

Chang Gung Memorial Hospital

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Study Protocol:

Patients aged 40–80 years from the outpatient clinic of the Department of Pulmonology of a tertiary care medical centre who had bronchiectasis were eligible. Bronchiectasis was confirmed by clinical history, such as coughing, shortness of breath and exertional dyspnoea, pulmonary function tests and high-resolution computed tomography.

Those who were using steroids (including inhalation or oral), had recent exacerbation within six weeks, poor consciousness level and cerebrovascular or neuromuscular disorders were excluded. The eligible subjects were then randomly divided into either inspiratory muscle training or control groups. All technicians who performed the different measurements and assessed the outcomes were blinded to group allocation, and all measurements were performed at the beginning and end of the eightweek programme. The pulmonary function tests were performed in a pulmonary functional laboratory using a standard spirometer (Vitalograph, Serial Spirotrac, Buckingham, USA) according to the American Thoracic Society recommendations, and the measurements included parameters of forced vital capacity (FVC), FEV1 and maximum mid-expiratory flow. The best FVC measurement was recorded along with FEV1 and FEV1/FVC calculations.

After pulmonary function parameters were recorded, the bronchodilator test was used to check if the participant had a hypersensitive airway. The reversibility of the airway obstruction was defined as a 15% or greater improvement in FEV1 and at least a 200 mL increase in FEV1. None of our eligible patients showed a positive bronchodilator response. All measurements are presented as percentage predicted value. Baseline characteristics including height, weight, body mass index and duration of the disease, and the resting oxyhaemoglobin saturation (SpO<sub>2</sub>), lowest resting SpO<sub>2</sub>, Borg Scale during a 6-minute walking test, MIP, maximal expiratory pressure (MEP),and St George's Respiratory Questionnaire (SGRQ) were obtained in the Department of Respiratory Therapy.

SpO<sub>2</sub> was measured using a finger pulse oximeter (FingerPrint, BCI International, Wisconsin,USA). Resting dyspnoea was quantified using the modified Borg Scale, which ranges from 0.5 to 10.27 The 6-minute walk work (6Mwork) value was calculated as body mass × distance covered during the 6-minute walking test. MEP was measured after maximal inspiration, while MIP was measured after maximal expiration with each subject seated and wearing a nose-clip. An experienced respiratory therapist strongly urged the subjects to make maximum

inspiratory and expiratory efforts at or near residual and total lung capacity, respectively.

Determinations were repeated until two technically satisfactory measurements were recorded, with the highest value used for calculations. St George's Respiratory Questionnaire has 76 items on symptoms (frequency and severity of respiratory symptoms), activity (activities caused or limited by breathlessness), and impact (social functioning and psychological disturbances resulting from airway disease) on daily life. The scores range from 0 to 100, with higher scores indicating poorer health. A mean change score of 4 units was defined as slightly efficacious treatment, 8 moderately efficacious, and 12 very effective treatment.

The inspiratory muscle training programme was started at an intensity of 30% MIP, and increased by 2 cmH<sub>2</sub>O each week. A pressure threshold device (Threshold IMT HS730, Resironics Inc, Cedar Grove, NJ, USA) was used. During training, patients were in a sitting position with a nose-clip and were instructed to place their lips around the mouthpiece, inhale with enough force to open the valve, exhale through the mouthpiece, and then continue inhaling and exhaling without removing the device from their mouths. Patients could take intermittent periods of rest if they felt uncomfortable. They were encouraged to perform inspiratory muscle training for 30 minutes per day, at least five days a week, for eight weeks. If the training sessions could not be completed due to increased resistance, the last part of the session was performed with the previous resistance setting.

Patients in the control group did not receive any training programme. Both groups were monitored by telephone call once or twice a week until the end of the study. The medication profiles were also recorded. No medication was altered during the study period.

The Institutional Review Board of Chang Gung Memorial Hospital, Kaohsiung Medical Center approved the study protocol and all patients provided informed consent.

### **Statistical analysis**

Baseline characteristics were compared using the Student's t-test for continuous variables and Fisher's exact test for categorical variables.

Results are presented as absolute number (percentage) or mean (standard deviation) and adjusted for age by linear regression analysis.

The difference for each variable was compared with two-way repeated measures analysis of variance between the two groups and within each group. Paired sample T-tests were used for comparison within each group. A two-tailed P-value of less than 0.05 was considered significant. All statistical analyses were performed using the SPSS 14.0 software package (SPSS Inc., Chicago, IL, USA).