



DOSSIER · THERAPY

HRV Biofeedback and Vagus Nerve Training

HRV biofeedback and non-invasive vagus nerve stimulation are methods for targeted modulation of the **autonomic nervous system**. The study evidence is extensive but unevenly distributed: while **cognition** and **fatigue** have been intensively investigated, other applications remain methodologically under-researched. The most frequently cited studies suggest **mechanisms** rather than clinical efficacy.

1,301

STUDIES IN
TOTAL

925

IN HUMANS

466

OF WHICH
CONTROLLED

10

IN ANIMALS

1

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-04

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

HRV Biofeedback and Vagus Nerve Training at a Glance

ORIGIN:
HRV biofeedback and non-invasive vagus nerve stimulation (nVNS) are behavioural therapeutic and stimulatory methods, respectively, for modulating the autonomic nervous system, particularly its parasympathetic component. HRV biofeedback uses real-time feedback of heart rate variability (HRV) to train rhythmic breathing, while nVNS applies electrical or mechanical stimuli to the vagus nerve. Both methods originate from psychophysiology and are often combined with relaxation techniques.

EVIDENCE BASE:
1,301 evaluated studies · 466 controlled human trials · 459 observational studies · 105 review articles · 10 animal studies · 1 cell culture study

- STRONGEST EVIDENCE:**
- Episodic cluster headache Double-blind, sham-controlled trials demonstrate significant efficacy of nVNS in episodic cluster headache (response rate 34.2–48% vs. 6–13% sham), but no effect in the chronic form. Short-term safety and tolerability are established, though long-term data are lacking.
 - **Safety and tolerability:** nVNS and HRV biofeedback cause mild, transient side effects such as local skin irritation or pain at the stimulation site. Systematic long-term studies on tolerability or rare adverse effects do not exist.
 - Migraine (preventive) A multicentre, randomised trial (PREMIUM) found no significant difference in the reduction of migraine days between nVNS and sham. However, post-hoc analyses in high-compliance subgroups showed significant effects (2.27 vs. 1.53 days).
 - Cognitive effects and stress HRV biofeedback consistently produces measurable HRV changes, but clinical effects on cognition or stress (e.g., subjective scales) are not reliably established. Combination studies complicate the attribution of specific effects.
 - Depression The most cited study on HRV biofeedback for depression was open-label and uncontrolled. Controlled trials show no consistent effects on depression scores, despite detectable HRV changes.

- LIMITATIONS:**
- Long-term effects Nearly all studies examine short-term effects (weeks to months). Sustained efficacy or long-term tolerability remains unknown.
 - Patient selection It is unclear which patient groups (age, comorbidities) benefit most. Systematic research on optimising target populations is lacking.
 - Dose-response relationship It is unresolved whether longer or more intense stimulation yields better effects or if habituation occurs. Optimal stimulation parameters are undefined.

CLASSIFICATION:
HRV biofeedback and non-invasive vagus nerve stimulation are safe methods for modulating the autonomic nervous system, with demonstrated HRV changes. However, their clinical efficacy is limited and only established for specific indications (e.g., episodic cluster headache).

Download this page as PDF · Summary

1. What HRV Biofeedback and Vagus Nerve Training Are

HRV biofeedback is a behavioural therapeutic method in which patients receive real-time feedback on their heart rate variability (HRV) via sensors. The goal is to learn rhythmic breathing to enhance coherence between heartbeat and respiration. The method originates from psychophysiology and is often combined with relaxation techniques. Non-invasive vagus nerve stimulation (nVNS) uses electrical or mechanical stimuli (e.g., via the ear or neck) to activate the vagus nerve. Both approaches aim to modulate the autonomic nervous system, particularly by strengthening the parasympathetic component.

The common denominator of both methods is the measurement of HRV as a key biomarker. HRV describes the temporal fluctuations between successive heartbeats and is considered an indicator of the adaptability of the autonomic nervous system. While HRV biofeedback relies on behavioural change, nVNS acts through direct stimulation. Both approaches are often combined with breathing techniques, meditation, or cognitive training. Implementation varies: HRV biofeedback is typically delivered via mobile devices or laboratory setups, while nVNS uses transcutaneous stimulators. A critical consideration in interpreting studies is that HRV changes do not automatically equate to clinical effects.

2. What the Studies Show in Detail

The pivotal human studies and key reviews—organised by application, including population, duration, preparation, outcome measures, and results—as reported in the original publications. Numbers are included only where explicitly stated in the studies.

Distribution of controlled human studies by field of application — the figures cannot be summed as a single study may be assigned to multiple fields:

FIELD OF APPLICATION	CONTROLLED STUDIES
Cognition and mental health	242
Safety and tolerability	176
Fatigue and stress	175
Musculoskeletal system	86

FIELD OF APPLICATION	CONTROLLED STUDIES
Inflammatory processes	60
Heart and circulation	50
Immune system	43
Gut and microbiome	34

Safety and Tolerability

Participants received either nVNS or sham stimulation for up to 1 month. The primary endpoint was the response rate, defined as pain freedom at 15 minutes without rescue medication. In the subgroup with episodic cluster headache (eCH), nVNS showed a significant effect (34.2% vs. sham). In chronic cluster headache (cCH), no difference was observed. The study suggests that nVNS may be safe in eCH, but data on long-term tolerability are lacking ².

The response rate at 15 minutes was 48% in the nVNS group and 6% in the sham group for eCH (P < 0.01), whereas no difference was observed in cCH (5% vs. 13%). The study provided a hint of an effect of nVNS in eCH but no effect in cCH. The most common adverse effects were local skin irritation and transient pain at the stimulation site. The study highlights the tolerability of nVNS, though data on long-term use are lacking ³.

A multicentre, randomised, double-blind, sham-controlled study (PREMIUM) involving 477 patients investigated nVNS for the preventive treatment of episodic migraine. Participants were instructed to perform two 120-second stimulations three times daily over 12 weeks. The primary endpoint (reduction in monthly migraine days) showed no significant difference between nVNS (2.26 days) and sham (1.80 days, P = 0.15). However, a post-hoc analysis of participants who completed at least 67% of the prescribed stimulations revealed a difference (2.27 vs. 1.53 days, P = 0.043). The study suggests that nVNS could have an effect with good compliance, though data on the optimal stimulation dose and duration are lacking.

Assumption: The available studies indicate that nVNS and HRV biofeedback are generally well tolerated, causing only mild, transient side effects such as local skin irritation or pain at the stimulation site. Safety appears plausible even with prolonged use, though systematic long-term studies are still pending.

Systematic investigations into the long-term tolerability of nVNS and HRV biofeedback, as well as data on rare but potentially serious adverse effects, stand out as areas where further research is needed.

Overall Picture

Methodology of the evidence base

The existing studies on HRV biofeedback and vagus nerve training encompass a broad spectrum of designs, including open-label pilot studies, randomised controlled trials (RCTs), and observational studies. Typical study durations range from single sessions to several weeks or months, with most interventions conducted over 4–12 weeks. Primary endpoints vary by application and include psychometric scales (e.g., HAM-D, BDI-II), physiological parameters (e.g., HRV, baroreflex sensitivity), inflammatory markers (e.g., CRP, IL-1β), and clinical outcomes such as pain freedom or reduction in migraine days. However, systematic long-term studies with follow-up phases exceeding six months, direct comparisons with established therapies, and studies with sufficient power to detect rare adverse effects are lacking. Additionally, many studies are limited by small sample sizes, lack of blinding, or inadequate control of placebo effects.

HRV biofeedback and nVNS: Mechanisms without clinical proof?

The **MOST COMMON ASSUMPTION** is that HRV biofeedback and nVNS have been investigated for **strengthening the parasympathetic nervous system** to **inhibit inflammation, reduce stress, or enhance cognitive performance**; however, controlled results are inconsistent. While **controlled studies** demonstrate **consistent HRV changes**, **clinical endpoints** (e.g., depression remission or pain reduction) are rarely achieved. The **most frequently cited study on depression** was **open-label and uncontrolled**—its citation frequency reflects scientific interest, not evidence. Even in **cluster headache**, where nVNS was tested in **double-blind studies**, the **effects are moderate and not observed in all patients**.

A **CENTRAL ISSUE** is the **conflation of mechanism and effect**. HRV changes are a **physiological marker**, not a **clinical outcome**. **Review articles** emphasise that **biofeedback** may **optimise breathing patterns** but does not constitute a **causal therapy**. For nVNS, it remains unclear whether **vagus nerve stimulation** genuinely induces the investigated **central nervous system effects**. **Animal studies** demonstrate **anti-inflammatory effects**, but **human data are still emerging**. Even in **migraine**, the **difference from sham control was minimal**. The **high citation count** of many studies obscures their **methodological limitations**.

3. How Robust the Research Is

The **controlled human studies examined** represent a substantial portion of the evidence base for HRV biofeedback and vagus nerve training, alongside a comparable number of **observational studies**. Among these studies, **depression, cluster headache, and migraine** are the most frequently investigated applications, while **cognition and fatigue** are also common. **Inflammation, cardiovascular, and oncology** outcomes are far less common within this field.

Basic science and mechanism reviews dominate citation frequency, indicating a strong interest in mechanisms of action for these methods. Animal and cell studies play a subordinate role in this research area.

The methodological quality of the studies is heterogeneous. Double-blind, sham-controlled designs are primarily found in nVNS studies (e.g., for cluster headache or migraine), whereas HRV biofeedback is often investigated in open-label or single-blind studies. Cognitive effects and fatigue are frequently measured using subjective scales, which may favour placebo effects and do not constitute evidence of clinical efficacy. Safety data are robust, but long-term studies are lacking. Review articles highlight that while HRV changes are consistently detectable, they do not constitute evidence of clinical efficacy. Combination studies (e.g., with mindfulness or exercise) complicate the isolation of effects.

4. Common Claims—and What the Data Show

CLAIM	EVIDENCE BASE
HRV biofeedback is effective for depression	The most-cited study was open-label and uncontrolled. Later controlled studies show no consistent effects on depression scores. HRV changes are detectable.
nVNS helps with chronic pain	For cluster headache and migraine, there are double-blind studies, but no long-term data. For other pain syndromes (e.g., fibromyalgia), the data are limited.
HRV biofeedback improves cognitive performance	The studies examined measure subjective scales or short-term effects. Long-term cognitive improvements are not substantiated. Combination studies (e.g., with mindfulness or exercise) complicate the isolation of effects.
A pilot study on rheumatoid arthritis was small and uncontrolled. No robust clinical recommendations can be made.	

5. The Most Robust Studies

Ranked by evidential strength, not by prominence. The full evaluation includes significantly more studies; only the most reliable are listed here.

Controlled Human Studies

- 1 Preliminary results of an open label study of heart rate variability biofeedback for the treatment of major depression (2007)
- 2 Non-Invasive Vagus Nerve Stimulation for the ACute Treatment of Cluster Headache: Findings From the Randomized, Double-Blind, Sham-Controlled ACT1 Study (2016)
- 3 Non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A randomized, double-blind, sham-controlled ACT (2018)
- Non-invasive vagus nerve stimulation acutely improves spontaneous cardiac baroreflex sensitivity in healthy young men: A randomized placebo-controlled trial (2017)
- 4 Heart rate variability biofeedback as a behavioural neurocardiac intervention to enhance vagal heart rate control (2005)
- Non-invasive vagus nerve stimulation (nVNS) for the preventive treatment of episodic migraine: The multicentre, double-blind, randomised, sham-controlled trial (2019)
- Short-term transcutaneous non-invasive vagus nerve stimulation may reduce disease activity and pro-inflammatory cytokines in rheumatoid arthritis: Results of a pilot study (2021)
- A randomised controlled trial comparing daily mindfulness meditations, biofeedback exercises, and daily physical exercise on attention control, executive functioning, and mindful awareness (2016)
- 5 Heart rate variability biofeedback based on slow-paced breathing with immersive virtual reality nature scenery (2019)
- 6 Open-label pilot study: Non-invasive vagal nerve stimulation improves symptoms and gastric emptying in patients with idiopathic gastroparesis (2020)
- 7 Combined heart rate variability and pulse oximetry biofeedback for chronic obstructive pulmonary disease: Preliminary findings (2004)
- Non-invasive brain stimulation techniques for the improvement of upper limb motor function and performance in activities of daily living after stroke: A systematic review (2023)
- 8 Non-invasive stimulation of vagal afferents reduces gastric frequency (2020)
- 9 Non-invasive vagus nerve stimulation enhances mood recovery after effort exertion (2022)
- Neurophysiological approach by self-control of the stress-related autonomic nervous system in patients with depression, stress, and anxiety (2021)
- 10 Increasing coordination and responsivity of emotion-related brain regions with a heart rate variability biofeedback randomised controlled trial (2023)
- Inter-ictal assay of peripheral circulating inflammatory mediators in migraine patients under adjunctive cervical non-invasive vagus nerve stimulation (nVNS) (2019)

- Non-invasive vagus nerve stimulation for COVID-19: Results from a randomised controlled trial (SAVIOR I) (2022)
- ¹¹ Effects of heart rate variability biofeedback on EEG alpha asymmetry and anxiety symptoms in male athletes: A pilot study (2016)
- ¹² Non-invasive vagal nerve stimulation decreases brain activity during trauma scripts (2020)
- ¹³ Non-invasive vagus nerve stimulation for migraine: A systematic review and meta-analysis of randomised controlled trials (2023)
- Vagus nerve stimulation in ischaemic stroke: A systematic review (2023)
- ¹⁴ Heart rate variability biofeedback for paediatric irritable bowel syndrome and functional abdominal pain: A clinical replication series (2014)
- ¹⁵ One-year cardiovascular prognosis of the randomised, controlled, short-term heart rate variability biofeedback trial among patients with coronary artery disease (2018)

6. Summary

1) **What is established:** HRV biofeedback and nVNS are safe and well-tolerated, with mild, transient side effects such as local skin irritation. In episodic cluster headache, nVNS showed efficacy in double-blind studies (response rate 34–48%), whereas no effects have been shown for the chronic form. For migraine, one study suggests a potential preventive effect with high compliance, though without a significant difference in the primary endpoint. HRV changes are consistently detectable but do not constitute evidence of clinical efficacy. The evidence base is heterogeneous, with methodological limitations such as small sample sizes, lack of blinding, or placebo effects. Safety and mechanisms have been studied more extensively than clinical outcomes.

2) **What is plausible and what this might imply (hypothesis):** **Hypothesis:** The methods may exert anti-inflammatory or stress-reducing effects via parasympathetic enhancement, though controlled human trials on this are limited. **Hypothesis:** HRV biofeedback could serve as a supportive measure in combination with other therapies (e.g., mindfulness) without acting as a standalone causal treatment. **Hypothesis:** nVNS may represent an option for specific indications (e.g., episodic cluster headache) if long-term data confirm efficacy. **Hypothesis:** The discrepancy between HRV changes and clinical effects suggests that physiological markers cannot be automatically equated with therapeutic benefit. Combination studies complicate the isolation of specific effects, limiting the interpretation of results.

3) **What a study would need to clarify:** Systematic long-term studies with follow-up phases of at least 6–12 months are necessary to capture sustained effects and rare side effects. Direct comparisons with established therapies (e.g., medication, behavioural therapy) would better contextualise the clinical relevance of these methods. Studies with sufficient power and rigorous methodological standards (double-blinding, sham control) must determine whether HRV biofeedback or nVNS can be targeted to specific patient groups (e.g., by age, comorbidities). Additionally, the dose-response relationship should be investigated to define optimal stimulation parameters (duration, intensity, frequency). Finally, studies are needed to disentangle mechanisms (e.g., anti-inflammatory effects) from clinical outcomes to clarify the causal role of these interventions.

7. What Remains Unclear

- **Dose-response relationship:** It remains unclear whether **longer or more intensive stimulation** in the studied ranges yields better effects—or whether **habituation effects** occur.
- **Long-term effects:** Nearly all studies examine **short-term effects**. Whether **HRV biofeedback or nVNS** produce sustained benefits is **unknown**.
- **Patient selection:** Which **patient groups** (e.g., by age, pre-existing conditions) **benefit most** has **not been systematically investigated**.

Frequently Asked Questions

Can HRV biofeedback be used for anxiety disorders?

The **evidence base is limited**. A **meta-analysis** found **small effects** on **anxiety symptoms**, but **most studies** were **small and uncontrolled**. **HRV changes** are **detectable**, but **clinical relevance** remains **unclear**. When combined with **cognitive behavioural therapy**, it may have a **supportive role**, but it is **not a substitute for established treatments**.

Is nVNS suitable for treating Long COVID?

There are **no specific studies** on Long COVID. **Individual pilot studies** (e.g., on **fatigue** or **inflammation**) show **theoretical approaches**, but **no robust data**. Since **Long COVID** is heterogeneous, **individual assessment** would be required—**no general recommendation** can be made.

How reliable is HRV as a biomarker for therapeutic success?

HRV changes are **consistently detectable**, but **not a reliable predictor** of **clinical effects**. Studies show that **HRV biofeedback** increases **variability**, but this does **not indicate symptom improvement**. **Clinical endpoints** (e.g., pain, mood) must be **measured separately**.

Sources

- 1 Preliminary results of an open label study of heart rate variability biofeedback for the treatment of major depression
Karavidas MK, Lehrer PM, Vaschillo E, Vaschillo B, Marin H, Buyske S et al. · 2007
- 2 Non-Invasive Vagus Nerve Stimulation for the ACute Treatment of Cluster Headache: Findings From the Randomized, Double-Blind, Sham-Controlled ACT1 Study
Silberstein SD, Mechtler LL, Kudrow DB, Calhoun AH, McClure C, Saper JR et al. · 2016
- 3 Non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A randomized, double-blind, sham-controlled ACT2 study
Goadsby PJ, de Coo IF, Silver N, Tyagi A, Ahmed F, Gaul C et al. · 2018
- 4 Heart rate variability biofeedback as a behavioral neurocardiac intervention to enhance vagal heart rate control
Nolan RP, Kamath MV, Floras JS, Stanley J, Pang C, Picton P et al. · 2005
- 5 Heart Rate Variability Biofeedback Based on Slow-Paced Breathing With Immersive Virtual Reality Nature Scenery
Blum J, Rockstroh C, Göritz AS · 2019
- 6 Open-label pilot study: Non-invasive vagal nerve stimulation improves symptoms and gastric emptying in patients with idiopathic gastroparesis
Gottfried-Blackmore A, Adler EP, Fernandez-Becker N, Clarke J, Habtezion A, Nguyen L · 2020
- 7 Combined heart rate variability and pulse oximetry biofeedback for chronic obstructive pulmonary disease: preliminary findings
Giardino ND, Chan L, Borson S · 2004
- 8 Non-invasive stimulation of vagal afferents reduces gastric frequency
Teckentrup V, Neubert S, Santiago JCP, Hallschmid M, Walter M, Kroemer NB · 2020
- 9 Non-invasive vagus nerve stimulation boosts mood recovery after effort exertion
Ferstl M, Teckentrup V, Lin WM, Kräutlein F, Kühnel A, Klaus J et al. · 2022
- 10 Increasing coordination and responsivity of emotion-related brain regions with a heart rate variability biofeedback randomized trial
Nashiro K, Min J, Yoo HJ, Cho C, Bachman SL, Dutt S et al. · 2023
- 11 Effects of Heart Rate Variability Biofeedback on EEG Alpha Asymmetry and Anxiety Symptoms in Male Athletes: A Pilot Study
Dziembowska I, Izdebski P, Rasmus A, Brudny J, Grzelczak M, Cysewski P · 2016
- 12 Non-invasive vagal nerve stimulation decreases brain activity during trauma scripts
Wittbrodt MT, Gurel NZ, Nye JA, Ladd S, Shandhi MMH, Huang M et al. · 2020
- 13 Noninvasive vagus nerve stimulation for migraine: a systematic review and meta-analysis of randomized controlled trials
Song D, Li P, Wang Y, Cao J · 2023
- 14 HRV biofeedback for pediatric irritable bowel syndrome and functional abdominal pain: a clinical replication series
Stern MJ, Guiles RA, Gevirtz R · 2014
- 15 One-Year Cardiovascular Prognosis of the Randomized, Controlled, Short-Term Heart Rate Variability Biofeedback Among Patients with Coronary Artery Disease
Yu LC, Lin IM, Fan SY, Chien CL, Lin TH · 2018

International Health Research

Research, put in context. Every statement leads to the original paper; the decision in the individual case rests with the treating professional.
ih-research.com/en/knowledge/hrv-biofeedback-and-vagus-nerve-training/ · Last updated 2026-10-04