



Effects of physical training on the perception of happiness in individuals with COPD: study protocol of a randomized controlled trial

Efeitos do treinamento físico na percepção de felicidade em indivíduos com DPOC: protocolo de um ensaio clínico randomizado e controlado

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Abstract

Background: individuals with chronic obstructive pulmonary disease (COPD) exhibit reduced quality of life and a high prevalence of anxiety and depression. Given that physical exercise enhances the perception of happiness in healthy individuals, this study hypothesizes that physical training could improve happiness in individuals with COPD. **Aim:** to evaluate the effects of physical training, compared to usual care, on the perception of happiness in individuals with COPD. **Methods:** a two-group, parallel, randomized controlled trial with allocation concealment in a 1:1 ratio and intention-to-treat analysis. The control group will receive usual clinical care. The intervention group will receive usual care plus an eight-week physical training program (three weekly sessions over eight weeks). The program will include 30 minutes of aerobic training (treadmill or cycle ergometer) and resistance training. The primary outcome is happiness (Subjective Happiness Scale and the Cantril Ladder Scale). Secondary outcomes: Life satisfaction (Life Satisfaction Scale), peripheral muscle strength (handgrip strength and 30-second sit-to-stand test), functional capacity (six-minute walk test and Timed Up and Go test), dyspnea (modified MRC scale), fatigue (Manchester COPD Fatigue Scale), quality of life (Saint George's Respiratory Questionnaire), anxiety and depression (Hospital Anxiety and Depression Scale). **Discussion:** this study will be the first to assess the impact of physical training on happiness in individuals with COPD. The construct of happiness has not yet been explored in the context of pulmonary rehabilitation, which could enhance the understanding of its multiple benefits.

Keywords: Happiness; Chronic Obstructive Pulmonary Disease; Rehabilitation; Physical Training.

Resumo

Introdução: indivíduos com doença pulmonar obstrutiva crônica (DPOC) apresentam qualidade de vida reduzida e alta prevalência de ansiedade e depressão. Considerando que o exercício físico aumenta a percepção de felicidade em indivíduos saudáveis, a hipótese deste estudo é de que o treinamento físico pode melhorar a percepção de felicidade em indivíduos com DPOC. **Objetivo:** avaliar os efeitos do treinamento físico, em comparação com o cuidado clínico, na percepção de felicidade de indivíduos com DPOC. **Métodos:** ensaio clínico randomizado controlado, com alocação cega com proporção 1:1 e análise por intenção de tratar realizado com participantes com DPOC. O grupo controle receberá o cuidado clínico usual. O grupo intervenção receberá o cuidado usual mais um programa de treinamento físico de oito semanas (três sessões semanais). O programa incluirá 30 minutos de exercício aeróbico (esteira ou cicloergômetro) e exercícios resistidos. Desfecho primário: felicidade (Escala de Felicidade Subjetiva e Escala de Cantril). Desfechos secundários: escala de satisfação com a vida, força muscular periférica (preensão manual e teste senta e levanta de 30 segundos), capacidade funcional (teste de caminhada de seis minutos e teste Timed Up and Go), dispneia (escala modificada do MRC), fadiga (Escala de Fadiga de Manchester), qualidade de vida (Saint George's Respiratory Questionnaire), ansiedade e depressão (Escala Hospitalar de Ansiedade e Depressão). **Discussão:** este será o primeiro estudo a avaliar o impacto do treinamento físico na felicidade de indivíduos com DPOC. O construto felicidade ainda não foi explorado no contexto da reabilitação pulmonar, o que pode ampliar a compreensão dos seus múltiplos benefícios.

Palavras-chave: Felicidade; Doença Pulmonar Obstrutiva Crônica; Reabilitação; Exercício Físico.

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) can result in dyspnea, fatigue, limitation in daily activities, physical inactivity, reduced independence, functional capacity, and effort tolerance^{1,2}. These impacts can lead to a reduction in quality of life, as well as anxiety and depression³.

Although no specific studies have been conducted to date on the perception of happiness in individuals with COPD, a comprehensive analysis of happiness in the general population revealed that individuals with COPD have a low perception of happiness. This perception is lower when compared to individuals affected by other chronic diseases, such as cancer, cardiovascular diseases, stroke, systemic arterial hypertension, diabetes, asthma, and arthritis⁴.

Regular physical exercise can have an impact on various emotional aspects, mitigating negative emotional sensations, reducing anxiety and depression, while promoting an increase in positive emotional sensations, improving well-being, good mood and self-image⁵⁻⁸. Furthermore, it has previously been demonstrated that physical exercise can also increase the perception of happiness^{4,9-13}.

Physical training is a component of a pulmonary rehabilitation program, considered the most effective non-drug therapeutic intervention to improve symptoms, functional capacity, effort tolerance and quality of life in individuals with COPD¹⁴. Furthermore, in addition to the physical and functional benefits, this therapeutic approach has also demonstrated psychological effects, including the reduction of depression and anxiety, increased general well-being and improved neuropsychological functioning such as attention, memory and reasoning^{7,8}.

The hypothesis proposed in this study is that physical training has the potential to enhance the perception of happiness in individuals diagnosed with COPD. Such an outcome would provide a novel contribution to the understanding of the therapeutic benefits of pulmonary rehabilitation, expanding its recognized scope of impact. The objective of this study is to assess the effects of physical training, in comparison to standard clinical care, on the happiness perception of individuals living with COPD.

METHODS

Study design

Protocol for a two-group, parallel, randomized controlled trial, with allocation concealment that will utilize a 1:1 ratio and intention-to-treat analysis, designed by independent investigators. The clinical trial was registered in the Brazilian Clinical Trials Registry (ReBEC), number RBR-8tv29dc. This trial was designed according to the Standard Protocol Items: Recommendations for

Intervention Trials (SPIRIT) statement and checklist¹⁵. The study will follow the guidelines and flowchart of the Consolidated Statement of Standards for Reporting Clinical Trials (CONSORT) (Figure 1)¹⁶, and to report the interventions, the Model for Description and Replication of Interventions (TIDieR) will be followed¹⁷. The study protocol will follow the ethical guidelines of the Declaration of Helsinki and was approved by the Research Ethics Committee of the University Hospital of the Federal University of Juiz de Fora, MG/Brazil (CAAE: 53651321.2.0000.5133, nº 6.187.583). Eligible participants will be informed about the objectives, risks and benefits and will be required to complete the informed consent form according to the Brazilian National Health Council Resolution 580/2018.

Sample size

The sample size was calculated using the G*Power software (Heinrich-Heine-Universität Düsseldorf). Based on the results of a previous study that evaluated the effects of a physical training program on the perception of happiness in elderly individuals¹¹, an effect size of 1.2 was demonstrated. Considering an alpha error of 0.05 and power of 0.8, a sample of 24 participants was considered adequate. Anticipating a sample loss of around 20%, the sample size considered adequate is 29 participants.

Participants

Participants will be recruited from a secondary care university hospital. All data collection, assessments, and interventions will be conducted at the Cardiorespiratory Ambulatory of the University Hospital, Federal University of Juiz de Fora/MG, Brazil.

The inclusion criteria are individuals with a confirmed diagnosis of COPD, without other respiratory diseases, of both sexes, aged over 18 years, clinically stable, do not engaged in regular physical exercise, without unstable cardiovascular diseases and without neurological or musculoskeletal disorders that would prevent the performance of assessments and interventions proposed in the study. Participants will be excluded if they have acute health complications, such as COPD exacerbation, cardiovascular or musculoskeletal complications, require hospitalization for any reason, or have an attendance rate below 80% in the physical training program.

Randomization and allocation

Participants included in the study will be randomized into two groups. They will be randomly assigned to each arm of the study in a 1:1 ratio through a list of random numbers generated by an independent individual who will not be involved in the study. The randomization process will be conducted through the website www.randomization.com. The allocation will be kept confidential through sequentially numbered and sealed opaque envelopes. The envelope

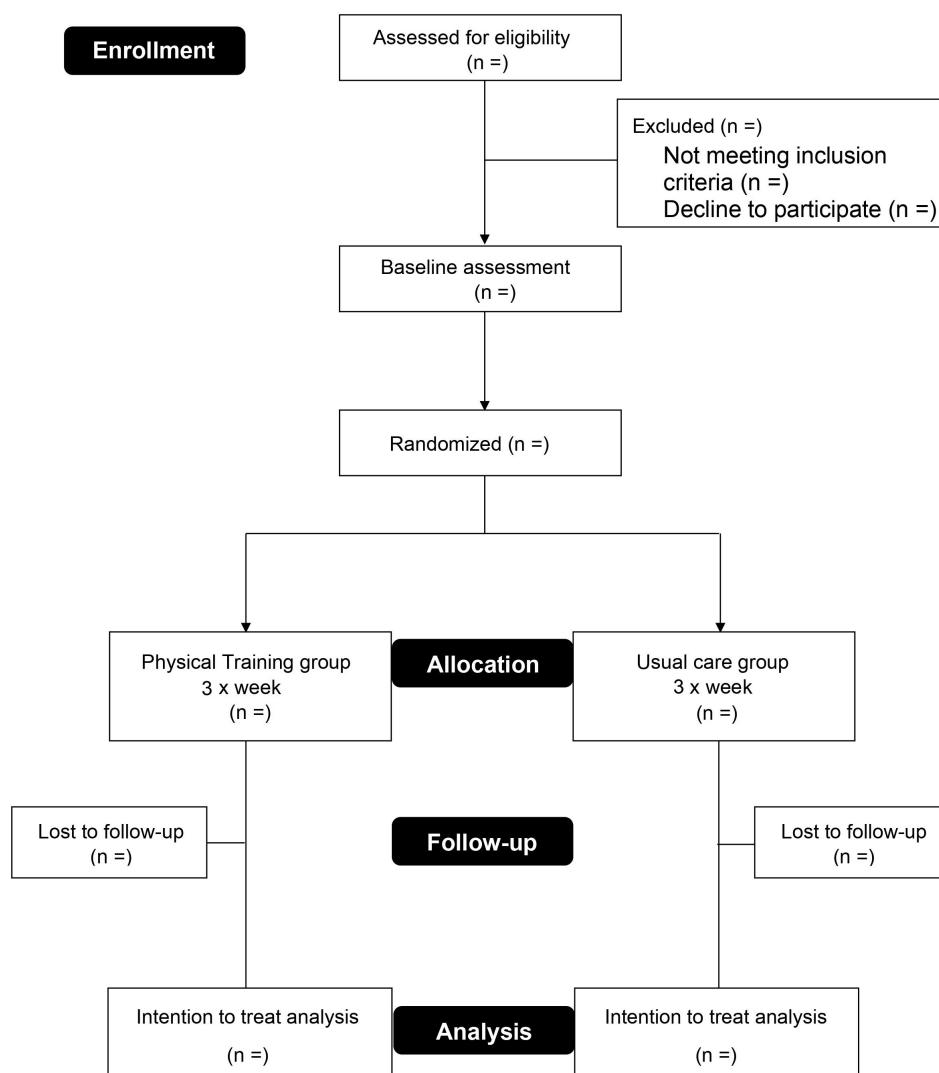


Figure 1. CONSORT flow diagram of the study protocol.

will only be opened after the participant has registered in the study.

Blinding

Randomization, participant enrollment, and assignments to interventions will be conducted by an independent researcher who is not involved in the study. Both participants and the physiotherapists responsible for the interventions will remain blinded to the initial assessment and all outcomes. All other healthcare professionals involved will be unaware of the study. The researcher responsible for measuring outcomes will not be blinded to participant allocation.

Physical training group

Participants allocated to the physical training group will receive standard clinical care, identical to the control group. In addition, they will carry out a physical training program, in accordance with the ATS/ERS Statement on

Pulmonary Rehabilitation¹⁴ and the American College of Sports Medicine (ACSM)¹⁸. Physical training will involve of a structured program consisting of three weekly sessions for eight weeks.

Aerobic training

Aerobic training will be carried out for 30 minutes by walking on an electronic treadmill or on a cycle ergometer, according to the best adaptation and preference of the participant. The initial treadmill training intensity will be adjusted to match a speed of 70% of the speed found in the six-minute walk test. The initial intensity of training on the cycle ergometer will be adjusted by establishing a load that provides a heart rate (HR) around 70% of the maximum HR of the individual. The progression of exercise load will be carried out using HR, perception of dyspnea and fatigue as markers of exercise intensity. The perception of dyspnea and/or fatigue will be maintained between 4 and 6 on the modified Borg scale¹⁹. The HR will be maintained between 60 to 80% of the maximum heart rate, using the equation:



FCT = FCR + 0.6 to 0.8 (MHR-RHR), where RHR is the resting heart rate and MHR is the maximum heart rate (220 - age). The opposite will be done, with the regression of exercise intensity, if the perception of dyspnea, fatigue or HR are above these established levels.

Resistance training

Resistance training will include four exercises: elbow flexion, shoulder abduction, squats, and ankle flexion. Each exercise will be performed in three sets of 8 to 12 repetitions, with a one-minute rest interval between sets. For upper limb exercises, resistance will be provided using handheld dumbbells, with the load determined according to each participant's ability to complete the prescribed repetitions with proper technique.

At the end of each exercise, muscular fatigue will be evaluated using the modified Borg Rating of Perceived Exertion scale (0–10)¹⁹. Participants will be instructed to maintain a fatigue level between 4 and 6 in the target muscle, which corresponds to a moderate to vigorous intensity range, as recommended by established guidelines^{14,18}. If the perceived fatigue for upper limb exercises is reported to be below 4, the dumbbell load will be increased by 1 kilogram. For lower limb exercises, load progression will be achieved by increasing the number of repetitions.

Load progression was applied differently for upper and lower limb exercises to ensure safety and practicality. For upper limbs, weight was increased using dumbbells to allow precise control of intensity. For lower limbs, progression was achieved by increasing the number of repetitions, a safer and more practical approach for functional exercises like squats, especially in individuals with balance, musculoskeletal problems or mobility limitations.

Control group

Participants allocated to the control group will receive standard medical and clinical care, as recommended by current guidelines¹ and routinely provided by the university hospital where the study will take place. This care includes optimized pharmacological treatment according to clinical guidelines (e.g., bronchodilators, inhaled corticosteroids), periodic medical and nursing follow-up, general health education focused on medication adherence, prevention of exacerbations, smoking cessation, and vaccination. Additionally, participants will receive verbal and written guidance encouraging unsupervised walking, without a structured or individualized physical training prescription. After the eight weeks defined in the study protocol, participants in the control group will be invited to take part in the physical training program, identical to the one implemented in the physical training group.

Assessments

Assessments will be conducted in the respiratory rehabilitation unit of the university hospital where participants will be recruited. All assessments will be performed by a single researcher, previously trained to ensure proper standardization. Participants will undergo all evaluations at two time points: before starting the intervention protocol [or usual care], and at the end of the 8-week study period.

Spirometry will be performed with a portable spirometer (Spirobank II, Medical International Research, New Berlin, USA) and will follow the International Guidelines for Spirometry²⁰. The data will be expressed in absolute values and percentage of predicted²¹. The severity of COPD will be classified according to the degree of airway obstruction¹. The impact of COPD symptoms will be assessed using the COPD Assessment Test (CAT) Questionnaire²². The economic classes of individuals will be classified as A1, A2, B1, B2, C, D and E, according to the Brazilian Economic Classification Criteria (BECC)²³.

Primary outcome

The assessment of the perception of happiness will be carried out using the Subjective Happiness Scale (SHS) questionnaire and the Cantril scale. The SHS has four questions, each of which must be answered on a seven-point Likert scale^{24,25}. The total score of the scale ranges from 1 to 7 with higher score indicating a greater perception of happiness. The Cantril ladder evaluates the perception of happiness based on an image of a ladder with steps numbered from 0 to 10, where the first step represents the worst life possible and the last step represents the best possible life²⁶.

Secondary outcomes

Life satisfaction will be assessed using the Life Satisfaction Scale. The questionnaire has five questions, each of which must be answered on a 7-point Likert scale. The total result of the scale varies from 5 to 35 and the higher the score, the greater the perception of satisfaction with life²⁷.

Peripheral muscle strength will be measured using handgrip strength, performed with a manual hydraulic dynamometer. The test will be performed only with the dominant hand and three measurements will be taken and the best measurement will be considered for analysis. The outcome will be presented in kgf and as a percentage of predicted²⁸. The 30-second sit-stand test (TSL30) will also be used as a correlated measure of peripheral muscle strength. The measurement will be the number of repetitions that the participant can perform in 30 seconds and the percentage of predicted²⁹.

Functional capacity will be assessed using the Six-Minute Walk Test (6MWT). Two tests will be carried out with a 30-minute rest interval between them. The test with the



longest distance covered will be considered for analysis. The main measurement will be the distance covered in six minutes and the percentage of the predicted distance^{30,31}. Functional capacity will also be assessed using the “Timed up and go” (TUG) test. The test consists of getting up from a chair, walking a distance of 3 meters, returning and sitting down. The test will be carried out three times and will be considered the test with the shortest time for analysis³².

Dyspnea will be assessed using the modified Medical Research Council scale (MRCm). This scale is made up of five activities whose dyspnea rating varies from 0 to 4. The higher the score, the more dyspnea limits activities of daily living³³.

Fatigue will be assessed using the Manchester Fatigue Scale for COPD. This scale consists of 21 questions, with a total score ranging from 0 to 54 points. Higher scores indicate worse fatigue³⁴.

Quality of life will be assessed using the Saint George's Respiratory Questionnaire (SGRQ). The instrument presents a total value and addresses aspects related to three domains: symptoms, activities and psychosocial impacts. The results will be presented in absolute value and as a percentage of the predicted value. Lower scores indicate better quality of life³⁵.

Anxiety and depression will be measured using the Hospital Anxiety and Depression Scale (HADS). The scale consists of 14 items divided into Anxiety Disorder and Depressive Disorder. The score varies from 0 to 21 points for each domain and from 0 to 42 for the total value. Higher scores indicate greater severity³⁶.

Statistical analysis

Statistical analysis will be performed using the SPSS for Windows version 20.0 (SPSS, Chicago, Illinois). The Shapiro-Wilk test will be used to check whether the data distribution adheres to the normality curve. The characterization of the sample will be presented as mean $\pm$ standard deviation, median (interquartile range) or frequency (percentage), depending on the characteristics and distribution of the data. Comparisons between groups to characterize the sample will be performed using the Student's t test for independent samples for parametric variables and the Mann-Whitney test for non-parametric variables and the chi-square test for categorical variables. The primary and secondary intragroup and intergroup outcomes will be analyzed using generalized linear models with a post hoc test using the minimally significant difference, demonstrated using mean $\pm$ standard deviation and 95% confidence interval. The associations will be conducted using stepwise univariate and multivariate linear regression analysis. The dependent variables will be the happiness scales (EFS and Cantril), and the independent variables will be those with a p-value < 0.05 in bivariate analysis, using Pearson or Spearman's correlations. The collinearity of the target variables will be checked using

the collinearity statistics of multiple regression analyses (i.e., Tolerance and Variance Inflation Factor). The analysis will be carried out using the concept of intention to treat. The effect size of the primary outcomes and sample power will be evaluated applying Cohen's d test using the G*Power program (Universität Düsseldorf: Psychologie - HHU). A p <0.05 will be considered statistically significant.

DISCUSSION

This study represents the first attempt to evaluate the effects of physical training on the perception of happiness in individuals with Chronic Obstructive Pulmonary Disease (COPD). The construct of “happiness” has not previously been the subject of scientific investigation in individuals with respiratory diseases, making it a novel and unexplored area with significant potential to broaden our understanding of the benefits of physical training. Previous research has consistently demonstrated the positive effects of physical training on quality of life and the alleviation of anxiety and depression symptoms^{7,8}. Consequently, it is plausible to hypothesize that physical training may also exert a beneficial impact on the perception of happiness.

The potential mechanisms underlying this effect include the physiological release of endorphins, reductions in stress levels, and improvements in self-image, all of which are well-documented contributors to enhanced emotional well-being and overall mental health³⁷⁻⁴⁰. Exploring the influence of physical training on the perception of happiness in COPD patients could yield groundbreaking insights into the multifaceted therapeutic benefits of pulmonary rehabilitation.

Such findings would expand the recognized scope of this intervention beyond traditional outcomes, such as symptom management and physical function, to include psychological and emotional dimensions. Demonstrating improvements in happiness could also encourage healthcare professionals to prioritize physical training programs, resulting in increased referrals, greater patient adherence, and a wider dissemination of its benefits. Ultimately, this innovative exploration has the potential to enhance the overall well-being and quality of life for a larger population of individuals living with COPD.

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Nothing to declare.

CONFLICT OF INTEREST

Nothing to declare.

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Nothing to declare.



RESEARCH DATA AVAILABILITY

The data are available from the corresponding author upon reasonable request.

AUTHOR CONTRIBUTIONS

Layla Cristine de Toledo: conception and design of the study; drafting the article; final approval of the version to be submitted.

Cristino Carneiro de Oliveira: conception and design of the study; revising the article; final approval of the version to be submitted.

Joyce Gomide Nolasco de Assis: revising the article; final approval of the version to be submitted.

Larissa Guimarães Paiva: revising the article; final approval of the version to be submitted.

Leandro Ferracini Cabral: conception and design of the study; revising the article; final approval of the version to be submitted.

Túlio Medina Dutra de Oliveira: drafting the article; final approval of the version to be submitted.

Carla Malaguti: conception and design of the study; revising the article; final approval of the version to be submitted.

Anderson José: conception and design of the study; drafting the article; final approval of the version to be submitted.

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