# Effects of Expiratory Muscle Training and Pursed-Lips Breathing on Health Status and Dyspnea among Chronic Obstructive Pulmonary Disease Patients

## Aida El Gamil, Mimi M. Mekkawy & Khaled H.Ahmed.

Assistant Professor, Medical Surgical Nursing, Faculty of Nursing, Alexandria University, Egypt. Assistant Professor, Department of Adult Nursing, Faculty of Nursing, Assiut University, Egypt. Assistant Professor, Department of Chest, Faculty of Medicin, Assiut University, Egypt.

## Abstract

**The aim** was to examine the effectiveness of expiratory muscle training and pursed-lips breathing on health status and dyspnea among patients with chronic obstructive pulmonary disease. A true experimental design was utilized. **Setting:** The study was carried out in the outpatient chest clinic at Assuit university hospital. **Subjects:** A purposeful sample of 127 diagnosed as COPD patients. They were randomly distributed to 4 subjects, classified into 3 study and one control group . **Three tools** : Tool 1: Structured interviewing questionnaire tool, Tool 11: ST George's Respiratory Questionnaire (SGRQ), Tool III: Assessment of the patients' condition includes the modified Borg scale and MRC breathlessness scale. **Results**: majority were male patients, more than 50 years old. There was significant improvement in total health status P= 0.001 and shortness of breath among the study subjects than the control subjects'=0.01. Also, there was statistical significant improvement in the pulmonary function tests PE<sub>max</sub>, PI<sub>max</sub>, paco<sub>2</sub>, Hco<sub>3</sub> and Sao<sub>2</sub>in the study subjects than the control subjects' *P* value (0.002, 0.005, 0.001, 0.001, 0.001) respectively. **Conclusion**: There was statistical significant improvement after implementation of the respiratory training in total health status score and Borg scale post Six Minute Walk Distance)6 MWD( among PLB and Both exercise subjects when compared with the EMT and control subjects after 8 weeks. **Recommendation**: Further researches is required to identify clearly the benefits of breathing exercises in breathless patients with COPD and treatments should be closely monitored for variations in response and modified accordingly.

# Key words: Chronic Obstructive Pulmonary Disease, Expiratory Muscles Training, Pursed Lip Breathing & Dyspnea.

## Introduction

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity and mortality, with the expectation that prevalence will increase rather than decrease in the coming years (Mannino & Buist, 2007). Its pulmonary component is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases. The characteristic symptoms of COPD are cough, sputum production, and dyspnea upon exertion (Rabe et al., 2007). COPD severity is classified according to the reduction in pulmonary function, but the disease also causes reduced functioning beyond the respiratory system. Among such impacts are limitations in activities of daily living (ADL) (Garcia -Aymerich et al., 2006 & Vorrink et al., 2011)

COPD is an international health problem with a worldwide prevalence of at least 9.34/1000 in men and 7.33/1000 in women. It is the fourth leading cause of death worldwide (**WHO**, 2011) & will be the third leading cause of death globally by 2020 and it will be the fifth leading cause of lost disabilityadjusted life years (**Tkacova**, 2010).

According to Statistics by Country for COPD, (2013) the extrapolation of undiagnosed prevalence rate of COPD in Egypt is 4,197,651 and the diagnosed prevalence rate in Egypt is 3,777,886. It was estimated that 80 million people worldwide have moderate to severe COPD. COPD symptoms and exacerbation are responsible for considerable healthcare consumption, with high levels of physician consultation and hospitalization (Khattab et al., 2012 & Idrees et al., 2012).

The diagnosis and definition of COPD severity was established in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines (Lotte, et al., 2006 as cited in Abdel Raouf, & Al Sebaee, 2011). GOLD stage 0 (patient at risk) is diagnosed when patients report chronic cough and sputum production whilst their lung function is still normal In GOLD I, Mild COPD, there may be mild airflow limitation but patient may be unaware that lung function has started to decline. Forced expiratory volume in one second (FEV1) will be greater than or equal to 80% of the predicted normal values with an FEV1/FVC (forced vital capacity) that is less than 70 percent. Patient may not yet have any COPD symptoms, or may have symptoms of chronic cough and excessive mucus.

During GOLD II, Moderate COPD, airflow limitation worsens and patient may start to notice symptoms, particularly shortness of breath upon exertion along with cough and sputum production. FEV1 will be anywhere between 50% and 79% of the predicted normal values and FEV1/FVC will be less than 70 percent. Once the disease has advanced to GOLD III, Severe COPD, limitation of airflow significantly worsens, shortness of breath becomes more evident and COPD exacerbation is common. FEV1 will be between 30% and 49% predicted and FEV1/FVC will be less than 70 percent. In this stage, patient may notice a decrease in activity tolerance and an increase in fatigability. By the time a COPD patient reaches

GOLD IV, Very Severe COPD, their quality of life is greatly impaired and COPD exacerbations are life threatening. Airflow limitation is severe (FEV1 less than 30% predicted or less than 50% predicted and FEV1/FVC will be less than 70 percent.

Chronic respiratory failure is often present at this stage, and may lead to complications with heart, such as cor pulmonale and/or eventually, death (Leader, 2013).

Dyspnea is identified as a perception or observation of abnormal and disturbing sensation of breathing. Dyspnea also called breathlessness or shortness of breath, in which the patients experience labored, uncomfortable breathing, and may produce secondary physiological, emotional, cognitive, and behavioral responses (Aras el al., 2009). Patients with COPD complain primarily of incapacitating dyspnoea and reduced functional capacity. The role of chest physiotherapy in the management of COPD includes addressing issues relating to reducing work of breathing, promoting airway clearance, improving mobility and promoting rehabilitation and contributing to the provision of effective noninvasive ventilation services. The key to successful management of these complex patients is twofold: the accurate assessment of the patient to identify clear goals of treatment and teamwork, which underpins a thorough knowledge of the individual patient. The way in which various chest physiotherapy treatment techniques are used will depend on the changing clinical presentation of each patient and physiotherapy should be tailored to meeting different needs according to whether patients are in an acute exacerbation of COPD or in a stable phase. Variations in the application of techniques will be pointed out, and may involve a change in performance of the technique or in the regime of treatment. Concordance between patients and clinical staff in determining a treatment plan for patients should be a main aim of treatment in order to optimize and promote self-management (Mikelsons, 2008).

Dyspnea is a complex, prevalent, and distressing symptom of chronic obstructive pulmonary disease (COPD) associated with decreased quality of life, significant disability, and increased mortality. It is a major reason for referral to pulmonary rehabilitation (**Norweg & Collins 2013**). Functional status is reduced and social isolation is likely (**Kapella, 2011**). Alleviating dyspnea is a primary goal of pulmonary rehabilitation (PR) and self-management (SM) interventions in chronic obstructive pulmonary disease. (**Global Initiative for COLD, 2013**).

Dyspnea is traditionally managed with pharmacologic modalities to reduce airway inflammation and bronchospasm as well as self-care management strategies such as breathing pattern retraining. One commonly used breathing pattern retraining strategy is pursed-lips breathing (PLB). It is defined as "a variable expiratory resistance that is created by constricting the lips (Nield et al., 2007). PLB is purported to change the breathing pattern so that dyspnea is reduced. PLB involves the patient breathing in through the nose and out through the mouth against a resistance created by pursing the lips. which helps to prevent airway collapse. It has been shown that PLB performed during exertion can lead to a reduction in respiratory rate and increased recovery rate compared with spontaneous breathing, but no differences in dyspnoea or exercise tolerance were found.12 PLB during exertion may therefore be a useful addition to the breathless patients' regime and may be taught as a strategy to reduce respiratory rate in patients with COPD.

People with COPD have insufficient time for expiration due to increased airway resistance and pressure-dependent airway collapse. During exercise, expiratory flow limitation worsens and leads to incomplete expiration, air trapping, and dynamic hyperinflation. This is manifested by an increase in end-expiratory lung volume at increased levels of ventilation, (Gosselink, 2004) as opposed to a decrease in end-expiratory lung volume in healthy unobstructed people (Niel, 2007). It then becomes necessary for increased breath frequency to compensate for the associated decreased tidal volume. Each succeeding inspiration is initiated at a higher lung volume which requires increased elastic effort and may be perceived as increasing dyspnea.

Dyspnea may be reduced by prolonging expiratory time to reduce dynamic airway compression and air trapping (**Niel, 2007**). Most patients with COPD have inspiratory muscle weakness, which may contribute to the perception of dyspnea, that they can be trained, and improved as a result of respiratory training. On the other hand the expiratory muscles have been specifically trained. Such training tended to enhance expiratory muscle strength to improve cough efficacy. Also, improve the perception of dyspnea when patients with COPD were received respiratory training, the strength of both inspiratory muscle were increased, with beneficial effect on exercise performance and quality of life.

Breathing pattern retraining that focuses on gentle, prolonged exhalation addresses the main physiologic impediment in these patients.(**Spahija & Grassino 2005**) and(**Sianchi et al., 2005**) Pursed-lips breathing and expiratory muscle training (EMT) with a handheld device that provides resistance on exhalation are 2 strategies that directly prolong exhalation. (**Niel, 2007**)

When COPD patients start to feel short of breath, they worry that they are not getting enough air, which causes anxiety. Anxiety makes patient breath harder and faster, which makes the dyspnea worse. When people experience this, it can be so distressing that they start to limit their activities in order to avoid anything that may cause them to feel shortness of breath as they get into dyspnea cycle. The dyspnea cycle is not only frightening, but can lead to feelings of sadness and worry. If these feelings become overwhelming, they can start to interfere with daily life (**Talbot, 2012**).

There are several reports showing that expiratory muscle strength and endurance can be impaired in patients with COPD. This muscle weakness may have clinically relevant implications. Expiratory muscle training tended to improve cough and to reduce the sensation of respiratory effort during exercise in patients other than those with COPD.( Weiner et all 2003). It is well known that patients with significant COPD have respiratory and peripheral muscle weakness, but it does not affect all muscles to a similar extent. (Gosselnik, Troosters & Decramer, **2000**). The inspiratory muscles have been extensively investigated in patients with COPD. It has been shown that most patients with COPD have inspiratory muscle weakness, which may contribute to the perception of dyspnea, that they can be trained, and that exercise performance and dyspnea may improve as a result of such training.( Weiner et all,2000)

The objective of the present study was to evaluate the effectiveness of expiratory muscle training and pursed-lips breathing on health status and dyspnea as compared with a control subjects of adult's patients with moderate to severe COPD.

## Significance of the study

Living with COPD can be challenging, as the disease dramatically impacts patients' daily life. Individuals with COPD undergo a high amount of activity restriction and dependency due to dyspnea (Akbal, 2003). Dyspnea may be severe and often interferes with the patient's daily activities and the patient cannot participate in even mild exercise. As COPD progresses, dyspnea occurs even at rest (Smeltzer et al., 2010). To avoid the distressing sensations of dyspnea and other symptoms, the majority of COPD patients reduce their physical activities. As a result, some patients may lead an extremely sedentary lifestyle that may further decrease their abilities to perform physical activities (Rabe et al., 2006). Severe exacerbations of COPD that lead to unscheduled visits/admissions to hospital result in the significant economic burden, increase morbidity and mortality rate associated with the disease. These aforementioned reasons emphasize the need for more effective breathing pattern retraining (PLB and EMT) that focuses on gentle, prolonged exhalation to improve patients' dyspnea and decrease health impairment.

Nurses are involved with COPD patients across the spectrum of care, from outpatient and home care to critical care and the hospice setting. Patients with COPD need care from nurses who not only have astute assessment and clinical management skills, but who also understand how these disorders can affect patients' quality of life. Patient and family teaching is an important nursing intervention to enhance self-management of COPD.

#### The Aim of Our Present Study

was therefore to examine the effectiveness of expiratory muscle training and pursed-lips breathing on health status and dyspnea among patients with chronic obstructive pulmonary disease. This aim will be achieved through the breathing pattern retraining program of prolonged exhalation using Pursed-Lips Breathing (PLB) or expiratory muscle training (EMT) or both, on dyspnea among patients with Chronic Obstructive Pulmonary Disease.

#### Specific objectives of our present study were

- To examine the effectiveness of EMT and PLB on health status among patients with COPD.
- To examine the effectiveness of EMT and PLB on dyspnea among patients with COPD.
- To examine the effectiveness of EMT and PLB on level of activities among patients with COPD.
- To examine the effectiveness of EMT and PLB on Pulmonary functions among patients with COPD.

## Hypothesis of the study

It was hypothesized that: I. Patients with COPD who were receive Pursed-Lips Breathing (PLB) and expiratory muscle training (EMT) were improvement health status than control subjects. II. Patients with COPD who were receiving Pursed-Lips Breathing (PLB) and expiratory muscle training (EMT) were having improved level of daily activities than control subjects. III. Patients with COPD who were receiving Pursed-Lips Breathing (PLB) and expiratory muscle training (EMT) were having decrease dyspnea and improved pulmonary functions than control.

## Materials and Method

**Design:** A true experimental design was utilized.

**Setting:** The study was carried out in the outpatient chest clinic at Assuit university hospital.

Subjects: A purposeful sample of 127 adult patients diagnosed as COPD stage II and stage III and clinically stable as decided by the physician were included in this study. Who were available during the time of data collection in the previously mentioned setting were recruited. The patients were randomized distributed into 4 subjects: control subjects including 40 patients; the other 3 subjects were considered the study (experimental) subjects. Twenty patients were assigned to receive Expiratory Muscle Training (EMT), 20 patients were assigned to receive PLB, twice daily, six times a week, each session consisting of 25 min. of respiratory training, for 8 weeks and 47 patients were assigned to receive both PLB once /day & EMT once /day. During the follow up, 7 patients were not complying with both PLB& EMT, so the total sample size became 120. Inclusion criteria patients with expiratory airflow limitation evidenced by forced expiratory volume 1 second/forced vital capacity percent (FEV1/FVC%) less than 70 and FEV1% predicted less than 80 with no reversibility by inhaled bronchodilator, and self-report of shortness of breath when walking. In addition, exclusion criteria should be considered and any comorbidities taken into account (e.g. exacerbation of symptoms e.g. dyspnea, increased sputum volume, and/or increased sputum purulence) within the past 4 week, hospital admission within the past 4 weeks, change in bronchodilator therapy within the past 2 weeks, inability to walk, unstable angina, unstable cardiac dysrhythmia, unstable congestive heart failure, unstable neurosis or patients who are seriously ill and with cognitive impairments, or participation in a structured pulmonary rehabilitation program within the past year).

Tools: Four tools were used to collect data of this study: Tool I: Structured interviewing questionnaire tool designed by the researchers to

gather information related to patient's sociodemographic data such as age, gender, and marital status, level of education, occupation and smoking history. It also covered data related to duration of disease, stage of COPD, types of breathing exercise, medication.

Tool II: ST George's Respiratory Questionnaire (SGRO) (pre/post breathing exercises): The SGRO that was developed by Stein et al., (2004) is a selfreported questionnaire designed to measure health impairment in patients with asthma and COPD. It has four score: Symptoms score, activity, impacts and total scores. The Symptoms score: (Questions 1-7) addressed the frequency of respiratory symptoms to assess the patient's perception of their recent respiratory problems. Activity score: (Questions 8-14) addressed the patient's current state and disturbances to daily physical activity (i.e. how they are these days). The Impacts score covered a range of disturbances of psycho-social function, also correlated quite strongly with exercise performance (6-minute walking test), breathlessness in daily life and disturbances of mood (anxiety and depression). The impacts score is covering the whole range of disturbances that respiratory patients experience in their lives; and total score covered the impact of the disease on overall health status Each component as well as the Total is scored on a scale from 0 to 100. where a score of "0" is indicating absence of problems and a score of "100" suggest the worst state possible. A change in the SGRQ score of 4 units is considered as clinically significant (Jones et al 1992). St. George's Respiratory Questionnaire (SGRQ) has been shown to be reliable, valid, and responsive when used with COPD patients (Jones et al 1992). This tool was adopted from Stein et al., (2004) and translated into Arabic language then retranslated into English to assure its accuracy.

#### **Total Score**

The Total score is calculated by summing the weights to all the positive responses in each component. The score for each component is calculated separately by dividing the summed weights by the maximum possible weight for that component and expressing the result as a percentage: The Total score is calculated as follows:

Score = 100 x Summed weights from all positive items in the questionnaire

**Sum of weights for all items in the questionnaire** Scoring system

- Calculate the mean and SD of each item
   (Symptoms score, Activity score, Impacts score and total score )
- If the patient scored less than mean-SD considered good

- If patient scored between mean-SD and mean+ SD considered moderate
- If patient scored more than the mean+ SD considered poor

**Tool III: Assessment of the patients' condition**. To assess patient's dyspnea level (pre/post

breathing exercises). It includes the two scales:

Modified Borg Scale (MBS): This tool is a subjective perception used to assess the severity of breathlessness during various activities using Vertical 0 - 10 item scales with words describing degrees of perceived exertion anchored to numbers. No breathlessness at all (0), very slight breathlessness (Just Noticeable) (0.5), very slight breathlessness (1), slight breathlessness (2), moderate breathlessness (3), somewhat severe breathlessness (4), severe breathlessness (5), very severe breathlessness (6-7), very severe breathlessness(Almost Maximum) (8-9) and maximum breathlessness (10). This tool was adopted from Borg (1982). The scores given by each patient were summed up and divided by the total number of patients, giving a mean score for the scale.

Medical Research Council The (MRC) breathlessness scale: This scale used to assess the dyspnea grades. It grades the effect of breathlessness on daily activities. It was adopted from (Fletcher et al., 1959). It comprises five statements that describe almost the entire range of respiratory disability from none (Grade 1) to almost complete incapacity (Grade 5). This tool was self-administered or, administered by the researcher by asking subjects to choose a sentence that best describes their condition. The patients choose the number that best fits their level of activity. A score usually was obtained in a few seconds. The Six Minute Walk Distance (6MWD) is used as a stimulus for dyspnea with the Borg scale administered at both the beginning and end of the 6MWD. This tool was adopted from Borg (1982). The scores given by each patient are summed up and divided by the total number of patients, giving a mean score for the scale.

#### Methods

An official permission was obtained from the managers and authorities of the outpatient chest clinic, after explanation of the nature and objectives of the study.

An exploratory visit was done to respiratory outpatients' clinic in order to estimate the rate of admission and suitable time for collecting data. Besides, personal communication was done with outpatient nurses and physician to explain the purpose of the study and gain their best possible cooperation. After a thorough review of literature, the researchers developed the socio- demographic part of the interview and selected the tools to be used in the study. Contents of the tools were tested regarding to the knowledge accuracy, relevance and competence. In addition, content validity was done also for the proposed protocol to test its consistency, accuracy, applicability, relevance and feasibility

## Validity and reliability

Content and face validity was ascertained through experts' opinions. Those experts included five experts in Medical Surgical Nursing and two experts in chest department at Faculty of medicine, at Assuit university hospital. The selected tools were translated into Arabic by the researchers and back to English by the five experts. The needed modifications of some Arabic words were done. Their opinions were elicited regarding to the tools format layout, consistency and scoring system. Contents of the tools were measured regarding, accuracy of knowledge, relevance and competence. Testing reliability of the tools items was done using Cronbach alpha test: tool I = 0.94, tool II = 0.84, tool III = 0.93 and, Also, the content validity of the educational materials was tested by the same experts.

**Ethical considerations:** Prior to the pilot study, ethical approval was obtained from the Scientific Research Ethical Committee of Faculty of Nursing, Assuit University. Also, a written informed consent was obtained from each participant. In addition, they were assured that anonymity and confidentiality would be guaranteed and they have the right to withdraw from the study at any time without any reason.

# **Pilot study**

A pilot study was carried out on 10% of patients with COPD, based on statistical percentage to test applicability and clarity of the tools, as well as to estimate the time needed to fill in each tool. The structured interviewing questionnaire took approximately 5 to 7 minutes to complete and was administered before the modified Borg scale. The other tools took at least one hour to be completed for each patient in the study subjects. Those who participated in the pilot study were included in the main study sample as there were no modifications required for the study tools.

#### Procedures

Data were collected in Chest Department at Assuit University Hospital. Sampling was started and completed within one year. It was designed in three phases; assessment, implementation and evaluation.

# Assessment phase

- The patients who met the study criteria were included in the study after explaining the nature and purpose of the study and obtaining their consents. The interview questionnaire was distributed to all patients to assess patients' educational needs and obtain baseline data. The objectives and content of the retraining breathing exercises were established based on review of related literatures as well as patients' educational needs obtained from the collected data. The educational contents were prepared in Arabic language. It pertained two parts: The first part (theoretical part) included; knowledge about COPD (such as; definition, causes, risk factors, signs and symptoms especially dyspnea and complications) and the second part (practical part) included the PLB and EMT exercises. Media was prepared by the researchers, including the handout, logbook and audiovisual materials as CD.

#### Implementation phase

**ST** George's Respiratory Questionnaire was completed in a quiet area, free from distraction and the patient was sitting at a desk or table. The researcher explained the tools and the importance to be completed as honestly and frankly as possible to give the researchers the opportunity to understand how their illness affects them and their daily life. Also, the researcher stressed that there is no right or wrong answers, and they are free to ask for clarification of any question.

2-Random allocation of subjects to control and experimental subjects using the **modified Borg scale** and breathlessness scale: Patients were asked to walk for 6 minutes and they were monitored during the 6-minute walk distance (6MWD). Those who reported "moderate" on the modified Borg score or greater at the end of the 6MWD were randomly assigned to PLB, EMT, both or a control subjects.

3-During implementation phase **EMT Patients** (subjects 1) were taught to use the spirometer. The content of the educational sessions was similar for all of them.

It consisted of an explanation by researcher on the benefits and the technique of EMT.

#### **Instructions for EMT**

- Sit in a comfortable position and place a nose clip on your nose so that all of your breathing is done through the mouth.
- Practice placing your device: Open your mouth and place lips around the mouthpiece; make sure mouthpiece sits behind the front teeth. When you are sure you know where the device belongs, and can place it there quickly, take your device out of your mouth.
- Take a deep breath in and quickly place your device in your mouth. Then blow out into your device as hard as you can until you hear and feel air flowing through the device. Keep exhaling for as long as you can. Doing this may be a little tiring, but should not be exhausting. If you feel

excessively tired or lightheaded, discontinue the exercise, and let us know when we call to check in.

- Take the device out of your mouth and rest for 30-60 seconds.
- Repeat Steps 3and 4 four more times
- Each breath through the device valve is considered one trial of training. Five trials performed in a row is one set. The protocol is 25 trials (or 5 sets) per sitting, completed 5 days per week.
- Take a one to two minute break between sets (each five trials or breaths). Try to do the training at the same time every day.

A copy of the instructions was given to each member of the study subjects. Participants were encouraged to log daily use in an effort to maintain consistency and note any adverse effects. The researcher assured patients that doing this may be tiring, but not exhausting. Then the researcher followed the explanation by demonstration of the technique as a role play, and then the patients were asked to perform the same technique in front of the researcher for at least three perfect times. Educational session for each patient lasted for 30 minutes averagely. Participants in the study subjects were contacted via phone once per week to ask questions regarding performance of the exercises, and to address any concerns related to the EMT. (Adapted from Sapeinza & Troche, 2012).

**PLB Patients** (subjects 2). The content of the educational sessions was similar for all of them. It consisted of an explanation delivered by the researcher about the benefits and the PLB technique and how to perform it.

#### Instruction for pursed lips breathing

- Sit in a comfortable position. Relax your shoulders.
- Take an easy breath in through your nose. Slowly and gently squeeze your air out through

pursed lips. Keeps a steady stream of air flowing through the center of your lips. Concentrate on breathing out as long as you can comfortably. Then gently breathe in through your nose.

- Remember to relax and to not put much pressure in your chest. Think of making a candle flicker when you are breathing out.
- Place your hands on the lower sides of your rib cage when you breathe in to help remember to "fill all around your waist."
- Use your pulse oximeter to watch the increase in your oxygen saturation %.
- Practice in front of a mirror to remind yourself to keep your shoulders and upper chest still.

- Practice 10 min/d total for the first week. Use frequent short practices during the day (eg, early morning, late morning, afternoon, evening). Increase the practice session time by 5-minute intervals to a maximum of 25 minutes total per day by the end of week 4. One session should last no longer than 10 minutes.
- 10 min/d the first week minimum
- 15 min/d the second week minimum
- 20 min/d the third week minimum
- 25 min/d the fourth week minimum
- Use the Daily Logbook to record your home practice sessions and any unexpected events.

practice sessions and any unexpected events.

Patients were trained for both PLB & EMT (subjects 3) using the same instructions and demonstrations conducted for subjects 1 and subjects 2. At the end of educational session the patients were instructed to perform the type of respiratory exercise they practiced with the researcher for four times a day before each meal and before sleep for at least 30 minutes. Patients were instructed to begin daily practice sessions. Logs were given to record their practice times and potential adverse events. The patients were also given the researchers' telephone number and were asked to contact the researchers if they experienced chest pain and sever dyspnea during the exercises. The researcher phoned patients every week and checked them for their compliance and any complication. A simple booklet was given to each patient with individualized explanation and a video tape.

As for the control subjects (subjects 4), the routine medical and nursing care was rendered to them.

**Evaluation phase**: After 8 weeks follow-up for all patients in the study and control subjects were invited to the outpatient chest clinic for pulmonary function test and final evaluation was done similar to the initial process including, tool II, III, IV.

Pulmonary Function Test and blood gases were done for study and control subjects. As:

FEV1 FEV1/FVC PI max cm H<sub>2</sub>O PE max, cm H<sub>2</sub>O PH PaO<sub>2</sub>, mm Hg PaCo<sub>2</sub> HCO<sub>3</sub> SaO<sub>2</sub>

#### **Results of the tests were categorized as follows**

Normal = more than 85 % of the predicted values. Mild = more than 65 % but less than 85 % of the predicted values.

Moderate = more than 50 % but less than 65 % of the predicted values.

Severe = less than 50 % of the predicted values.

- Comparison between the collected data before and after 8 weeks was done to determine the effectiveness of respiratory exercises.

## Statistical analysis

After completion of data collection the raw data were coded and transformed into coding sheets. The results were checked. Then, the data were entered into statistical package for social science (SPSS) software package version 18. Finally, analysis and interpretation of data were conducted. Data were presented using descriptive statistics in the form of mean, standard deviations, and percentages. Quantitative variables were compared using paired T test and Kruskal Wallis test. Statistical significance was considered at P-value <0.05.

# Results

Table	(1):	Baseline	demograph	nic and	clinical	charact	eristics fo	or COPD	subjects.
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clinical characteristics	ЕМТ	(n=20)%	PLB	(n=20) %	Both	ı ( <b>n</b> =	40) %	Contro	l (n=40)%	P. value	
Gender:											
male/	12	62.5	10	50	33	3 82.2		28	68.5	0.889	
female	8	37.5	10	50	7		17.8	12	31.5		
Age  yrs M <u>+</u> SD	50	<u>+</u> 3.2	5	54 <u>+</u> 3	5	7 <u>+</u> :	5.3	6	60 <u>+</u> 2		
Level of education											
Illiterate	10	(50)	10	(30)	18	(	(45.1)	16	16 (40.5)		
Basic	10	(50)	4	(20)	11	(	(27.5)	10	(25.5)	0.070	
Secondary	0	(0)	2	(10)	9	(	22.5)	7	(17.5)	0.079	
University	0	(0)	4	(20)	2		(5)	10	(17.5)		
Occupation											
Professional	0	(0)	4	(20)	7	(1	7.5)	3	(7.5)		
Clerical	5	(25)	0	(0)	8	(2	20.5)	4	(10.1)	0 222	
Manual worker	5	(25)	4	(20)	18	(	45.5)	21	(51.1)	0.235	
Housewife	10	(25)	12	(60)	7	(1	17.5)	12	(31.3)		
Residence	-									-	
Urban	10	(50)	10	(50)	10		(25)	8	(20)	0.053	
Rural	10	(50)	10	(50)	30		(75)	32	(80)	0.055	
Smoking											
Non-smoker	8	(40)	6	(30)	18		(45)	16	(40)	1 000	
Smoker	12	(60)	14	(70)	22		(55)	24	(60)	1.000	
Quit smoking	8	(40)	6	(30)	10		(25)	16	(40)	0.179	
Passive smoker	4	(20)	8	(40)	12		(30)	8	(20)	0.179	

Table (2): Distribution of self –reported health status among the study and control subjects.

Heelth status levels	Study	(n=80)	Contro	l (n=40)	$\mathbf{v}^2$	Р.						
Health status levels	N.	%	N.	%	Λ	value						
Symptoms level												
Good	9	11	4	11.1								
Moderate	58	72.5	27	68.5	1.11	0.921						
Poor	13	17.5	9	20.4								
Activity level												
Good	17	22.2	9	20.4								
Moderate	41	50.8	21	53.7	0.07	0.948						
Poor	22	27.0	10	25.9								
Impacts level												
Good	16	20.6	7	18.5								
Moderate	50	63.5	26	64.8	0.09	0.958						
Poor	14	15.9	7	16.7								
Total level												
Good	15	19.0	7	18.5								
Moderate	48	60.3	26	64.8	0.35	0.843						
Poor	17	20.6	7	16.7								

p < 0.01 highly statistically significant P < 0.05 statistically significant

Demonstrad accura	Pre Exe	rcise(80)	Post Exe	D voluo	
Reported scores	<b>N.</b>	%	Ν.	%	P. value
Symptoms score	_				
Good	9	11.1	39	49.2	
Moderate	57	71.4	39	49.2	< 0.001**
Poor	14	17.5	2	2.5	
Activity score					
Good	18	22.2	67	84.1	
Moderate	40	50.8	13	15.9	< 0.001**
Poor	22	27.0	0	0.0	
Impacts score					
Good	16	20.6	70	87.3	
Moderate	50	62.5	10	12.7	< 0.001**
Poor	14	17.9	0	0.0	
Total score					
Good	15	19.0	72	90.5	
Moderate	48	60.3	8	9.5	< 0.001**
Poor	17	20.6	0	0.0	

Table (3 ): comparison between pre and post respiratory exercises of study subjects according to SGRQ test N=80.

*p*<0.01 highly statistically significant

P < 0.05 statistically significant

Table (4): Comparison between pre and post scores reported on the SGRQ test among the experimental and control subjects.

D		EMT	(n=20	)			PLB (	n=20	)			Both	(n=40	)		Contr	ol(40)	)	
health	exe	Pre ercise	F exe	Post ercise	P. value	Pre exercise		I exe	Post ercise	P. value	Pre exercise		Post exercise		Pre		Post		
level	N.	%	N.	%		N.	%	N.	%		N.	%	N.	%	N.	%	N.	%	
Symptoms	level	_				_	_	_	-				_		_				
Good	7	37.5	7	37.5		0	0.0	10	50.0		4	8.9	20	51.1	3	6.8	4	11.1	
Moderate	7	37.5	13	62.5	0.287	18	90.0	10	50.0	0.028*	29	73.3	19	46.7	28	71.4	27	68.5	< 0.001**
Poor	6	25.0	0	0.0		2	10.0	0	0.0		7	17.8	1	2.2	9	22	9	20.4	
Activity lev	Activity level																		
Good	0	0.0	17	87.5		8	40.0	16	80.0		9	22.2	34	84.4	9	22.2	9	20.4	
Moderate	17	87.5	3	12.5	0.002**	6	30.0	4	20.0	0.104	20	48.9	6	15.6	20	50.8	21	53.7	< 0.001**
Poor	3	12.5	0	0.0		6	30.0	0	0.0		11	28.9	0	0.0	11	27.0	10	25.9	
Impacts lev	vel																		
Good	6	25.0	17	87.5		4	20.0	18	90.0		8	20.0	35	86.7	8	20.6	7	18.5	
Moderate	14	75.0	3	12.5	0.012*	12	60.0	2	10.0	0.007**	25	62.2	5	13.3	25	63.5	26	64.8	< 0.001**
Poor	0	0.0	0	0.0		4	20.0	0	0.0		7	17.8	0	0.0	7	15.9	7	16.7	
Total level																			
Good	3	12.5	17	87.5		4	20.0	18	90.0		8	20.0	36	91.1	8	19.0	7	18.5	
Moderate	17	87.5	3	12.5	0.003**	10	50.0	2	10.0	0.006**	23	57.8	4	8.9	24	60.3	26	64.8	<0.001**
Poor	0	0.0	0	0.0	0.005	6	30.0	0	0.0	0.000	9	22.2	0	0.0	8	20.6	7	16.7	<b>\0.001</b>

Good (>66.6%) Moderate (33.3-66) Poor (<33.3%).

p<0.01 highly statistically significant

P < 0.05 statistically significant

Shortnoss of brooth			St	udy	Contro	l(n-40)	Test			
shortness of breath grades	EMT	Г( <b>n=20</b> )	<b>PLB(n=20)</b>		Both(n=40)		Contro	DI(11 <b>=4</b> 0)	$\mathbf{X}^2$	<b>P-value</b>
grades	Ν	%	Ν	%	Ν	%	Ν	%		
Grade 1	10	50.0	10	50.0	17	42	4	10		[
Grade 2	5	25.0	4	20.0	8	20	15	37.5		
Grade 3	3	15	4	20.0	11	28	15	37.5	26.5	< 0.01
Grade 4	2	10	2	10.0	2	5	4	10		
Grade 5	0	0.0	0	0.0	2	5	2	5		

Table (5): Patients, reported grade of shortness of breathing among study subjects and control post respiratory exercises.

*p*<0.01 *highly statistically significant* 

*P* < 0.05 statistically significant

#### Table (6): Pulmonary Function Test.

EX Pulmonary Function Test	EN	ЛТ	PL	В	Во	th	Control			
	Pre	Post exercise	Pre	Post exercise	Pre	Post exercise	Pre	Post exercise	P value	
	M <u>+</u> SD	M+SD	M <u>+</u> SD							
FEV1	69.8 <u>+</u> 12.2	54.1 <u>+</u> 11	56.6 <u>+</u> 19.3	53 <u>+</u> 13.5	53.8 <u>+</u> 20.6	50.5 <u>+</u> 22.2	62.4 <u>+</u> 21.6	61.4 <u>+</u> 21.6	0.076	
FEV.FVC	79.6 <u>+</u> 10.6	70.6 <u>+</u> 0.1	69.4 <u>+</u> 22.5	65.3 <u>+</u> 5	79 <u>+</u> 17.4	77.8 <u>+</u> 14.8	71.8 <u>+</u> 12.1	75.8 <u>+</u> 12.1	0.525	
PE.max	44 <u>.1+</u> 20.4	41.4 <u>+</u> 10	46.4 <u>+</u> 22.3	31 <u>+</u> 11	41.8 <u>+</u> 21.9	39 <u>+</u> 24.4	44.5 <u>+</u> 11.1	42.5 <u>+</u> 11.1	0.002**	
PI.max	62.8. <u>+</u> 11	67.4 <u>+</u> 15	63.8 <u>+</u> 25.5	70.1 <u>+</u> 15.2	66.1 <u>+</u> 24.8	70.4 <u>+</u> 10	64.9 <u>+</u> 11.1	64.9 <u>+</u> 11.1	0.005**	
PH	7.54 <u>+</u> 0.2	7.4 <u>+</u> 0.1	7.4 <u>+</u> 0.1	7.2 <u>+</u> 0.1	7.4 <u>+</u> 0.1	7.4 <u>+</u> 0.1	7.4 <u>+</u> 0.1	7.4 <u>+</u> 0.1	0.786	
PaO2	59.1 <u>+</u> 15.7	60.5 <u>+</u> 7.5	69.9 <u>+</u> 14.9	61.9 <u>+</u> 10.6	64.7 <u>+</u> 11.7	60.6 <u>+</u> 12.1	69 <u>+</u> 18	67 <u>+</u> 18	0.099	
PaCO2	58.3 <u>+</u> 7.5	50.5 <u>+</u> 10.4	57.9 <u>+</u> 9.3	54.2 <u>+</u> 5	53.9 <u>+</u> 11.4	54.1 <u>+</u> 3.7	66.5 <u>+</u> 17	67.5 <u>+</u> 13	< 0.001**	
HCO3	37.4 <u>+</u> 14.8	31.5 <u>+</u> 12	33.7 <u>+</u> 5.8.	30.3 <u>+</u> 6	33.5 <u>+</u> 10.1	30.2 <u>+</u> 10.3	33.2 <u>+</u> 3.2	3.2 <u>+</u> 3.2	< 0.001**	
SaO2	78.9 <u>+</u> 13,4	73.7 <u>+</u> 4.8	73.8 <u>+</u> 13.1	77.6 <u>+</u> 5.2	75.4 <u>+</u> 10.4	78.4 <u>+</u> 5.3	87.8 <u>+</u> 13.2	87.8 <u>+</u> 13.2	< 0.001**	

p<0.01 highly statistically significant P < 0.05 statistically significant **PImax**, inspiratory muscle strength; **PEmax**, expiratory muscle strength; **FEV1**, forced expiratory volume for 1 second; **FVC**, forced vital capacity; **PaO**<sub>2</sub>, partial pressure, arterial oxygen.

Table (7): Difference between severity of the dyspnea among the study & control subjects Post exercises.

			Stu	dy		Co	ntrol	Test		
Dyspnea Borg	EMT(n=20)		<b>PLB(n=20)</b>		Both(n=40)		( <b>n=40</b> )		$\mathbf{v}^2$	D voluo
scale (max=10)	Ν	%	Ν	%	Ν	%	Ν	%	Λ	1 -value
Non	10	50	16	80	18	44.4	0	0	10.5	< 0.01
Mild (1-3)	5	25	2	10	13	33.5	15	37.03		
Moderate (4-7)	5	25	2	10	7	15.5	18	46.2		
Severe (8-10)	0	0	0	0	2	6.6	7	16.6		
Mean score MBS (0-10)	3.2 ±	-2.1	$4.0 \pm 0.1$		$3.2 \pm 1.1$		7.1 ±2.1		Kruskal Wallis test 4.60	0.07

p < 0.01 highly statistically significant P < 0.05.



Figure (1): Changed Borg Score.

 Table (8): Dyspnea at pre exercises and post for 4 groups.

Group Variable	Time	EMT	PLB	Both	Control	F	Р
Modified Borg	Pre ex	$4.1 \pm 0.9$	$3.8 \pm 1.3$	$3.8 \pm 1.1$	$3.8 \pm 0.7$	2.54	0.05*
After 6MWD	Post exe	$3.7\pm0.7$	3.0±1.0	3.0±1.2	$4.0 \pm 1.4$	2.34	0.03
	Preex	$65 \pm 19$	$68 \pm 24$	$67 \pm 22$	$58 \pm 28$	1.60	0.16
wike(breathlessness)	Post exe	$68 \pm 22$	$59 \pm 17$	$57 \pm 15$	$69 \pm 24$	1.09	0.16

*PLB*, pursed-lips breathing; *EMT*, expiratory muscle training; 6MWD, 6-minute walk distance; Medical Research Council (MRC) breathlessness.

*F value, Group \_ Time interaction. For both instruments, the lower the score, the less dyspnea. Values are mean T standard deviation.* \* *P e .05.* 

Table (1): The results revealed that there were no significance differences in both groups as regarding baseline demographic and clinical characteristics among the patients in the study and control group. This means that the two groups are matched and homogenous before the intervention. The percentage of males was higher than that of females. They are distributed as follows. 62.5% for EMT, 50%, for PLB, 82.2% for both EMT, PLB and 68.5% for control subjects respectively. The mean age of the studied and control subjects are  $50 \pm 3.2$ ,  $54 \pm 3$ ,  $57 \pm 3.2$ 5.3, 60  $\pm$  2 respectively, the majority of patients are illiterate 50 % EMT, 33.3% control subject. As regards their occupation and residence the majority of patients are manual workers and from rural areas (50% PLB, 75% both) and( 80% control), regarding smoking more than half of patients are smoker 70% of PLB and 60% of control.

**Table (2):** illustrates the health status measures of the study and control subject before respiratory exercises. As regards symptom level, 72.5% of study subjects perceived the frequency of respiratory symptoms as moderate, compared to 68.5% of the control subject. Likewise, half of patients reported a moderate level of disturbances to daily physical activity, and moderate impacts level also, and 60% of patients reported moderate total health status level. There was

no statistical significant difference between the two subjects.

Table (3): shows the differences of health status measures among the studied patient using Expiratory Muscle Training, pursed lips breathing and both. The results show high statistical significant improvement reported by patients about effect of respiratory symptoms, their frequency and severity as presented by symptom scores, the activities that were limited by breathlessness as presented by activity score, the social functioning and psychological disturbances resulting from airways disease as presented by impact score and the impact of the disease on overall health status as presented by total score were improved post respiratory exercise to be good with statistical significant difference between pre and post exercises as follows (11.1%  $\rightarrow$  49.2%), ( 22.2%  $\rightarrow$  84.1 %)  $(20.6 \rightarrow 87.3\%)$  and  $(19\% \rightarrow 90.5\%)$  respectively. It means that respiratory exercises had an excellent effect on health status among COPD patients.

**Table (4)**: shows the comparison between health status of the three experimental subjects' pre and post respiratory training intervention. As for the diaphragmatic breathing, there is no statistical significant improvement in the post test than that of the pretest in the symptom scores, while there is highly statistical significant improvement in the

Activity level and Total level scores. Concerning PLB, there is statistical significant improvement in the reported symptoms level high statistical significant improvement in the impacts level and total level. Also, the table illustrates high statistical significant improvement in the four health status scores in the post test than that of the pretest where  $p<0.001^{**}$  among the subjects who practiced both EMT, and PLB.

**Table (5):** illustrated the comparison between grades of shortness of breath of the study and control subject. There is highly statistical significant improvement in the grads of shortness of breath in pre and post respiratory exercises. Also, the table shows that grade 1 was reported by 9.2 % of the patients of the control subject compared to 50%, 50%, and 44.4% of patients who used PLB, EMT, and both respectively. Also, grade 4 was reported by 7.4% of the patients with in control subject compared to 0%, 0% and 8, 8% of those who used PLB, EMT, and both. The differences are statistically significant.

**Table (6):** This table presents a comparison of the effect of respiratory exercises of study subject versus control subject on pulmonary function and blood gases. It could be observed that the all parameters of study subject are improved after respiratory training with a highly statistical significant difference in relation to PI<sub>max</sub>; PE<sub>max</sub>, Paco<sub>2</sub>, HCO<sub>3</sub> and SaO2 (p=  $0.002^{**}$ ,  $0.005^{**}$ ,p<  $0.001^{**}$ , p<  $0.001^{**}$ , p< 0.001

Table (7): Concerning severity of dyspnea pre and post respiratory exercises table VII shows the difference between reported severity of the shortness of breathing among the studied patients of the control subject and after the respiratory training using the Modified Borg scale. It reveals that 50%, 80%, and 40% who used EMT, PLB, and both reported no dyspnea respectively post respiratory exercises compared with 0.0 % at post intervention with highly significant difference. Also, the same table shows that the number of patients with severe dyspnea was lower in post intervention (6.6%) with highly statistically significant difference compared to 16.6% in control subject (P< 0.01). Moreover, there is a highly statistical significant improvement in the mean scores of dyspnea severity at post respiratory exercises than that of control subject.

**Figure (1):** Borg Score, illustrated that reduction of dyspnea from pre to post after 6 -minute walk distance for three groups than control, firstly for patients who used both (PLB and EMT) then patients who used PLB and finally for patients who used EMT .reduction= -2.1,-1.4,and -0.9 respectively.

 Table (8): Illustrated that improvement for the modified Borg scale after the 6MWD was found for

the PLB group and both when compared with the EMT and control groups (P = .05) at week 8.

# Discussion

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity, mortality, and health care use. Idrees (2012). Exercise intolerance is one of the most troubling manifestations of COPD Zhang, Exercise and activity limitation 2008) are characteristic features of chronic obstructive pulmonary disease. Exercise intolerance may result from ventilator limitation, cardiovascular impairment, and/or skeletal muscle dysfunction. Exercise training, is a core component of pulmonary rehabilitation. Exercise training pulmonary rehabilitation may be undertaken in an inpatient, outpatient, or home based setting, depending on the individual needs of the patient and availability of resources Murtagh, (2005)Pursed lips breathing and expiratory muscle training techniques used to optimize ventilatory function at rest and during exercise for persons with COPD.

The results of present study revealed that the majority of COPD patients' were males and their ages was more than 50 years. This finding is inconsistent with **Kapella et al.**, (2011) who found that the majority of COPD patients were male and had mean age than 55 years. This finding could be due to sample selection.

Concerning the health status impairment in patients with COPD, more than half of the studied patients reported that the respiratory symptoms, frequency and severity were at moderate level and only small percentage reported "good". However, these percentages improved after implementation of the respiratory exercise where almost half of the studied patients reported "good" at the symptom score and only one person reported poor. Also, the majority of the studied patients reported improvement in the activity score, impact score and the total health status score with high statistical significant differences. This finding means that the activity did not cause or limited by breathlessness as before respiratory training thus the respiratory exercise was effective in improving patients' health status and functions and the intervention had a significant good impact on their health. This finding is supported by Gosselnik et al., (2000) who stated that pulmonary rehabilitation is considered as an important component in the clinical management of people with COPD, it improves the physical and psychological condition of people with chronic respiratory disease and promotes long term adherence to health enhancing behaviors. Also, this result is supported by Weiner et al. who mentioned that training both inspiratory and expiratory muscles results in

improved exercise performance, health related quality of life, and dyspnea in daily living activities in COPD patients.

The study showed that half of studied patient had a good perception of frequency of respiratory symptom with significant difference between pre and post pursed lips breathing intervention, in addition, the majority of the studied patients had "good" level of daily living activity with a highly statistically significant difference between pre and post intervention with EMT and both types of training respectively, and assisted the patients in carrying out their activities of daily living. This result was in line with **Pitta et al.**, (2006) reported positive effects of an outpatient supervised exercise program on exercise capacity in individuals with chronic obstructive pulmonary disease with improved health status.

The study portrays pulmonary function test of the study and control subjects after respiratory training, a general improvement in all parameters was observed with highly statistical significant improvement in relation to pulmonary functions (PE<sub>max</sub>, PI<sub>max</sub>, paco<sub>2</sub>, Hco<sub>3</sub> and Sao2) and improvement of Borg scale post-6MWD was found for the PLB and Both excises group when compared with the EMT and control group after 8 weeks and there was a reduction in breathlessness only for Both exercise group but the change did not achieve statistical significance which explain improvement in the global measure of dyspnea and physical function, This result is in accordance with Abdel Raouf, (2011) who demonstrated physiological gains in aerobic fitness following 12 weeks of exercise training (30 min/day, 3 days/ week) in persons with sever COPD.Also Zhang (2008) mentioned that feasible physiologic mechanism is a sustained increase in inspiratory muscle strength over time for the study subjects, with greater inspiratory muscle strength, less force is generated with each breath, which may reduce motor output to the respiratory muscle and decreased the perceived sense of respiratory effort. Nield (2007). stated that Pursed lip breathing versus expiratory muscle training After 12 weeks there were no significant differences between PLB training and EMT for breathing frequency, inspiratory time, expiratory time or inspiratory time to expiratory time ratio; however, the data were not reported

The study evaluated the shortness of breath grades of the study and control subjects, it was obvious that there is a statistical significant difference between the number of COPD patients with different grades pre and after 8 weeks of respiratory training. Almost half of the studied patients were in "grade I" shortness of breath post respiratory training compared to only 9.2% of the control subjects. This result were supported by **Kim(2008).** who stated that 30% of muscle mass gets wasted in an average COPD patient. This could be because exercise training builds up muscle mass and strength and improve the lung function and reduce shortness of breath. It has been known to increase exercise capacity, improve health related quality of life measures and reduces symptoms of dyspnea. Evidence now supports the use of PLB and EMT, but there is clearly a need for further research in order to clarify where skills and training should be focused, particularly in relation to other interventions, in order to optimize benefit and outcomes for our patients.

In current study expiratory muscle strength ( $PE_{max}$ ) and inspiratory muscle strength( $PI_{max}$ ) significant increased after EMT,PLB and both subjects, while the PLB and both were significant increased more than EMT group. These inline with **Akiyoshi et al.**,

(2001) revealed that EMT significantly increases not only expiratory but also inspiratory muscle strength. This may be attributable to the function of abdominal muscles in inspiration, as well as expiration. Also our study disagree with 55Sasaki ,55 Kurosawa , and 55 Kohzuki (2005) who stated that only expiratory muscle strength (PE<sub>max</sub>) increased after EMT , where is inspiratory muscle strength (PI<sub>max</sub>) were unchanged .

Several explanations for the PLB benefit compared with EMT and control are likely. The simplest is the ready availability of PLB. No device is required to practice prolonged expiration as with EMT. Pursedlips breathing can be used every waking hour and with every activity, including walking. Pursed-lips breathing can be incorporated into a patient's daily routine, and therefore, is less likely to be subject to extinction. Any dyspnea relief would reinforce its continued use.

## Conclusion

It can be concluded that there was statistical significant improvement after implementation of the respiratory training in total health status score and Borg scale post 6 MWD among PLB and Both exercise subjects when compared with the EMT and control subjects after 8 weeks.

## Recommendations

From the results of this study, the following recommendations are suggested:

- Greater emphasis should be placed on patient education regarding pulmonary rehabilitation.
- COPD patients should be given a written instruction plan for daily self-management which includes EMT and pursed lips breathing to be followed at home.

- Further research is required to identify clearly the benefits of breathing exercises in breathless patients with COPD and treatments should be closely monitored for variations in response and modified accordingly

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