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ORIGINAL RESEARCH

Effect of high-intensity home-based respiratory muscle training on strength of respiratory muscles following a stroke: a protocol for a randomized controlled trial☆

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Abstract
Background: Respiratory muscle training has shown to increase strength of the respiratory muscles following a stroke. However, low duration and/or intensity of training may be responsible for the small effect size seen and/or absence of carry-over effects to an activity, e.g., walking. Therefore, an investigation of the effects of long-duration, high-intensity respiratory muscle training is warranted.
Objective: This proposed protocol for a randomized clinical trial will examine the efficacy of high-intensity respiratory muscle training to increase strength and improve activity following a stroke.
Methods: This study will be a two-arm, prospectively registered, randomized controlled trial, with blinded assessors. Thirty-eight individuals who have suffered a stroke will participate. The experimental group will undertake a 40-min of respiratory muscle training program, seven days/week, for eight weeks in their homes. Training loads will be increased weekly. The control group will undertake a sham respiratory muscle training program with equivalent duration and scheduling of training. The primary outcome will be the strength of the inspiratory muscles, measured as maximal inspiratory pressure. Secondary outcomes will include expiratory muscle strength, inspiratory muscle endurance, dyspnea, respiratory complications, and walking capacity. Outcomes will be collected by a researcher blinded to group allocation at baseline (Week 0), after intervention (Week 8), and one month beyond intervention (Week 12).

☆ **Trial registration**: Clinical Trials, NCT02400138. Registered on March 23rd, 2015 (https://clinicaltrials.gov/show/NCT02400138).

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Conclusion: High-intensity respiratory muscle training may have the potential to optimize the strength of the respiratory muscles following a stroke. If benefits are carried over to activity, the findings may have broader implications, since walking capacity has been shown to predict physical activity and community participation on this population.

Introduction

Following a stroke, the loss of the ability to generate normal amounts of force also affects the respiratory muscles.[1] Mean inspiratory muscle strength has been reported as ~51 cmH_2O in stroke patients, compared with ~92 cmH_2O in healthy adults, and expiratory strength as 67 cmH_2O, compared to ~117 cmH_2O.[2] That is, respiratory muscle strength in people suffering from a stroke is half of that expected in healthy adults. Weakness of the respiratory muscles has been related to decreased walking capacity,[3,4] which, in turn, has been related to restrictions in community participation. Additionally, respiratory muscle weakness may limit participation in community exercise programs, due to the reduced capacity to walk long distances.[5]

Respiratory muscle training has the potential to increase the strength of the respiratory muscles,[6] and its effect has been previously examined in people with acute and chronic respiratory conditions,[7,8] heart failure,[9] and stroke.[1,10,11] With this type of training, patients are asked to perform repetitive breathing exercises against an external load (e.g., using a flow-dependent resistance device or a pressure threshold device?[8,10]), in order to increase muscle strength and/or endurance. There have been four systematic reviews[1,10–12] with meta-analysis of randomized trials examining the effect of respiratory muscle training on measures of respiratory muscle strength following a stroke. However, two reviews included only two trials of inspiratory training with substantial statistical heterogeneity (I^2 = 95%), leading to inconclusive findings.[1,11] More recent systematic reviews[10,12] examined the effect of both inspiratory and expiratory muscle training following a stroke. Gomes-Neto et al.[12] included seven randomized trials of reasonable quality and reported increases of 7 cmH_2O in inspiratory strength (95%CI: 3–12; I^2 = 45%) and forced vital capacity (MD 2 L, 95%CI: 1–3, I^2 = 86%), forced expiratory volume at 1 second (MD 1.2 L, 95%CI: 1–2; I^2 = 51%), and exercise tolerance (SMD 0.7, 95%CI: 0.2–1.2; I^2 = 0). However, the results were not significant for expiratory strength (MD 6 cmH_2O, 95%CI: −4 to 15; I^2 = 57%). Menezes et al.[10] included five randomized trials of reasonable quality and reported increases of 7 cmH_2O in inspiratory strength (95%CI: 1–14; I^2 = 33%) and 13 cmH_2O for expiratory strength (95%CI: 1–25; I^2 = 12%). However, the results were inconclusive regarding inspiratory endurance, occurrence of respiratory complications, and carry-over to everyday activity. Furthermore, only one of the trials included combined training (i.e., inspiratory plus expiratory training), a combination which has the potential to optimize the effects of training.

Although evidence appears to recommend respiratory muscle training to increase the strength of the respiratory muscles, the magnitude of the effect was small and the effect size may potentially be increased if training is of appropriate duration and/or intensity. The majority of the trials, which were included in the reviews, targeted only inspiratory or expiratory muscles, had a mean training duration of four weeks, and did not systematically progress training. As respiratory muscles respond to training stimuli in a similar fashion to other skeletal muscles, they can be overloaded by requiring them to work longer, at high intensities, and/or more frequently, than they are normally accustomed to.[2] Thus, the effect of respiratory muscle training on strength and activity following a stroke may be increased with higher intensity training (i.e., increased frequency, duration and training of both muscle groups).

Therefore, this protocol for a randomized clinical trial will examine whether high-intensity respiratory muscle training is effective in increasing strength and endurance of the respiratory muscles, decreasing dyspnea sensation and respiratory complications, and improving walking capacity following a stroke.

Methods

Study design

A prospective, randomized trial with concealed allocation, blinded assessors, and intention-to-treat analysis will be carried-out (Fig. 1). Community-dwelling people who have suffered a stroke will be recruited and randomly allocated to either a respiratory muscle training (experimental) group or a sham training (control) group. Outcome measures will be collected by trained researchers at baseline (Week 0), at the end (Week 8), and one month after the cessation of the training (Week 12). Data collection and analysis will be carried-out by a researcher blinded to the group allocation. Participants will be informed about the study and will provide consent before participating in the trial. The study obtained ethical approval from the Institutional Research Ethical Committee (CAAE: 40290114.8.0000.5149) of the *Universidade Federal de Minas Gerais*, Belo Horizonte, Brazil. The trial was prospectively registered at the ClinicalTrials.gov (NCT02400138).

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