

primary studies - published RCT

## **Contribution of behavior therapy to dietary treatment in cystic fibrosis: a randomized controlled study with 2-year follow up.**

**Code:** CN-00623750    **Year:** 2003    **Date:** 2006

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### **Study design (if review, criteria of inclusion for studies)**

double-blind, parallel-group randomized trial

### **Participants**

164 patients with stable cystic fibrosis who were at least six years old

### **Interventions**

inhale 4 ml of either 7 percent hypertonic saline or 0.9 percent (control) saline twice daily for 48 weeks, with quinine sulfate (0.25 mg per milliliter) added to each solution to mask the taste. A bronchodilator was given before each dose, and other standard therapies were continued during the trial.

### **Outcome measures**

slope in lung function (reflected by the forced vital capacity [FVC], forced expiratory volume in one second [FEV1], and forced expiratory flow at 25 to 75 percent of FVC [FEF25-75], n° of pulmonary exacerbations, bacterial infection and inflammation

### **Main results**

The rate of change (slope) in lung function during the 48 weeks of treatment, did not differ significantly between groups ( $P=0.79$ ). However, the absolute difference in lung function between groups was significant ( $P=0.03$ ) when averaged across all post-randomization visits in the 48-week treatment period. As compared with the control group, the hypertonic-saline group had significantly higher FVC (by 82 ml; 95 percent confidence interval, 12 to 153) and FEV1 (by 68 ml; 95 percent confidence interval, 3 to 132) values, but similar FEF25-75 values. The hypertonic-saline group also had significantly fewer pulmonary exacerbations (relative reduction, 56 percent;  $P=0.02$ ) and a significantly higher percentage of patients without exacerbations (76 percent, as compared with 62 percent in the control group;  $P=0.03$ ). Hypertonic saline was not associated with worsening bacterial infection or inflammation.

### **Authors' conclusions**

Hypertonic saline preceded by a bronchodilator is an inexpensive, safe, and effective additional therapy for patients with cystic fibrosis.

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### **See also**

Behavior Therapy YR: 2003 VL: 34 DE: RCT

### **Keywords**

Adolescent; Adult; Albuterol; Anti-Bacterial Agents; Child; Combined Modality Therapy; hydration; Hypertonic Solutions; Inhalation OR nebulised; Isotonic Solutions; pharmacological\_intervention; Sodium Chloride; Adrenergic beta-Agonists; Respiratory System Agents;