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# Effects of Smoking Intervention and the Use of an Inhaled Anticholinergic Bronchodilator on the Rate of Decline of FEV<sub>1</sub>

## The Lung Health Study

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## Abstract

**Objective.** —To determine whether a program incorporating smoking intervention and use of an inhaled bronchodilator can slow the rate of decline in forced expiratory volume in 1 second (FEV<sub>1</sub>) in smokers aged 35 to 60 years who have mild obstructive pulmonary disease.

**Design.** —Randomized clinical trial. Participants randomized with equal probability to one of the following groups: (1) smoking intervention plus bronchodilator, (2) smoking intervention plus placebo, or (3) no intervention.

**Setting.** —Ten clinical centers in the United States and Canada.

**Participants.** —A total of 5887 male and female smokers, aged 35 to 60 years, with spirometric signs of early chronic obstructive pulmonary disease.

**Interventions.** —Smoking intervention: intensive 12-session smoking cessation program combining behavior modification and use of nicotine gum, with continuing 5-year maintenance program to minimize relapse. Bronchodilator: ipratropium bromide prescribed three times daily (two puffs per time) from a metered-dose inhaler.

**Main Outcome Measures.** —Rate of change and cumulative change in FEV<sub>1</sub> over a 5-year period.

**Results.** —Participants in the two smoking intervention groups showed significantly smaller declines in FEV<sub>1</sub> than did those in the control group. Most of this difference occurred during the first year following entry into the study and was attributable to smoking cessation, with those who achieved sustained smoking cessation experiencing the largest benefit. The small noncumulative benefit associated with use of the active bronchodilator vanished after the bronchodilator was discontinued at the end of the study.

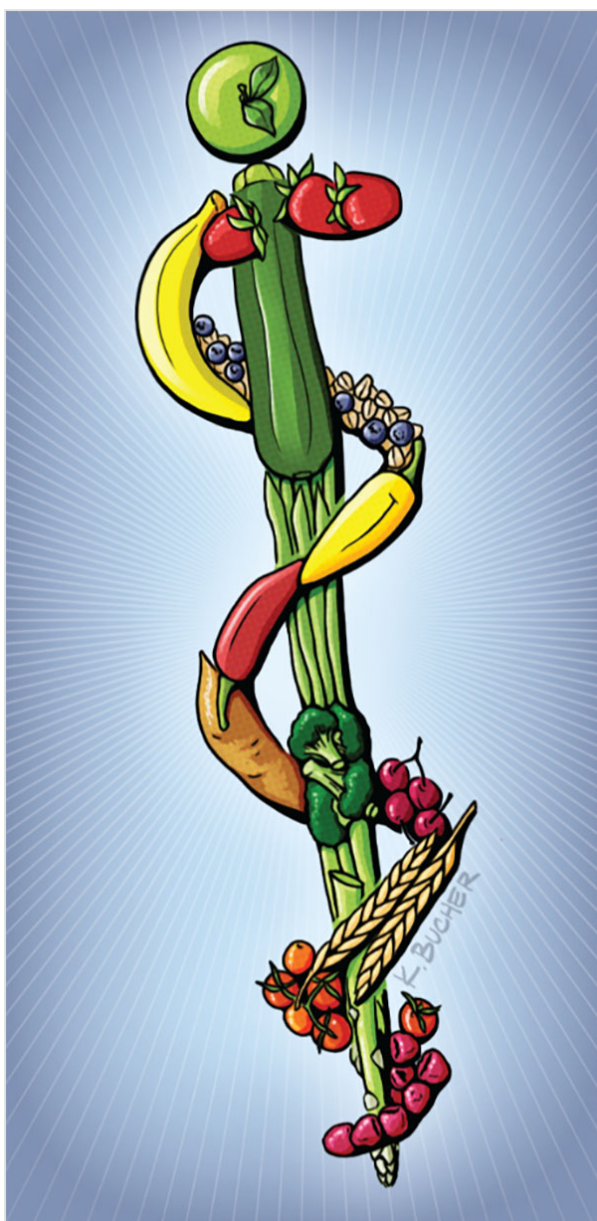
**Conclusions.** —An aggressive smoking intervention program significantly reduces the age-related decline in FEV<sub>1</sub> in middle-aged smokers with mild airways obstruction. Use of an inhaled anticholinergic bronchodilator results in a relatively small improvement in FEV<sub>1</sub> that appears to be reversed after the drug is discontinued. Use of the bronchodilator did not influence the long-term decline of FEV<sub>1</sub>. (*JAMA*. 1994;272:1497-1505)



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