

Efficacy of Probiotics Administration in Patients with Uncontrolled Asthma: A Randomized Placebo Controlled Trial

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Background: Regulatory T (Treg) cells suppress the allergic immune response that plays a vital role in the immunopathology of asthma. Probiotics can modulate the immune system by inducing Treg cells and decreasing allergen-induced airway hyperresponsiveness. We hypothesized that the organism *Bifidobacterium longum* subspecies *infantis* (*B.infantis*) 35624 administration together with conventional asthma treatment will improve asthma control in adults.

Methods: Sixty-four partly controlled and uncontrolled asthmatic patients were enrolled in this study and randomized to take oral probiotic (*B.infantis* 35624) or placebo for 4 weeks. Forced expiratory volume 1 (FEV1), forced vital capacity (FVC), asthma control test (ACT) score, visual analog scale (VAS), absolute eosinophil counts (AEC) and dysfunctional regulatory T cells (CRTH2⁺ Treg) were investigated at baseline and after 4 weeks treatment period. All patients received full asthma treatment without systemic corticosteroid.

	Active n = 31	Placebo n = 29
Sex (Female)	22	15
Age	57.74±15.76	58.37±14.05
BMI	25.68±5.42	26.02±5.25
Duration (year)	24.16±16.63	22.03±13.58
History of smoking	4	7
Allergic disease		
AR	24	21
Allergen sensitization		
Mite	22	23
Cockroach	12	11
Inhaled corticosteroid dose		
High	10	6
Moderate	11	19
%FEV1	76.87±20.79	77.72±17.76
%FVC	94.45±16.59	97.27±19.21
%FEV1/FVC	80.83±13.20	78.89±13.89
%PEFR	91.19±27.81	89.86±29.52
Asthma control test score	19.19±3.21	18.58±4.25
Visual Analogue scale	3.58±1.74	3.42±1.2
Absolute Eosinophil (cells/μl)	325.16±215.47	392.17±432.96

Table 1
Baseline patient characteristics

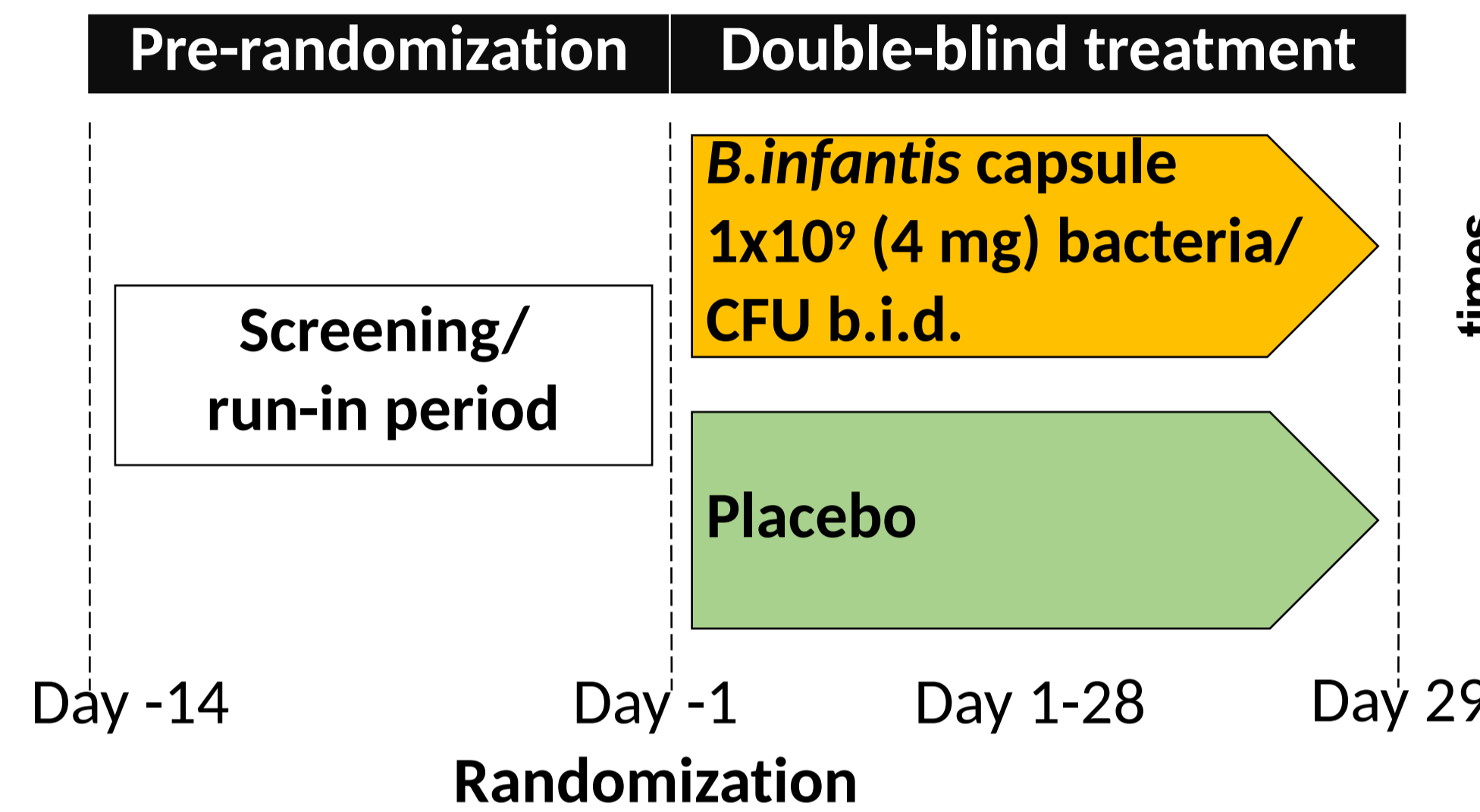


Figure 1 Study design

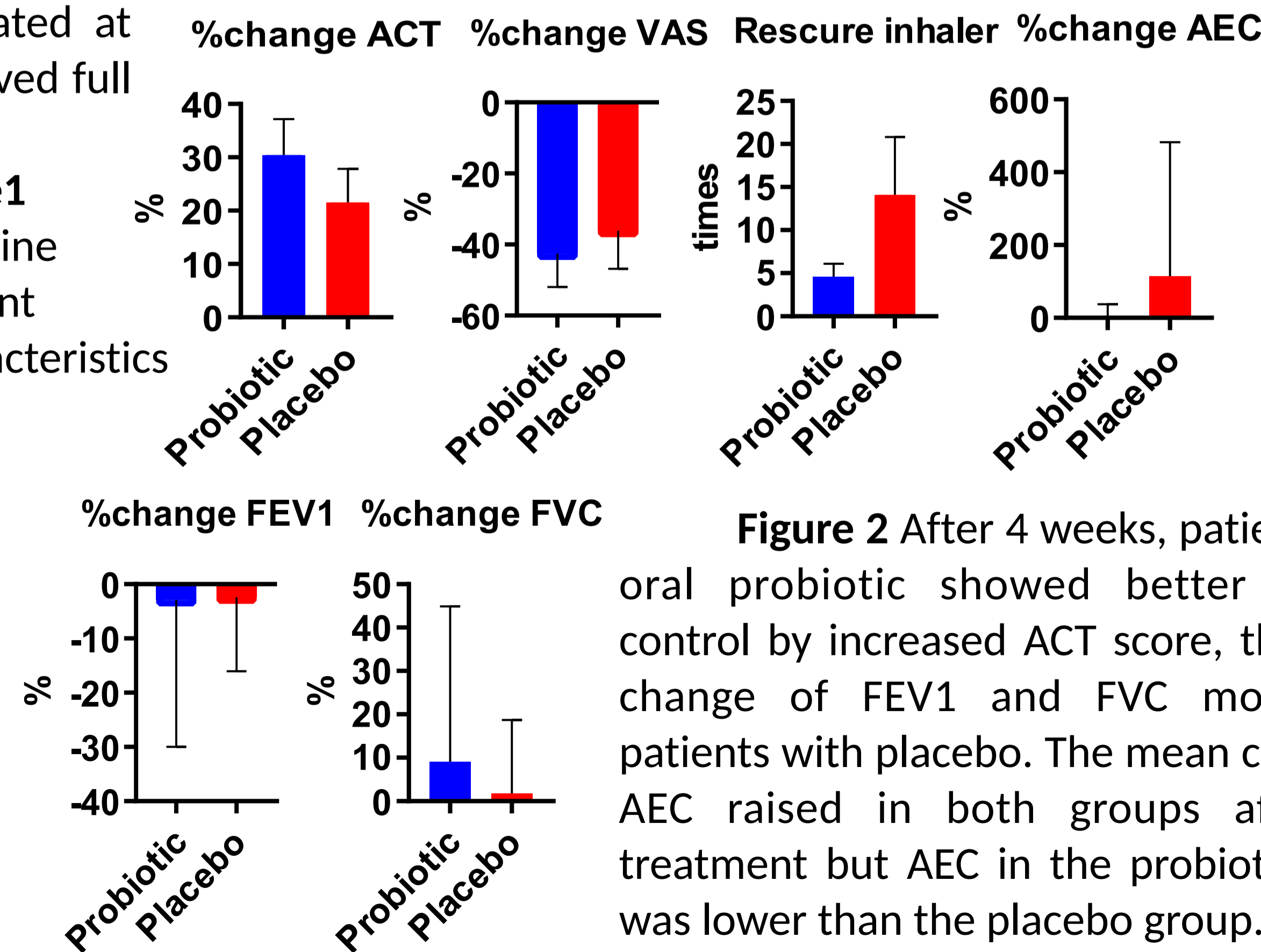


Figure 2 After 4 weeks, patients with oral probiotic showed better asthma control by increased ACT score, the mean change of FEV1 and FVC more than patients with placebo. The mean change of AEC raised in both groups after the treatment but AEC in the probiotic group was lower than the placebo group.

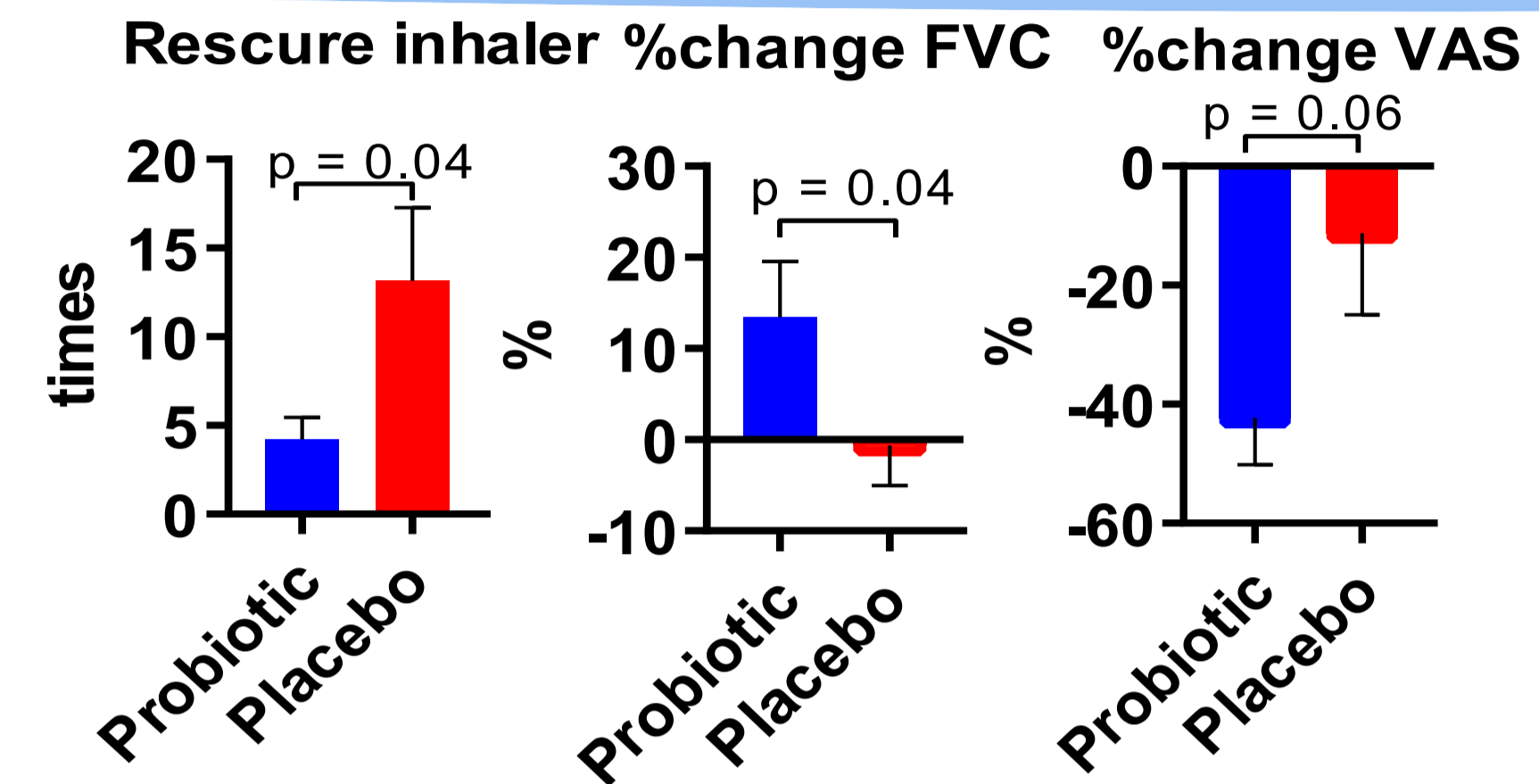


Figure 3 In subgroup analysis, uncontrolled asthmatic patients (defined by ACT < 20) of the probiotic group showed significantly increased lung function (p = 0.03) and reduced number of rescue inhaler usage (p = 0.04).

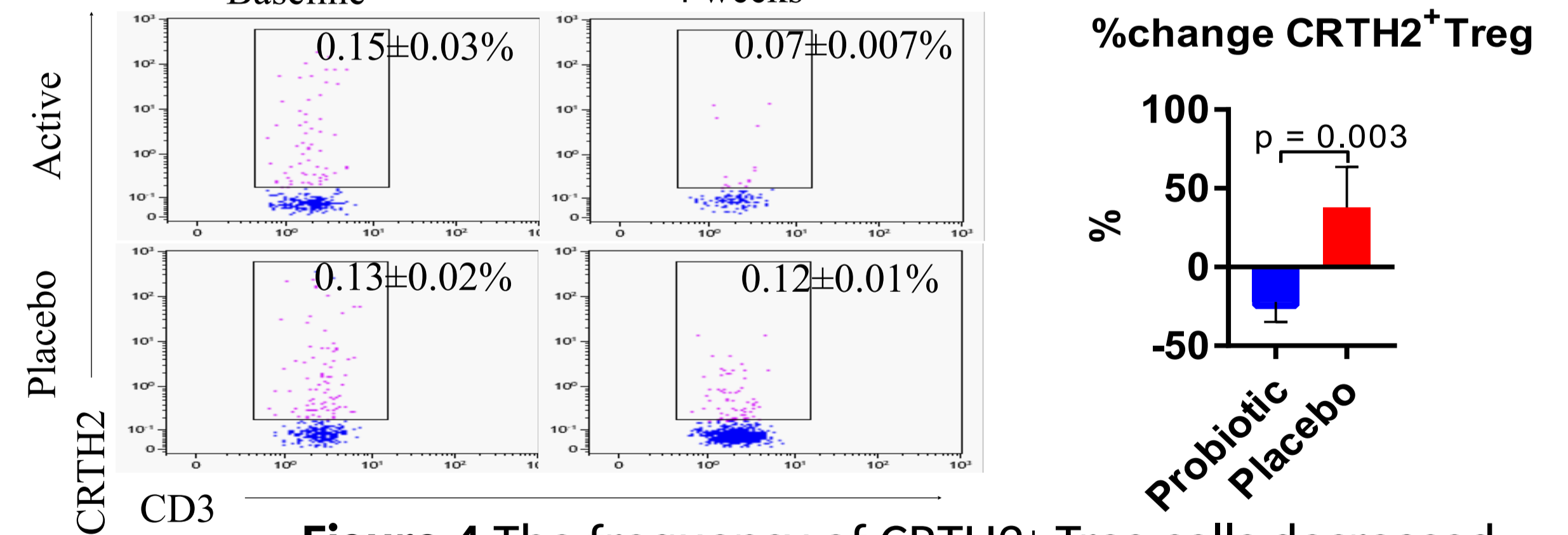
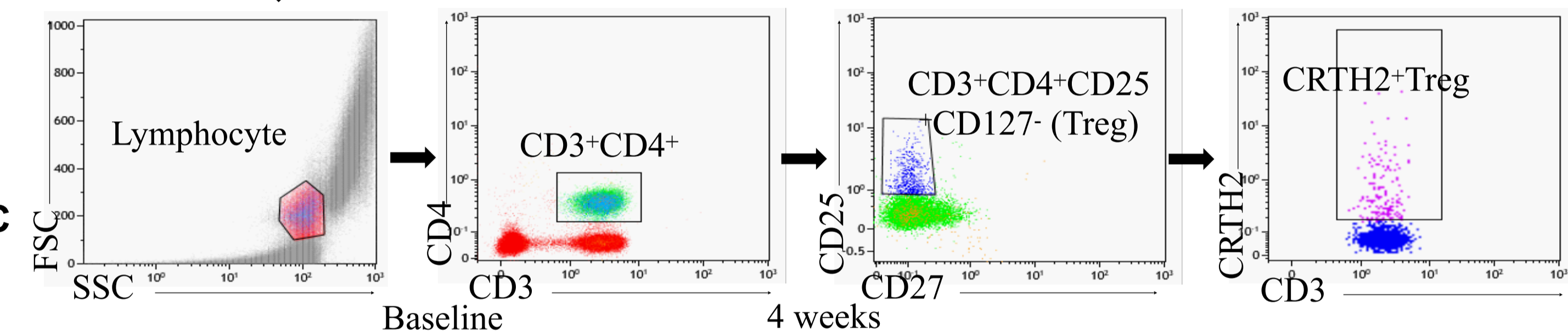


Figure 4 The frequency of CRTH2⁺ Treg cells decreased in the probiotic group more than the placebo group.

Conclusion: *B.infantis* 35624 administration for 4 weeks might improve asthma control symptom and lung function, particularly in partly/uncontrolled asthmatic patients. A long-term study should be conducted to support the efficacy of probiotics as an add-on treatment in asthmatic patients.