Efficacy of Pulmonary exercise administered in Supine, 45°, or 90° long sitting position on cardiopulmonary parameters and quality of life of patients with chronic obstructive pulmonary disease: A Randomized Control Trial Study Protocol.

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ABSTRACT

Background: Pulmonary rehabilitation (PR) is a program commonly structured for the rehabilitation of chronic lung diseases like Chronic Obstructive Pulmonary Disorders (COPD), chronic bronchitis, and emphysema. It aims to increase the patients' quality of life by decreasing the symptoms frequently experienced from respiratory diseases.
Aim: The overall aim of the study is to compare the effect of pulmonary exercises administered on COPD patients in Supine, 45° or 90° body position on selected cardiopulmonary parameters and quality of life of COPD patients and identify the most efficacious body position during its administration.
Methods: Forty-two (42) female and male patients aged forty (40) years and above with COPD of greater than six months duration, diagnosed at the respiratory unit of the Lagos State University Teaching Hospital (LASUTH) will be assessed for eligibility for the study. Patients on hospital admission, recent history of myocardial infarction, and on cardiac pacemakers will be excluded from the study. Eligible participants will be required to attend the study Centre three (3) times per week for a period of 12 weeks, with each session encounter not exceeding 30 minutes. The study design will be a randomized parallel-group design with three intervention groups and three parallel placebo control groups. Active Cycle of Breathing Technique (ACBT), Autogenic drainage (AD), and Reciprocal Pulley Exercise (RPE) will be administered as an intervention in various body position for 5 minutes, respectively. Ten continuous outcomes (FVC, FEV_1, PEFR, FEV_1/FVC, $FEF_{25-75\%}$, $SP0_2$, HR,RR, SBP, and DBP) will be measured at baseline, before and after every (treatment) procedure. Short Form 36 (SF- 36) Health Survey Questionnaire, Medical Research Council (MRC) dyspnea scale, Six Minutes' Walk Test (6MWT), and COPD Assessment Test (CAT) will be assessed fortnightly on a six-time points per subject. Data obtained will be analyzed using descriptive statistics of bar charts and pie charts, while a one-way repeated measures MANOVA will be utilized as inferential statistics to evaluate the

normality, variance equality, continuity of data, and a test of statistical significance within and between group interactions at P≤0.05.
Discussion: The study outcome will determine the efficacy of ACBT, AD, and RPE in supine, 45°, and 90° body positions on selected cardiopulmonary parameters and quality of life of patients with COPD and identify the most efficacious body positioning in the administration of the pulmonary exercises.
Trial Registration: www.pactr.org: PACTR202005890624077

Keywords: Pulmonary rehabilitation, COPD, 6MWT, PFT, CAT SCORE, MRC Dyspnea scale, SF-36

BACKGROUND

Chronic obstructive pulmonary disease (COPD) is one of the most prevalent chronic diseases in the world currently affecting over 80 million people in the world, it's a group of progressive lung diseases commonly associated with emphysema, chronic bronchitis, or both; emphysema and bronchitis can lead to airway obstruction following the destruction of air sacs in the case of emphysema and mucus build-up from inflammation that occurs in the case of bronchitis (1). According to Similowski, Agusti (2), COPD is characterized by progressive, partially reversible airflow obstruction with significant extrapulmonary (systemic) manifestations, lung hyperinflation, and comorbid conditions that may add to the severity of the disease in individual patients.

COPD diagnosis should be considered in persons with chronic cough symptoms, sputum production, shortness of breath, or wheezing, especially among those with prolonged exposure to risk factors for the disease (3). Inspiratory to expiratory (I: E) ratio is shortened, pursed-lip breathing (PLB) is present, use of accessory muscles, jugular venous distension, labored breathing signs, pulsus paradoxus, barrel-shaped chest, peripheral edema, dyspnea relieving posture and muscle wasting and during palpation subxiphoid shift of apex beat, restricted chest expansion, hyper resonant lung field, obliteration of cardiac dullness, lower level of liver dullness, lower diaphragmatic levels, diminished breath sound, early inspiratory crackles, a loud pulmonic component in the second heart sound and rhonchi or wheeze in expiration (4, 5).

COPD has been identified with many complications ranging from mild dyspnea to an advanced inability to perform simple task like walking through a short distance (6, 7). Strategies like single and double arm elevation above the shoulder have been explored and found to improve cardiorespiratory parameters of COPD patients (8), while strategies like body positioning and breathing exercises are often adopted by physiotherapists to relieve dyspnea (9).

Body posture has long been identified as a very important factor impacting lung volumes (10). Also, body positions are clinically significant even in a healthy population because they are often used during treatment, resuscitation, everyday activities, and surgical procedures (11).

Although the effective patient positioning may be associated with marked improvement in partial pressure of oxygen (PaO2) and plays an essential role in the conservative management of pulmonary dysfunction by reducing the effect of a shunt or dead space, some positions may deteriorate Ventilation/Perfusion (V/Q) matching (12).

Pulmonary rehabilitation (PR) is a multidisciplinary, and comprehensive intervention that is evidence-based for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities (13-15). The essential components of PR are Education, self-management training, nutrition, and psychological support, while exercise training is the cornerstone of the PR (15, 16). PR has been demonstrated to increase exercise tolerance, lower the dyspnea perception, and improve the quality of life in COPD patients, the patients' responses to PR differ, and no improvement can be achieved in some patients (15, 17). Hornikx, Van Remoortel (18), Franssen and Rochester (19), reported the presence and number of comorbidities as a factor that may affect PR's positive effects on dyspnea , functional exercise capacity, and quality of life.

Pulmonary function test is a simple and accurate tool to assess airflow obstruction, patients forced expiratory volume in 1 second (FEV_1)/forced vital capacity ratio is reduced, and FEV_1 is reduced in COPD (20). A reversibility testing differentiates COPD from asthma as in COPD patients do not show reversibility in airflow obstruction after administering bronchodilators (20). Severity staging of COPD is important for disease prognostication as well as for treatment. GOLD guidelines classify COPD into mild (FEV1 ≥80% predicted), moderate (FEV1 ≥ 50% - < 80%), severe (FEV1 ≥ 30% - <50%), and very severe (FEV1 <30%) disease (20).

Pulmonary rehabilitation (PR) is an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities (13, 15, 21). Education, self-management training, nutrition, and psychological support are essential components of PR; exercise training is the cornerstone of the PR (15, 16). PR has been demonstrated to increase exercise tolerance, lower the dyspnea perception, and improve the quality of life in COPD patients, the patients' responses to PR differ, and no improvement can be achieved in some patients (15, 17).

Several randomized controlled trials have demonstrated the efficacy of upper limb exercises, autogenic drainage, and ACBT in pulmonary rehabilitation on COPD patients. However, to the best of our knowledge, none has compared the impact of pulmonary rehabilitation on cardiopulmonary parameters and quality of life of patients with COPD in different fundamental body positions. This study aims to evaluate the efficacy of a 12-week pulmonary exercise administered in supine, 45° long sitting and 90° body positions in improving cardiopulmonary parameters and quality of life of patients with COPD.

This study is therefore structured to answer the following questions.

1. What will be the effect of PR administered in Supine, 45° or 90° body

position on SF-36, MRC dyspnea scale, Six minutes' walk test, CAT score of patients with COPD over a period of 3 months?

2. What will be the effect of PR administered in Supine, 45° or 90° body position on HR, RR, SBP, DBP, $SP0_2$, FVC, FEV_1, PEFR, $FEF_{25-75\%}$, and FEV_1/FVC score of patients with COPD over a period of 3 months?
3. Will PR improve the cardiopulmonary parameters and quality of life better in Supine position than patients who received PR in 45° or 90° body position of patients with COPD over the period of 3 months of the study?
4. Will PR improve the cardiopulmonary parameters and quality of life better in 45° position than patients who received PR in supine or 90° body position of patients with COPD over the period of 3 months of the study?
5. Will PR improve the cardiopulmonary parameters and quality of life better in 90° position than patients who received PR in 45° or 90° body position of patients with COPD over the period of 3 months of the study?
6. Will PR administered in Supine, 45° or 90° body position improve the cardiopulmonary parameters and quality of life better than patients who did not receive PR in Supine, 45° or 90° body position?

AIM OF THE STUDY

Overall Aim of the study

The overall aim of the study is to determine the effect of PR applied in Supine, 45° or 90° long sitting on SF-36, MRC dyspnea scale, 6MWT, CAT score, HR, RR, SBP, DBP, $SP0_2$, FVC, FEV_1, PEFR, $FEF_{25-75\%}$, and FEV_1/FVC of patients with COPD patients attending respiratory clinic of Lagos State University Teaching hospital, Ikeja. Lagos.

Specific Objectives

To determine

i) The effect of PR in 3 fundamental body positions on the SF-36, MRC dyspnea scale, 6MWT, CAT score of patients with COPD attending the respiratory clinic.

ii) The effect of PR in 3 fundamental body positions on the HR, RR, SBP, DBP, $SP0_2$, FVC, FEV_1, PEFR, $FEF_{25-75\%}$, and FEV_1/FVC of patients with COPD attending the respiratory clinic.

Hypotheses.

Main Hypothesis

It is hypothesized that: a 12-week pulmonary rehabilitation program applied in supine, 45° or 90° body position will significantly improve:

i) Cardiopulmonary parameters (HR, RR, SBP, DBP, $SP0_2$, FVC, FEV_1, PEFR, $FEF_{25-75\%}$, and FEV_1/FVC score) of patients with COPD over a period of 3 months.
ii) Functional performance and quality of life (SF-36, MRC dyspnea scale, Six minutes' walk test, CAT score) of patients with COPD over a period of 3 months.

Sub Hypotheses

i) There will be no significant difference in the SF-36, MRC dyspnea scale, 6MWT, CAT score before and after administration of PR in Supine, 45° long sitting, and 90° long sitting of the experimental group.
ii) There will be no significant difference in the SF-36, MRC dyspnea scale, 6MWT, CAT score before and after pulmonary rehabilitation administration in Supine, 45° long

sitting, and 90° long sitting of the control group.

iii) There will be no significant difference in the HR, RR, SBP, DBP, $SP0_2$, FVC, FEV_1, PEFR, $FEF_{25-75\%}$, and FEV_1/FVC score before and after administration of PR in Supine, 45° long sitting, and 90° long sitting of the experimental group.

iv) There will be no significant difference in the HR, RR, SBP, DBP, $SP0_2$, FVC, FEV_1, PEFR, $FEF_{25-75\%}$, and FEV_1/FVC score before and after administration of PR in Supine, 45° long sitting, and 90° long sitting of the control group.

Delimitation

This study will be delimited to 42 patients with COPD attending Lagos State University Teaching Hospital's respiratory clinic, Ikeja, Lagos on outpatient basis, who has fully read and understood the informed consent form, patients who fulfils the study inclusion and exclusion criteria and who are willing to fulfil the study requirements of study attendance of total duration of 12 visits, with each visit not exceeding 30 minutes.

Significance of the study

It is expected that the outcome of this study will establish the relationship between Pulmonary rehabilitation administered in different body positions and the SF-36, MRC dyspnea scale score, CAT scores, 6MWT, cardiovascular and pulmonary variables of patients with COPD. The findings of this study will provide the clinicians with more effective intervention options that can enhance patient recovery if proof of efficacy is established. It is expected that the outcome of this study will provide empirical evidence of the therapeutic value of this Physiotherapy management approach to COPD. The randomized parallel-group clinical trials design proposed for this study would allow a range of ideas about the management of COPD using exercise in different fundamental positions to be generated and tested quickly and cost-effectively. By exploring the efficacy of several physiotherapy management approaches for COPD simultaneously, it is possible to compress the concept development time frame, and combine all concepts generated so that the eventual outcome benefits from all ideas are proposed.

METHOD

Study Design: The study is a 12-week randomized parallel-group design. The study will involve six (6) groups, three intervention groups, and three placebo control groups.

Participants: The participants for this study will consist of male and female adult COPD patients aged 40 years and above attending Lagos State University Teaching Hospital (LASUTH), Ikeja, Lagos, Nigeria, West African.

The inclusion criteria involve patients with a COPD history of about or more than six months of duration attending the respiratory clinic of LASUTH.

The exclusion criteria involve patients with COPD on a cardiac pacemaker, supplemental oxygen therapy, asthma, cardiac conditions, and patients with psychological impairments.

Participants who met the required criteria will be asked to read and sign an informed consent approval for this study by the appropriate institutional review board.

Setting: Patients with COPD attending the respiratory clinic of Lagos State University Teaching Hospital Ikeja, Lagos State, Southwest Nigeria, would be recruited for

the study. The hospital is a tertiary health facility within the state and receives referral from within and outside the state.

Sample size: Pulmonary function test is the primary outcome of interest for the study and the expected clinically relevant difference for pulmonary rehabilitation in various body positions using LLN and GLI reference equation proposed by Quanjer PH (21). Therefore, the sample size (N) will be determined using G-Power statistics software. The power is selected at 95% =0.95, confidence level at 5% =0.05 and effect size of 0.35. We intend to investigate the main effects, within and between interactions for two factors, namely:

Factor A – Therapy with two levels (No Therapy and Therapy)
Factor B – Positioning of patients with three levels (Supine, 45 and 90 long sitting), nested within factor A

This gives 2x3 = 6 groups of subjects from which repeated measurements are to be obtained. We are also planning to measure ten continuous outcomes at different time points. The minimum repeated measurements are expected to be 6 per subject for some of the outcomes and a maximum of 36 per subject. Suppose a minimum of 6 repeated measures is to be obtained from each subject. In that case, it is estimated that a minimum total sample size of 42 patients is required to detect an effect size v = 0.35 with 95% confidence (5% Type I) and having similar studies also expected to produce similar results about 80% of the time (Power of test 80%). In the case that during the time of the data collection, the hospital experiences a heavy burden of COPD patients or resources permit, there is an allowance to increase the total sample size to at most 59 subjects with a corresponding increase in the power of the test to about 95% and still detecting effect sizes between 0.3 and 0.4 (See Figure 1). This translates to the possibility of recruiting between 7 and 10 patients per group. Hence, the sample size estimates suggest that recruiting more than ten patients per group for this kind of study will be a waste of resources.
To the best of our knowledge, currently there are no previous studies that have reported on the variance-covariance of the measurements in 6 groups like the ones being investigated in our study. Hence, any possible violation of homogeneity of variance-covariance assumptions are to be taken into consideration using Pillai's trace, a test statistic which is robust to departures from these assumptions (Pillai, 1955) and it is assumed that the desired sample size be able to detect a Cohen's medium effect size of 0.35 (Cohen, 1988). Given the suggested effect size of 0.35, and a minimum of 6 repeated measurements to be obtained from each subject, using GPower 3.1.9.7 software for power analysis, it is estimated that a minimum total sample size of 42 patients is required to detect the effect size of v = 0.35 and the associated Pillai's V = 0.546 which is relatively smaller indicating the less chance of violating the homogeneity of variance-covariance assumptions in the 7 subjects per group. With this sample size, we will have 95% confidence (5% Type I error) of our conclusions and the MANOVA test will be able to reject the null hypothesis about 80% of the time (Power of test) when it is indeed false. In the case that during the time of the data collection, the hospital experiences a heavy

burden of asthmatic patients or resources permit, there is an allowance to increase the total sample size to at most 90 subjects with a corresponding increase in the power of test to about 95% and still detecting effect sizes between 0.3 and 0.4 (See Figure 1). This translates to the possibility of recruiting between 4 and 9 patients per group. Hence, the sample size estimates suggest that recruiting more than 9 patients per group for this kind of study will be a waste of resources.

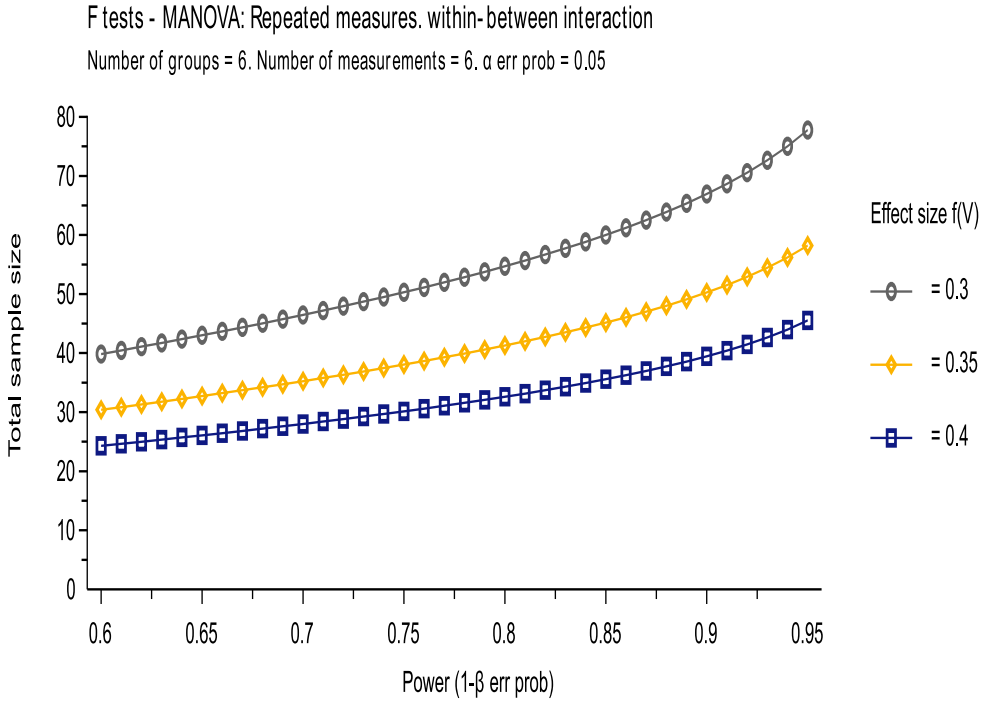

Figure 1: Sample Size Calculation.

Randomization and blinding: The contact numbers of participants will be randomly extracted from the respiratory patients' database attending the respiratory clinic of Lagos State University Teaching Hospital Ikeja. A bulk Text message captioned "Invitation to a study on COPD will be circulated using the Luxury bulk SMS platform. Respondents will be assessed for eligibility, and those that meet the inclusion and exclusion criteria will participate in the study.

Participants will be randomly selected by simple randomization using a randomization table created by a computer software program (22). The software program (www.randomization.com) will be used to allocate participants into study group A and control group B. Group A will be further assigned to subgroup x, y, z and group B will be assigned to subgroup e, f, g. Subgroup x and e connotes supine position, y and f connotes 45°long sitting, while z and g represent 90° long sitting position respectively figure 2.

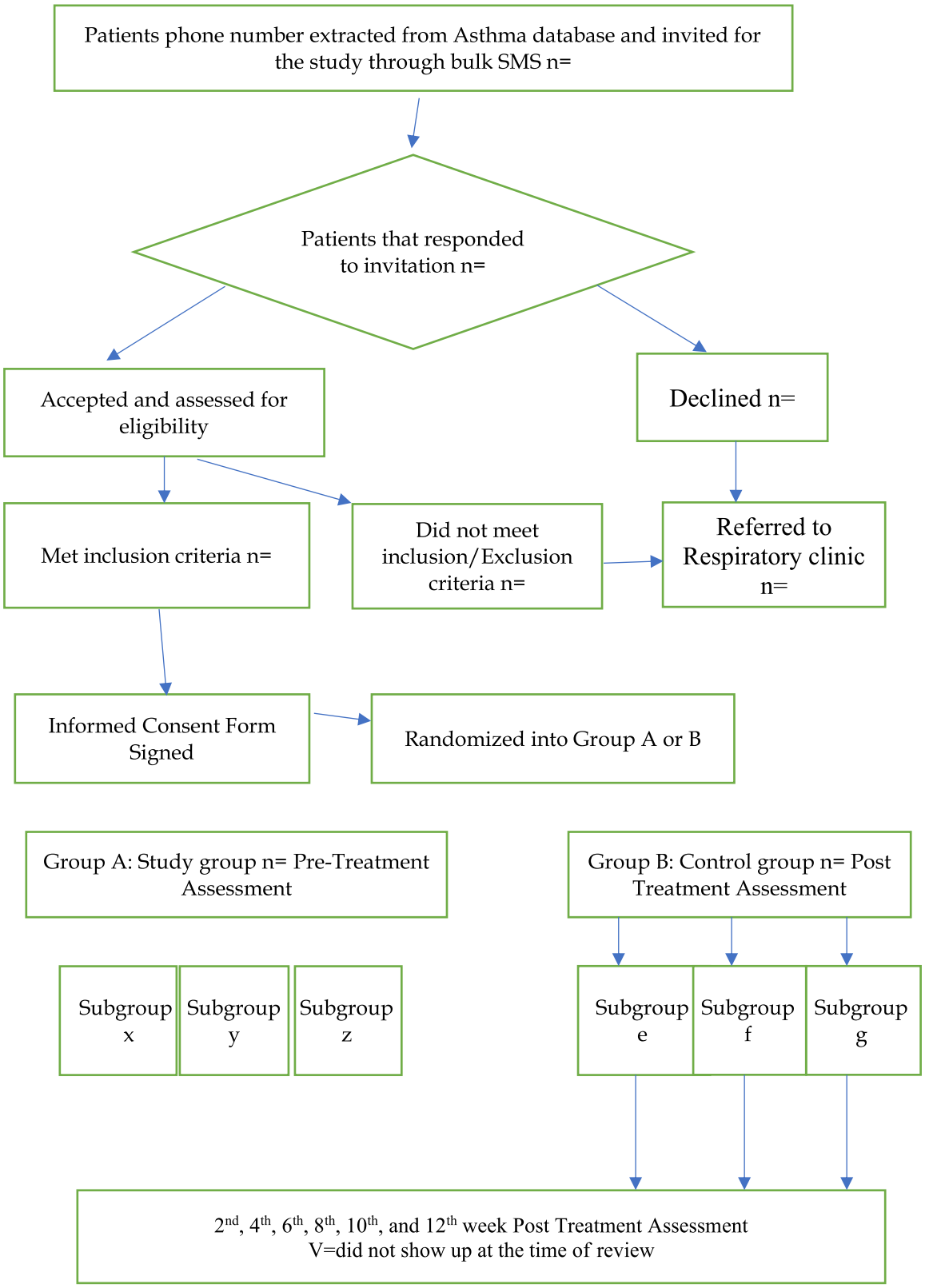

Figure 2: Outline of the study CONSORT flow diagram from enrolment to analysis

INTERVENTION

Participants will be briefed about the nature of the study, the effect and benefit of the study. They will be encouraged to clarify issues regarding the study if any, written informed consent will be obtained from participants before the study's commencement. Participants will be randomly assigned into two groups: Study (Group A) and Control group (Group B).

Six minutes' walk test, MRC dyspnea scale, and CAT score will be measured and recorded before intervention in both groups. Reassessment will be done after the 2nd, 4th,6th, 8th, 10th, and 12th week of the study intervention.

The study group (Group A) will receive reciprocal pulley exercise, Autogenic drainage, and ACBT, with each procedure not exceeding a period of five minutes. If the patient presents any sign of distress during treatment, the treatment will be immediately discontinued, and the patient will be placed under close observation. If the situation persists, the patient will be referred to the respiratory unit for further reevaluation. So long as the subject experiences no distress, the intervention will last a total of twenty (20) minutes with an average rest time of 90 seconds between procedures.

Autogenic Drainage

The subjects will be asked to blow their nose and clear the throat before commencing the procedure with the subject in the test position (Supine, 45° long sitting or 90° long sitting). The technique will be explained to the participants as follows; the technique involves three phases, which are the unsticking phase, collecting phase, and evacuating phase. The first stage involved the subject in taking a deep breath, then breathing out completely. After this, the subjects will be required to take a small breath and breathe out completely. When the subject feels the secretions' movement, the subject will move to the collecting phase in which the subject will be required to take a deeper breath, and the expiration should not go very deep into the expiratory reserve volume. Once the secretion is felt moving to more central airways, the subjects will be asked to take very deep breathes to reach the inspiratory reserve volume and enter the evacuating phase. As the subjects feel that the secretions have reached high in the central airways, they will be required to cough out the sputum into the sputum tray beside the treatment bed. The subjects will be asked to control the cough during the cycle of breathing exercise (5). The cycle will be repeated for 5 minutes.

ACBT

With subjects in the fundamental starting position (Supine, 45° long sitting or 90° long sitting). ACBT will be explained to the participants as follows; ACBT involves three stages which are breathing control, deep breathing exercise, and Forced Expiratory Techniques (FET). The cycle involves a sequence of breathing control in which the subject will be required to do quiet relaxed abdominal breathing, deep breathing exercise in which the subject will be required to take 3 or 4 deep breaths to expand the thoracic region. The first two stages will be repeated for five to six times before reaching the third stage which is the FET in which the subject will perform 1 or 2 huffs, from low lung volume followed by huff from high lung volume and relaxed

abdominal breathing (5). The entire technique will be continued for 5 minutes.

Control group

The control group (Group B) in addition to the baseline pulmonary function test will also receive counselling on COPD and enjoy free musculoskeletal assessment. They will be divided into 3 subgroups and labelled e, f and g and placed in Supine, 45 degrees and 90 degrees long sitting respectively. They will be asked to maintain their respective positions for a period of 20 minutes. If the subject is experiencing respiratory difficulty, the procedure will be discontinued.

Outcomes

Six-minute walk Test

According to ATS (23) six minutes' walk test (6MWT) is a practical simple test that requires a 100-ft hallway with no exercise equipment or advanced training, it measures the distance that a patient can quickly walk on a flat, firm surface in a period of 6 minutes (the 6MWD). it evaluates the global and integrated responses of all the systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism.

MRC Dyspnea scale

The MRC breathlessness scale quantifies the disability associated with breathlessness by identifying that breathlessness occurs when it should not (Grades 1 and 2) or by quantifying the associated exercise limitation (Grades 3–5) (24).

According to Mahler and Wells (25), there is up to 98% agreement between observers recording MRC breathlessness scores, the score correlates well with the results of other breathlessness scales, lung function measurements, and with direct measures of disability such as walking distance (23).

The MRC breathlessness scale is widely used to describe patient cohorts and stratify them for pulmonary rehabilitation interventions, predict survival and use as complementary to FEV1 in describing disability in those with COPD (26-28). It has demonstrated its worth in 50 years of use (25).

CAT Score

According to Jones, Harding (29), the CAT was created using COPD patients' input, developed using modern questionnaire methodology, psychometric analysis and item response theory using Rasch analysis to identify items with the best fit to form a unidimensional instrument, it is a self-administered questionnaire consists of eight items assessing various manifestations of COPD (cough, sputum, dyspnea, chest tightness) aiming to provide a simple quantifiable measure of Health Related Quality of Life (HRQoL).

CAT scores from 0–40, higher scores denote a more severe impact of COPD on a patient's life, the difference between stable and exacerbation patients is five units, no target score represents the best achievable outcome, its intra-class correlation coefficient=0.8, its internal consistency Cronbach's α=0.88 and has a high correlation with SGRQ (r=0.84) across 7 European countries (29).

SF- 36

According to Tsavlis, Tsimtsiou (30), SF-36 survey questionnaire is an established tool that relates to general health status of COPD patients. In their research, which compared disease specific instruments in

assessing health related quality of life in COPD, a strong correlation was identified between FEV_1 and the domains of general health perceptions and vitality with a pearsons rank correlation score r≥ .7. The SF-36 health survey questionnaire is structured on the assumption that the physical and psychosocial attributes of health can be viewed using the physical functioning, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning, and mental health as the eight sections constructed for the instrument (30) The score ranges from 0 to 100, and the closer the participant is to 100 the better the QoL is considered.

SPIROMETER

Koko SX 1000 Standalone Version 7 Pneumotach, a portable lightweight and comprehensive diagnostic tool will be used to conduct pulmonary function test. The Koko Legend II spirometer has a built-in thermal printer and a touch screen display, it can perform FVC, Pre vs. Post and SVC tests. Test data and patient information is stored directly to an internal SD card that can be replaced and re-used if necessary. All the stored information can alternatively be downloaded via a USB cable onto a PC for back up or storage. This device supports daily calibration checks, complies with ATS-ERS 2005, and has several Predicted Authors and includes GLI-2012.

Daily calibration of the device will be conducted using a 3L syringe.

The participant's condition can be shown by the ratio of the measured value and the predicted value. Flow rate-volume chart, volume-time chart display, data memory, delete, upload and review, trend chart display, scaling (Calibration), information prompts when volume or flow goes beyond the limits are features available in the device.

Data analysis

The Statistical Package for Social Sciences (SPSS Inc, Chicago, II) version 26.0 for windows package program will be used to analyze data. Descriptive statistics of mean, standard deviation, frequency, and percentage will be used to summarize the results. Bar charts, pie charts, and histograms will be utilized for pictorial illustration. Multilevel analysis of variance (ANOVA) will be used to compare the outcome variables [selected cardiovascular variables (RR, HR, SBP, and DBP), body position (Supine position, 45 degrees long sitting and 90 degrees long sitting), pulmonary function variables (FEV1, FVC, FEV1/FVC), MRC dyspnea scale, Six minutes' walk and CAT score among each group, dependent t-test will be used to compare the pre and post-test results while independent t-test will be used to compare the outcome variable across the two groups. The level of significance will be set at p0.05

Harms

The research does not potentially involve risk or harm as all interventions can only be performed within the limit of the patient's tolerance. However, those participants may experience mild discomfort due to the exercise, this may include temporary muscle soreness, increase in heart rate, blood pressure, sweating, and dizziness. Although all necessary care will be in place to prevent the occurrence of any adverse event, however, in case of a report of serious adverse events (e.g., comorbidities,

injuries, persistent excruciating pain, dizzy spells, headache etc.) after intervention or at any point during the trial, then we would consider unblinding the participant to the intervention for his/her safety. Additionally, the participants will be instructed to report any adverse events to the PI and/or the physiotherapist supervising their group. To ensure adequate supervision and safety of the participants, the number of participants per group to be attended in a day will be limited to a maximum of 3. Arrangements have been made with the Accident and Emergency units, the hospital where the research will be conducted for the provision of a standby medical team. However, the University of KwaZulu-Natal insurance scheme on clinical trials has fully covered the participants in this type of study.

DISCUSSION

Despite the existence of a sizable number of randomized control trial on the effectiveness of pulmonary rehabilitation in the management of COPD, information on the effectiveness of PR in different body positions is lacking.

According to Mohammed, Abdulateef (31), at the Aminu Kano Teaching Hospital, Kano, on the effect of different body positioning on lung function variables among patients with bronchial asthma, FEV1 and FVC increased in the standing position compared to sitting and supine position among 20 participants.

On the contrary, Katz, Arish (32) in a systematic review further reported no statistical difference in the pulmonary parameters of patients with COPD in sitting vs Standing position.

It is expected that the findings of this study will give a clearer understanding of the effect of pulmonary exercise on selected fundamental body positions of patients with COPD and serve as a guideline for pulmonary rehabilitation in the management of patients with COPD.

Access to Protocol

https://pactr.samrc.ac.za/Researcher/ManageTrials.aspx The protocol was registered on 1st of May 2020 with identifier number PACTR202005890624077 and the trial organization is UKZN

Ethical Considerations and consent to participate.

This study has been approved by the Biomedical Research Ethics Committee of the University of KwaZulu Natal (South Africa) (Ethics Number: BREC/00001883/2020), and by the Human Research Ethics Committee of Lagos State University Teaching Hospital, Ikeja, Lagos, Nigeria, West Africa (LREC/06/10/1428). The study has been registered with ClinicalTrial.gov with the following registration number: PACTR202005890624077. A written and signed informed consent will be obtained from all recruited participants for the study by a third party who is independent and not part of the core study team; the consent form is designed by the Biomedical Research Ethics Committee of University of KwaZulu-Natal (BREC) according to the WMA Helsinki declaration and good clinical practice (GCP).

During the conduct of this trial, the PI will communicate in writing to the RECs in the event on the need to modify or amend the protocol, especially inclusion or exclusion criteria of the study.

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. However, the findings from the study would be made available to participating researchers as required by law.

Competing interests
The authors declared that they have no competing interests.

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Authors' Contributions
AOE developed the idea for the study; AOE and MSS (developed the title and all contributed to the study design. All authors were involved in designing the IIS and EIS procedure and the selection of outcome measures for the study. AOE was responsible for drafting the initial manuscript. AO helped with editing and critical review of the manuscript to add value to its intellectual content, and all authors read, critically revised, and approved the final version of the manuscript.

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Abbreviations
ANOVA - Analysis of Variance
CAT - COPD assessment Test
COPD - Chronic Obstructive Pulmonary Disease
DBP - Diastolic blood pressure
FEV1 - Forced expiratory volume in 1 second
FVC - Forced Vital Capacity
FRC - **Functional** residual Capacity
GLI - **Global** Lung Initiative
HR - Heart rate
HRQoL. – Health Related Quality of Life
LASUTH - Lagos State University Teaching Hospital
LLN - Lower Level of Normal
MANOVA- Multiple Analyses of Variance
MRC - Medical Research Council
MS. - Microsoft
$PA0_2$ - Partial pressure of oxygen
PEFR - Peak expiratory flow rate
PFT - Pulmonary Function Test
RCT - Randomized Control Trial
ROM. - Range of Motion
RR - Respiratory rate
SBP. - Systolic Blood pressure
SF-36. – Short Form 36 Health survey questionnaire
SPSS. - Statistical Package for Social Sciences
UKZN - University of Kwazulu-Natal
V/Q. – Ventilation/Perfusion coefficient
6MWT - Six minute's walk test
6MWD - Six minute's walk distance

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