

An FDA-Cleared Option For Acute and Preventive Treatment



Prescribe gammaCore™
(non-invasive vagus nerve stimulator)
for patients living with Migraine
and Cluster Headache

Scientific and Clinical Support:

7 FDA Cleared Indications

7 Randomized Controlled Trials

>30 Mechanism of Action Peer Reviewed Papers

>40 Peer Reviewed Clinical Papers

Review

Cephalalgia  International Headache Society

Non-invasive vagus nerve stimulation for primary headache: A clinical update

Stephen D Silberstein¹, Hsiangkuo Yuan¹, Umer Najib¹, Jessica Alani², Andrea Lopes de Morais¹, Paul G Mathew^{3,4,7}, Eric Liebler⁴, Cristina Tassorelli^{1,10} and Hans-Christoph Diener¹¹

Abstract
Background: Non-invasive vagus nerve stimulation (nVNS) is a proven treatment for cluster headache and migraine. Several possible mechanisms of action by which nVNS induces headache have been identified.
Methods: We conducted a narrative review of recent scientific and clinical research into nVNS for headache, including findings from mechanistic studies and their possible relationships to the clinical effects of nVNS.
Results: Findings from animal and human studies have provided possible mechanistic explanations for nVNS efficacy in headache involving four core areas: Autonomic nervous system functions; cortical spreading depression inhibition; neurotransmitter regulation; and nociceptive modulation. We discuss how overlap and interplay among these areas may underlie the utility of nVNS in the context of clinical evidence supporting its safety and efficacy as acute and preventive therapy for both cluster headache and migraine. Possible future nVNS applications are also discussed.
Conclusions: Significant progress over the past several years has yielded valuable mechanistic and clinical evidence that, combined with the excellent safety and tolerability profile of nVNS, suggests that it should be considered a first-line treatment for both acute and preventive treatment of cluster headache, an effective option for acute treatment of migraine, and a highly relevant, practical option for migraine prevention.

Cephalalgia
ISSN 1472-7287
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DOI: 10.1177/1472728719851844
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Activate The Pain Relieving Power of the Vagus Nerve:

- ✓ The vagus nerve, the body's superhighway, modulates various systems and functions throughout the body
- ✓ nVNS offers a multimodal mechanism of action including: effects on autonomic nervous system functions, inhibition of cortical spreading depression, neurotransmitter regulation, nociceptive modulation
- ✓ The overlap and interplay of these mechanisms help to restore, reset, and replenish vagal parasympathetic balance

An FDA Cleared Treatment Administered By Your Patients:

- ✓ Safe and well tolerated non-drug treatment
- ✓ Avoids many drug like side effects
- ✓ Can be used with other medications, as necessary
- ✓ Can be used for multiple attacks per day (up to 24 stimulations)

Scan here to visit
[gammaCore.com](https://www.gammaCore.com)



Please see reverse side for Indication and Important Safety Information

Indication and Important Safety Information

gammaCore™ (non-invasive vagus nerve stimulator) is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. gammaCore is indicated for:

- The preventive treatment of migraine headache in adolescent (age 12 and older) and adult patients.
- The acute treatment of pain associated with migraine headache in adolescent (age 12 and older) adult patients.
- Adjunctive use for the preventive treatment of cluster headache in adult patients.
- The acute treatment of pain associated with episodic cluster headache in adult patients.
- Treatment of hemicrania continua in adults.
- Treatment of paroxysmal hemicrania in adults.

- The effectiveness of gammaCore has not been established in the acute treatment of chronic cluster headache
- gammaCore is contraindicated for patients if they:
 - Have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
 - Have a metallic device, such as a stent, bone plate, or bone screw, implanted at or near the neck
 - Are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)
- Safety and efficacy of gammaCore have not been evaluated in the following patients:
 - Adolescent patients with congenital cardiac issues
 - Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
 - Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
 - Pediatric patients (younger than 12 years)
 - Pregnant women
 - Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia

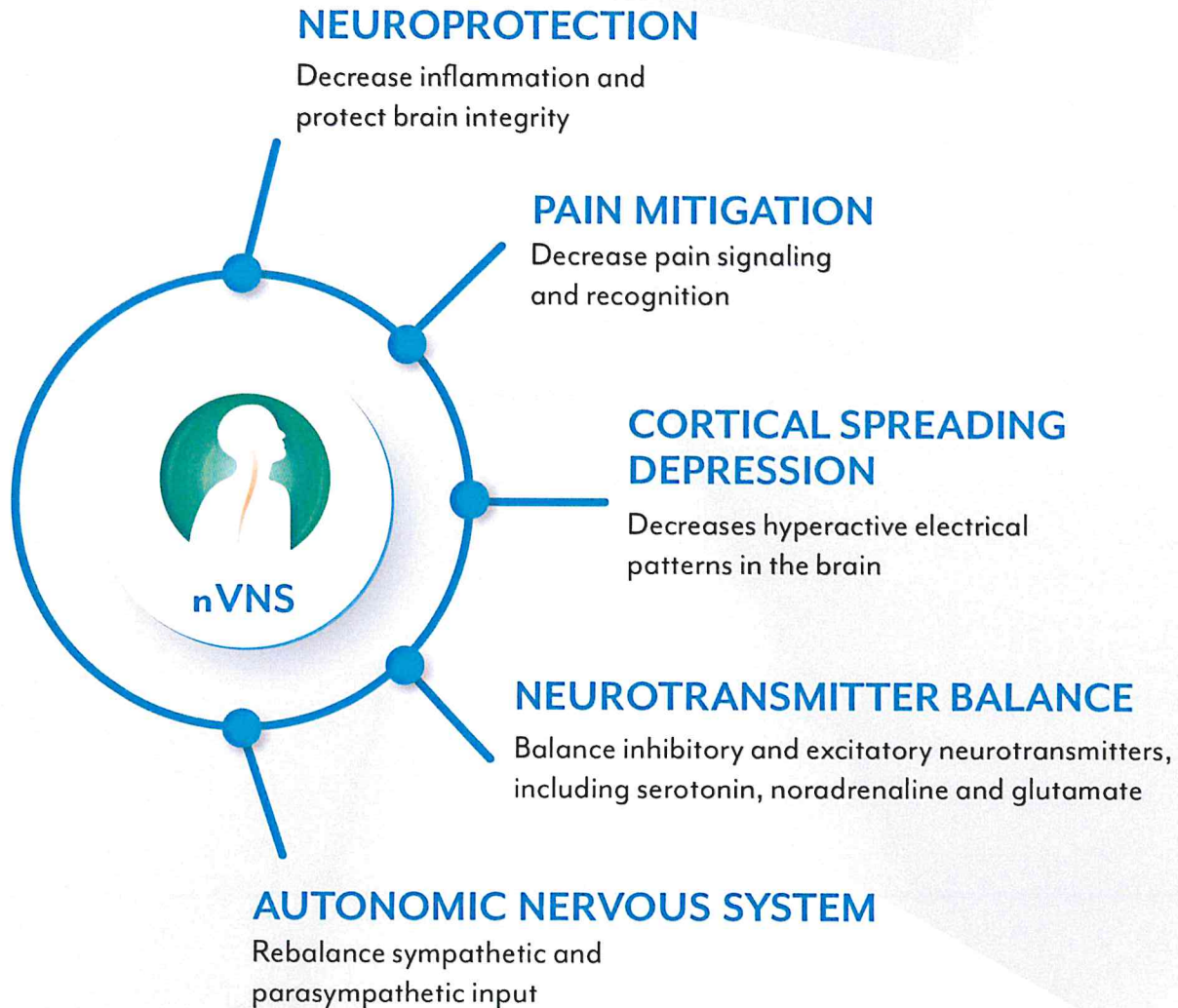
NOTE: This list is not all inclusive. Please refer to the gammaCore Instructions for Use for all of the important warnings and precautions before using or prescribing this product available at gammaCore.com.



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EPM-01323 Rev 1 Rel: 10/2021

Mechanisms of Action

Stimulating the vagus nerve offers a multi-modal mechanism of action, and the overlap and interplay of these mechanisms help to restore the sympathetic and the parasympathetic balance.



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Available by prescription only. US Federal Law restricts this device to sale by or on the order of a licensed healthcare provider. Please visit gammaCore.com for Important Safety Information and Instructions for Use.

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A Drug-free Option for Patients Living With Headache



An FDA-cleared option for acute and preventive treatment



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- Scan the QR code
- Visit gammaCore.com
- Contact Customer Service at: **888-903-2673** or customerservice@electrocore.com

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Involved Systems, Mechanisms of Action, and Clinical Effects of nVNS in Headache¹



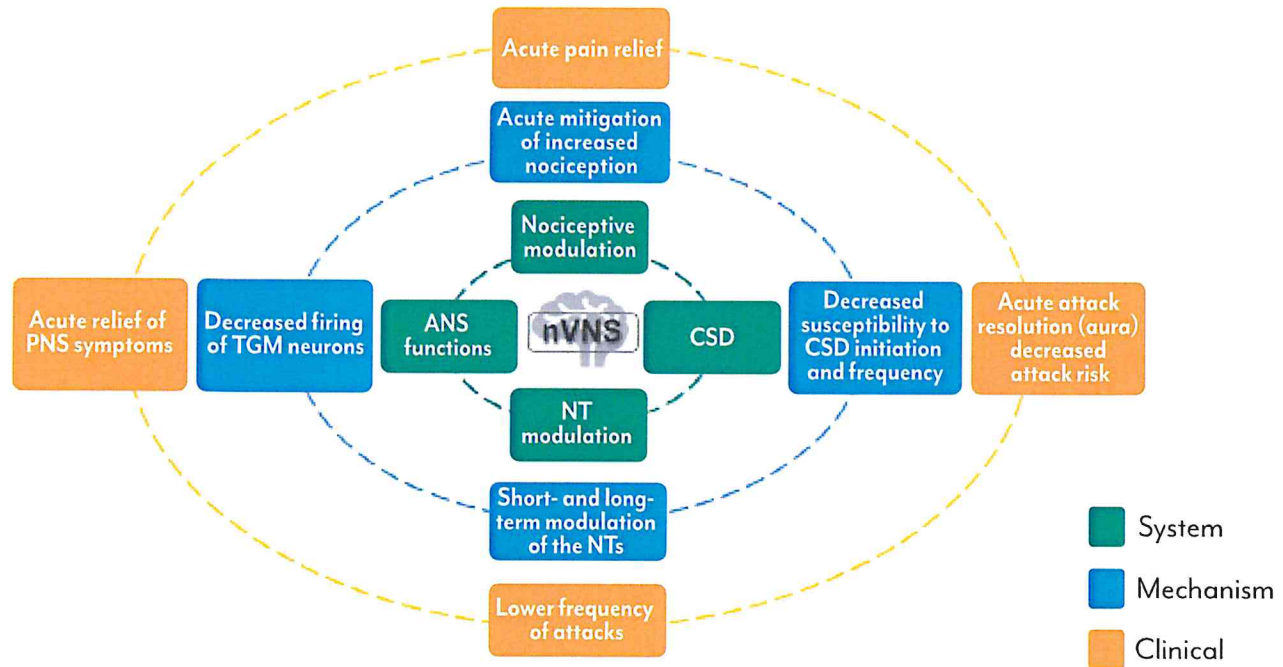
Effects on autonomic nervous system function



Inhibition of cortical spreading depression (CSD)



Neurotransmitter regulation and nociceptive modulation



ANS: autonomic nervous system; CSD: cortical spreading depression; NT: neurotransmitter; nVNS: non-invasive vagus nerve stimulation; PNS: parasympathetic nervous system; TGM: trigeminal.

Conclusion: “Significant progress over the past several years has yielded mechanistic and clinical evidence that, combined with the excellent safety and tolerability profile of nVNS, suggests that **it should be considered first-line treatment for both acute and preventive treatment of cluster headache**, an effective option for acute treatment of migraine, and a highly relevant, practical option for migraine prevention.”¹

Mild and transient adverse event profile²

When all available safety data was pooled from clinical studies, the following AEs occurred in >1% but <5% of patients (and are, therefore "common"). There were no reported side effects that occurred in >5% of study patients.

AEs Reported in >1% of Participants	
Application site discomfort	4.58%
Application site irritation/redness	3.39%
Local pain, face/head/neck area (including toothache)	2.75%
Muscle twitching and/or contractions, face/head/neck area (including facial droop and/or lip pull)	2.66%
Headache/migraine	2.57%
Dizziness	2.02%
Tingling, pricking, or a feeling of “pins and needles” on the skin where the device is applied (paresthesia/dysesthesia)	1.65%

Based on 1,091 patients.



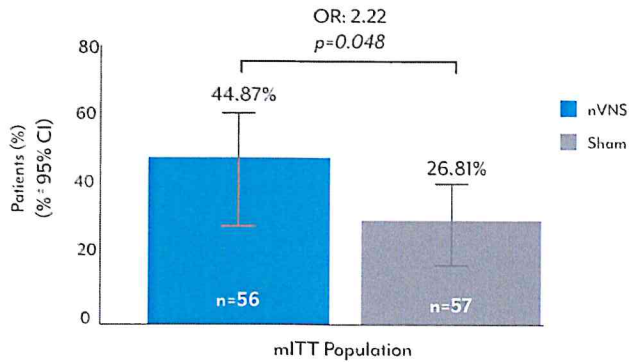
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Migraine

Prevent Migraine Pain

As published in *Cephalalgia*³

≥50% Responder Rate
Reduction in monthly migraine days



PREMIUM II study design: A prospective double-blind, sham-controlled, randomized trial evaluated the clinical safety and effectiveness of gammaCore in 113 patients. Patients were aged 18 to 75 years with a diagnosis of migraine with or without aura were instructed to self-administer treatment consisting of three 2-minute stimulations on either side of the neck, as follows: first daily treatment within 1 hour of waking, second daily treatment 4-6 hours following the first daily treatment, and a third daily treatment within 1 hour of going to sleep.

Safety and tolerability: Most AEs were mild and transient and occurred during the time of active treatment. None of the serious adverse events were considered device-related.

- ✓ Therapeutic gains with gammaCore were greater for patients with migraine with aura
- ✓ Safety and tolerability offer use as a stand-alone or adjunctive treatment
- ✓ Significant Quality of Life (as measured by HIT-6) improvement

Preventive Treatment for Migraine

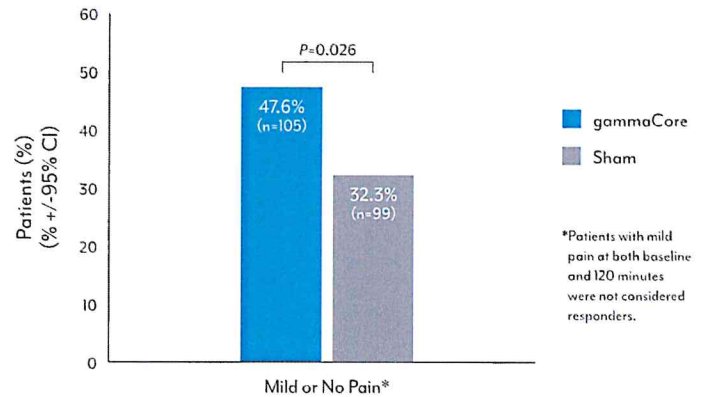
Daily:
A treatment consisting of 2-two minute stimulations on the same side of the neck at morning and night.



Relieve Migraine Pain

Class I evidence as published in *Neurology*⁴

≥50% Responder Rate
Migraines treated at 120 minutes



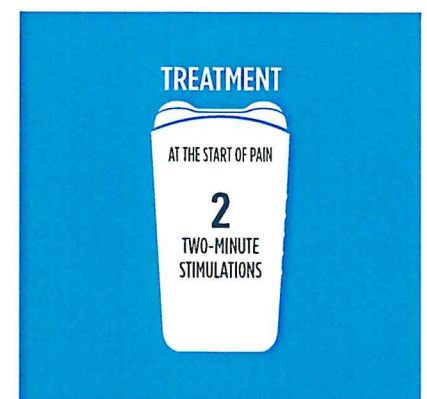
PRESTO study design: A double-blind, randomized, sham-controlled trial evaluated the efficacy, safety, and tolerability of gammaCore in 243 patients with migraine headache for 3 periods over 12 weeks. Patients were aged 18-75 years who had been diagnosed with migraine and experienced 3-8 migraine attacks per month and less than 15 headache days a month.

Safety and tolerability: Most AEs were considered mild and transient and occurred primarily during administration. The most common device-related AE ≥2% where gammaCore was greater than sham was application-site discomfort (2.5% vs. 0.8%).

- ✓ Fast relief from the first treated attack, as soon as 30 minutes
- ✓ Reduction in pain intensity over 3x greater than sham at 60 minutes and over 6x greater at 120 minutes
- ✓ 75% of patients who were pain-free at 2 hours were also pain-free at 24 hours

Acute Treatment for Migraine

At the earliest sign of pain:
A treatment consisting of 2-two minute stimulations on the same side of the neck as needed; repeat treatment if pain persists.

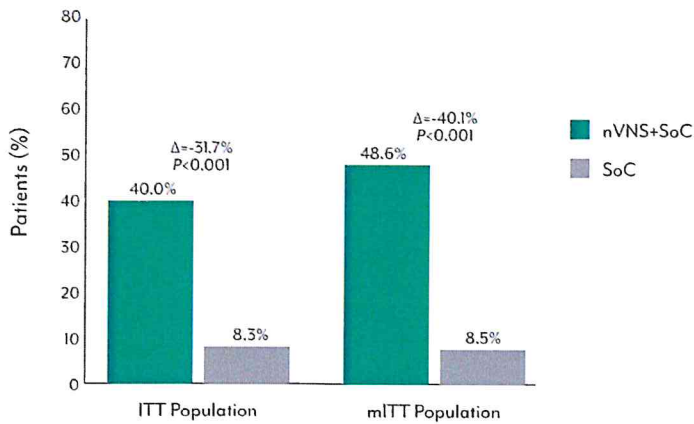


Cluster Headache (CH)

Prevent CH Pain

As published in *Cephalalgia*⁵

≥50% Responder Rate
Reduction in weekly CH attacks



PREVA study design: A prospective, open-label, randomized study compared adjunctive prophylactic gammaCore (n=48) with SoC alone (control [n=49]). Patients were aged 18-70 years and diagnosed with chronic cluster headache (cCH) ≥1 year before enrollment.

Safety and tolerability: Most adverse events (AEs) were considered mild or moderate. No serious AEs were considered device-related. The most common device-related AEs ≥5% where SoC + gammaCore was greater than SoC alone were headache (8% vs. 2%), oropharyngeal pain (6% vs. 2%), and neck pain (6% vs. 0%).

- ✓ 40% decrease in attack frequency from baseline
- ✓ 57% decrease in frequency of use of acute medication use
- ✓ A safe, well-tolerated, flexible drug-free therapy

Preventive Treatment Cluster Headache

Daily:
A treatment consisting of 2-two minute stimulations on the same side of the neck at morning and night.*

*Additional treatments may be recommended for cluster headache and other trigeminal autonomic cephalalgias

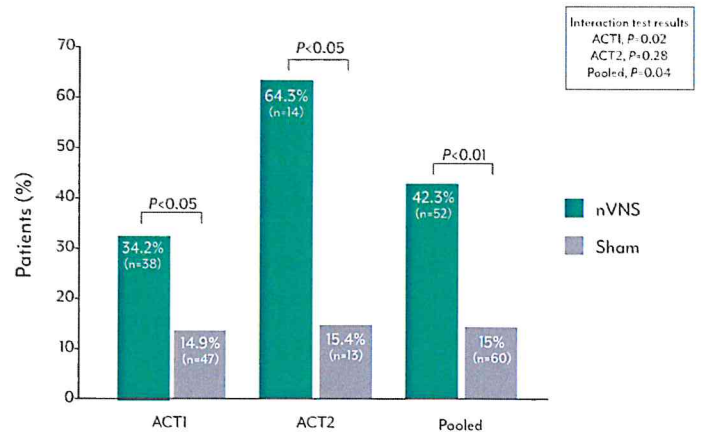


Relieve Episodic CH Pain

As published in *Headache and Cephalalgia*^{6,7,8}

ACT1/ACT2 Pooled Analysis (eCH Subgroup Data)

≥50% Responder Rate
CH attacks treated at 15 minutes



ACT1 study design: A randomized, double-blind, sham-controlled clinical study measuring the percentage of people who responded after gammaCore to treat their first attack. 150 cluster headache patients (101 eCH, 49 cCH) were chosen and instructed to treat their attack at the onset of pain with 3 two-minute stimulations.^{8,9}

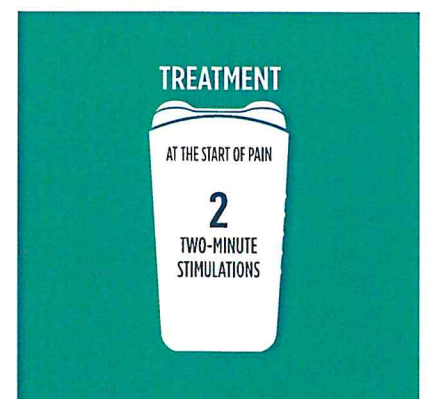
ACT2 study design: A randomized, double-blind, sham-controlled clinical study measuring the percentage of total attacks that were pain-free 15 minutes after using gammaCore. 102 cluster headache patients (30 eCH, 72 cCH) were chosen and instructed to treat their attack at the onset of pain with 3 two-minute stimulations (they could administer 3 additional two-minute stimulations if pain persisted).^{8,9}

Safety and tolerability: Most AEs were considered mild and transient and occurred primarily during administration. No serious AEs were considered device-related. The most common device-related AE ≥5% where gammaCore was greater than sham was lip or facial drooping/pulling/twitching (11% vs. 0%).

- ✓ Fast relief from the first treated attack, as soon as 15 minutes
- ✓ Reliable relief for at least half of treated attacks
- ✓ Reduction in the duration and intensity of attacks

Acute Treatment for Cluster Headache

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A treatment consisting of 2-two minute stimulations on the same side of the neck as needed; repeat treatment if pain persists.





A Drug-free Option for Patients Living With Headache



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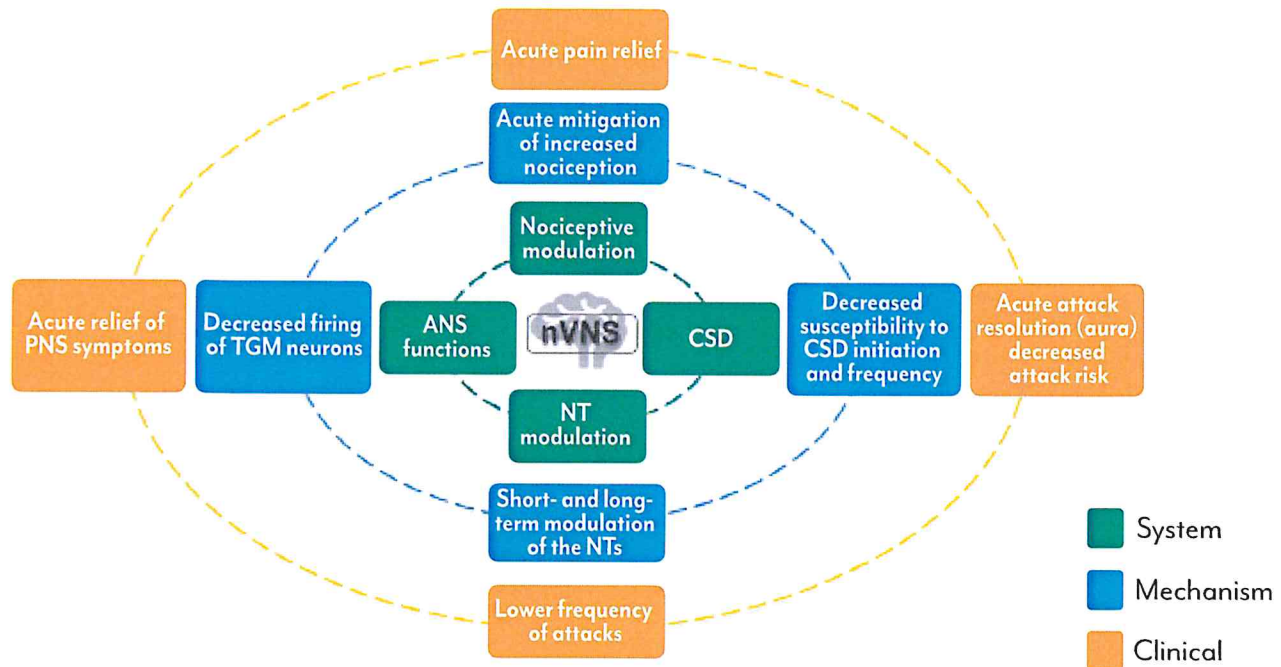
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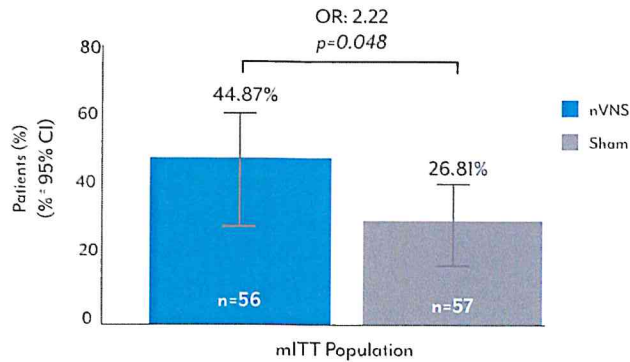
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Migraine

Prevent Migraine Pain

As published in *Cephalalgia*³

≥50% Responder Rate
Reduction in monthly migraine days



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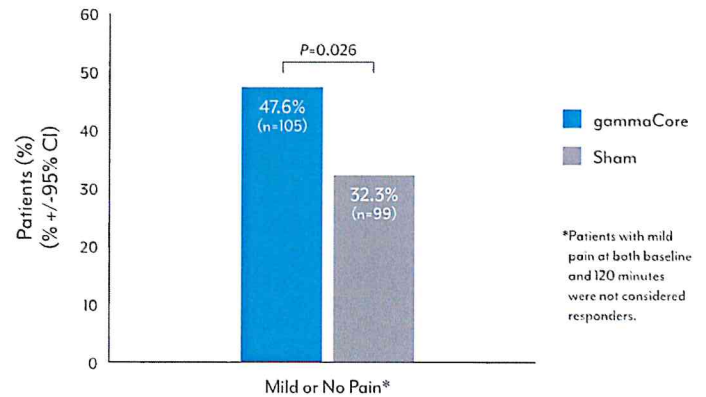
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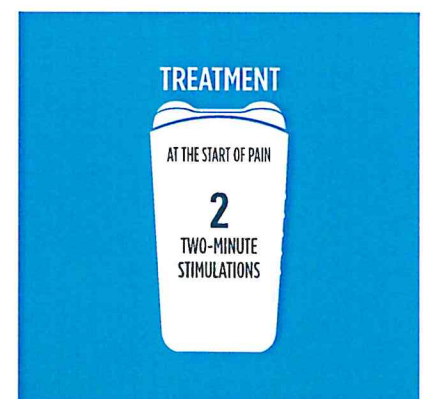
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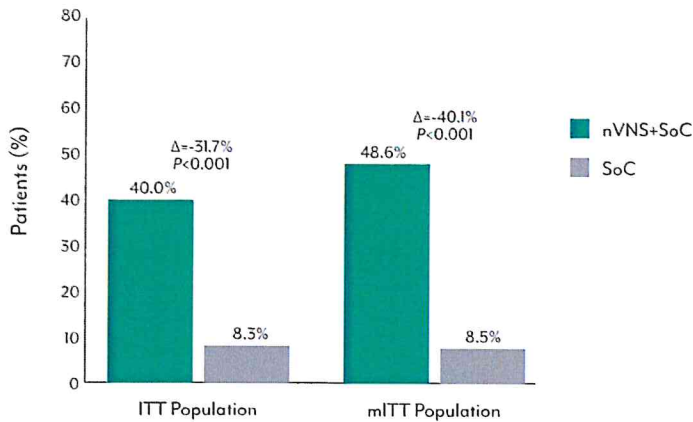


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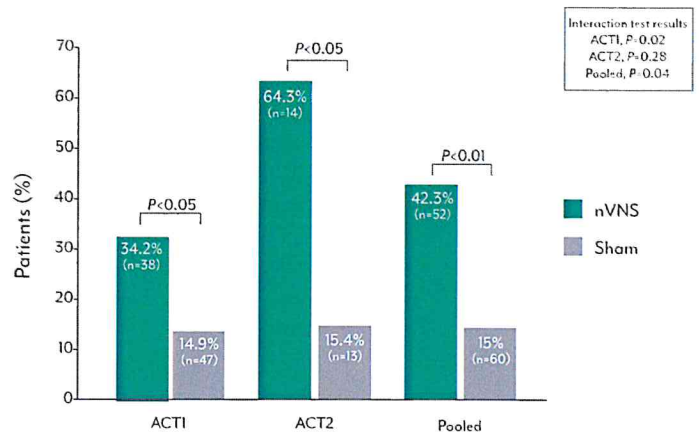


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