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<sup>1</sup>Mosca E; Remmers J; et al. In-home mandibular repositioning during sleep using MATRx plus predicts outcome and efficacious positioning for oral appliance treatment of obstructive sleep apnea. Journal of Clinical Sleep Medicine. Vol. 18, No. 3, March 2022.

<sup>2</sup>Sall E. Precision Oral Appliance Therapy: The Prime - Time Treatment for OSA. World Sleep Congress. Rome, Italy. Poster Abstract #289. March 2022.
<sup>3</sup>Smith K; et al. Efficacy of a Novel Precision Iterative Device and Material. World Sleep Congress. Rome, Italy. Poster Abstract #081. March 2022.
<sup>4</sup>Murphy M; et al. Device Design's Impact on Dose in Oral Appliance Therapy. Journal of Dental Sleep Medicine. Vol. 8, No. 3 2021. Abstract #004.

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#### Reflecting on a Year of Insightful Sleep Content and Collaboration

ow, this year flew by! It's been an exciting and fun year as editor of Sleep Lab Magazine. The varied content keeps things fresh and stimulating. I want to thank our many authors throughout the year who have contributed their knowledge, skills, and insights to the world of sleep health. Our regular columns from the

BRPT, AADSM, and one of our newest Wake Up Narcolepsy keep the readership up to date with information on their respective organizations. It's always good to see differing perspectives and provide specific insights to various viewpoints.

I have been privileged to work with every one of you and look forward to next year's adventures. In addition to our regular features, this edition features an update on fibromyalgia and sleep. We also feature an article on the impact of servant leadership and mentoring in the sleep clinic.

Thank you to our subscribers for your continued engagement with Sleep Lab Magazine. As you know, it is free to subscribe, and the content is easy to read and, hopefully, actionable in your practices.

I would encourage you to contact me if you have a specific topic you want to see covered, and we will do our best. In addition, please consider submitting an article for publication.

Thank you to our advertisers. Your continued support allows the magazine to be available to the sleep specialists everywhere.

This year has been challenging for many people in many countries. We hope people can find peace and healing in the coming year.

Thank you all again for a wonderful year, and look forward to 2024.

And Make Sleep Inquiry an Always Event.

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# **SLEEP** and Fibromyalgia

Joshua Roland, MD, FAASM

ibromyalgia is a complex chronic condition associated with pain, myalgias, and arthralgias, as well as a constitution of other debilitating symptoms such as fatigue and cognitive, gastrointestinal, sleep, and mood issues.<sup>1</sup> Sleep disturbances are a hallmark feature of the condition and have a significant bidirectional relationship with other symptomatology, especially pain.<sup>2</sup> Diagnostic criteria have slight variation between defining bodies such as the American College of Rheumatology, but generally include widespread pain across multiple sites in the body, along with sleep, fatigue, and other aforementioned associated symptoms all occurring for at least three months, without other physical exam, radiological, or laboratory explanations. Exact etiologies of fibromyalgia remain debated, but inflammatory, neuroendocrine, and autoimmune causes are speculated to interact with an array of biopsychosocial factors contributing to dysregulation of central nervous system mechanisms resulting in hypersensitivity to pain.<sup>3</sup> Due to the interconnection of etiological factors, progressive models for the treatment of fibromyalgia thus involve a multifaceted approach to address potential contributors. Exercise, counseling, stress reduction techniques, and potentially pharmacotherapy for mood and pain (typically in the form of tricyclic antidepressants, selective serotonin and norepinephrine reuptake inhibitors, or anti-epileptic drugs) are supported as part of a global therapeutic approach.<sup>4</sup> Addressing sleep issues is a crucial component of fibromyalgia management, both in terms of mitigating the sleep-related symptoms associated with the condition as well as sleep being a target for improving other symptoms such as pain and mood.



#### **SLEEP AND PAIN**

Sleep, a necessary and conserved process across nearly all species, impacts practically every human biological system. Its role in maintaining sound cognitive, mood, endocrine, and immune function has been well documented.<sup>5-7</sup> Factors contributing to pain and pain perception are complex, with contributions across multiple of these systems. Poor sleep has been shown to dysregulate components of these processes, resulting in increased sensitivity to pain.<sup>2</sup> Alternatively, having pain can worsen sleep quality and duration, perhaps leading to somewhat of an amplification feedback loop in fibromyalgia. This interaction between sleep and pain, with poor sleep having the ability to potentiate pain and pain contributing to disrupted sleep, is a key concept with multiple implications in the condition of fibromyalgia.

#### SUBJECTIVE AND OBJECTIVE SLEEP FINDINGS AND CO-MORBIDITIES

Sleep complaints in fibromyalgia can be diverse and varied, but issues with sleep onset, sleep maintenance, and sleep being non-restorative are consistently reported,<sup>8</sup> with the majority of individuals with fibromyalgia (potentially as high as 90%)<sup>9</sup> reporting some degree of sleep disturbance or quality impact. In addition to insomnia, other comorbid sleep disorders can further compound sleep disturbance and may be seen at a higher rate in fibromyalgia. Restless legs syndrome (RLS) has been reported to occur in approximately 38% of patients with fibromyalgia,<sup>10</sup> with medications used for mood and pain, such as SSRIs, SNRIs, and TCAs, also serving to potentially exacerbate RLS. The presence of RLS in fibromyalgia has been shown to worsen sleep quality, daytime sleepiness, and quality of life as measured by the Pittsburgh Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and Fibromyalgia Impact Questionnaire (FIQ) when compared to fibromyalgia patients without RLS.11 Obstructive sleep apnea (OSA) has been reported to be as high as 45%-65%, 9% in patients with fibromyalgia,<sup>12,13</sup> with retrospective analysis also supporting OSA/ fibromyalgia association and recommending evaluation via sleep study in all patients with fibromyalgia.<sup>14</sup>

While opioids are not routinely prescribed for fibromyalgia, if given for pain, they have the potential to precipitate respiratory depression and central sleep apnea as well as worsen daytime somnolence. Substantial evidence has not been reported on an association between fibromyalgia and central disorders of hypersomnolence such as narcolepsy, but if present, symptom burden may be even greater in these patients.

Polysomnography findings have been, in part, inconclusive in capturing a universal picture of patients with fibromyalgia; however, several studies have reported decreased sleep efficiency (SE), as well as increased sleep fragmentation, wake after sleep onset (WASO), and light sleep (N1) in this population.<sup>15,16</sup> Quantitative EEG during polysomnography has reported significant differences in the ratio of delta to alpha frequency power in patients with fibromyalgia compared to controls, citing a ratio of  $\leq$ 1 being 95% specific for fibromyalgia,<sup>13</sup> perhaps serve as a marker for altered sleep function in fibromyalgia.

#### MANAGEMENT CONSIDERATIONS

Due to the burden of sleep-related associated symptoms, potentially increased co-morbidity of other sleep disorders, and sleep's ability to modulate pain and mood, attention to evaluating and optimizing sleep should be a routine part of fibromyalgia treatment.

Sleep hygiene and utilization of cognitive behavioral therapy for insomnia (CBT-I) when appropriate can not only improve sleep but may have a positive impact on other aspects of fibromyalgia, such as mental health and quality of life.

Exercise, one of the consistently supported recommendations for fibromyalgia, has benefits for pain, mood, and sleep.<sup>17</sup>

Stress management and addressing any comorbid anxiety and depression can improve sleep as well as other symptomatology of fibromyalgia.

Sleep evaluation and treatment for any underlying sleep disorders should be a consistent aspect of management.

Pharmacotherapy for fibromyalgia ideally should take sleep quality into consideration, with several agents typically used in the treatment of fibromyalgia, such as duloxetine and pregabalin, also potentially improving sleep as well as pain.<sup>18</sup> While hypnotic pharmacotherapy is not necessarily routinely recommended, studies on several agents have demonstrated additional benefits in fibromyalgia. Orexin receptor agonist, suvorexant, demonstrated increased total sleep time and reduction in pain sensitivity in patients with fibromyalgia.<sup>19</sup> Sodium oxybate has demonstrated improvements in symptoms of pain and fatigue, as well as reduction of alpha intrusion and sleep onset latency,<sup>20</sup> although it was denied FDA approval in 2010 for fibromyalgia due to concerns about safety and misuse.

Appreciation of the complex bidirectional relationship between sleep and fibromyalgia is crucial to improving symptom burden. Care

coordination models where sleep providers and rheumatologists collaborate both for diagnosis and treatment are likely the ideal approach and should be able to provide better patient outcomes than either specialty can accomplish alone, even for the symptoms typically within their respective realms of care. Research into sleep and fibromyalgia remains ongoing, offering hope for better management and relief for those living with the chronic and debilitating condition of fibromyalgia.

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# **Embracing Technology and Insights to Screen the Millions We Are Missing**

#### Drew Copeland, RPSGT, CCSH

here's a scene in "Home Alone" where Harry and Marv put their ears to the attic door to identify a loud sound. They are suddenly knocked to the floor as a large object crashes through the door. From his back, Marv eloquently states, "That was the sound of a tool chest. Falling down the stairs." Well, my sleep friends, we are Harry and Marv. And that tool chest? It's the tsunami of OSA patients heading toward us.

I'm not here to address the intricacies of evaluating, diagnosing, or treating OSA; I want to focus on finding it in the wild. This discussion is necessary because, despite all the news stories, research studies, and public awareness campaigns, OSA remains a condition where the gap between prevalence and diagnosis remains notably wide. This gap is not due to a lack of understanding of OSA's impact but rather the hurdles in its identification.

The reality is that the current process for screening OSA often depends on a sleep-deprived individual becoming frustrated with living like a zombie or a snorer receiving a nudge from their bed partner to seek medical advice or move to the couch. This is why we continue to hear that 8-year-old Frost & Sullivan statistic "80% of people with OSA are undiagnosed" shouted from the rooftops year after year. We just haven't figured out how to move the needle.

As specialists in the field, the question we face isn't just about identifying OSA but about doing so in an efficient and scalable manner. The potential for improved screening methodologies is enhancing patient outcomes and adapting our approaches to the realities of modern healthcare systems and evolving patient expectations.

However, the future looks promising as consumer hardware, medical software powered by Artificial Intelligence, and data from alternative diagnostic tests are changing how we approach OSA screening. These advancements are technological upgrades and a new way of thinking that offers more personalized, accessible, and data-driven approaches. As we explore these innovations, we must understand what and how they work and their implications in the broader context of sleep medicine's future. Let's see how deep this rabbit hole goes.

#### THE RISE OF WEARABLES, NEARABLES, AND SMART MATTRESSES WEARABLES

Everyone these days is tracking their sleep. Even the barista at my local coffee shop shows me her sleep data for insights. With advancements in technology, sleep-tracking devices such as rings, bracelets, and headbands have become increasingly accurate, offering valuable insights into the wearer's sleep health. Their ease of use and continuous monitoring make them a convenient option for preliminary screening of obstructive sleep apnea (OSA), even if they may not match traditional sleep studies' precision. With the rich data they provide, these devices have become invaluable tools for monitoring sleep health. Let's all reserve judgment until the results of studies like these have been published.

#### Nearables

Nearables are like wearables that don't like to cuddle; when it's time to sleep, they want you to keep your distance. Devices like bedside monitors, smart home devices, and even your cell phone all qualify (yes, you should avoid cuddling with your phone at night!) By monitoring environmental factors and physiological signals, these devices can assess sleep quality and might even be able to screen for OSA without directly attaching to the body. The challenge lies in refining these technologies to ensure they offer reliable data that can be used in a clinical context.

#### **Smart Mattresses**

Considering what a typical mattress costs, it's hard to imagine a market for an even more advanced mattress. However, smart mattresses, including models that automatically elevate when snoring is detected, are on the rise (ba dum ching). These mattresses are embedded with sensors that can track a range of sleep metrics, potentially including indicators of OSA. The appeal is the integration of sleep monitoring into an object already central to the sleep experience, making the process as seamless as sleeping on a cloud. The accuracy and clinical relevance of data from smart mattresses are areas of ongoing development. Still, they promise a future where one's bed plays a crucial role in monitoring sleep health, including detecting the likelihood of OSA.

#### **Author's Prediction**

The role of consumer hardware in OSA screening is expected to grow and evolve significantly in the coming years. As these technologies become more integrated with medical software and AI, they have the potential to revolutionize OSA screening, making it more accessible, patient-friendly, and a part of our daily lives. Our bedrooms could serve as the first line of defense in identifying and managing sleep disorders like OSA.

#### FROM EHR ANALYSIS TO AI-POWERED PREDICTIVE MODELING Retrospective EHR Sifting

The pendulum is swinging back. We had paper charts, where it didn't matter what anyone wrote because no one could read it anyway. Then we went to early (and sometimes current) electronic health records (EHR), where you must click 17 times to confirm that the patient is not a smoker. And now, artificial Intelligence (AI) and machine learning (ML) have revolutionized how EHRs are utilized in healthcare. In the context

of OSA, AI algorithms can sift through vast EHR databases to identify undiagnosed cases. These algorithms analyze patterns in symptoms, diagnostic tests, and other health indicators that might have been overlooked. By correlating these data points with known OSA profiles, AI can flag individuals exhibiting potential signs of OSA but not formally diagnosed. This retrospective analysis is particularly valuable in uncovering cases in populations that might not typically present for sleep studies.

#### "Live" Guidance for Non-Sleep MDs

Al tools are increasingly being integrated into clinical software used by general practitioners, assisting non-sleep-specialized physicians during routine check-ups by providing real-time guidance on obstructive sleep apnea (OSA) risk assessment. With these tools, it's like having a sleep doctor standing behind every primary care physician, ready to assist. The AI system can analyze a patient's responses to general health questions, medical history, and physical examination findings, prompting the doctor to ask more in-depth sleep questions and ultimately consider OSA a differential diagnosis. This proactive approach enhances the likelihood of early detection and referral for specialized sleep studies, eventually leading to better patient outcomes.

#### Predictive Modeling Based on Current Health State

Without OSA, you can't spell . . . Nostradamus! (Wow, that was bad. Even for me). Al models are particularly adept at predictive analysis. By evaluating a patient's current state of health, including factors like weight, blood pressure, age, and family history, these models can predict the risk of developing OSA. The integration of machine learning algorithms with patient data enables the prediction of OSA even before symptoms become pronounced. This predictive capability is crucial for early intervention and can lead to improved patient outcomes.

#### **Author's Prediction**

The potential of AI/ML in OSA screening is enormous. We can expect the development of more sophisticated models that can incorporate a broader range of data, including genetic information and lifestyle factors. These advancements could lead to personalized OSA risk assessments, more timely preventative measures, and tailored treatment plans. Furthermore, AI could revolutionize the continuous remote monitoring of patients, using medical and consumer technology to track sleep patterns and adjust treatment plans in real-time. The evolution of AI/ML will enhance the accuracy of OSA screening and transform the overall approach to sleep disorder management.

#### MOLECULAR INSIGHTS AND ADVANCED IMAGING TECHNIQUES

#### Genetic, Blood, and Urine Testing

Someday, I'm going to walk into a doctor's office, and they aren't going to take some kind of fluid from me. No. No, they won't. But that could be a good thing for OSA screening! Venturing into molecular diagnostics, genetic, blood, and urine testing offers a promising avenue for OSA screening. These tests could identify biomarkers associated with OSA, offering a glimpse into the body's internal workings. Imagine being able to predict the risk of OSA with a simple blood draw or urine test, much like checking the weather forecast. This approach could revolutionize early detection, enabling interventions before the condition exacerbates.

#### Cross-Sectional Imaging (CT/MRI)

Every go looking for your remote in your couch and find money? Well, what if OSA was that money? Cross-sectional imaging techniques such as CT and MRI scans provide a detailed view of the airway's structure. Like explorers mapping uncharted territories, these imaging modalities create internal maps of the throat and nasal passages. While these scans are typically used to assess traumatic injuries, inflammatory diseases, and some forms of cancer, they can potentially uncover the hidden anatomical contributors to OSA, prompting the non-sleep provider to look into OSA.

#### Nomogram

Using a nomogram in OSA assessment blends various patient factors into a comprehensive risk profile. It's like a finely tuned orchestra, where each instrument – or, in this case, clinical variable – contributes to the overall assessment. Or it can look like the guy's back room in "A Beautiful Mind." Either way, this tool simplifies the complex interplay of factors into a straightforward visual guide, aiding clinicians in evaluating the likelihood of OSA.

#### Author's Prediction

In closing, as we explore the future of sleep medicine, it's clear that advancements in screening and assessment methods are on the horizon. Genetic, blood, and urine testing offer a promising avenue for OSA screening, potentially allowing us to predict the risk of OSA with a simple test, much like checking the weather forecast. Cross-sectional imaging techniques like CT and MRI scans are like explorers mapping uncharted territories in the airway, uncovering hidden anatomical contributors to OSA. Using a nomogram in OSA assessment is like a finely tuned orchestra, simplifying the complex interplay of factors into a visual guide for clinicians. With these tools and approaches, we're moving towards more efficient and effective ways of identifying and managing sleep disorders like OSA, bringing better sleep and health to all.

#### WHAT'S NEXT?

As we come to the end of our exploration into the future of OSA screening, we find ourselves on unfamiliar ground, much like Kevin from "Home Alone," who outsmarted burglars with creative traps. We're leading the way in developing innovative strategies to outsmart OSA in the rapidly evolving world of sleep medicine.

Evolving technology, AI-powered diagnostics, molecular insights, and advanced imaging techniques are turning points in approaching OSA screening. We're shifting from a reactive approach to a proactive strategy, detecting OSA before it progresses into serious health problems.

With each step, we're pushing the boundaries of what's possible in sleep medicine, improving wearables, integrating smart technology into our lives, and leveraging AI. Genetic, blood, urine testing, cross-sectional imaging, and nomograms offer exciting prospects. The future is bright and unpredictable (much like Kevin McCalister), but our commitment to improving lives remains constant. "Keep the change, ya filthy animal."

# Sleep Technologist Shortage: Can it be Helped with Mentorship and Servant Leadership?



here are so many issues facing the sleep industry today. Outside of concerns of reimbursement and payor requirements, the biggest factor impacting sleep labs appears to be the lack of qualified sleep technologists to perform the tests, to instruct patients and to fill various roles requiring credentials. While there is clearly a supply and demand issue at play, there must be more focus on staff retention, management styles, and mentorship through servant leadership.

"Before you are a leader, success is all about growing yourself. When you become a leader, success is all about growing others" – Jack Welch.

#### SERVANT LEADERSHIP IN THE SLEEP LAB

For the greater part of my 25-year career in sleep diagnostics testing, I was part of the executive management team at a large multi-site independent diagnostic testing facility (IDTF) chain of sleep labs in California. A private equity investment group owned the company and abruptly closed due to a series of issues, one of which was COVID. During this upheaval, I witnessed things out of my control, which left me disappointed in how the closure was handled. In my estimation, there was no concern for the sleep technologists and other positions, and they felt they were not treated well; many felt "discarded." This situation led me to question leadership choices and vow that if I were ever in such a position, I would not allow this type of treatment to occur. It also has made me a stronger mentor and leader. It became my honor and privilege to make telephone calls, write letters of recommendation, leverage relationships, and ensure that all credential holders found jobs during this difficult transition.

We have all experienced exceptional and poor leadership in our professional lives, sometimes probably wondering, "How did they get that job?" We assess how we and others are treated. Were we treated fairly? Are the leaders condescending? Was our voice heard? Did we fear retribution, or were our ideas met with respect and consideration? Sometimes, things are out of our control due to business decisions that just don't sit right. We are left to ponder the characteristics of leadership. I pose here the concept of the servant leader in the sleep laboratory. I will also explore how mentorship and leadership go hand in hand.

Although the field of sleep health provides medical services to patients requiring diagnostic and therapeutic support, the reality is that sleep diagnostics testing is a business. As such, business managers are allowed to choose how to operate their businesses. In my circle of technologists, a few have stated that private sleep labs are exploiting technologists, demanding that they work with higher than recommended technologists-to-patient ratios. With sicker patients, this could lead to unsafe patient care and put the patient and technologist at risk.

In his book, *The Servant as Leader*, Robert Greenleaf says, "Servant leadership is a philosophy and set of practices that enrich the lives of individuals, build better organizations, and ultimately create a more just and caring world." Servant leadership rethinks the traditional hierarchical model of leadership.

Servant Leadership flips the model upside down, putting the key leader at the bottom in a supporting, serving position.

"Servant leadership takes on principles of communication, empathy, awareness, healing, persuasion, conceptualization, foresight, stewardship, commitment to the growth of people, and building community." Let's now explore what servant leadership might look like in a sleep lab using each of Greenleaf's principles.

**Communication** is a two-way process that involves both talking and listening. Great organizations listen to their staff and their patients to receive feedback. Sleep technologists are the face of any sleep business as they are often the only people patient-customers will see after scheduling. Actively listening to your technologists intently and acting in a meaningful way is a surefire way to have your staff feel seen, heard, and appreciated. The patient's experience is more than satisfaction and begins with the first communication they have. Sleep technologists play a huge role in creating that positive experience. For management, learning about the patient experience is key to understanding and growing the business.

**Empathy** in the workplace is about getting to know your teams, their strengths and weaknesses, likes and dislikes. I never want to inconvenience a patient, but I also want to acknowledge that things will come up in the personal life of a sleep technologist. We need to understand that there will be difficulties in and outside of work, creating stress and anxiety and making life difficult to manage.

**Awareness** is about understanding your strengths and talents, weaknesses, and areas for improvement. Awareness is also about understanding the same of your team, as a collective team, and in every individual on the team. There are opportunities to pair complimentary technologists together or for perpetual learning from others within the environment. Not every technologist has the same set of hard or soft skills, and we can learn from each other. This is a form of mentoring. When deciding which technologist is assigned to which patient, try to create as much balance as possible in the workload to yield the best outcome for all patients.

**Healing** is not just healing physically from illness or disease but more from the holistic level through coaching, mentoring, and increasingly relationship-orientated leadership. Servant leaders can listen, understand, and provide healing through positive work environments, expressing value for employees, making people feel valued, and giving them the tools they need to succeed.

**Persuasion** is the ability to gain followers through collaboration, not through power, authority, or coercion. The totalitarian-authoritative-dictator management style with commandments like "do it or else" is a thing of the past.

**Conceptualization** gives a clear understanding of where you are today and where your entire organization is heading in the future. Technologists want to be part of something big and empowering within the sleep community. Good leaders will share goals and visions with the team, and they will become more engaged and want to work hard towards your mutual goals.

**Foresight** enables leaders to understand the lessons learned from the past and outcomes of prior decisions to inform the likely outcome of future decisions. Talk to your teams about what has gone right and what has gone wrong; what are your wins and your losses? As part of your accreditation, you are already putting together performance improvement plans (PIP); share this with your team. Only that which is measured can be improved.

**Stewardship** is how a leader guides their organization throughout the journey. They work for the greater good of society. They have an authentic, ethical focus on more than just profit. Patients go to sleep



centers to feel better, not just to be diagnosed. Sharing with team members how you are helping patients and the good your organization is doing to improve the world. If sleep apnea is your primary area of focus, consider sharing with your team how many sleepy drivers you have helped take off the road or how many more accidents there could have been in the world if not for their direct contribution.

**Commitment to the growth** of people is essential to being a servant leader. Jack Welch once famously said, "Before you are a leader, success is all about growing yourself; when you become a leader, success is all about growing others." Try to see the intrinsic value of your staff beyond what they do for the company. Encourage them to obtain credentials, attend meetings, and continue to grow in the industry. If the time comes when a great tech has outgrown what you can offer as a company, do not hold them back. Support and encourage their growth and be as selfless as possible.

**Building Community** is one of the best things that servant leaders can do to engage credential holders. Sleep is a niche profession, and there needs to be more outreach and acknowledgment to these amazing credential holders. I highly encourage you to join and attend your national and state sleep societies and to encourage your staff to do the same. Additionally, patients diagnosed with sleep disorders are also in need of community. Successful sleep programs will bridge these unique communities

#### **Combining Mentorship and Leadership**

As noted above, being a great leader often combines leadership and mentoring. A mentor can be another technologist, a manager, or a CEO! In addition, some professional organizations provide mentoring programs to connect the mentee and mentor, along with providing training. According to Bally, in order to retain nursing staff, mentoring is a necessity. This can also apply to the field of sleep health. According to the <u>American Academy of Sleep Medicine</u>, there is a growing lack of qualified sleep professionals including technologists. In many ways, the technologist forms the center of the sleep health practice. Thus, it becomes imperative to provide mentorship, job growth and leaders to engage the next cohort.

## SUMMARY AND CONCLUSIONS

I have tried to provide a personal journey and hope that you learn from my experiences in a private sleep laboratory setting, while differences may exist between hospital or academic center-based facilities, the qualities of a servant leader apply to each. There are no "one size fits all" solutions to such a complicated topic, in such a complicated industry. I often hear private sleep lab owners saying that they "cannot compete against hospitals and universities" when it comes to pay and benefits. But if your credential holders have genuine opportunities to pursue work

at these more desirable institutions, then it is logical that continuing business operations under traditional means, may in fact create the exact labor problem that you were trying to avoid.

Servant leadership in any aspect of healthcare is a powerful approach that fosters a culture of compassion, empathy, and collaboration. By embracing this philosophy, sleep labs can create an environment where the needs of patients, employees, and communities are prioritized. In advocating for the credential holder, it is essential to recognize the transformative impact they can have on staff retention, leading to improved patient care and organizational success. Their commitment to serving others, combined with their expertise and dedication, elevates the standard of care and inspires those around them, and as a result, will be a place that naturally attracts and retains credential holders.

Although I used my learnings/references throughout, I did not cite them as this article provides more of a personal perspective and narrative, however, I have some of the links I learned from below that you might want to access.

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# Impact of Mobile CBT-I Sleep Coaching Program on Sleep Quality

#### Michael A. Grandner, PhD, MTR, CBSM

Poor sleep health affects a significant portion of the American population, with prevalent sleep-related issues impacting overall quality of life! A tiered approach to sleep health services is necessary, ranging from intensive interventions for severe cases to more widely accessible options for milder problems. Sleep coaching programs have emerged as a potential solution for addressing minor sleep concerns, offering education, support, and motivation to promote beneficial sleep habits.

While clinical interventions like cognitive behavioral therapy for insomnia (CBT-I) are well-established for severe sleep problems,<sup>2</sup> less-intensive interventions for subclinical issues are still limited. Sleep coaching interventions aim to bridge this gap by providing support for improving sleep behaviors. Some recent pilot studies have demonstrated the efficacy of sleep coaching in enhancing sleep health for various populations, including shift workers, military personnel, and adolescents with chronic illnesses.

A recent study published in the journal *Frontiers in Sleep*<sup>3</sup> evaluated the impact of a 12-week app-based sleep coaching program called "Sleep Reset" in a real-world setting. The program combines personal-

TABLE 1.	
Week	Topic Areas
1	Initial assessment, personalized sleep evaluation, introduction to the program, introduction to key techniques and concepts, setting an initial schedule
2	Begin stimulus control and some sleep compression, journaling, worry lists, and relaxation exercises
3	Daytime support activities, including managing bright light expo- sure, exercises, caffeine intake, napping, motivation, and self-talk
4	Addressing bedtime issues, snacking at night, environmental factors, sleep supplements, relaxation exercises
5	Bedroom-related factors, sleeping positions, mattresses, sleep technologies, reflection, and behavior change
6	Physical activity, nutrition, sleep as part of overall health, rest and recovery
7	Embracing setbacks, cultivating self-compassion, cognitive and emotion-focused techniques
8	Managing anxiety, reducing stress, dreaming, muscle relaxation and self-reflection
9	Reflection and maintenance of healthy habits, reinforcing stimu- lus control and schedules
10	Reflection and maintenance of healthy habits, reinforcing daytime and evening routines that support sleep health
11	Wapping up, relapse prevention, revisiting helpful behavioral exercises and ideas
12	Wrapping up, relapse prevention, revisiting helpful cognitive and emotional exercises and ideas

ized coaching, education, and tracking components to promote healthier sleep habits. A total of 564 participants who completed the program were included in the study. Participants were initially screened for medical and psychological conditions that might contraindicate participation. Those individuals who likely needed more intensive care were referred to clinical resources.

The Sleep Reset program spans 12 weeks and includes three main aspects: tracking and assessment, education on sleep and circadian habits, and interactive coaching with a live coach. The coaches communicate with participants through the app, offering personalized recommendations and feedback. The curriculum covers a range of sleep-related topics, from sleep compression to managing stress and anxiety.

The study's primary goal was to assess whether participants completing the Sleep Reset program would show subjective improvements in sleep continuity (parameters like sleep latency, wake after sleep onset, number of awakenings, sleep efficiency), sleep duration, and use of sleep aids. It was hypothesized that participants would experience reduced sleep latency, wake after sleep onset, and awakenings, along with increased sleep duration and efficiency.

The results of the study demonstrated significant improvements in sleep parameters among participants who completed the program. Notably, there were reductions in sleep latency and wake after sleep onset, as well as improvements in sleep efficiency, number of awakenings, and total sleep time. Moreover, individuals with lower initial sleep efficiency and shorter sleep duration experienced more pronounced improvements. These findings suggest that the Sleep Reset program had a positive impact on sleep continuity and duration.

Among those who completed the program, sleep latency was reduced by 41%, wake time after sleep onset by 35%, and number of awakenings by 17%. They increased sleep efficiency by a relative 8%





TABLE 2.								
Week 1			Week 12			Paired t-test		
	Mean	SD	Range	Mean	SD	Range	t	p-value
Sleep Latency (min)	27.52	21.52	2-135	16.50	16.32	2-120	-12.40	<0.00001
Wake After Sleep Onset (min)	81.00	45.96	10-253	53.02	39.55	5-247	-14.42	<0.00001
Sleep Efficiency (%)	82.21%	10.11%	38%-98%	88.79%	8.40%	36%-99%	15.49	<0.00001
Number of Awakenings (#)	2.38	0.83	1-5	1.97	0.78	1-5	-9.61	<0.00001
Total Sleep Time (min)	383.27	82.56	139-720	427.32	77.16	158-720	11.21	<0.00001

#### **Sleep Latency**

Sleep Reset members decreased their time to fall asleep by **53%** over the course of our sleep program.



**FIGURE 2.** Note: Sleep Reset members defined as those who completed the program

#### Wake After Sleep Onset (WASO)

Sleep Reset members decrease the time spent awake in the middle of the night by an average of **46%** over the course of our program.



**FIGURE 3.** Note: Sleep Reset members defined as those who completed the program

TABLE 3.								
Low Sleep Efficier	Lo	t-test						
	Change	95% CI	Change	95% CI	t	p-value		
Sleep Latency (min)	-16.17	(-18.94, -13.40)	-5.65	(-7.58, -3.72)	6.06	<0.00001		
Wake After Sleep Onset (min)	-47.32	(-52.94, -41.71)	-7.23	(-11.04, -3.41)	11.46	<0.00001		
Sleep Efficiency (%)	11.20%	(10.01%, 12.38%)	1.63%	(0.78%, 2.48%)	-12.76	<0.00001		
Number of Awakenings (#)	-0.48	(-0.60, -0.36)	-0.34	(-0.450.22)	1.62	0.106		
Total Sleep Time (min)	65.32	(53.69, 76.95)	31.19	(18.83, 45.54)	-3.96	<0.00001		

TABLE 4.							
Short Sleep (		t-test					
	Change	95% CI	Change	95% CI	t	p-value	
Sleep Latency (min)	-12.8	(-15.79, -9.81)	-10	(-12.15, -7.84)	1.53	0.126	
Wake After Sleep Onset (min)	-36.82	(-43.48, -30.17)	-22.29	(-26.79, -17.80)	3.70	0.0002	
Sleep Efficiency (%)	10.14%	(8.58%, 11.70%)	4.29%	(3.44%. 5.15%)	-6.99	<0.00001	
Number of Awakenings (#)	-0.49	(-0.63, -0.35)	-0.36	(-0.46, -0.25)	1.58	0.115	
Total Sleep Time (min)	85.10	(40.30, 97.18)	25.51	(14.41, 36.60)	-6.95	<0.00001	



#### FIGURE 4.

and sleep duration by about 45 minutes, or 11%.

Like any sleep intervention, those who stand the most to benefit are more likely to see greater improvements. Those who started with a lower sleep efficiency (<85%) were compared to those with a higher sleep efficiency at the outset. Those whose sleep efficiency started lower experienced greater improvements.

Taken together, on average, those who completed the Sleep Reset program saw notable, significant improvements in several dimensions of their sleep health. They were falling asleep faster, staying asleep longer, waking fewer times, and sleeping more hours. These effects were especially pronounced for those who started with worse sleep health since they had more room for improvement.

The study has some important limitations, including the absence of a control group and the focus on program completers, which might introduce biases. The reliance on self-reported sleep data Adapted from Gorovoy SB, Campbell RL, Fox RS and Grandner MA (2023) App-supported sleep coaching: implications for sleep duration and sleep quality. *Front.* Sleep 2:1156844.doi: 10.3389/frsle.2023.1156844 *Dr. Michael Grandner, a licensed clinical psychologist, is board-certified in behavioral sleep medicine and Lead Scientific Advisor to Sleep Reset.* 

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through diaries could lack objectivity. Rigorous methodologies, such as control groups and intent-to-treat analyses, are needed to accurately assess the program's effects.

This study highlights the potential of an app-based sleep coaching program, Sleep Reset, to improve sleep parameters and continuity for individuals without diagnosed sleep disorders. The multifaceted coaching, education, and tracking approach effectively promotes healthier sleep habits. However, further research involving control groups and broader samples is required to confirm the program's efficacy. As sleep-related issues continue to affect public health, interventions like Sleep Reset offer promise for enhancing sleep health in various populations.

# **New Sleep Products in 2023**

Among the sleep innovations unveiled in 2023 is a device specifically designed for restless legs syndrome therapy, novel oral appliances, a chin-worn HST, a finger-worn HST, software designed to assist sleep specialists in broadening their diagnostic services and streamlining HST backlogs, and a personalized sleep app grounded in cognitive behavioral therapy for insomnia (CBT-I).



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Zmachine HomeDirect has been meticulously developed to aid sleep laboratories/ physicians specializing in sleep medicine in expanding their services and managing HST backlogs efficiently by dispatching a Zmachine Synergy directly to patients on their behalf.

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#### SleepImage FingerTip

The Fingertip is a rechargeable device that patients keep to collect data as instructed by their clinician for multiple nights and over time. The data is automatically transmitted to a Clinician's Portal on the cloud-based SleepImage System for clinical diagnosis and management of sleep-disordered breathing.

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# Home Sleep Tests: The Case for Multi-Night Studies from the View of a Sleep Physician

#### Haramandeep Singh, MD, D. ABPN

n the world of sleep medicine, the evaluation of sleep-disordered breathing, particularly obstructive sleep apnea (OSA), has seen a paradigm shift with the introduction of home sleep tests (HSTs). As a sleep physician, I often grapple with the decision of whether to recommend a one-night or multi-night HST for my patients. While the choice may appear to be a matter of convenience and cost-effectiveness, it is far more nuanced than it seems. This article delves into the perspective of a sleep physician and explores the compelling case for multi-night studies.

#### THE VERSATILITY OF HOME SLEEP TESTS

HSTs have gained popularity due to their ability to provide valuable insights into an individual's sleep patterns in the comfort of their own home. These tests involve the use of portable devices that monitor various physiological parameters, allowing us to detect signs of sleep disorders, primarily OSA. However, not all HSTs provide the same data, and they may have different types of sensors and bio-signals.

#### THE ONE-NIGHT VS. MULTI-NIGHT DEBATE

While one-night HSTs are convenient and cost-effective, multi-night studies offer a deeper understanding of sleep patterns and variations. From a sleep physician's perspective, the choice between one-night and multi-night HSTs hinges on several crucial factors.<sup>1-3</sup>

#### **One-Night Home Sleep Test**

- Simplicity and Cost-Effectiveness: One-night HSTs are relatively simple for patients to use and more affordable. They involve a single night of monitoring at home, and the data is subsequently analyzed.
- 2. Screening for Severe Cases: For patients with severe OSA, a one-night HST might suffice, as their condition is often readily detected within this brief timeframe. It is important to be able to screen for patients that may have severe OSA, such as a very elevated Epworth Sleepiness Scale, STOP-BANG score, Berlin questionnaire score, and medical co-morbidities, before deciding whether to do one night or more. But even 20% of cases that use a single night may be misclassified.

#### Multi-Night Home Sleep Test

 Comprehensive Data: Multi-night studies offer a wealth of data, painting a more detailed and complete picture of a patient's sleep patterns and potential variations from one night to the next.

- Detecting Variability: Sleep patterns can vary significantly, and some individuals experience "night-to-night variability." Multinight HSTs are instrumental in detecting these variations and ensuring a more accurate diagnosis.
- Uncovering Mild and Moderate Cases: For patients with milder forms of sleep apnea or other sleep disorders, a single-night test might not capture the full extent of the issue. Multi-night studies are often indispensable for making a conclusive diagnosis in these cases.

#### BENEFITS OF MULTI-NIGHT HOME SLEEP STUDIES

From a sleep physician's standpoint, multi-night HSTs offer a range of benefits:

- Increased Diagnostic Accuracy: The most significant advantage of multi-night HSTs is the heightened diagnostic accuracy they provide. These tests can capture variations in sleep patterns and are instrumental in diagnosing mild to moderate sleep apnea cases.
- 2. Unveiling Night-to-Night Variability: Night-to-night variability is a phenomenon in which sleep patterns change from one night to the next. A single-night HST may overlook this variability, potentially leading to an inaccurate diagnosis. Multi-night studies help account for this phenomenon.4
- Enhanced Patient Engagement: Patients often find it more convenient to undergo several nights of testing at home rather than in-lab sleep studies, which can be disruptive, uncomfortable, and delay times for scheduling. Enhanced engagement leads to a more accurate assessment.
- 4. Personalized Treatment: Understanding a patient's sleep patterns over multiple nights allows sleep physicians to design more personalized treatment plans. Each patient's sleep issues are unique, and multi-night studies help us tailor recommendations accordingly.
- 5. Detecting a Range of Sleep Disorders: While HSTs are primarily employed for OSA, multi-night studies may also aid in identifying other sleep issues, such as insomnia, pain-related sleep difficulties, or the possibility of periodic limb movement disorder, contributing to a more personalized and holistic understanding of the patient's sleep health.

#### THE PERSPECTIVE OF A SLEEP PHYSICIAN

As a sleep physician, my primary goal is to provide the best care

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for my patients, and that includes making accurate diagnoses and delivering effective treatments. While one-night HSTs are suitable for severe cases of OSA and offer a quick diagnosis, multi-night studies are invaluable for capturing the complexity of sleep patterns, detecting variability, and diagnosing milder cases. In my practice, I often lean toward multi-night HSTs for the following reasons:

- Diagnostic Precision: Accurate diagnosis is fundamental to effective treatment. Multi-night studies offer a comprehensive view of a patient's sleep, helping me make more informed decisions.
- 2. Night-to-Night Variability: I've seen many cases where patients exhibit different sleep patterns on different nights. Multi-night HSTs are the best way to account for this variability.
- Patient-Centered Care: I prioritize patient comfort and engagement. By reducing the patient burden, patients are more likely to use the device for multiple nights, have an improved, less intrusive experience, and I am able to obtain the information I need for diagnostic purposes.
- 4. Personalized Approach: Every patient is unique. With multi-night studies, I can tailor treatment plans to address individual sleep issues effectively.
- Holistic Understanding: Sleep disorders are not limited to OSA. Multi-night studies enable me to explore a broader range of possible sleep conditions, ensuring a more holistic approach to my patients' sleep health.

#### CONCLUSION

The decision between one-night and multi-night home sleep tests is far from straightforward. From a sleep physician's perspec-

tive, the choice depends on the patient's specific circumstances and the need for diagnostic precision. While one-night HSTs are convenient and cost-effective, multi-night studies offer a deeper insight into a patient's sleep patterns, accommodating night-to-night variability and diagnosing milder cases accurately. To provide the best care, I believe in the value of multi-night studies, ensuring that my patients receive the most personalized and precise sleep medicine possible.

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#### **Sponsored Content**

## A Case Study: How the Rise of COVID-19 Changed the Sleep Lab

#### Lisa Spear

fter the COVID-19 pandemic swept over the globe, no one could have predicted what lasting effects sleep medicine providers would see years later, but as we approach the four-year anniversary of the virus's emergence, it's due time that we look back and reflect.

Despite the devastation that COVID-19 brought, the virus also inspired rapid evolution in the field of sleep medicine. When COVID-19 hit, sleep labs quickly shut down in-lab operations and some pivoted to meet their patients' needs remotely, shipping out home sleep tests and quickly launching telehealth platforms seemingly overnight.1 The rise of telemedicine appeared to spread as fast as the virus itself. Home-based sleep testing increased significantly and durably and has been associated with faster time to treatment than initial in-lab testing.<sup>2</sup>

"Since the pandemic, we have done a complete 360," says Jennifer Jones, RPSGT, RST, a lead sleep technologist at FusionSleep in Georgia.

A prime example of the successful implementation of telemedicine was seen at FusionSleep, a business unit of Nox Health, which runs two sleep labs with a total of 12 beds. There, when COVID surfaced in the United States, the sleep lab launched a telemedicine practice in just four days using Zoom. The sleep medicine providers went from seeing zero telemedicine patients to seeing only telemedicine patients.

"We went from some home sleep studies to doing all home sleep studies within a couple of days," says Jones.

And since those early pandemic days, FusionSleep's telemedicine practice has continued to expand. Just before the pandemic, the practice only saw patients within a 30-mile radius of either of their Georgia locations. Now, the providers at FusionSleep see patients all throughout the state of Georgia and can consult with patients, ship the Nox T3s home sleep tests directly to their homes, and set patients up on CPAP therapy — all remotely.

"The world changed. We had to make it happen, so we did," says FusionSleep's Executive Vice President of Operations Shawn Roberts.

FusionSleep providers can now reach more patients than ever before, and they are reaching many patients who might not have otherwise had access to care. FusionSleep even launched an innovative program within Publix, in which anyone doing their grocery shopping can stop into a digital kiosk to fill out a sleep survey. If needed, at the end of the survey, the person may be referred to a FusionSleep clinic for a sleep evaluation.

"This, to me, is an example of our reach because we are now in 170 Publix grocery stores across the state of Georgia," says Roberts. As of December of 2023, approximately 97% of FusionSleep's patient visits are administered via telemedicine and many of them are "self-referred" via the Publix surveys. As many as 50% to 75% of those patients receive a home sleep test with the Nox T3s device, the only home sleep testing equipment that is used by the Georgia clinics.

Overall, FusionSleep has continued to keep telemedicine rates up and is a prime example of a sleep medicine-telemedicine success story. The business has not seen the telemedicine patient appointment rate drop below 80% at any time since the pandemic hit, according to reports from the sleep lab.

"We are now seeing more home sleep testing than ever before," says Roberts. "I think sleep is on the frontlines more than ever before and our volume has increased a lot there because of the visibility of sleep health has been elevated."

Currently, in addition to running in-lab polysomnography sleep studies with the Nox A1s, FusionSleep is administrating approximately 275 home sleep tests per month. The influx of home sleep testing has changed the dynamics of how the sleep lab staff manage their work. Clinicians don't just need to interact with patients; they also need to provide technical support and give clear instructions remotely.

FusionSleep uses a software system that automatically creates a link that is sent to the patient. All the patient has to do is just click on the link to open a web browser to go straight to the virtual visit. The platform is easy and accessible for all patients, even those who are not technologically savvy.

"There has definitely been an improvement since the pandemic," says Shakyra Jacobs, RPSGT, FusionSleep lab manager. "We can now accommodate patients who don't want to come into the sleep lab, and we can reach a wider range of people."

"Now, I am running a clinic, and it is in the cloud," says Roberts. "Telemedicine is here to stay."

Lisa Spear is a science writer and content creator who specializes in sleep medicine. She currently works as the content manager for Nox Medical.

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**INSIGHTS ON OAT** from the AADSM

# The P4 Approach: What is it and How is it Being Used in Dental Sleep Medicine?

**Kevin Postol, DDS** 

A medicine is an evolving approach to personalized medicine that involves four key elements of care: 1) predicting who will develop disease and comorbidities, 2) preventing rather than reacting to disease, 3) personalizing diagnosis and treatment, 4) having patients participate in their own care.<sup>1</sup> This approach is gaining traction in both medicine and dentistry as technology and research evolve, and we gain a greater appreciation for the importance of personalized medicine. Even though P4 terminology isn't often used in dental sleep medicine, it is an approach that American Academy of Dental Sleep Medicine (AADSM) Qualified Dentists apply in their practices every day. The model below is used to identify and treat obstructive sleep apnea (OSA) but also ensures patients are active participants in their journey to better overall health.<sup>2</sup>

#### PREDICT

Most dental organizations recommend that all dentists screen for OSA during biannual hygiene visits. Through physical assessment, validated screening questionnaires and tools, and medical history and clinical findings, dentists can identify patients suspected of having OSA. Dentists see their patients regularly and build relationships, sometimes across generations, so they can identify changes in lifestyle or health that may signal that the patient is at a higher risk for OSA.<sup>2</sup>

#### PREVENT

Treatment of OSA is not only key to managing symptoms like snoring, but it is also essential for preventing conditions that may develop when left untreated. For example, untreated OSA has been associated with many cardiovascular diseases. Currently, there aren't any evidence-based therapies to prevent OSA, but dentists do frequently discuss obesity and sugar intake with patients throughout their everyday interactions, hoping not only to prevent OSA but also cavities and other dental diseases. Using oral appliances also can help prevent dangerous side effects of lack of sleep, including sleepiness, brain fog, and drowsiness while driving.

#### PERSONALIZE

By definition, oral appliances (OA) are custom-fit and personalized for each patient. A qualified dentist selects the appropriate type of appliance for a patient based on individual craniofacial structures and oral, dental, and periodontal tissues; cognitive ability, manual dexterity, visual acuity, range of motion, and nasal patency; and number, location, and health of remaining teeth.

The clinical tooth height, angulation, undercuts, current dental restorative conditions, and anticipated dental restorative needs, along with allergies and/or sensitivities, are also considered because they may limit the type and material to be used in the fabrication of an oral appliance. Appliance selection considers patient preferences, including comfort, ease of use, and patient financial considerations.

The calibration of the appliance to the appropriate therapeutic position is also personalized to each patient. Calibration is based on multiple factors, including the patient's range of motion, level of disease severity, patient comfort, and resolution or improvement of signs and symptoms. The appropriate endpoint to the oral appliance advancement process achieves improvement of signs, symptoms, or objective indices while allowing the patient to use the appliance comfortably every time they sleep.

The patient education qualified dentists provide covers individualized risk factors based on demographics, ethnicity, and sex, as well as individualized risk modifiers that can shape disease severity. Education includes reviewing information with the patient about their OSA severity and the metrics that will be critical for determining whether oral appliance therapy (OAT) treatment is successful, as determined by the patient, qualified dentist, and the patient's treating medical provider. Open communication with the patient is important in achieving success with OAT, and qualified dentists are sensitive to each patient's unique concerns and desired outcomes, including additional therapies that might be considered in the face of an inadequate response to OAT.

#### PARTICIPATE

Oral appliance therapy requires patients to actively participate in their therapy, as they are responsible for wearing their appliance while they sleep. To ensure patients understand the importance of wearing their appliance consistently, qualified dentists explain the impact of OSA on a patient's overall health and educate them about the importance of sleep hygiene and sleep deprivation. During discussions about adherence, qualified dentists stress that the patient should sleep a minimum of seven hours per night and wear their appliance for the duration of their sleep period. The AADSM defines compliance as "the appliance being worn for a minimum of  $\geq$ 80% per night, starting when the OA is placed in the mouth and ending when the OA is removed from the mouth,  $\geq$ 5 nights per week."<sup>3</sup> The AADSM encourages qualified dentists to categorize patients as fully compliant, improving over

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time, or non-compliant based on the collected compliance data and to encourage patients to improve their compliance.

Qualified dentists also follow up with patients every six months during the first year and at least annually thereafter. This follow-up schedule is important for evaluating patient compliance and any factors that may reduce compliance. During these appointments, the dentist evaluates the function and structural integrity of the appliance, reviews any side effects that may be occurring, and takes steps to reduce or minimize them to ensure the patient can continue to adhere to therapy. The follow-up visits also monitor symptoms and changes in sleep, lifestyle, and medical factors that may impact the severity of OSA.

The AADSM's standards for practice guides qualified dentists in how to provide personalized care to their patients. To ensure that patients

are receiving the personalized care they deserve, it is important to refer patients to qualified dentists for oral appliance therapy.<sup>4</sup>

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# The Future of Sleep Advocacy

#### Cara Weaver

n November of 2008, Wake Up Narcolepsy was founded by two parents of a child with narcolepsy, Monica & David Gow, and one adult living with narcolepsy, Kevin Cosgrove.

Monica, currently executive director for WUN, reflected on how they felt after their then 10-year-old son was diagnosed with narcolepsy with cataplexy, saying they were "mystified by the lack of knowledge among healthcare professionals."

When she looked for more information online, she realized that resources for those living with narcolepsy and their loved ones were scarce. She also learned that while her son's diagnostic period of three months had felt like a lifetime to them, it was almost record-time compared to many. Many people exceed ten years before getting a diagnosis—something needed to change.

It was time for a wake-up call about narcolepsy. Thus, "Wake Up Narcolepsy" was born.

Over the past 15 years, WUN has grown into a national leader in narcolepsy awareness and research, never compromising on its mission. That mission can be accomplished by:

- -Accelerating research for better treatments and a cure
- -Decreasing time-lapse from symptom onset
- -Increasing awareness

-Providing supportive resources for people with narcolepsy and their families

In summary, it was about research, education, and awareness.

#### RESEARCH

One of the biggest things that stood out to the founders when deciding to create WUN was that no other organizations were raising money to support narcolepsy research. As a frequently misunderstood and stigmatized disorder, narcolepsy needed to not only be known by the general public and healthcare providers but also studied by researchers. "I was diagnosed with narcolepsy with cataplexy over 25 years ago," said Nicole Jeray, WUN Board Member and retired LPGA player. "The treatments for narcolepsy have gotten so much better, and it's because of Wake Up Narcolepsy, pharmaceutical companies, and the wonderful researchers that we have in this world that have made lives so much better for people like me."

Since its inception in 2008, Wake Up Narcolepsy has donated \$1.35 million to narcolepsy research.

- Some of the proudly funded research grants have gone to:
- -Emmanuel Mignot, MD, PhD, at Stanford University
- -Thomas Scammell, MD, at Harvard Medical School, Beth Israel Dea coness Medical Center
- -Kiran Maski, MD, MPH, at Boston Children's Hospital, Harvard Med ical School
- -Young Investigator Brandon Toth, University of Michigan
- -John Peever, PhD, University of Toronto
- -Jason Ong, PhD, at Northwestern University
- -Indra Narang, BMEDSCI, MBBCH, MD, at SickKids Toronto
- -Laura Lewis, PhD, and Ewa Beldzik, PhD, at Massachusetts Institute of Technology through a co-funded grant with American Association of Sleep Medicine (AASM) Foundation

WUN also consistently updates the organization's website to include current and past clinical trial and research study opportunities.

#### **EDUCATION**

To combat the robust number of stereotypes associated with narcolepsy, education on what narcolepsy truly is must be shared. To achieve this, Wake Up Narcolepsy has hosted many education days, webinars, panels, and other in-person and virtual learning opportunities over the years. Notably, WUN started a "Brown Bag Webinar" series in 2022 that continued into 2023, each year having eight webinars with experts



on the topic. The topics ranged from teaching people living with narcolepsy about <u>accommodations</u> and <u>advocating for themselves</u> to <u>un-</u> <u>derstanding clinical trials</u>, <u>medication and treatment options</u>, and the differences between types of narcolepsy and idiopathic hypersomnia.

These webinars provide opportunities for people to learn from professionals and then present their questions at the Q&A that follows. Each session is also recorded and uploaded to <u>Wake Up Narcolepsy's</u> <u>YouTube channel</u> for anyone unable to attend.

On top of these events, Wake Up Narcolepsy also creates <u>education-</u> <u>al resources</u> that help reduce the burden of educating others off the plates of people living with narcolepsy. These undertakings lead to the final piece of the puzzle.

#### **AWARENESS!!!**

Awareness is something that goes hand in hand with both education and research. In order for treatments, understanding, education, and support to evolve for people with narcolepsy, the general population must be made aware of what it truly is.

Through social media, <u>email newsletters</u>, website updates, <u>blog posts</u>, resources, and <u>in-person and virtual events</u>. Wake Up Narcolepsy raises awareness every day. One of the more recent developments is the patient advocacy program expanding into local meet & greets where people can talk to other people affected by narcolepsy living near them.

#### LOOKING FORWARD

The Wake Up Narcolepsy team is ever-growing. At the end of October, <u>Alejandro Bruner-Solas</u>, a person living with narcolepsy, was welcomed to the staff as patient advocacy manager. The board of directors and volunteer list has been growing as well.

Wake Up Narcolepsy continues to accomplish its mission and is eager to share more details about 2024 plans as they are developed.

The organization recently announced its 15th Anniversary with a <u>statement</u> and <u>celebration video</u>, as well as opened registration for their <u>2024 National Summit</u> in Seattle, Washington, on April 27th.

To learn more about the organization and how you can help support their mission, visit <u>www.wakeupnarcolepsy.org</u>.



Cara Weaver is the marketing and communications coordinator at Wake Up Narcolepsy and is also a person with narcolepsy type 2.

Wake Up Narcolepsy (WUN) is a 501(c) (3) nonprofit organization dedicated to driving Narcolepsy awareness, education and research towards improved treatments and a cure

# **Sleep Pharmaceutical Update**

**Sleep Lab Magazine Staff** 

#### EUROPEAN COMMISSION FINES TEVA AND CEPHALON \$65 MILLION FOR DELAYING GENERIC MODAFINIL

The European Commission has fined the pharmaceutical companies Teva and Cephalon \$65 million (€60.5 million) for agreeing to delay for several years the market entry of a cheaper generic version of Cephalon's drug for sleep disorders, modafinil, after Cephalon's main patents had expired. The agreement was concluded well before Cephalon became a subsidiary of Teva. The agreement violated EU antitrust rules and caused substantial harm to EU patients and healthcare systems by keeping prices high for modafinil.

The decision concerns a patent settlement agreement whereby Cephalon induced Teva not to enter the market with a cheaper version of modafinil in exchange for a package of commercial side deals that were beneficial to Teva and some cash payments. Teva held its own patents relating to modafinil's production process, was ready to enter the modafinil market with its own generic version, and even started selling its generic in the UK. Then, it agreed with Cephalon to stop its market entry and not challenge Cephalon's patents.

The infringement lasted for almost all EU Member States and EEA countries, from December 2005 to October 2011, when Teva acquired Cephalon and they became part of the same group.

#### HARMONY BIOSCIENCES RELEASES PHASE 3 INTUNE STUDY RESULTS FOR PITOLISANT IN IDIOPATHIC HYPERSOMNIA PATIENTS

Kumar Budur, M.D., Chief Medical Officer at Harmony Biosciences, said, "We are very encouraged by the magnitude of the response seen in the initial open-label treatment period, where 83% of patients completing this phase responded with an average 9.4 point improvement in the Epworth Sleepiness Scale (ESS). Equally encouraging is the number of patients, almost 90%, electing to continue into the long-term extension study, allowing us to generate additional safety and efficacy data in this patient population. Positive trends in other important outcomes like sleep inertia add to the totality of evidence that pitolisant has a clinical benefit for patients with IH."

The INTUNE study was a Phase 3 placebo-controlled, double-blind, randomized withdrawal study. Approximately 83% of patients who completed the 8-week open-label treatment period with pitolisant were responders (as defined by a decrease on the ESS of  $\geq$ 3 points) and experienced a robust clinical response, with an average ESS change from baseline of – 9.4 points. A positive trend favoring pitolisant was observed during the 4-week double-blind, randomized withdrawal period. However, no statistically significant difference was observed between pitolisant and placebo groups on ESS, the primary endpoint. Positive trends favoring pitolisant were also observed across additional prespecified endpoints, including the IHSS, which approached statistical significance, as well as on the SIQ. Further data analyses are being conducted. Approximately 88% of patients in the study continued into a 12-month long-term extension study, which is ongoing. The safety and tolerability profile of pitolisant in adult patients with idiopathic hypersomnia was consistent with the established safety profile and no new safety signals were observed.

Dr. Budur added, "We are grateful to the patients, family members and clinicians who participated in the INTUNE study. We remain committed to the IH patient community and understand their strong desire for a non-scheduled treatment option for IH. Following a thorough review of the full data set, we will work closely with the FDA to discuss next steps and a path forward for pitolisant in IH."

Pitolisant is marketed as WAKIX<sup>®</sup> in the U.S. for the treatment of EDS or cataplexy in adult patients with narcolepsy. Pitolisant is not approved for IH and is currently being evaluated as an investigational agent in adult patients with IH.

#### APNIMED LAUNCHES JOINT VENTURE WITH SHIONOGI TO DEVELOP NOVEL THERAPIES FOR SLEEP DISORDERS, INCLUDING OSA

Apnimed, Inc. announced a new joint venture with Shionogi & Co., Ltd., a leading global research-driven pharmaceutical company based in Japan, to develop novel pharmacologic therapies to treat obstructive sleep apnea (OSA) and other sleep disorders. The newly formed joint venture, Shionogi-Apnimed Sleep Science, LLC, initially focuses on accelerating the discovery, preclinical and clinical development of novel pharmacologic solutions designed to address the complex pathology of OSA.

Shionogi-Apnimed Sleep Science combines Apnimed's deep knowledge of OSA, highly experienced clinical-stage drug development team and robust network of sleep medicine clinical sites with Shionogi's highly efficient small molecule drug discovery engine and proven ability to create best-in-class compounds. The joint venture is owned equally by Apnimed and Shionogi. In addition to making a cash contribution to fund the operations of the Shionogi-Apnimed Sleep Science JV, Shionogi is making an equity investment in Apnimed. Both companies will share development responsibilities and benefit from joint venture products that reach the market. Apnimed's lead programs, AD109 (now in Phase 3 trials) and AD504 (in Phase 2 trials) are not included in the joint venture.

"Apnimed and Shionogi look forward to working together to transform the treatment of sleep apnea. This strategic collaboration builds on the strengths of both companies to accelerate the development of potential new treatments for the hundreds of millions of people worldwide with OSA who are looking for options that don't require a device or surgery," said Larry Miller, MD, Chief Executive Officer of Apnimed. "Our new partnership is a win for Apnimed, Shionogi and, most importantly, patients."



# Each Year, The BRPT Offers Four Scholarship Opportunities Which One Is Right For You?

Michelle DiMaria, BS, RRT, RPSGT

n the past few years, the BRPT has developed a focused Scholarship Program centered on offering sleep technologists – at various levels of their careers – the chance to further their education and professional goals. These scholarships range from offering a tuition grant to someone new to polysomnography, to a sleep technologist working towards achieving the RPSGT credential, and seasoned RPSGTs interested in acquiring the advanced CCSH credential. The application window for each scholarship is typically open for one month, after which members of the BRPT's Scholarship Committee will review all applications through a carefully crafted rubric to determine the best-qualified applicant(s).

## THE CCSH PATHWAY 3 EDUCATIONAL GRANT

During the first quarter of the year, the BRPT offers a series of CCSH Educational Grants to assist RPSGTs interested in pursuing the CCSH credential through Pathway 3. These educational grants are intended for RPSGTs who do not meet the criteria through CCSH Pathways 1 or 2 or are unable to financially pursue the CCSH designated education program(s) approved for Pathway 3 of the CCSH credential.

Each CCSH educational grant will cover up to, but not to exceed, \$250.00 of the registration cost for an approved in-person conference or the cost to complete online modules for any approved CCSH educational program, such as the AAST'S CCSH Designated STAR Education Program, the AASM A-STEP CCSH Education Program, the Academy of Sleep and Wellness Program, and the Collin College Continuing Education Health Sciences Program. The BRPT will select up to 10 grant recipients, each of whom will have up to three months to start the educational modules or register for the conference.

#### Requirements

Applicants must be active RPSGT credential holders who have recertified at least once. In addition, applicants must hold current BLS/ CPR certification for healthcare workers who follow the most recent AHA Guidelines or international equivalent.

## A-STEP/STAR DESIGNATED EDUCATIONAL GRANT

During the second quarter of each year, the BRPT will offer the A-STEP/STAR Designated Educational Scholarship program intended to provide educational assistance to an individual who's interested in pursuing a career in sleep technology or who's currently working as a sleep technician and would like to become an RPSGT. The winner will receive a grant of up to \$800 towards an A-STEP or STAR-designated educational program.

#### Requirements

Applicants must hold a high school diploma or equivalent. In addition, applicants must hold a current BLS/CPR certification for healthcare workers that follows the most recent AHA Guidelines or international equivalent.

#### THE DEI EDUCATIONAL GRANT PROGRAM

This year, the BRPT was excited to offer for the first time its Diversity, Equity, and Inclusion Educational Grant program intended to provide financial assistance to current sleep technologists who are eligible to sit for the RPSGT exam via one of the five pathways, or a CCSH exam candidate who is eligible to sit for the exam via one of the three pathways available. This grant is offered during the third quarter of the year.

The grant will cover the cost of one exam fee for either the RPSGT or CCSH exam. This grant will recognize a sleep technologist actively championing or involved with DEI initiatives within their community and/or healthcare institution, influencing continual impacts on patient care.

#### Requirements

Applicants must be eligible to sit for the RPSGT or CCSH exam with no sanctions by the BRPT's Professional Review Committee. Candidates who already submitted an exam application and have an active exam approval on file are not eligible to apply for this grant.

## THE JOMO MARTIN NKUNIKA MEMORIAL SCHOLARSHIP



Available during the last quarter of the year, this scholarship, named in honor of Jomo Martin Nkunika, MSHCA, BS, CCSH, RPSGT, a former member of the BRPT Board of Directors, offers a \$3,000 tuition grant to a promising student of polysomnography. Jomo was a strong advocate of sleep education and was the program director and adjunct professor of the Sleep Medicine

Technology program at Montgomery College in Maryland. In addition, Jomo was a clinical manager with MedBridge Health at the Frederick Memorial Hospital Advanced Center for Sleep Studies.

Jomo was an integral part of the BRPT Board of Directors from 2016 until 2019, when he was diagnosed with Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease. Sadly, Jomo lost his battle against ALS in 2021.

#### Requirements

Applicants must have a high school diploma or an equivalent. In ad-

dition, applicants must be currently enrolled in an approved CAAHEP-accredited PSG program, a CAAHEP-accredited END program with a PSG add-on, or a CoARC-accredited program with a PSG add-on, OR must have proof of acceptance to an accredited program.

In the weeks leading up to the opening of each scholarship application window, the BRPT will issue a "Call for Applications" informing technologists and colleagues of these opportunities. This call for applications – issued via email blast and social media posts – will direct all interested applicants to a dedicated web page with details on eligibility, application criteria, and a downloadable application. Winners are typically announced one month after the application window closes.

In addition to applications from the United States, we've received strong applications from across the globe, including India, Malaysia, the UK, Australia, Saudi Arabia, and other countries.



The number of compelling applications we receive each cycle for all scholarships continues to grow. The BRPT is excited to see this level of interest in our profession, and we are thrilled to help support members of the next generation of sleep technologists.

Michelle DiMaria, BS, RRT, RPSGT, is the Chair of the BRPT Scholarship Committee.



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