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

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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 1. 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



Espie, C. A., Machado, P. F., Carl, J. R., Kyle, S. D., Cape, J., Siriwardena, A. N., & Luik, A. I. (2018). The Sleep Condition Indicator: reference values derived from a sample of 200 000 adults. Journal of Sleep Research, 27(3). Pal, G. & Velkumary, S. (2004). Effect of short-term practice of breathing exercises on autonomic functions in normal human volunteers. Indian Journal of Medical Research. Russo, MA., Santarelli, DM. & O'Rourke, D. (2017). The physiological effects of slow breathing in the healthy human. Breathe.

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

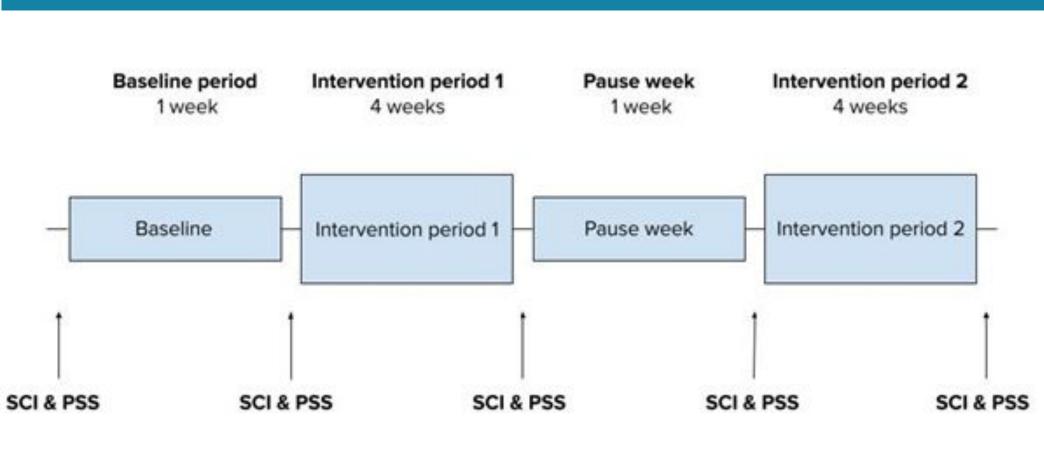
- Two different proprietary feedback algorithms were tested in a within subject design with a pause week between two intervention periods.
- Questionnaires were filled in five times and they were about the preceding period.

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

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



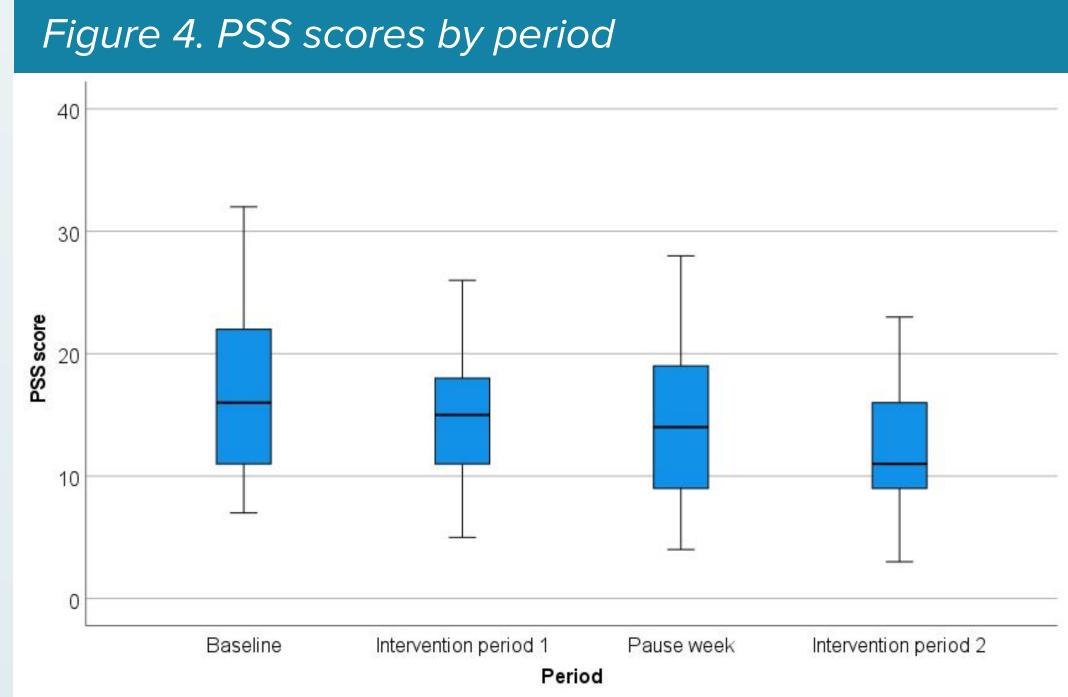
Results

SCI and PS	S			
	Week	1 (M ± SD)	Week 10 (M ± SD) p-value
SCI	9.8	1 ± 3.84	17.29 ± 5.54	<0.001
PSS	17.5	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			
leep 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			
nese variables were measured on a 1-5 scale, with higher scores indicating a					

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



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.

SOMOX

Figure 3. SCI scores by period

