

## Article

# Efficacy of *Lactobacillus* Administration in School-Age Children with Asthma: A Randomized, Placebo-Controlled Trial

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**Abstract:** Probiotics may have immunomodulatory effects. However, these effects in asthma remain unclear and warrant clinical trials. Here, we evaluated the effects of *Lactobacillus paracasei* (LP), *Lactobacillus fermentum* (LF), and their combination (LP + LF) on the clinical severity, immune biomarkers, and quality of life in children with asthma. This double-blind, prospective, randomized, placebo-controlled trial included 160 children with asthma aged 6–18 years (trial number: NCT01635738), randomized to receive LP, LF, LP + LF, or a placebo for 3 months. Their Global Initiative for Asthma–based asthma severity, Childhood Asthma Control Test (C-ACT) scores, Pediatric Asthma Severity Scores, Pediatric Asthma Quality of Life Questionnaire scores, peak expiratory flow rates (PEFRs), medication use, the levels of immune biomarkers (immunoglobulin E (IgE), interferon  $\gamma$ , interleukin 4, and tumor necrosis factor  $\alpha$ ) at different visits, and the associated changes were evaluated. Compared with the placebo group by generalized estimating equation model, children receiving LP, LF, and LP + LF had lower asthma severity ( $p = 0.024$ ,  $0.038$ , and  $0.007$ , respectively) but higher C-ACT scores ( $p = 0.005$ ,  $< 0.001$ , and  $< 0.001$ , respectively). The LP + LF group demonstrated increased PEFR ( $p < 0.01$ ) and decreased IgE levels ( $p < 0.05$ ). LP, LF, or their combination (LP + LF) can aid clinical improvement in children with asthma.

**Keywords:** *Lactobacillus*; probiotics; asthma; Childhood Asthma Control Test; peak expiratory flow rate; immunoglobulin E

## 1. Introduction

Asthma, a chronic complex disease of the airways, is characterized by reversible airflow obstruction, bronchial hyperresponsiveness, and underlying inflammation [1]. The prevalence of asthma has increased in the past decades. A potential mechanism underlying this high prevalence is the microbial hypothesis [2], which argues that less microbial exposure upregulates the cytokine production of T-helper cell type 2 (Th2), leading to an increase in allergic diseases. According to this hypothesis, probiotic administration is an alternative treatment for atopic disease, which when administered in adequate amounts, can confer a health benefit to the host [3]. The researchers found that probiotics have some health effects in atopic disease patients through immunity balancing of T-helper cell type 1 (Th1) and Th2, particularly in those with atopic dermatitis (AD). However, relevant studies focusing on asthma patients are limited.