

# Impact of the use of dust mites covers manufactured with ISO 13485 certified processus on the quality life of allergic patients – A follow-up study carried out of 52 patients

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## Background

- **Pathology:** allergic rhinitis<sup>1</sup> (prevalence: 31% of the French population)
- **Major cause:** dust mites
- **Symptoms:** breathing difficulties, nasal discharge and cough
- **Solution:** dust mites covers are tightly woven to create a mechanical barrier<sup>2</sup>
- **Purpose:** to evaluate the evolution of rhinitis symptoms of patients who used dust mites covers designed and manufactured according to the standards of the medical device (ISO 13485: 2016)

## Study material

Several brands of dust mites covers have been used by our patients (Texaal Cotton, Texal Polyester, Noxaalon, and Noxaalon Bamboo). These covers are not chemically treated, and their anti-mite properties rely solely on mechanical filtration (mesh size: 0.5-5 µm).

## Study method

- Fifty-two of the 107 questionnaires distributed to allergic people who have given their consent to attend the survey were returned.
- The questions were designed to assess patient satisfaction with the use of dust mite covers as well as the symptoms they experienced. **The level of discomfort felt was assessed using a score of 0 (no discomfort) to 10 (severe discomfort).**
- Values were expressed as mean ± standard error of the mean (SEM). Parametric Student test or non parametric Wilcoxon test was used to evaluate statistically differences depending on the distribution and the variance of samples (\*\* p-value <0.01, \*\*\* p-value <0.001, \* p-value <0.05).

## Results

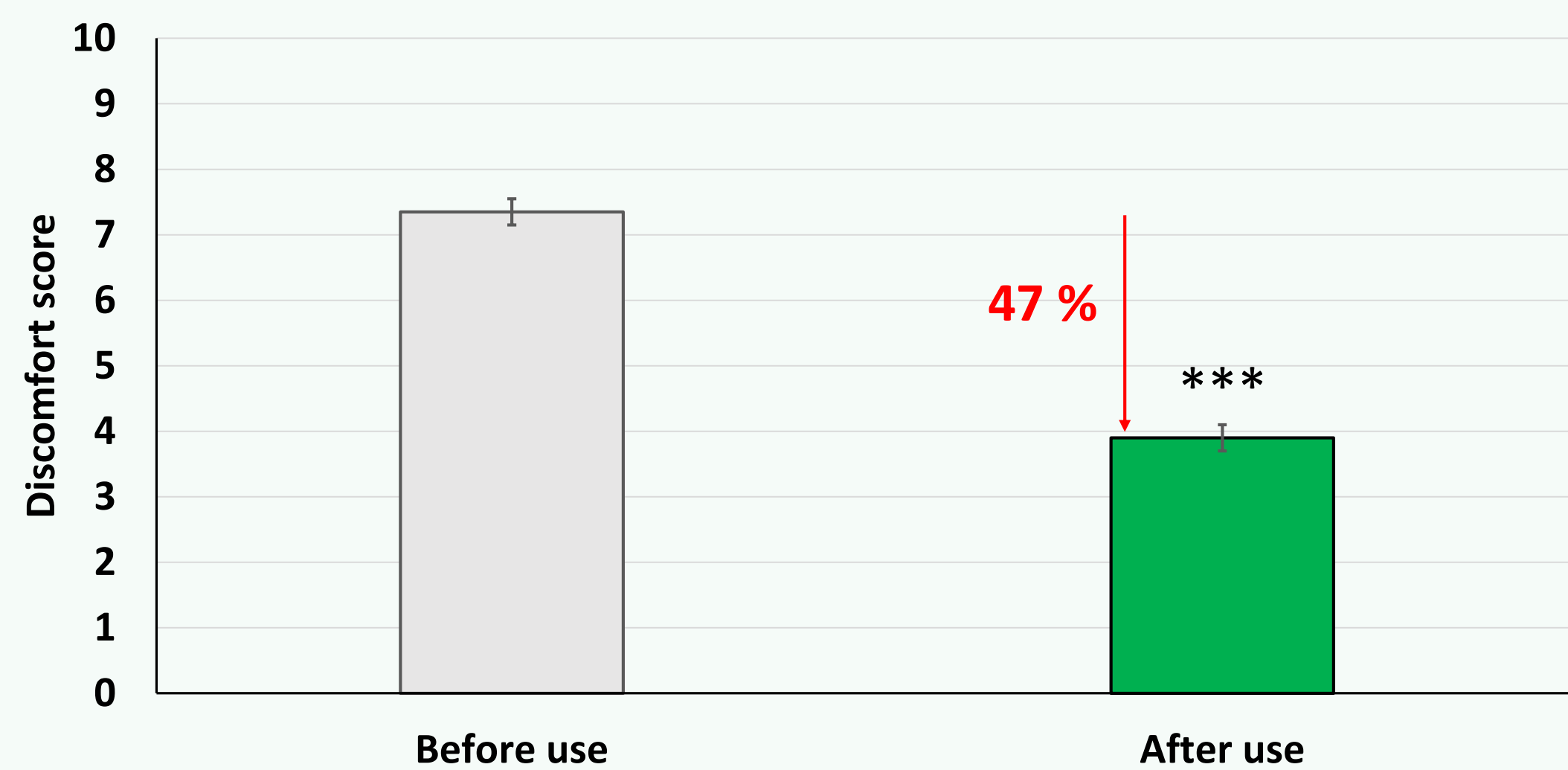


Figure 1: Decrease of discomfort score from the first wave (between August and December 2018)

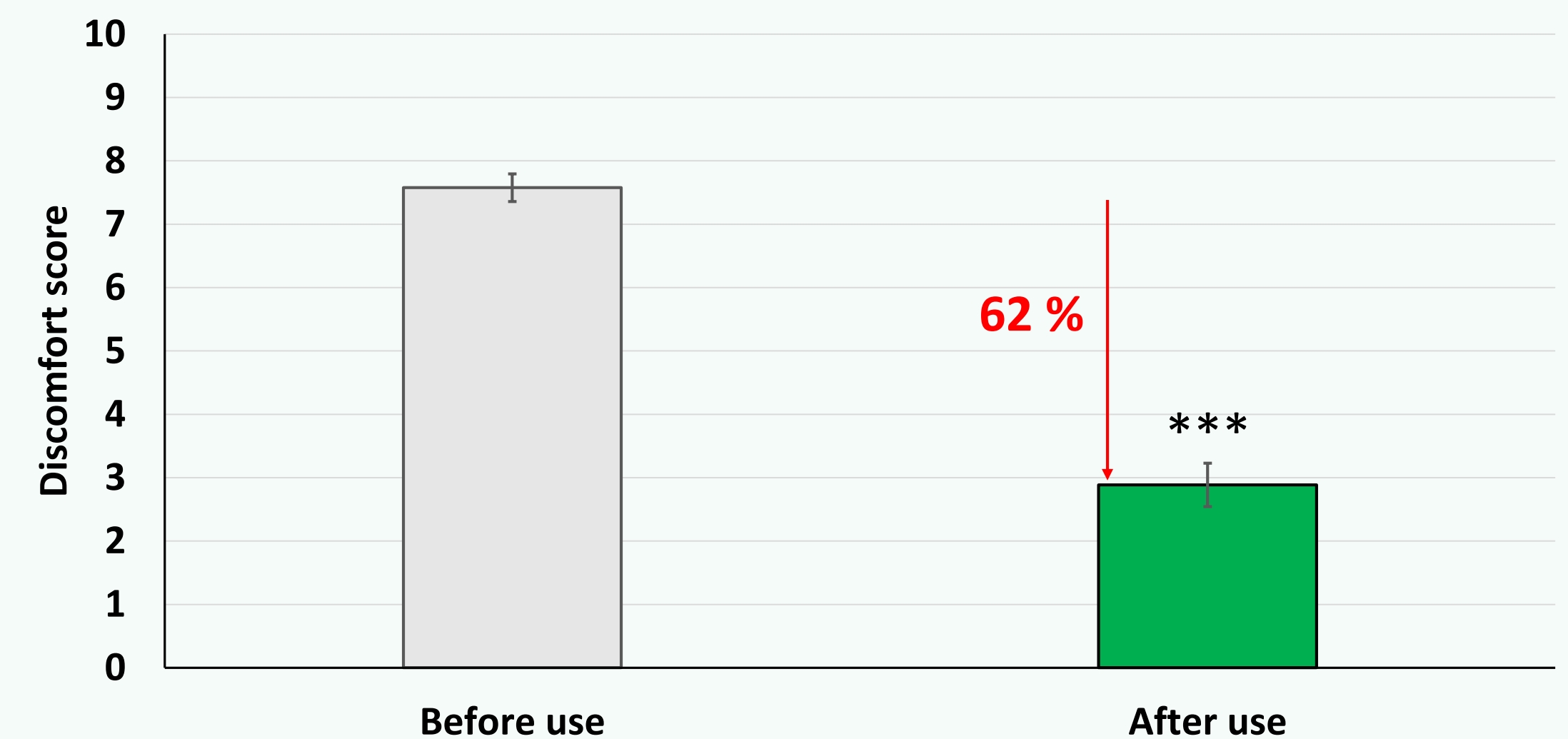


Figure 2: Decrease of discomfort score from the second wave (between January and August 2019)

The first wave (for 6 months) had determined that the level of discomfort felt by patients decreased considerably after the use of dust mites covers: 7.35 +/- 0.2 vs 3.9 +/- 0.2, i.e. a decrease in symptoms of 47%. The second wave of questionnaire (for 8 months) had determined that the level of discomfort felt by the patients decreased considerably after the use of dust mites covers: 7.58 +/- 0.2 vs 2,88 +/- 0.2, i.e. a decrease in symptoms of 62%. The difference in decreasing discomfort score between these two waves (47% VS 62%) is particularly explained by the season (autumn and winter, respectively)<sup>2</sup>.

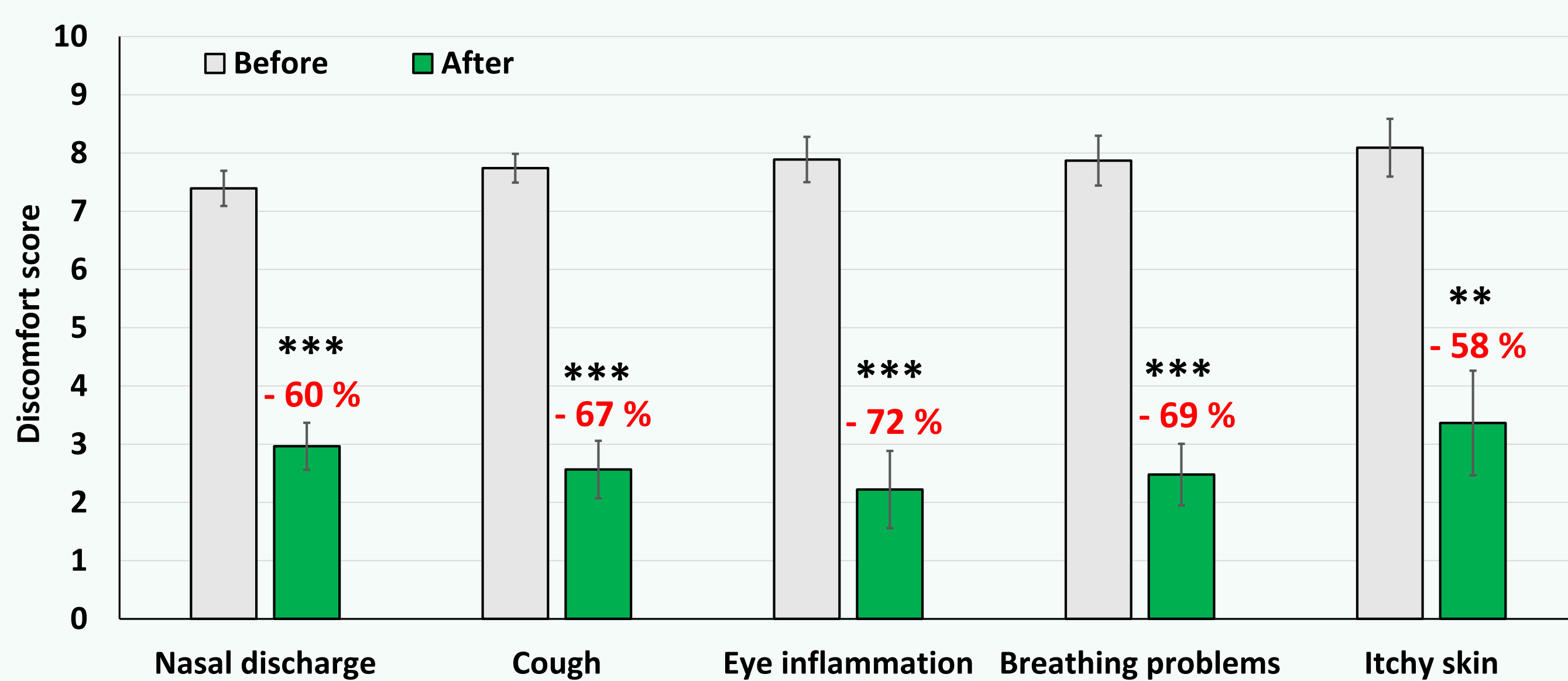


Figure 3: Evaluation of discomfort score per symptoms before and after implementation of dust mites covers

The discomfort score was systematically lower (from -58% for itchy skin to -72% for eye inflammation) in patients who used dust mites covers independently of the etiology of rhinitis.

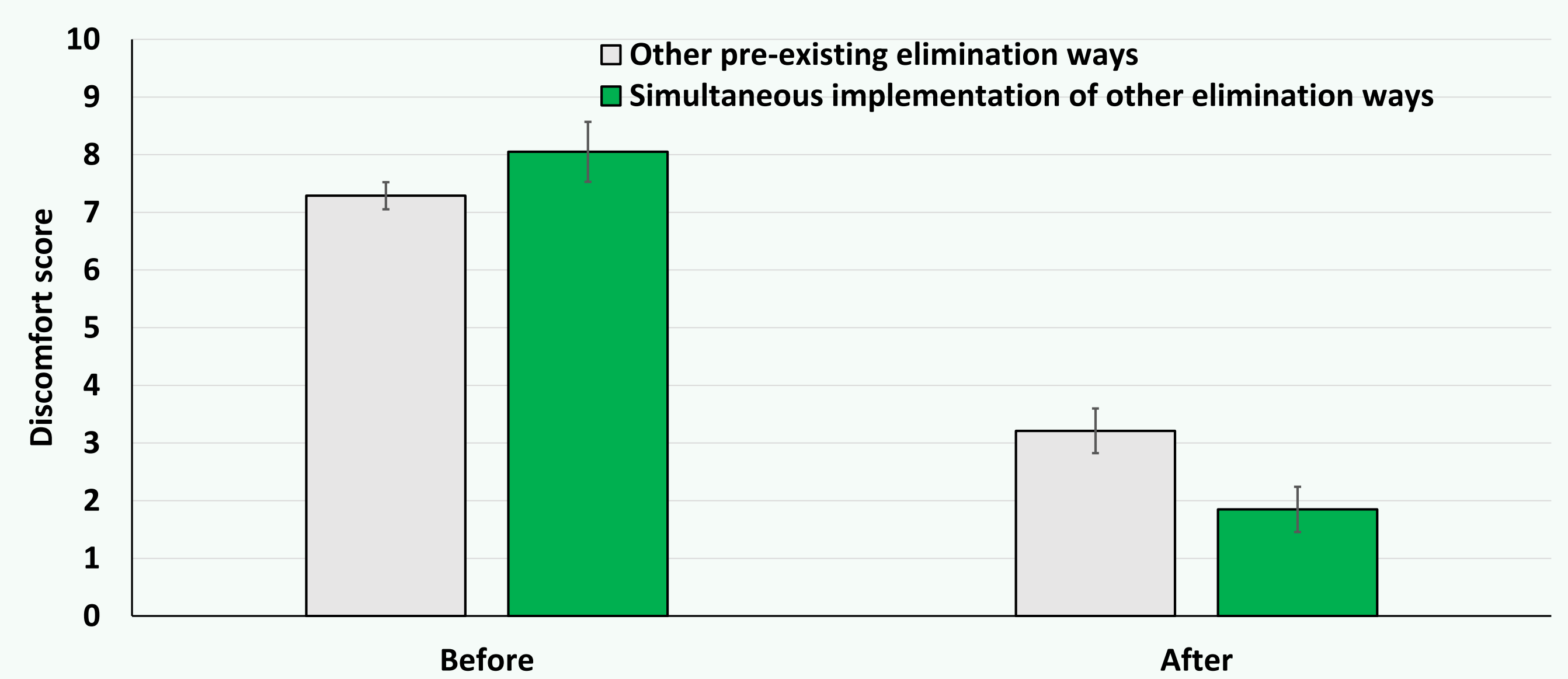


Figure 4: Evaluation of discomfort score related to the moment of implementation of other elimination ways added to the use of dust mites covers

The implementation of other elimination ways seems to decrease the discomfort score (tendency). Moreover, no patient has implemented these eviction measures after the introduction of dust mites covers.

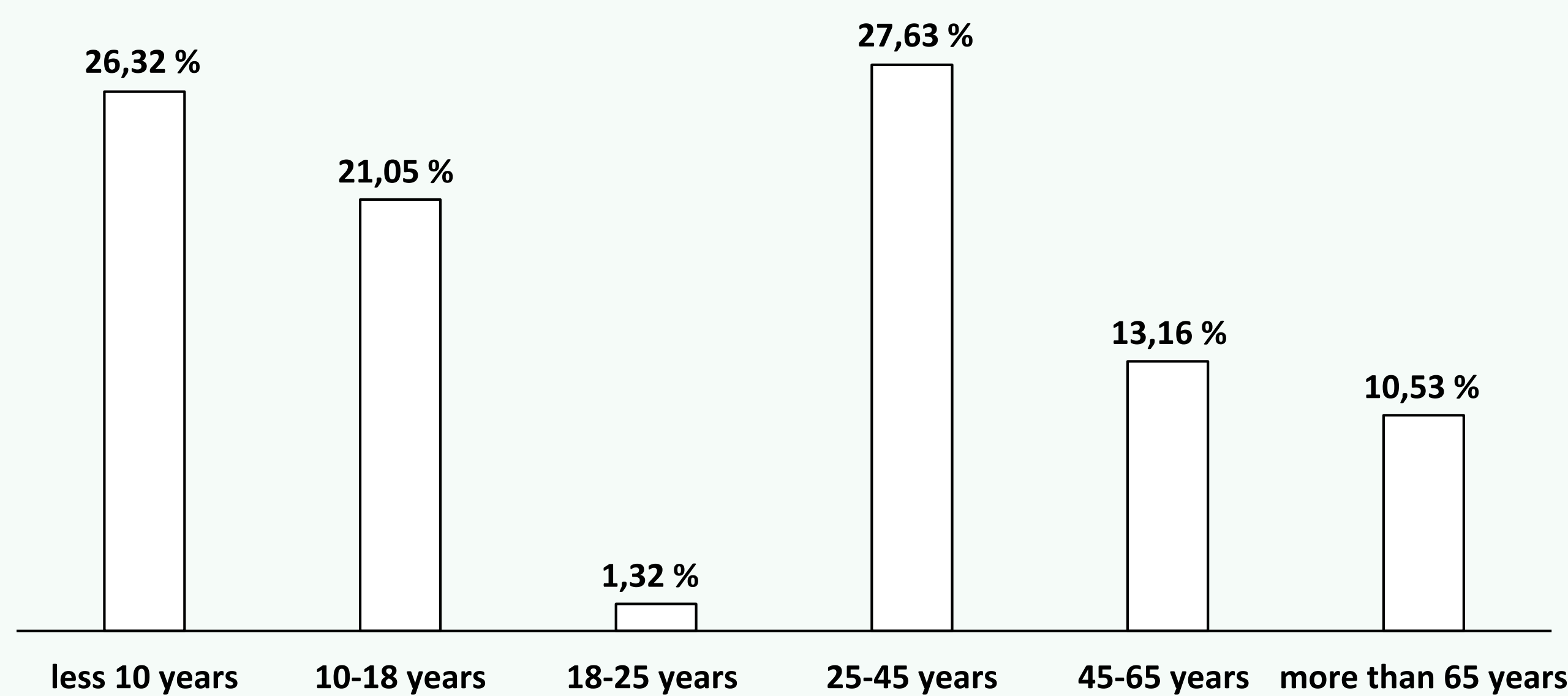


Figure 5: Distribution of allergic people who attend the survey according to age

Main users of dust mites covers are children less than 10 years old (26,32%) and people between 25 and 45 years old (27,63%).

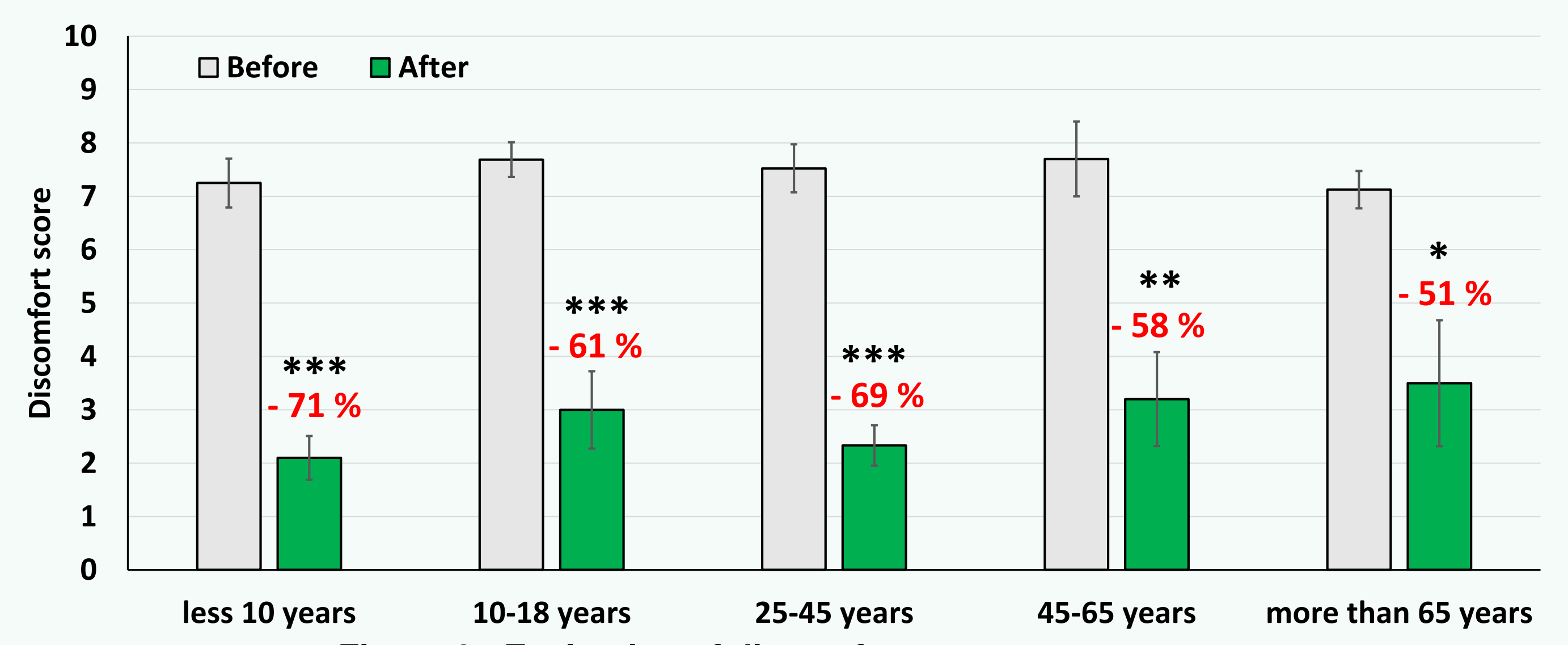


Figure 6: Evaluation of discomfort score per age group before and after implementation of dust mites covers

The discomfort score was significantly lower after the implementation of dust mites cover independently of the patient age. However, the effect was more pronounced for children less than 10 years (-71%) and 25-45 years (-69%) groups.

## Discussion

As all patients implemented other eviction measures, it is difficult to isolate the influence of dust mites covers from the influence of other eviction measures. Another study<sup>3</sup> performed in "double-blind against placebo covers" has demonstrated the effectiveness of dust mites covers independently of other eviction measures. The follow-up study provides ongoing evaluation of the benefit of these measures and interesting information on the application of a set of preventive measures.

## Conclusion

Using eviction measures, such as dust mites covers, enables the decrease of allergic rhinitis symptoms.

It would also be relevant to carry out a study distinguishing between patients those who have already implemented eviction measures and from those who have not yet done so, in order to quantify the decrease related solely to the use of ProtecSom dust mites covers.

## Bibliography

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