Our scientific *position*

What independent research shows about Somnox, and what it does not yet show.

Two independent randomized controlled trials, published in 2025 and 2026, now support Somnox as a supportive tool for stress-related sleep problems.

In a 2026 crossover trial at The Hague University of Applied Sciences (n=40), sleep quality was significantly higher during six weeks of Somnox use than during six weeks without it. In a 2025 trial at MSH Medical School Hamburg (n=31), the breathing function reduced perceived stress more than an identical device with breathing switched off.

The mechanism is well grounded: slow breathing reliably increases parasympathetic activity, and breathing interventions show small-to-medium effects on stress in meta-analyses.

The evidence base is still young. Samples are small, outcomes are self-reported, and an earlier trial found no significant effect. We say so openly.



2

Independent RCTs

Published 2025 and 2026, third-party funded, no conflicts of interest reported.

+4.2

Sleep quality vs no use

Sleep Condition Indicator (0–32), 95% CI 2.5 to 6.0, p<0.001.

0.67

Extra stress reduction

Standardized mean difference, breathing on vs breathing off.

Our position

Somnox is a well-tolerated, drug-free support for relaxation and sleep, complementary to cognitive behavioural therapy for insomnia (CBT-I), which remains first-line treatment. Somnox is a consumer wellness product, not a medical device, and makes no treatment claims.

Independent clinical *evidence*

All peer-reviewed studies of Somnox by independent research groups, newest first.

STUDY	POPULATION	DESIGN	MAIN FINDING
Brummer, Haanstra & De Witte 2026 *Frontiers in Psychology* Newest	40 adults with sleep problems and worry-related stress	Crossover RCT: 6 weeks Somnox 2 vs 6 weeks no intervention	Sleep quality +4.2 SCI points vs control ($p<0.001$), confirmed in first-period analysis. 85% improved; 27.5% reached reliable clinical change. Stress −1.8 PSS ($p=0.049$), not confirmed in first-period analysis. No effect on quality of life.
Lotzin et al. 2025 *Int. J. Clin. Health Psychol.* Active placebo	31 adults with PTSD and impaired sleep	Preregistered, evaluator-blinded RCT: 4 weeks Somnox 2 vs same device with breathing off	Greater stress reduction with breathing on (SMD 0.67, 95% CI 0.39 to 0.94). Sleep, PTSD symptoms and well-being improved equally in both arms. Used on 94% of days; 0% dropout.
Støre et al. 2023 *Journal of Sleep Research*	44 adults with insomnia	RCT vs waitlist: 3 weeks Somnox 1	Small improvement in insomnia severity, not statistically significant. Adherence below 50%.
Støre et al. 2023 *PLOS One*	4 adults with ADHD and insomnia	Mixed-method proof of concept, Somnox 1	Clinically relevant improvement in 3 of 4 participants; safe and well accepted.

In the 2025 and 2026 trials Somnox B.V. supplied devices only. Funding: ERDF Kansen voor West (2026) and the Daimler and Benz Foundation (2025). A 2022 company-initiated study without a control group is not counted as evidence of efficacy.

How the two trials *fit together*

Does using Somnox help, compared with not using it?

The 2026 trial compared the full product with no intervention. Sleep quality improved, and the result held in a stricter first-period analysis.

Does the breathing function itself matter?

The 2025 trial switched the breathing off in the control device. Breathing added stress reduction; sleep improved in both arms, pointing to the product as a whole: touch, comfort, routine and guided breathing.



The 2025 result is the only evidence that isolates the breathing mechanism against an active placebo. It also counters the low adherence seen in 2023: with Somnox 2, patients with severe PTSD used the device on 94% of days.

- **How we read it:** both trials are small, rely on self-report and were not powered for definitive claims. Consistent, promising signals; not proof.

Pictured: Somnox Pro and the handheld Somnox Go. Studies to date used Somnox 1 and 2; Somnox Go has not yet been studied.

Why guided slow breathing *plausibly works*

Somnox targets a well-described pathway from stress to poor sleep. Each link is supported by independent literature; the device makes the intervention effortless at bedtime.

1 **Stress and hyperarousal drive chronic poor sleep**

The hyperarousal model, the dominant framework in insomnia research, links elevated physiological and cognitive arousal to difficulty falling and staying asleep (Riemann et al. 2010).

2 **Slow breathing shifts the nervous system toward rest**

A meta-analysis of 223 studies found that voluntary slow breathing increases vagally mediated heart rate variability, a marker of parasympathetic activity (Laborde et al. 2022).

3 **Breathing interventions reduce stress**

A meta-analysis of 12 RCTs (785 adults) found breathwork lowered self-reported stress versus controls, a small-to-medium effect, g = −0.35 (Fincham et al. 2023).

4 **Paced breathing before bed can improve sleep**

In a small polysomnography study, 20 minutes of slow paced breathing before bed shortened sleep onset, reduced awakenings and raised sleep efficiency in people with insomnia (Tsai et al. 2015). A 30-day programme improved subjective sleep quality (Laborde et al. 2019).

5 **Tactile guidance and touch add comfort and adherence**

A pilot of a tactile breath pacer (n=39) found good acceptability and preliminary sleep improvement (Vermeylen et al. 2022); reviews link affective touch, including from devices, to lower stress (Eckstein et al. 2020).



An honest nuance

In a large placebo-controlled trial (n=400), breathing at about 5.5 breaths per minute was no better than paced breathing at 12 per minute (Fincham et al. 2023). Benefits may come from structured, guided breathing as a calming routine rather than one exact rate. This is consistent with the Somnox trial results.

What we claim, and *what we do not*

WE CAN SAY	WE DO NOT SAY
✓ Two independent randomized trials (2025, 2026) support Somnox for stress-related sleep problems	× Somnox is clinically proven
✓ People with stress-related sleep problems reported better sleep quality with Somnox than without	× Somnox treats insomnia, PTSD or any condition
✓ The breathing function reduced stress more than the same device without it	× Somnox improves sleep beyond placebo
✓ Trial participants used the device consistently (94% of days in 2025)	× Somnox replaces CBT-I or medical care

From promising signals to *confirmatory evidence*

The open questions are clear, and they shape our research agenda.

Specific effect on sleep

No trial has yet shown a sleep benefit beyond an active placebo. A larger, preregistered sham-controlled trial is the priority.

Objective outcomes

All results so far are self-reported. Actigraphy or polysomnography would show whether physiological sleep changes.



Durability and dose

Follow-up beyond six weeks, with device-logged usage, would show whether effects last and scale with use.

Who benefits most

About a quarter of 2026 participants reached clinically meaningful change. Identifying responders is key for clinical and payer pathways.

We welcome research partners to co-design these studies. Contact: info@somnox.com

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