## Multi-symptom Relief and Improvement of Quality of Life - A Comparative Multicenter Trial on ColdZyme® Mouth Spray in Common Cold

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## **ABSTRACT**

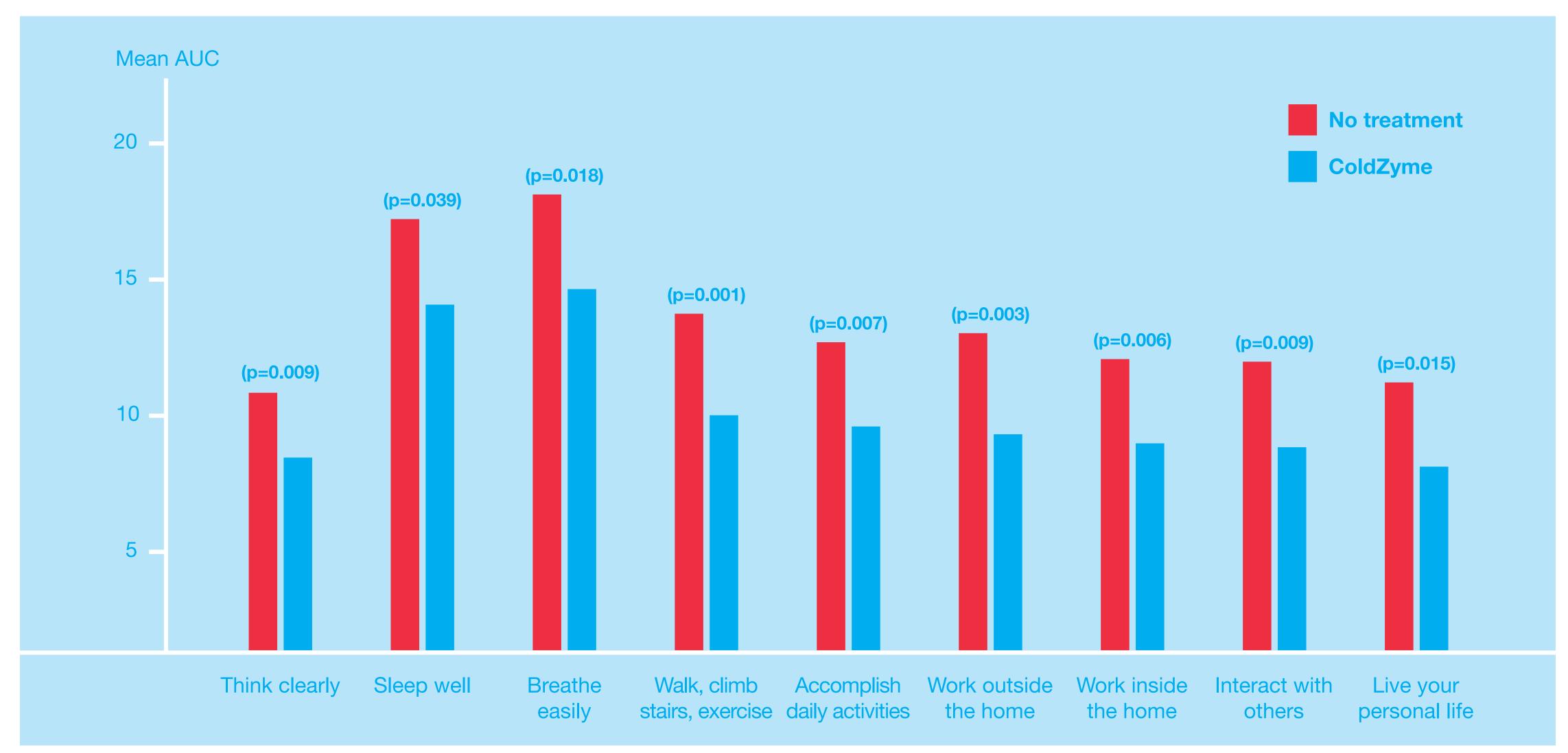
BACKGROUND: ColdZyme® Mouth Spray (Enzymatica AB, Sweden) is a CE-marked medical device for protection against common cold, consisting of a glycerol barrier containing trypsin from Atlantic cod. ColdZyme has been shown in vitro to completely inactivate up to 99 % of known common cold viruses, e.g. influenza virus, rhinovirus, adenovirus and corona virus.

MATERIAL & METHODS: Prospective, multicenter, singleblinded, randomized study comparing ColdZyme to no treatment in 267 patients with naturally occurring common cold. Use of ColdZyme, two sprays up to 6 times daily, started at first signs of common cold symptoms and continued until symptom free. Parallel intake of symptom-relieving medication (paracetamol, ibuprofen or nose decongestants) was recorded. Symptoms were assessed

according to Jackson (1958) and quality of life (QoL) by Wisconsin Upper Respiratory Symptom Survey-21 (WURSS-21), QoL component (Barret 2009).

**RESULTS:** A significant effect was seen on total symptom relief over 7 days, with an AUC for total Jackson score of  $39.6 \pm 23.9$  for ColdZyme vs  $46.2 \pm 25.8$  (p=0.025). ColdZyme improved every single symptom, with significant effects seen on sore throat, nose congestion and headache. QoL improved from day one, with significant effects seen for all QoL parameters during the disease period: as well as a significant shortening of disease duration (p = 0.030). Number of subjects using symptom-relieving medication throughout the first week was 23% lower in the ColdZyme group (p=0.037). No side effects attributable to ColdZyme were reported.

## IMPROVEMENT IN QUALITY OF LIFE



WURSS-21 Quality of Life subscore single items, mean AUC day 1-7. The higher score, the more negative impact on Quality of Life.

**CONCLUSION:** In this comparative, multicenter trial, ColdZyme demonstrates an ability to reduce the overall severity of a common cold and to improve Quality of Life significantly. The more frequent use of rescue medication in the control group further underlines the shown effect.