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Original article

WBVE in patients with COPD: A randomized trial protocol

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Abstract

Introduction: Patients with chronic obstructive pulmonary disease (COPD) have several impairments, reducing the quality of life (QoL). Pulmonary rehabilitation (PR) that does not exacerbate the disease, such as whole-body vibration exercise (WBVE), is recommended to improve patient outcomes. Objective: This study will describe a protocol for patients with COPD to assess respiratory parameters in two postures on a vibrating platform (VP). Methods: It will be a randomized controlled clinical trial with blind analysis. COPD patients will be allocated into three groups: Control Group (CG), Sitting Group (WBVE-S), and Standing Group (WBVE-ST). The intervention will be 6 weeks in alternating VP, with the same biomechanical parameters. Maximum inspiratory pressures (MIP), and maximum expiratory pressures (MEP), dyspnea, and QoL will be assessed. Discussion: Assess which posture will provide the best clinical results.

Keywords: COPD; Protocol; Exercise; Quality of life; Dyspnea; Respiratory muscle strength.

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Introduction

Chronic obstructive pulmonary disease (COPD) is one of the top five causes of morbidity and mortality worldwide.[1] Despite efforts, costs, and medical research around the world, COPD figures show a trend of continuous increase in mortality.[2] Exacerbations and comorbidities contribute to general severity in individual patients.[3] COPD is characterized by a reduction in airflow in the airways caused by an inflammatory response to inhaled toxins. This reduction leads to a significant decrease in muscle strength and endurance that can arise in relatively early stages of the disease, compromising the functional state and quality of life (QoL).[4] Treatment, pharmacological and non-pharmacological, is extremely important for the carrier of the disease. In this sense, pulmonary rehabilitation (PR) of COPD patients has emerged as a standard recommendation among non-pharmacological treatments.[6] Usually, a PR program has, among its objectives, to improve the symptoms of the disease, improve the QoL and promote the physical improvement of patients for activities of daily living.[7] However, patients with greater intolerance to exercise may not benefit from a traditional PR program, thus increasing the demand for health services.[9] An alternative intervention for PR exercises is the WBVE.[10] Studies in COPD patients have shown that WBVE has beneficial effects in improving exercise capacity, in addition to being easy, safe to perform, and cost-effective.[11] WBVE is an exercise modality in which the individual is exposed to mechanical vibrations produced on a vibrating platform (VP).[12] This vibratory stimulus is characterized by biomechanical parameters such as frequency, peak-peak displacement, and peak acceleration; and it can stimulate muscle spindles generating reflex activity similar to the tonic reflexes that cause involuntary muscle contractions triggered by monosynaptic drugs.[13] VP can be alternated (up and down oscillation on the opposite side), vertical (synchronous or tri-planar) and horizontal. WBVE can be performed with the individual standing (squatting) at the base of the VP[14] or sitting in a chair in front of the VP with feet at the

base of the VP. In individuals with COPD, WBVE can improve QoL[15] and functionality.[16] However, there are no standardized protocols to be implemented in these patients.[17] A common feature among studies involving individuals with COPD is the squat posture (patient standing with knee flexion at 1300) in PV.[18] As these individuals present worsening health status, some patients may not be able to maintain this posture and, consequently, will not receive the benefits offered by WBVE.[19] The present study aims to compare the clinical effects of the WBVE protocol in two different postures (squat and sitting in an auxiliary chair) on QoL, respiratory muscle strength, and dyspnea in patients with COPD.

Methods

This project was approved by the Certificate of Presentation of Ethical Appreciation (CAAE 49219115.3.0000.5259) of Hospital Universitário Pedro Ernesto (HUPE) and The Brazilian Registry of Clinical Trials (ReBEC RBR-72dqtm). The study was also registered in the procols.io platform (dx.doi.org/10.17504/protocols.io.376grre) and will follow the principles stated in the Declaration of Helsinki. All the participants of this work will sign a consent form.

Participants, interventions, and outcomes

Study settings

Outpatients of the Pulmonology Services of the *Hospital Universitário Pedro Ernesto* (HUPE), and *Policlínica Piquet Carneiro, Rio de Janeiro* of the *Universidade do Estado do Rio de Janeiro* (UERJ) will be recruited.

Inclusion criteria

Individuals of both sexes, aged 40 years or older, diagnosed with COPD based on the criteria established by the GOLD Document, patients with a stable disease with Forced Expiratory Volume in the First Second (FEV1) <50%, independent patients.

Exclusion criteria

Individuals with exacerbation the past 3 months; labyrinthitis; reported osteoporosis; other respiratory diseases; use of pacemakers; previous history of fractures and/or other orthopedic diseases submitted to surgeries with implantation of a metallic material; peripheral vascular disease and/or thromboembolism; decompensated cardiovascular disease; aneurysm; previous vitreous hemorrhage; malnutrition; a neurological disease that generates "fear" of VP movements; severe or disabling clinical disease at the discretion of the investigator; smoking and/or alcoholic individual.

Sample size

The sample size will be calculated using the quantitative formula of an infinite population[20] with the parameter "modified medical research council" (mMRC) from the article by[20] considering a standard deviation of 15.9 and a mean of 117 resulting in 25 patients for each group in this study. The formula for calculating sample sizes to describe quantitative variables in a population. n = sample size; Zα / 2 - critical value for the desired degree of confidence, usually: 1.96 (95%); δ - population standard deviation of the variable; E - standard error, usually: ± 5% of the proportion of cases (absolute precision), or ± 5% of the mean (1.05 mean).

Participant timeline

In figure 1, we show how patients WILL recruited for the protocol. After going through the eligibility process, we will do blind randomization using an opaque envelope, and define the 3 groups: Control Group (CG), Sitting Group (WBVE-S), and Standing Group (WBVE-ST). The next phase will be the comparison between the groups before the intervention and only then do we start the 6 weeks of intervention. At the end of this period, we will enter the last phase, which will be the reassessment between groups. The individual that develops a serious illness that limits participation in the study or with an adverse event to the WBVE will ask to give up.

Parameters at intervention with WBVE

WBVEG-ST and WBVEG-S patients will use alternating VP (*Novaplate* fitness evolution, DAF *Produtos Hospitalares Ltda, Estek, São Paulo,* Brazil). The biomechanical parameters used will be peak-to-peak displacement (DPP) of 2.5mm and frequency (*f*) of 25Hz. WBVE will and held once a week for 6 weeks. In each session, the individual will perform 5 bouts consisting of 1 minute with vibration, working time (WT), and 1 minute without vibration, rest time (RT). A supervisor will follow all the interventions to instruct the patient to report any discomfort.

Interventions

WBVEG-ST: Participants will stand on the base of the VP with their knees bent at 130° controlled by a goniometer[19] without shoes and with their hands resting on bars on the side of the VP.

WBVEG-S: Participants will perform the protocol while sitting in an auxiliary chair in front of the VP, with their hands on their knees bent at 130° with their elbows straight. This position facilitates the proper transmission of mechanical vibration throughout the patient's body.

CG: Participants will undergo initial clinical evaluations, which are the outcomes of this work, and will be instructed to continue their daily activities normally and not to participate in any other regular rehabilitation program for 6 weeks. After this period time, they will return to the final clinical evaluations.

Outcomes

Respiratory muscle strength: Three measurements of the maximum inspiratory pressures (MIP), and maximum expiratory pressures (MEP) will be performed, using the highest value obtained for analysis by manovacuometry (Murenas Produtos para Saúde Ltda, Brazil). These measurements will be performed before and after the first session and before and after the last session.[21]

QoL: Before the first and after the last intervention session, the St. Georges Respiratory Questionnaire (SGRQ)[22,23] will be used in the evaluation of the QoL.

Dyspnea: The modified Borg Scale,[24] *Medical Research Council (*MRC),[25] COPD Assessment Test (CAT),[26] and Subjective Effort Perception Scale for dyspnea (EPSE)[27] will be used to verify the exacerbations of the symptoms.

Data analysis

The Prism statistical program (GraphPad Inc. USA) will be used to perform the statistical analyses and the $p \leq 0.05$ will be considered significant. The intention-to-treat analysis will be performed including all participants in the analysis according to the original group allocation. Repeated measurement analysis of variance will be used to assess the difference between and within the group. The Bonferroni hoc test post will be used to compare the results.

Discussion

PR is one of the essential components of the non-pharmacological intervention in comprehensive COPD services,[13] including exercise.[18] The importance of prescribing physical activity to COPD patients is determined, among other factors, by (a) high morbidity and mortality associated with COPD;[16] (b) evidence that physical inactivity is associated with an increased risk of mortality and exacerbations;[16,17] (c) physical inactivity is associated with progressive exercise intolerance and muscle involvement;[18] (d) low levels of physical activity occur even in patients with mild COPD, suggesting the need for early intervention to reduce the risk of future comorbidities and, possibly, disease progression.[10,21]

An alternative type of exercise to be included in PR would be WBVE.[28] WBVE sessions show important positive responses for COPD patients. A diversity of protocols using different biomechanical parameters, as well as the positioning of the individual, working time (WT) and rest time (RT) between vibratory stimuli have been described.[17]

Regarding the positioning of the individuals on the VP, authors commonly consider the standing posture however, research is sparse regarding the advantages of this posture when compared to others.[29] The present study aims to perform a comparison of the findings related to respiratory muscle strength, dyspnea, and QoL with the individual in two positions, standing (squat) or sitting in an auxiliary chair. These results may provide evidence to support the beneficial effects of WBVE without the risk of causing the disease to exacerbate, and which patient positioning should adopt.

Braz Jr et al[15] reported that WBVE could be a safe and viable intervention in PR using the squat position protocol. Zhou J et al[11] suggested that WBVE could improve lung function and QoL in COPD patients about the change in FEV 1 (% predicates) and the SGRQ score. Using the protocol, low *f,* and, squat position [31], and Teixeira, et al [32], showed higher scores activity, impact, and in the total SGRQ domains, reflecting with this a greater disposition for daily activities with reduction of respiratory symptoms.

The importance of the current study is to present independent results for respiratory muscle strength, dyspnea, and QoL, and to be able to compare them between two positions on VP. This comparative result may show in which posture we will have a better response to the clinical conditions of that patient with COPD.

Limitations

This is a systematic review of the best available knowledge of the effects of physical exercise in patients with COPD with several protocols, and possible exacerbations that can show up. The potential prescription

and employment of physical exercise in selected COPD patients will require careful evaluation by multidisciplinary teams.

Declaration of conflicting interests

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