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Enter Modius: Neurovalens's Innovative New Solution to Insomnia

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Background

Adequate sleep is an important aspect of a healthy lifestyle that increasingly seems to evade many. Factors like elevated stress and poor sleep hygiene are some of the primary culprits behind this, and the consequences they can have on patients' health are hard to overstate. Insufficient sleep has been documented to have adverse long-term effects on patients' cardiovascular health, immune systems, and mental well-being, among many other facets of health[1]. Given this, patients with insomnia are at significantly elevated risk of developing these negative health outcomes over time. Insomnia is defined as difficulty with sleep onset or maintenance with associated daytime deficiencies, such as poor concentration. In Ireland, it has been estimated that up to 15% of the population struggle with this potentially debilitating disorder, surpassing some other European populations[2,3,4]. Further complicating things, the management of this disorder can be quite difficult and inconsistent. The pharmacological options we currently have at our disposal tend to either have limited efficacy, like melatonin receptor agonists, or carry the risk of dependence, such as benzodiazepines1. As for non-pharmacological therapies, our options are extremely lacking, with cognitive behavioural therapy being the only such treatment currently recommended by the Centers for Disease Control and Prevention (CDC)[1].

With that being said, this may not be the case for much longer. The gap in our management repertoire of insomnia may soon be shrinking with the recent FDA approval of Belfast-based Neurovalens's Modius SLEEP technology, which boasts the ability to help regulate circadian rhythms via electrical stimulation of the hypothalamus without a single drug needed[5]. Not only is this device non-pharmacological, it is also remarkably totally non-invasive, meaning the risks and side effects of using it are greatly reduced. Another important benefit is the device's ease of use. All patients need to do is simply wear the headset and turn it on for 30 minutes of totally painless neural stimulation an hour before sleeping – no need to keep it on while asleep[5]. Patients can even continue with activities like reading while the device is active. The simplicity and comfort of the process is an essential aspect of the Modius's appeal for patients and clinicians alike, as it makes it considerably less likely that patient compliance will be a major issue.

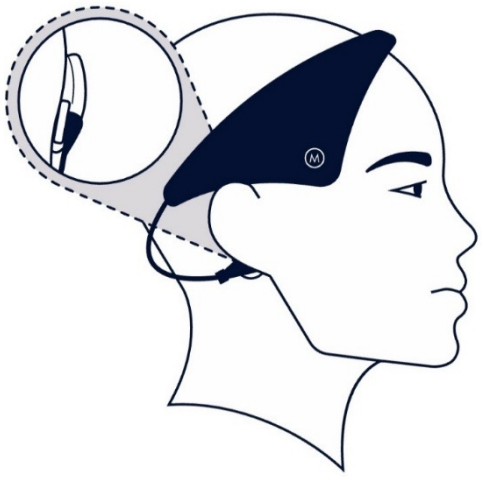


Figure 1 - How to wear the Neurovalens Modius SLEEP headset[5]

Mechanism of Action

Even more interesting, however, is how this technology works. The main target of the headset's neural stimulation is the suprachiasmatic nucleus, which is located on the anterior aspect of the hypothalamus and is responsible for regulating the body's sleep-wake cycle, also known as the circadian rhythm[5]. The usual challenge with accessing this region is that it is anatomically quite deep within the brain. This makes it extremely difficult to stimulate without the use of an implant, which would of course be very invasive and thus exacerbate both the risks and cost. The technological innovation Neurovalens's Modius uses to circumvent this obstacle is as elegant as it is potentially useful: it uses our understanding of neural pathways to first target peripheral nerve fibers that are both superficial enough to be easily accessed and project to the ultimate target structures. In this particular case, the initial target of the headset is the peripheral branches of the vestibular nerve (one of the two major branches of cranial nerve VIII), which

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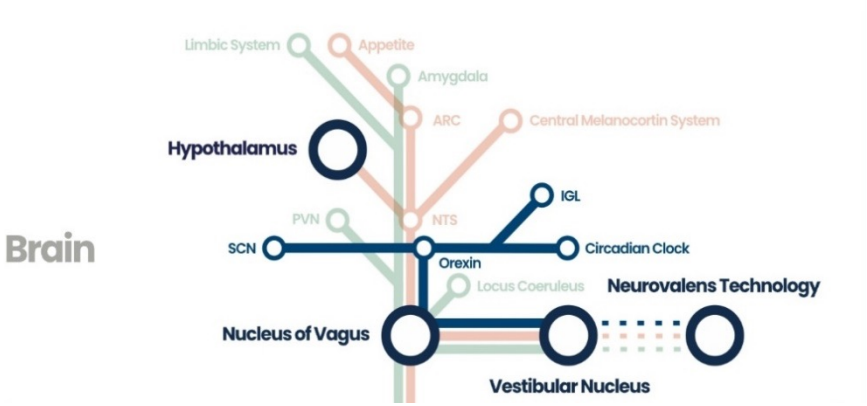


Figure 2 - The neural pathway used by the Modius headset to stimulate the suprachiasmatic nucleus (SCN: suprachiasmatic nucleus, IGL: intergeniculate leaflet)[5]

terminate at the mastoid process inferoposterior to the ear canal. Stimulating these nerve fibres propagates the electrical signal to the medial vestibular nucleus of the medulla oblongata, from where it proceeds to the hypothalamus[5]. In this way deep brain structures like the suprachiasmatic nucleus can be safely targeted for stimulation without any invasive procedures or drugs, so far as there is a known and accessible neural pathway that can direct the signal to it without adversely stimulating unintended brain structures.

The theory of this mechanism posits it will help normalize circadian rhythms and allow patients to have prolonged and higher quality sleep, and the available data suggests it does exactly that. A randomized controlled trial published in 2020 by S. Goothy and J. McKeown, the latter of whom is the founder and CEO of Neurovalens, sought to find the effect of electrical vestibular nerve stimulation on the sleep pattern of 20 patients with insomnia[6]. Specifically, they measured the change in subject scores on the Insomnia Severity Index (ISI), a standardized self reported questionnaire used to ascertain the severity of patients' insomnia. After just 14 days of regular use of the device, the mean experimental ISI scores were found to have dropped significantly from their baseline counterparts. Specifically, the mean ISI score dropped from 15.7 ± 4.7, which is classified as moderate insomnia, to 8.15 ± 3.6, which is considered sub-clinical. Furthermore, mean self-reported restfulness in the mornings on a 0-4 Likert scale increased from 1.6 ± 0.63 at baseline to 2.67 ± 0.56 during the second week with no reported adverse events[6]. This data is quite encouraging, and suggests that Neurovalens's Modius SLEEP technology could provide a viable alternative to insomnia management, though more research should (and seemingly will) be done to reproduce these findings[6,7].

Future Directions

The publication of this clinical trial was followed by the recent FDA approval of the Modius SLEEP device, meaning it can now be sold commercially and potentially provided via medical insurance with the prescription of a doctor. Speaking on this, Neurovalens CEO Dr. Jason McKeown said "Having the Modius Sleep technology as a certified medical device for the treatment of chronic insomnia is a landmark step for the company as we focus on future growth in the US market. Most other products on the market measure symptoms of insomnia, but Modius Sleep is a non-invasive device that actually treats the underlying issue, improving the lives of our patients[8]." Moreover, insomnia is not the only condition Neurovalens intends to address using this technology, and is investigating its therapeutic use for patients with anxiety, obesity, and even type II diabetes[5]. While we have yet to fully understand the potential of this technology or how useful it will truly be in a clinical setting, one thing remains clear: it certainly seems promising.



Figure 3 - Subject using a Modius headset[6]

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