

Sleep improvement and stress reduction by a breath-guiding device: An efficacy study of the Somnox 2 Breathe and Sleep Robot

This study was designed and carried out by: Kasper H. Schelvis, MSc, Nadine Rouleaux, MSc, and Roy J. E. M. Raymann, PhD
Somnox B.V.

Introduction

- In this study, the effectiveness of a breath-guiding device has been assessed using validated stress and sleep questionnaires in **a healthy user group experiencing self-reported sleep complaints due to stress**.
- The device used was the **Somnox 2 Breathe and Sleep Robot**, which allowed users to slow their breathing, following the breathing rhythm of the device.
- Slowed breathing has previously been shown to have positive impact on sleep and stress through activating the parasympathetic nervous system (Pal & Velkumary, 2004; Russo et al., 2017).

Hypotheses

As there is ample evidence on the effects of pre-sleep breathing and relaxation activities to improve stress and sleep outcomes, it was expected that:

- Insomnia severity and impact would decrease** after a period in which the device was used, compared to baseline (hypothesis 1)
- Stress would decrease** after a period in which the device was used, compared to baseline (hypothesis 2)

Figure 1. The device



Methodology

The approach was an efficacy study of 10 weeks, in which the effectiveness of the device in improving subjective sleep and stress and outcomes was explored.

Descriptive statistics

	N = 42	
Gender (% female)	90.5%	
	M ± SD	Range
Age	45 ± 9.25	30-64

Instruments

- To assess insomnia severity and impact, the **Sleep Condition Indicator (SCI)** was used. The SCI is a self-report questionnaire consisting of 8 items based on DSM-5 criteria to evaluate insomnia disorder. The global score ranges from 0 to 32, with a higher score indicating better sleep.
- To assess subjective stress complaints, the **Perceived Stress Scale (PSS)** was used: a self-report questionnaire consisting of 10 items measuring global stress levels by asking to which degree persons find their lives unpredictable, uncontrollable and overloaded. The global score ranges from 0 to 40, with higher scores indicating higher levels of stress.
- A **daily sleep diary** was used to track sleep.

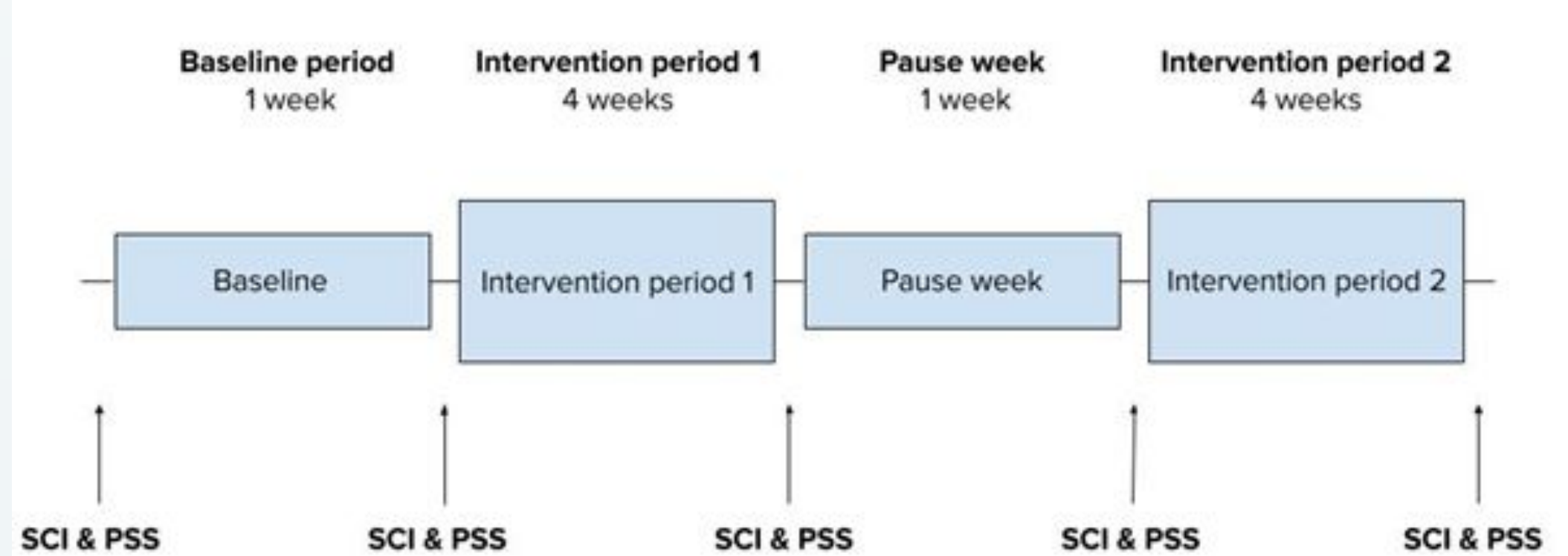
Design

- Two different proprietary feedback algorithms were tested in a within subject design with a pause week between two intervention periods.
- Questionnaires were filled in five times and they were about the preceding period.

Statistical analysis

- The data was pooled, as the initial analysis showed no differences between the two algorithms. Multiple Paired T-tests have been performed to test the hypotheses.

Figure 2. Study design



Results

SCI and PSS

	Week 1 (M ± SD)	Week 10 (M ± SD)	p-value
SCI	9.81 ± 3.84	17.29 ± 5.54	<0.001
PSS	17.52 ± 7.08	12.36 ± 5.02	<0.001

Sleep diary

	Week 1 (M ± SD)	Week 10 (M ± SD)
Sleep onset latency (min)	49.68 ± 48.02	28.52 ± 37.12
Total wake time (min)	153.25 ± 37.12	82.05 ± 63.92
Total sleep time (min)	379.55 ± 100.78	431.02 ± 86.28
Sleep efficiency (total sleep time/total time in bed)	72% ± 18%	84% ± 12%
Perceived sleep quality*	2.64 ± 1.01	3.57 ± 0.98
Stress level*	2.8 ± 1.1	2.27 ± 0.97
Rested level*	2.52 ± 0.97	3.36 ± 0.96

*These variables were measured on a 1-5 scale, with higher scores indicating a better sleep quality, more stress, and more restedness.

All sleep diary improvements were **statistically significant** (p < 0.001).

Figure 3. SCI scores by period

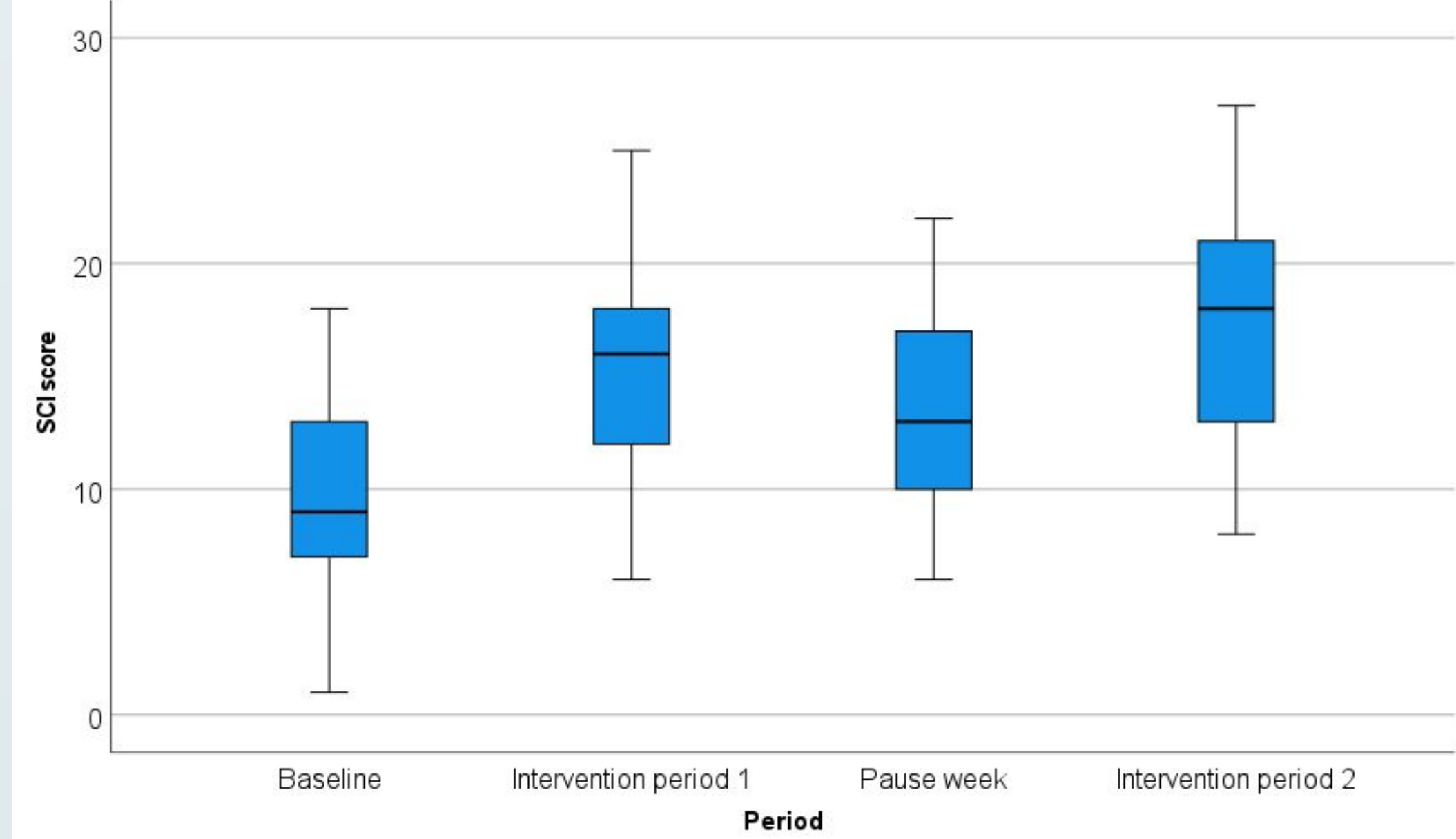
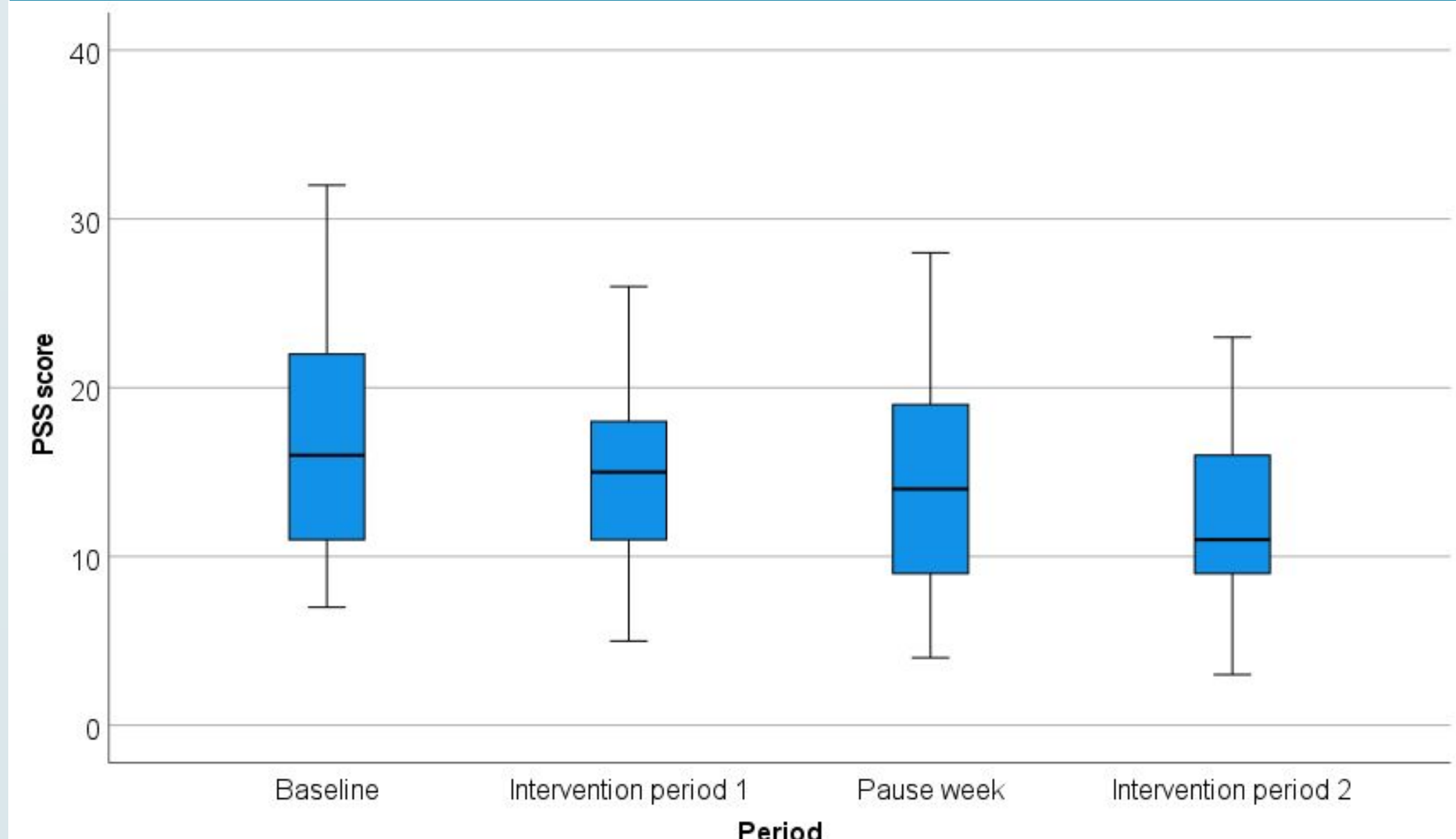


Figure 4. PSS scores by period



Conclusion

The results have shown that **insomnia severity and stress levels can be reduced by the Somnox 2 Breathe and Sleep Robot**.

During use of the intervention, the average score for SCI increased by 7.48, **changing from “probable insomnia disorder” to “no insomnia disorder”**. This increase should be regarded as meaningful and likely **clinically relevant**, since the observed change exceeds the Reliable Change Index of the SCI (Espie et al., 2018).

This study has shown that **the Somnox 2 Breathe and Sleep Robot is an effective intervention**, and can thus be considered as a non-pharmacological intervention to improve sleep and stress.