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Exercise programme in patients with cystic fibrosis: A randomized controlled trial

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Summary
Objectives: Assess the effects of a home exercise programme, based on aerobic training and muscle strength training, in patients with cystic fibrosis (CF), for a period of 3 months.
Methods: Randomised controlled clinical experiment, with an analysis of intention to treat including clinically stable patients with CF and of age $\geq$ 16. Assessments include: a 6 min walk test (6 MWT), one-repetition maximum strength test (1 RM), spirometry and quality of life questionnaires. The patients randomised for the exercise group exercise group followed a home exercise protocol, supervised by telephone, while the control group maintained their usual activities.
Results: 41 Patients were included, 22 in the control group and 19 in the exercise group. The exercise group presented a significant increase in muscle strength in upper limbs (UULL) on the 1 RM test. There was no significant difference between groups on the scores for general quality of life and specifically for CF and in the distance walked on the 6 MWT.
Conclusion: The study demonstrated that a home exercise programme had positive effects in adult patients with CF, including gain in muscle strength in UULL. No increase in tolerance to exercise was shown and improvement in the quality of life of the patients who received intervention.
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Introduction

Cystic fibrosis (CF) is a hereditary disease most common in the white population [1]. The clinical expression of the disease is very varied in general, showing multi-systemic involvement, characterised by intestinal motility, male infertility and high concentrations of electrolytes in sweat. However, pulmonary impairment is the main determinant of morbidity and mortality related to the disease [2,3].

Patients with CF frequently present a progressive limitation to physical exercise and reduction of their daily life activities [4–7]. However, when submitted to physical activity programmes, these patients present an increase in tolerance to exercise, improvement in cardiorespiratory function, in respiratory muscle endurance and in immunological function [8–12].

Training with aerobic exercise has been associated with improvement in the prognostic of patients with CF [11]. The best results were reached with supervised training programmes [5–14].

An important alternative to be considered in this population of patients would be to institute a home exercise programme supervised by the health care team. These home programmes correspond to a proposal closer to the reality of this population, that is, patients with varying seriousness of the disease, residents in different locations, with no possibility of carrying out the exercise protocol with weekly presential intervention at the centre, could benefit from this intervention. However, evidence of benefit from this approach is still precarious [16–18].

The aim of this study was to assess the effects of a home exercise programme, based on aerobic training and muscle strength training, in adult patients with CF, for a period of 3 months.

Methods

The study comprised a prospective, randomised controlled clinical trial, with an intention to treat analysis, and consecutively included patients attended through the Programme for Adults with CF at the Porto Alegre Clinical Hospital (HCPA) where volunteers stepped up. The protocol was approved by the Ethics Committee at the HCPA (07164) and a free informed term of consent was signed by each patient.

The study included patients diagnosed with CF in accordance with the criteria of the consensus [1], 16 years of age or older, with at least 30 days of clinical respiratory disease stability. Patients who refused to take part in the study, pregnant ladies, individuals with heart disease, orthopaedic or traumatological problems, were excluded.

The assessment of the study included: a 6 min walk test (6 MWT), muscle strength test, spirometry and quality of life questionnaire. These assessments were carried out at two moments: at the start and after three months of conducting the trials. These assessments were carried out by one of the researchers who was blind to the randomisation and the intervention, throughout the study. This researcher was responsible for controlling the filing of all the test results and transference of the test results to a database, numbered, with no nominal identification to keep the process a blind study for all the other authors.

The 6 MWT was carried out in accordance with the guidelines of the *American Thoracic Society* [19]. The total distance walked in 6 min was recorded in meters and in the % of the predicted distance [20]. The peripheral oxygen saturation (SpO_2) were measured by means of a pulse oxymeter (NPB-40; Nellcor Puritan Bennett; Pleasanton, CA, EUA). The perception of the sensation of dyspnoea and fatigue of the lower limbs were recorded according to the Borg scale [21].

Measuring muscle strength consisted of a one-repetition maximum strength test (1 RM). The 1 RM test is defined as the maximum weight lifted once during the performance of a standardised weight lifting exercise. The 1 RM test involves two muscle groups: elbow flexors and knee extensors [22].

Spirometry was performed by means of a spirometer (MasterScreen, v4.31, Jaeger, Würzburg, Germany). Forced vital capacity (FVC), forced expiratory volume in 1 s (FEV_1) and a FEV_1/FVC ratio were recorded. The test was carried out in accordance with the reproducibility and acceptability criteria of the Brazilian Society of Pneumology and Tisiology [23].

The quality of life was assessed by the questionnaire specifically for CF [24] (CFQ — Cystic Fibrosis Questionnaire), and by a questionnaire of general scope *Medical Outcomes Study-36 Item Short-Form Health Survey* (SF-36), also valid for the Portuguese language [25].

After the first assessment, the patients were submitted to the process of randomisation. This process uses a computer programme (*Random Allocation Software* version 1.0, developed by M. Saghaei, MD., *Department of Anaesthesia, University of Medical Sciences, Isfahan, Iran*), in blocks of six patients. The patients were allocated to two groups: an exercise group (G1) and a control group (G2).

The patients randomised for G2 continued receiving standard follow-up from the adult programme physiotherapist, every two months. In this follow-up the patients were advised on frequency and techniques of respiratory physiotherapy and on the practice of physical exercise.

The patients randomised for G1, as well as follow-up from the adult programme physiotherapist, they were advised, to do a specific home exercise programme.

After randomisation, the first meeting was booked for providing the training instructions, providing available material for the exercise and the patient was acquainted with its use. These orientations were reinforced at each return visit to the outpatient department and through weekly telephone contact during the three month period.

The exercise protocol was based on aerobic training and muscle strength training to be performed daily. The patients received printed guidance material and practical demonstration by the researcher, on the appropriate performance of each physical exercise recommended by the protocol.

For muscle strength training, the patients received practical guidance and printed copies of the exercise protocol for strengthening muscles. The patients were advised to perform the protocol daily.

The main outcome of the study was defined as the variation on the score for quality of life. The secondary

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