

Are Sleep Issues the Symptom or the Cause?

The Interaction of Nasal and Sinus Congestion With Sleep Issues



Over 85 million consumers over the age of 18 experience inflammation-related symptoms related to allergies, congestion, head pain, and sinus issues. 91% of these consumers have sleep issues such as trouble sleeping and waking up often, snoring, and obstructive sleep apnea. A recent study with over 2,000 consumers by Intellego Insights commissioned by Tivic Health highlights very interesting unmet needs related to sleep.



67% of consumer indicate they snore. 53% of those indicate the trouble sleeping is moderate to severe. And 32% indicate they have obstructive sleep apnea. 49% indicate they have tried everything, but nothing seems to relieve their sleep issue. Top side effects of their current treatments to address their symptoms include drowsiness, anxiety, and irritability.

When you experience sleep issues, what is your first course of action? What dissatisfactions and pain points do you have, and what workarounds or homemade solutions do you try? How do these findings compare to your routines and unmet needs?

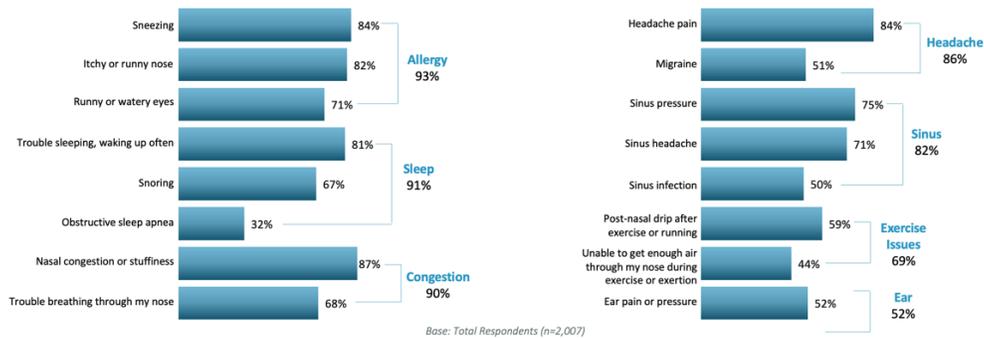


SYMPTOMS

Incidence of Symptoms

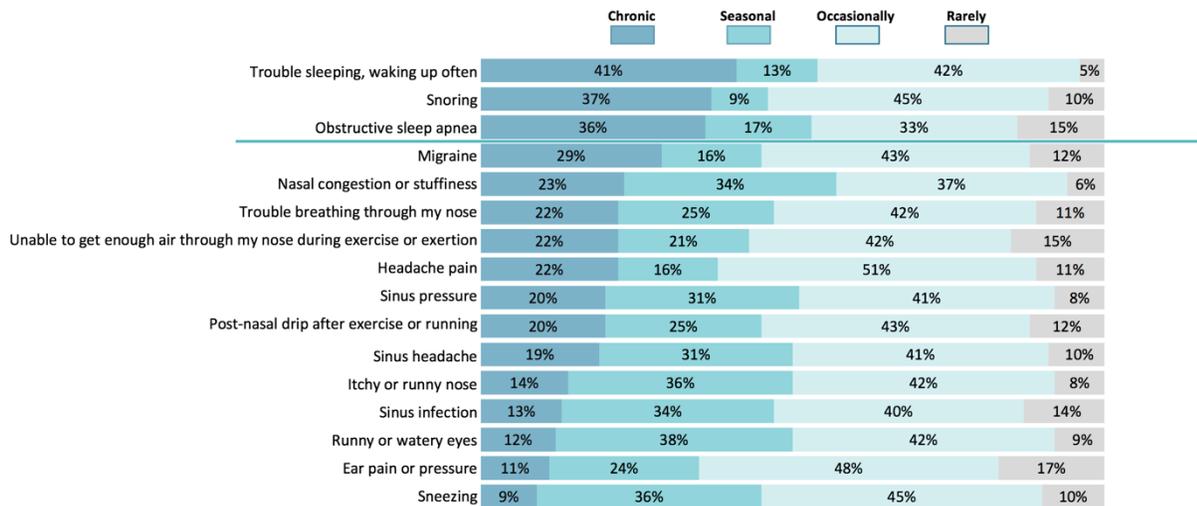
Sleep issues were among the top symptoms experienced by the consumers. 93% experienced allergies, 91% experienced sleep issues, and 90% experienced congestion, and 86% experienced head pain, while 82% experienced sinus issues.

% Experiencing Each Symptom



The most *chronic* symptoms are all sleep-related:

- Trouble sleeping, waking often
- Snoring, and
- Obstructive sleep apnea



Base: Experience Symptom (Varies)
How frequently do you experience each of the following?

The Relationship Between Sleep and Congestion

Most consumers that have inflammatory symptoms associated with nasal congestion, sinus pressure, and head pain also experience sleep issues. Congestion can have a significant impact on sleep quality. When a person is congested, the nasal passages and airways become narrowed, making it harder to breathe. This can result in snoring, breathing disruptions, mouth breathing, and even sleep apnea, which can all disrupt the sleep cycle and lead to poor sleep quality.

When a person's breathing is compromised due to congestion, the body may also have to work harder to get enough oxygen, which can cause the person to wake up feeling tired and groggy. Congestion can also lead to coughing, sneezing, and a sore throat, all of which can disturb sleep and prevent a person from getting the rest they need.

Additionally, congestion can cause discomfort and pain, making it difficult for a person to fall asleep. Congestion can also lead to headaches and sinus pressure, which can make it even harder to fall asleep. It is important to address the underlying cause of congestion to improve sleep and overall health.

The publication in NIH titled, [Sleep disruption in chronic rhinosinusitis](#), by Mahboobeh Mahdavinia, Robert P. Schleimer, and Ali Keshavarzian, indicates a relationship between the common disease of the upper airways and paranasal sinuses with a decline in quality of life related to sleep disruption.*

Chronic rhinosinusitis (CRS) is a common disease of the upper airways and paranasal sinuses with a marked decline in quality of life (QOL) and leads to CRS patients suffering from sleep disruption at a significantly higher proportion (60 to 75%) than in the general population (8–18%). This sleep disruption in CRS causes decreased QOL and is linked to poor functional outcomes such as impaired cognitive function and depression.

*<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5967413/>

What Causes Snoring

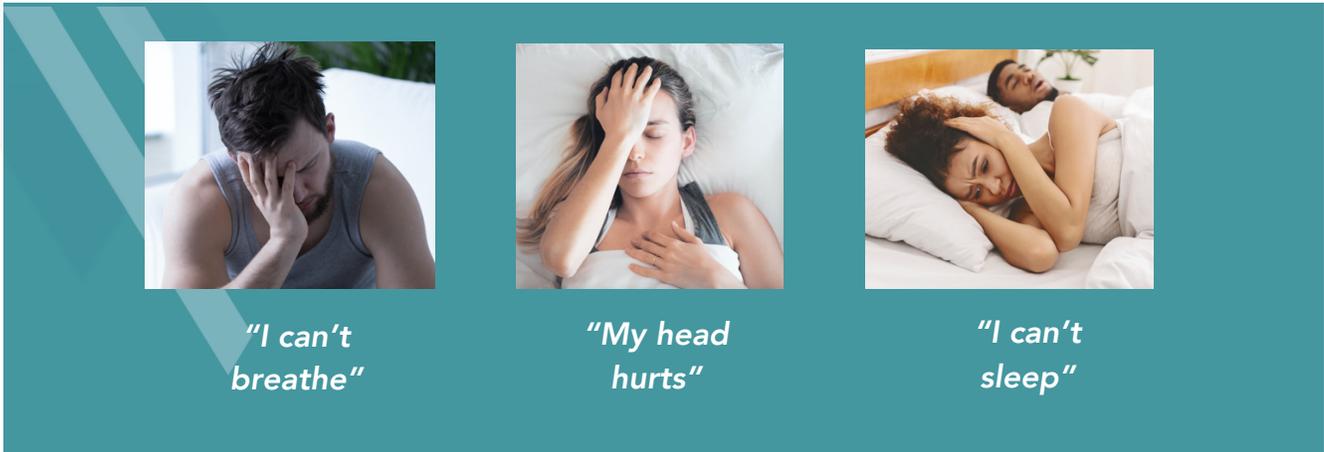
Snoring can be caused by a variety of factors, including mouth breathing. When you breathe through your mouth, it can cause the tissues in the back of your throat to vibrate, resulting in the sound of snoring. Mouth breathing can also cause your tongue and other tissues in your mouth to relax and fall back, further narrowing your airway and contributing to snoring.

However, snoring can also be caused by other factors such as obesity, sleep apnea, alcohol consumption, nasal congestion and certain medications.

Do you snore, and / or does your partner snore? While 67% of consumers in this study indicate they snore; 37% indicate they have a partner who snores. Of those who indicate their partner snores, 71% have issues falling asleep and staying asleep.

Sleep Cross-Symptom Incidence

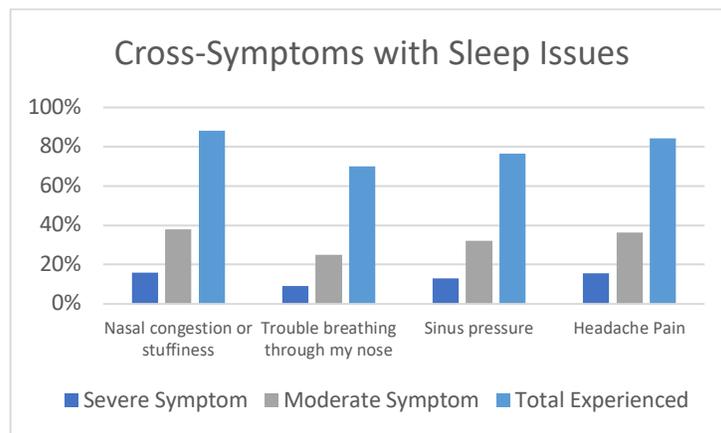
Since sleep issues are so common, the cross-symptom incidence closely mirrors that of the total sample in the research. Among those with sleep issues, they also had nasal congestion (88%), headache pain (84%), sinus pressure (77%), and trouble breathing through my nose (70%).



Among those with *moderate* or *severe* sleep issues, the incidence of also having *moderate* or *severe* additional symptoms are as follows. For example, 62% of moderate or severe sleep sufferers, also experience moderate or severe sinus issues.

Moderate to Severe Sleep sufferers (n=1,323)	Also experience Moderate to Severe other symptoms: %
Sinus	62
Allergy	63
Congestion	64
Headache	62
Exercise	43
Ear	27

Specific *moderate* or *severe* symptoms are related to congestion, pressure, and pain.



Base: Total Respondents (n=2,007)

Of the respondents with sleep issues:

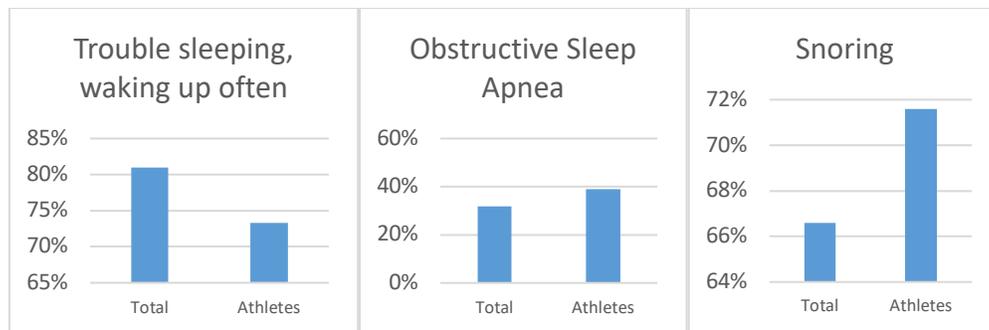
- 63% have allergies
- 22% have sinus infections that turn into bacterial infections
- 21% have dental pain
- 19% are regular smokers
- 17% have chronic sinusitis (3+ episodes a month)
- 15% have asthma
- 11% have TMJ
- 8% use a CPAP device

Sleep and Exercise

Exercise can help you sleep better. Regular physical activity has been shown to improve sleep quality and duration, as well as reduce the time it takes to fall asleep. Exercise can also help regulate your body's circadian rhythm, which is the internal biological clock that controls your sleep-wake cycle.

However, it's important to note that the timing and intensity of exercise can also impact sleep. Exercising too close to bedtime can increase your heart rate and body temperature, making it harder to fall asleep. It's generally recommended to finish moderate to vigorous exercise at least 3 hours before bedtime.

Additionally, some people may find that exercising too intensely or for too long can interfere with sleep, so it's important to listen to your body and adjust your exercise routine as needed. The data from this research indicates that self-described Athletes* don't have as much trouble sleeping as the total (73.3% vs 81%), but they do directionally have higher incidence of obstructive sleep apnea (39% vs 31.7%) and they snore more (71.6% vs 66.6%).



Base: Total Respondents (n=2,007)

Q.10 In the past 12 months which of the following, if any, did you experience? (Select one on each row.)

*Athletes, n=405, a sub-group that agreed that "I consider myself an athlete (e.g. played athletics in college, currently participate in competitive events, run 5K or more, play in an adult sports league, etc).

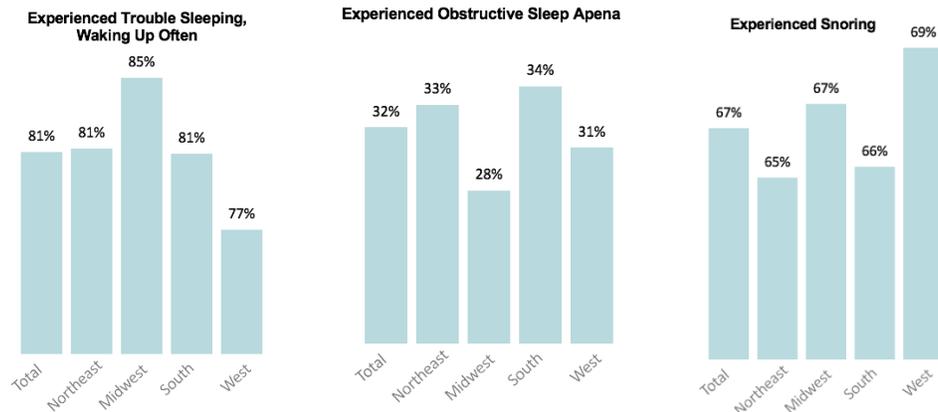
Regional Differences

Sleep issues were common across the United States, but there were differences by region.

Trouble Sleeping - Those living in the Midwest (85.3%) had significantly more trouble sleeping, waking up often than those in the West (76.9%). In the West, 23.1% indicated they did not experience trouble sleeping vs 14.7% in the Midwest, compared to 18.8% average across the country.

Sleep Apnea – Those living in the South (34%) had a significantly higher incidence of obstructive sleep apnea than those in the Midwest (28%).

Snoring – Incidence was 67%. Consumers in the West reported directionally higher snoring incidence, but that is not a statistically significant difference.



Base: Total Respondents (n=2,007)

Q.10 In the past 12 months which of the following, if any, did you experience? (Select one on each row.)



ROUTINES

Current Routines & Pain Points

Most consumers take medication for their symptoms, but they try to avoid medication, if at all possible. 94% of the consumers indicated they used medication for their symptoms, while 70% used natural remedies (e.g., humidifiers and herbal teas), and 14% used bioelectronic devices (e.g., for migraine or sinus relief).

While the vast majority of consumers use medication, many have limitations or have experienced side effects.

- 58% try to avoid medication, if at all possible.
- 37% indicate they cannot tolerate the side effects of medication.

Among those with sleep issues, many of these are *desperate Sleep Sufferers*.

49% agree "I have tried everything but nothing seems to relieve my sleep issues"

In this study, consumers with sleep issues indicate a range of side effects from their current medication-heavy routines. Fatigue, drowsiness, anxiety and irritability are the top side effects.

- 51% fatigue
- 40% drowsiness
- 30% anxiety
- 30% irritability
- 16% sadness
- 16% nose bleeds
- 13% medication dependence
- 10% safety concerns

n=1832

Have you experienced any of the following as a result of your current routine to address the symptoms you experience?

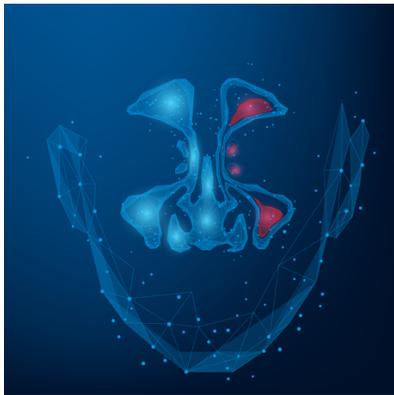
It is unclear if the frequency of sleep issues or headache is an original symptom from the inflammation, or if the use of medication is contributing to insomnia and/or headaches as one of their listed side effects.



CASE STUDY

ENT Example

Dr. Adam Spiess is a board-certified ENT (otolaryngologist) treating ear, nose, and throat conditions and early supporter of Tivic Health, creator of the ClearUP bioelectronic sinus device. Dr. Spiess describes how the nasal passages drain like an hourglass. The nose is divided in half by the nasal septum. Along the side are structures called turbinates that are like hot dogs that may swell from inflammation and cause sinusitis and nasal congestion. The lower turbinates are larger and are a main component of nasal congestion. The middle and superior turbinates are where the sinuses drain into narrow areas like an hour glass. If the narrow drainage pathway gets inflamed and swollen, the sinuses may not drain appropriately leading to sinusitis which may be acute or chronic. The inflammation is what causes the feeling of congestion, pressure, and pain.



Dr. Spiess focuses on the outcome of improving breathing so his patients can sleep better. When patients have chronic rhinitis, Dr. Spiess uses a toolkit of recommendations that include medication, bioelectronic sinus device, and sometimes even surgery to open the narrowed sinus drainage pathways. "Many of my patients don't want to take medication due to ongoing cost and side effects of continued medication use, including nose bleeds," says Dr. Spiess. "I recommend they try the FDA-approved Tivic ClearUP, and I have seen approximately an 80% success rate. My patients tell me they are grateful that I am using cutting edge technology to best meet their needs."

Dr. Spiess shared one case study of a 72 yr old male who had chronic frontal head pain due to allergic rhinitis. When this patient did not respond to nasal steroids, antibiotics, and oral steroids, he recommended that his patient try Tivic ClearUP. After a week of use as indicated, the patient felt a rush of drainage and has not had any pain or pressure since. ClearUP is indicated for use for sinus pain, pressure, and congestion, which can be caused by allergies, the flu, and the common cold.

Future Outlook

Sleep is critical to our functioning, but we are sleep-deprived. Whenever an industry has high unmet needs and pain points, there is room for innovation to better meet consumer needs. Drug-free relief, and solutions that don't adversely affect sleep will be welcomed by the many desperate sleep deprived sufferers. Blockage of airways and sinus pain, and sinus pressure in the sinus cavities due to allergic rhinitis also has the potential of decreased QOL due to sleep deprivation.

About Tivic Health

Tivic Health Systems, Inc. is a commercial-stage bioelectronic medicine company focused on treating diseases and conditions by modulating the electrical signals carried along various nerve pathways.

Its first FDA-approved product, ClearUP® Sinus Pain Relief ("ClearUP"), is a patented handheld device that uses ultra-low electrical current to relieve sinus pain and congestion, common symptoms of sinus and nasal inflammation. These symptoms are often associated with nasal allergies, sinus infections, chronic sinusitis, cold and flu, a \$9.9 billion U.S. market currently dominated by pharmaceutical companies. ClearUP, a non-invasive bioelectronic therapy, can safely and comfortably deliver therapeutic benefits with no significant side effects.

ClearUP is a US FDA Class II and EU Class IIa medical device that has received three regulatory clearances: (US FDA 510(k) number K182025, US FDA De Novo number DEN200006 and EU CE Mark Certificate number CE 704687). ClearUP is available on Amazon, Best Buy, Walmart and other major e-commerce websites.

The Tivic Health ClearUP Sinus Pain Relief device is intended to be used for the temporary relief of sinus pain associated with Allergic Rhinitis. ClearUP Sinus Relief device is also intended to be used for the temporary relief of moderate to severe congestion.

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