

# Dose-Dependency of *Echinacea* in the Treatment of Acute Common Colds in Children 4 – 12 Years

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## Introduction

Antipyretics, decongestants and cough medicine are used for acute cold symptom relieve but they have no effect on illness duration<sup>1</sup>. A swift recovery however is key to limit the strenuous effects of infections on children's immune system. *Echinacea* has been shown to shorten common colds, prevent recurrent infections and secondary complications in adults<sup>2</sup>. A child-friendly formulation was developed and tested in the pediatric population at two dosages of 1200 mg and 2000 mg Echinaforce® EF extract.

## Conclusion

Echinaforce® Junior tablets are a safe and efficacious option for the treatment of the common cold in children. Five tablets deliver 2000 mg EF extract daily and reduce the duration of cold episodes by 1.2 to 1.7 days. Symptoms are soothed from the first day of treatment and after 10 days, nine of 10 episodes are fully resolved.

## Methods

An alcoholic extract of *Echinacea purpurea* was developed into a child-friendly formulation (Echinaforce® Junior tablets (EFJ) A.Vogel Bioforce, Switzerland). 1200 and 2000 mg of EF extract were randomly applied in three or five tablets per day to children with acute cold symptoms. Up to 3 cold episodes could be treated per child. Parents recorded respiratory symptoms using a validated scoring method (e-diaries).

- Multicentre, open, randomized clinical study
- 79 children (4 – 12 years) included experiencing 130 cold episodes
- Acute treatment for max. 10 days or until symptom resolution
- Observation period of 5.3 months in average

## Results

### Efficacy Results

Most children (97.5%) finished the study as planned and only two subjects did not attend the final visit. A total of 130 cold episodes were treated with EFJ during the 5.3 months of observation. The dose increase from 1200 to 2000 mg EF extract shortened the episode duration from 8.1 ± 3.5 to 6.9 ± 3.5 days (ITT collective, p<0.05 in Wilcoxon-test, Figure 1). Children allocated to 1200 mg EF extract but with > 160% compliance were moved to the 2000 mg group, which further enhanced the treatment effect to 1.7 days (p=0.020). After 10 days with 2000 mg EF extract 8.7% of episodes remained unresolved in comparison to 23.5% with 1200 mg (Figure 2, p=0.005). Intake of co-medication was low and similar in both groups (6 children or 17.6%).

2000 mg decreased the risk for recurrent infections from 71.9% to 58.1% and thereby the overall cold incidence from 3.1 episodes (as per history) to 1.9 episodes (Figure 3, p<0.001).

### Safety Results

Tolerability of EFJ was by 98.5% of physicians and 99.2% of parents rated as "good" or "very good". Thirteen (13) children (19.1%) reported adverse events but none was causally related to EFJ nor serious. Finally, over 80% of parents (82.3%) stated that they would want to take the medicament again.

## References

- 1) Fashner J, Ericson K, Werner S. *American Family Physician* 2012;(86):153-159.
- 2) Schapowal A, Klein P, Johnston SL. *Advances in Therapy* 2015;32(3):187-200.

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Table 1: Demographic Data

	SAF POPULATION		ITT POPULATION	
	3 x 1 tab N = 36	5 x 1 tab N = 32	3 x 1 tab N = 32	5 x 1 tab N = 31
AGE [YEARS]	7.5 (SD 2.62)	5.9 (SD 1.85)	7.4 (SD 2.65)	5.9 (SD 1.88)
HEIGHT [CM]	125.6 ( 20.21)	115.6 ( 12.95)	125.2 ( 20.30)	115.5 ( 13.17)
NR. INFECTIONS IN PAST (MEAN, SD)	3.1 (0.17)	3.2 (0.21)	3.0 (0.19)	3.1 (0.20)
EXTERNAL CARE (MEAN HOURS, SD)	1.3 ( 2.43)	1.3 ( 2.68)	1.2 ( 2.34)	1.4 ( 2.71)
KINDERGARTEN OR SCHOOL	32 ( 88.9%)	25 ( 78.1%)	28 ( 87.5%)	24 ( 77.4%)
TREATMENT COMPLIANCE [N, %]			31 ( 96.9%)	29 ( 93.5%)

Figure 1: Time to symptom resolution by Kaplan-Meier curve (blue line = 1200mg, red line = 2000mg).

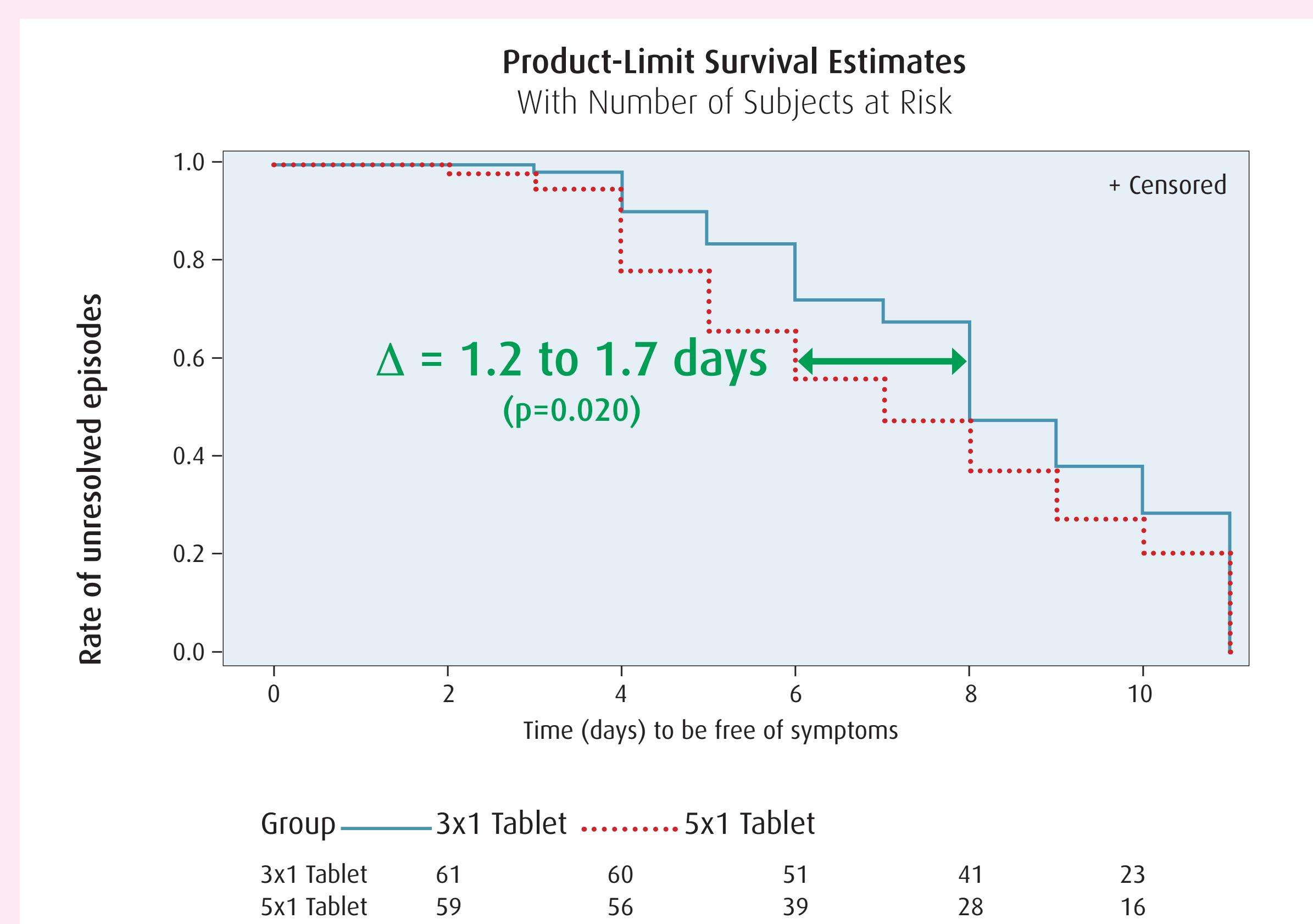


Figure 2: More children (91.3%) within the 2000 mg dose group fully recovered after 10 days treatment (\*\*p<0.01).

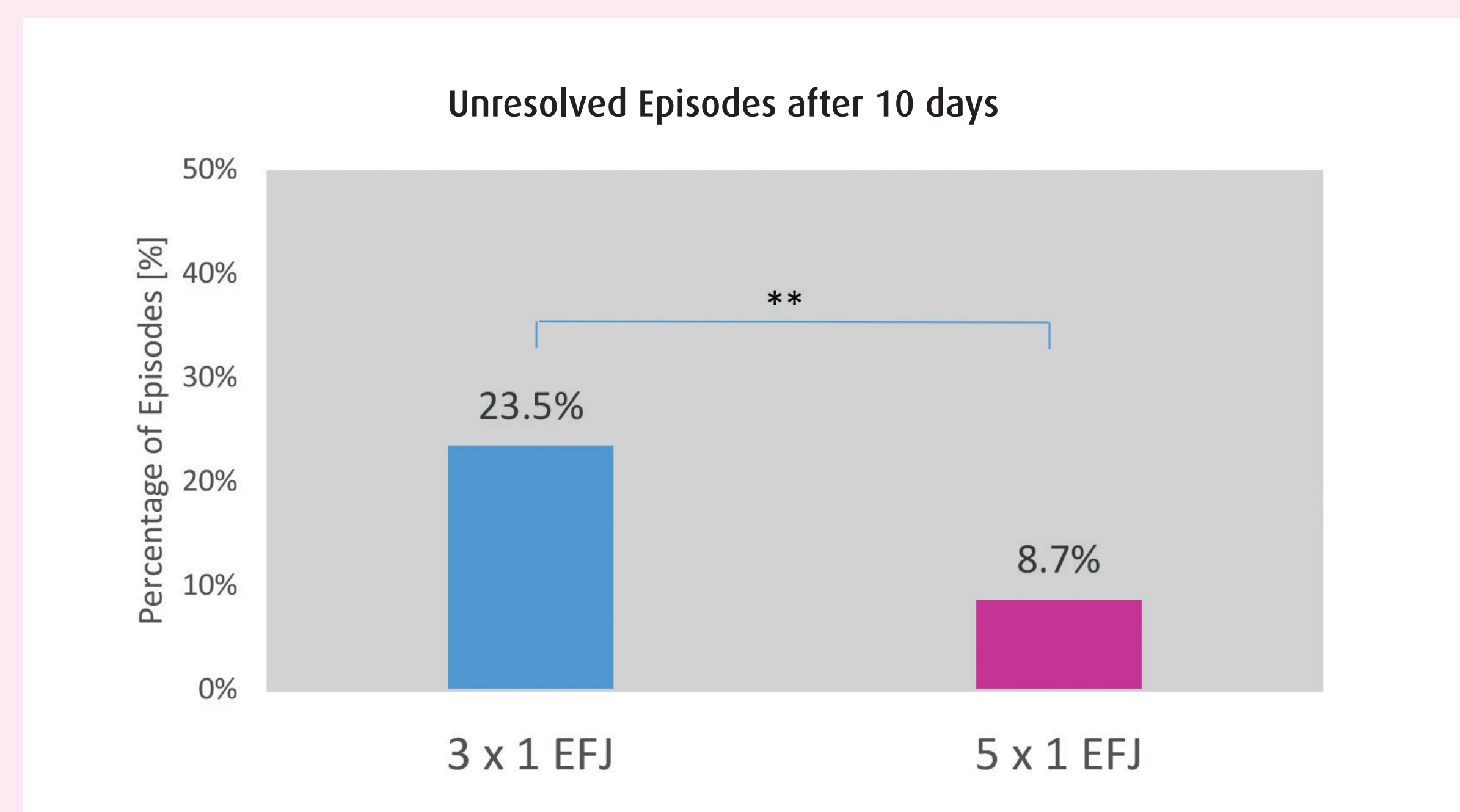


Figure 3: The reduction of recurrent infections finally lead to fewer cold episodes in comparison with the 3.1 infections reported in the past winter season (\*\*\*p<0.001).

