88 ±13.37	8.56	0.005*
	Mean difference (Pre vs. Post II)	24.89	16.63		
	Improvement %	25.26%	16.93%		
	P-value	0.001*	0.001*		
Oxygen saturation (%)	Pre-treatment	93.75 ±0.81	94.04 ±0.97	0.28	0.17
	Post-treatment I	96.80 ±0.82	96.85 ±0.89	0.05	0.79
	Post-treatment II	98.97 ±0.73	98.95 ± 0.81	0.02	0.88
	Mean difference (Pre vs. Post II)	5.22	4.92		
	Improvement %	5.57%	5.23%		
	P-value	0.001*	0.001*		
RPP	Pre-treatment	11898.65 ±595.11	11904.77 ±561.70	6.12	0.96
	Post-treatment I	10067.80 ±444.65	10085.05 ±438.35	17.25	0.86
	Post-treatment II	8749.27 ±284.31	8898.37 ± 270.80	149.1	0.01*
	Mean difference (Pre vs. Post II)	3149.38	3006.4		
	Improvement %	26.47%	25.25%		
	P-value	0.001*	0.001*		

Data are expressed as mean ± standard deviation (SD), P-value: probability value, * Significant (P<0.05), FEV1: forced expiratory volume at first second, FVC: forced vital capacity, MVV: maximal voluntary ventilation, RPP: rate pressure product.

Table 4: The frequency distribution as well as chi-squared test (Fisher Exact test) for comparison of physical fitness index among groups A and B.

Physical Fitness Index		Group A	Group B	χ^2	p-value	Sig
Pre treatment	Poor	25 (62.5%)	27 (67.5%)	0.22	0.63	NS
	Fair	15 (37.5%)	13 (32.5%)			
Post I	Poor	0 (0%)	4 (10%)	4.21	0.12	NS
	Fair	18 (45%)	14 (35%)			
	Good	22 (55%)	22 (55%)			
Post II	Fair	2 (5%)	7 (17.5%)	7.72	0.01	S
	Good	11 (27.5%)	18 (45%)			
	Excellent	27 (67.5%)	15 (37.5%)			
χ^2 : Chi squared value		p value: Probability value		S: Significant		

The trial's goals were to determine the physiological mechanisms by which 8 weeks of inspiratory muscle training (IMT) using a resistive inspiratory device enhanced inspiratory muscle power and endurance in mechanically impaired individuals who have moderate-to-severe COPD with a high Pimax. cause being that those patients' inspiratory neuronal impulse to the diaphragm, which is used for breathing during strenuous physical activity, was decreased after supervised IMT. The result was improved respiratory feeling and exercise tolerance, even with high ventilatory demands, severe mechanical overload of the respiratory system, and tidal volume restrictions met. In a recent study by Aung et al. (2022), 30 participants, ranging in age from 40 to 80, received a diagnosis with COPD by their attending physicians. The study included both males and females, and it used a threshold loading instrument to administer IMT [36]. The goals of the training were to measure improvements in inspiratory muscle strength using a manometer that measured maximum inspiratory pressure, to evaluate changes in exercise tolerance using the 6-MWT, to measure changes in FVC and FEV1 using a spirometer, and to evaluate quality of life using the COPD assessment test (CAT) questionnaire at 0, 2, 4, and 6 weeks. In the present study, the IMT using the threshold loading device improved inspiratory pressure, pulmonary functions, capacity for exercise, and QOL in a clinical and statistical aspect. Hence, COPD patients should consistently undergo IMT using a threshold loading tool. In a recent systematic review, Vázquez-Gandullo et al., (2022) sought to evaluate the effectiveness of IMT in COPD patients [37]. The researchers compared IMT-using respiratory rehabilitation programs to those that did not include IMT, in order to determine the impact of IMT on patients' symptoms, QOL, and psychosocial well-being. A variety of mechanical tools have been developed to aid in rehabilitation programs, and they have shown that IMT has a positive impact on patients' quality of life. Liu et al., (2020) conducted a study that aimed to examine the impact of 6-weeks of respiratory rehabilitation exercises using a resistive inspiratory instrument on pulmonary function, mobility, QOL, as well as psychological functioning in elderly individuals with COVID-19 [38]. The study included a total of 72 and used an array of tests determine pulmonary function, functional ability, QOL, functional independence, as well as mental status. They came to the conclusion that older people with COVID-19 can benefit from six weeks of respiratory rehabilitation in terms of increased respiratory function, quality of life, and anxiety, but that there is little evidence that it improves depression. Moreover, there was a substantial difference in PFI ($P=0.01$; $P<0.05$) among group (A) as well as group (B). The distribution of the PFI at post II of group a revealed that 2 (5%) subjects were fair, 11 (27.5%) were good and 27 (67.5%) were excellent, and in group B revealed that 7 (17.5%) were poor, 18 (45%) were good and 15 (37.5%) were excellent. There was a substantial significant improvement in the percent of subjects with excellent PFI of group A in comparison with that of B at post II ($p = 0.01$) (Table 4).

4. Conclusions

It can be concluded that combining the breather respiratory muscle trainer with traditional pulmonary rehabilitation in patients suffering from COPD post-COVID-19 might be more effective for reducing the symptoms and enhancing their quality of life, by improving the physical and cardiopulmonary fitness by increasing both the physical fitness index and the rate pressure product and improving the pulmonary function, than traditional pulmonary rehabilitation alone.

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