

01.24.2017

**THE CLINICAL EFFECTS OF EXERCISE PROGRAM ADDED
TO PULMONARY REHABILITATION PROGRAM IN PATIENTS
WITH CYSTIC FIBROSIS**

NCT Number: 03295201

This study was planned to be a prospective single-blinded randomized controlled study and was performed between March 2017 and October 2017. Local ethics committee approval was taken (Marmara University, Istanbul, Turkey). Informed consents were obtained from the families of children. The inclusion and exclusion criteria were determined as shown below:

Inclusion Criteria

1. Patients diagnosed with cystic fibrosis (CF)
2. Patients aged between 6-14
3. FEV1 greater than 30%

Exclusion Criteria

1. Presence of cor pulmonale
2. Spinal fracture story
3. Currently under IV medication
4. Severe gastroesophageal reflux

The patients were equally randomized into two groups according to the closed envelope system. One group planned to treat six weeks with pulmonary rehabilitation and postural exercise program (Group 1), while other group being treated with pulmonary rehabilitation program alone (Group 2). Patients were assessed for respiratory function with FEV1, pain level with Visual Analog Scale (VAS), quality of life with The Cystic Fibrosis Questionnaire-Revised Child Version (CFQR), exercise tolerance with Modified Shuttle Test (MST) and postural stability with Neurocom Balance Master® Device Limits of Stability Test (LOS). All tests were performed before treatment and six weeks, three months and six months after treatment. Cobb and Modifiye Cobb angles were measured on radiographic examinations to evaluate spinal deformities before and six months after treatment.

Treatment:

Pulmonary Rehabilitation

Active cycle of breathing techniques (ACBT) was preferred for pulmonary rehabilitation. ACBT was applied by a therapist once per a week for six weeks. A daily schedule was given for the other days of the week to ensure permanence of treatment. ACBT is a commonly used chest physiotherapy method for secretion removal from lungs. Each ACBT cycle consists a sequence of breathing control, thoracic expansion exercises and forced expiration technique. These cycles are performed consecutively until the secretion is completely discharged.

Postural exercise Program

Thoracic vertebra mobilization, pectoral stretching, scapula and thoracic extensors strengthening and core stability exercises were applied by a therapist once per a week for six weeks. A daily schedule was given for the other days of the week to ensure permanence of treatment.

Assessment:

The Cystic Fibrosis Questionnaire-Revised (CFQR)

The Cystic Fibrosis Questionnaire-Revised is the most commonly used quality of life measurement tool in patients with CF and is found to be valid and reliable in Turkish. The child version of this test consists 35 questions about physical function, emotional function, social function, body appearance, eating disorders, treatment difficulties, respiratory and digestive symptoms. Total score is calculated between 0-100 and higher scores define better condition.

Modified Shuttle Test (MST)

The Modified Shuttle Test is an easy test that can show exercise tolerance and cardiorespiratory status in children with CF. The patient is asked to walk until feeling tired between two fixed objects with a 10-meter interval, starting at normal walking speed and increasing the speed at the beginning of each minute. Maximum distance is measured for the test.

Limits of Stability Test (LOS)

The Limits of Stability Test consists a 18x60 inch of a pressure platform which connected to a computer system. The patient is asked to stand on the platform barefoot and watch the image which can be moved by trunk movement on the computer the monitor. It is required to move the image towards to target points on monitor with commands. Reaction time, movement velocity, endpoint excursion, maximum excursion and direction control parameters are calculated during these trunk movements.

Radiographic evaluation

The Cobb angle was measured on antero-posterior scoliosis graphs by the angle between the superior end plate of the vertebra corpus where the curve begins and the end plate of the vertebra corpus which the curve ends. The Modified Cobb angle was found on lateral scoliosis graphs by the angle between the superior end plate of the T4 vertebra corpus and the inferior end plate of the T12 vertebra corpus.

Statistical analysis

Statistical analysis of the study was calculated using the SPSS for Windows 20.0 program. Normal distribution of quantitative values was assessed by histogram, Q-Q graph and normality tests. The Mann-Whitney U test was used to compare the measurement values between the two groups, and the Friedman test was used to compare the intra-group parameters. A statistical significance level of $p < 0,05$ was accepted. The Wilcoxon test was used to compare pre-treatment and post-treatment 6th-week, 3rd-month and 6th-month values separately. Bonferroni correction was considered $p < 0,017$ statistically significant for evaluating the results. A Spearman and Pearson correlation analysis was performed to examine the relationship between the radiographic values measured by two different clinicians. The intraclass correlation coefficient for the interobserver reliability analysis was calculated for radiographic measurements.