

# Managing Chronic Insomnia: Therapeutic Effectiveness and Patient Acceptance of Vestibular Nerve Activation with Philips Respironics' SleepWave Medical Device

An open label, subjective assessment

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**Introduction:** This study was conducted to examine individuals' therapeutic experiences and acceptance of a novel vestibular nerve activation stimulator as a treatment for chronic insomnia.

**Study design:** An open-label, 30-day, uncontrolled study to examine the acceptance and effectiveness of a vestibular nerve activation device in adult participants with self-reported chronic insomnia symptoms.

**Setting:** Individualized face-to-face orientation and training was conducted in five (5) United States (US) cities or remotely via DVD guide with telephone support. Participants subsequently used the device as required, in a domiciliary setting, for the 30-day intervention period.

**Participants:** 105 adult participants with self-reported chronic insomnia symptoms.

**Measurements and results:** Qualifying participants were asked to complete a daily sleep journal for one (1) week to obtain a baseline prior to intervention, and then on a daily basis during the 30-day treatment phase. Additionally, an Insomnia Severity Index (ISI) questionnaire was completed pre- and post-intervention. Device usage was self-managed, based on individual participants' requirements for insomnia therapy. Each activation of the medical device provided vestibular apparatus stimulation for a one-hour period.

Statistically significant changes were identified between pre- and post-intervention for the following sleep variables: Sleep Onset Latency (SOL), Wake-After-Sleep-Onset (WASO), Sleep Efficiency (SE%), all  $p < .001$  and Total Sleep Time (TST),  $p = .001$ . Additionally, the ISI post-intervention mean scores (SD) [11.8 (5.3)] were significantly improved when compared to pre-intervention scores [17.8 (4.0)]  $p < .001$ .

**Conclusion:** The results of this study indicate that the use of Philips Respironics' SleepWave device produced statistically significant improvements in many measures of self-reported chronic insomnia symptoms.

## Introduction

Insomnia is one of the most common presenting symptoms in the primary care setting.<sup>1,2</sup> Defined as: “Complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep.” The disturbance may consist of one or more of three features: (1) difficulty in initiating sleep; (2) difficulty in maintaining sleep; or (3) waking up too early.<sup>3</sup> Insomnia can have a serious impact on work performance and maintaining healthy social relationships.<sup>4</sup> Chronic insomnia is differentiated from acute insomnia by individuals experiencing at least one of the symptoms described above for a minimum of 30 days.<sup>3</sup>

Predictably, there is a wealth of research in the areas of assessment and treatment for this sleep disorder given the impact insomnia has been shown to have on mental and physical health and wellbeing.<sup>3-5</sup> Incidence rates are around 9% of the general population regularly, escalating to 30% for those who report occasional suffering.<sup>6</sup> Many individuals continue to report symptoms of insomnia for many years after initial onset.<sup>7</sup> Areas of particular interest to clinicians, health-care professionals and insomnia sufferers include implementation, acceptance and adherence to therapies that provide effective long-term management.

Conventional treatments include prescription medications (sedative-hypnotics), cognitive-behavioral therapy (CBT) and other alternative therapies (e.g. alcohol, herbal remedies and off-label use of other medicines).<sup>3</sup> While sedative-hypnotics and CBT have been shown to be effective in the treatment of insomnia<sup>3,8</sup>, expert opinion counsels against long-term use of sedative-hypnotics because of residual sedative, rebound insomnia, memory impairment, dependency and withdrawal difficulties.<sup>9,10</sup> In addition, CBT is not easily accessed, and patients frequently have difficulty adhering to the strict behavioral program that is typically prescribed.<sup>11</sup> A further area of concern is the limited evidence supporting the efficacy and safety of alternative therapies, despite their widespread use.<sup>3</sup>

One promising approach to managing chronic insomnia is non-invasive mechanical vestibular nerve activation, which has been demonstrated to affect sleep.<sup>12-17</sup> The vestibular apparatus, in conjunction with visual and proprioceptive inputs, is responsible for maintaining balance under all conditions. Previous studies have used a mechanical rocking motion to induce vestibular activation, mimicking the sensation of infants being comforted by their parents. Improvements in sleep architecture and increased Total Sleep Time (TST), Sleep Efficiency (SE%), Rapid Eye Movement (REM) and decreased Sleep Onset Latency (SOL) have been demonstrated when using this technique.<sup>12-17</sup>

A unique therapy, designed to non-invasively stimulate the vestibular nerve to promote sleep onset, has recently been developed (SleepWave device), Philips Respironics, Monroeville, Pennsylvania, USA). As an alternative to the rocking motion delivered by mechanical action, a swaying sensation can be artificially created through mild electrical stimulation. Clinical studies have been previously conducted to investigate both the safety and efficacy of this medical device for the treatment of insomnia via a transient insomnia model, with positive outcomes.<sup>18,19</sup>

Individuals with chronic insomnia report similar issues in sleep disturbance to transient insomnia, although chronic or persistent in nature. Given the limitations of current effective therapies, and the recent emphasis on patient-centered care<sup>20</sup>, there is an increasing need for an alternative treatment for insomnia symptoms. It has been shown that patient preference for non-pharmacological treatment was over three-times greater than prescription medications<sup>21</sup>, and many would prefer a non-pharmaceutical approach if an effective one were available.<sup>11</sup> Vestibular nerve activation may provide a desirable treatment for chronic insomnia.

The objective of the study was to examine individuals' therapeutic experiences and acceptance of a novel vestibular nerve activation device as a treatment for chronic insomnia.

## SleepWave

This study examined individuals' therapeutic experiences and acceptance of a vestibular nerve activation device. The SleepWave device provides non-invasive electrical vestibular nerve activation. The stimulating electrode is shielded in an ear spiral that is fitted behind the ear. Electrically, the device is similar to cranial electrical stimulation (CES) devices. The SleepWave device is worn during sleep periods and when activated, has a one-hour duration. The device is programmed to deliver a peak current from 0.1 – 1.0 milli Amps at a frequency of 0.5 Hertz.

## Methods

An open-label, 30-day, uncontrolled study was conducted to examine the acceptance and effectiveness of a vestibular nerve activation device in adult participants with self-reported chronic insomnia symptoms. Inclusion and exclusion criteria are provided in Table 1. Eligible participants (n=105) were asked to complete a baseline nightly sleep journal for one week prior to an orientation and training session to determine baseline measurements.

Orientation and training for the study was managed in two ways – at one of five central sites (Pittsburgh, Chicago, Dallas, New York, and San Francisco) or remotely. Remote participants were oriented and trained using a DVD guide with telephone support.

Participants then completed a baseline questionnaire covering demographic data, current sleep habits and the Insomnia Severity Index<sup>22</sup> (ISI) questionnaire, which is adequately sensitive to measure treatment outcome.<sup>23</sup> The ISI is a 7-item questionnaire assessing the nature, severity, and impact of existing sleep difficulties. Measures assessed were: severity of sleep onset, sleep maintenance and problems with early morning awakening; sleep satisfaction; interference of sleep difficulties with daytime functioning; awareness of sleep problems by others; and distress caused by sleep difficulties.

Comprehensive training on operating the SleepWave device was then given. Sleep journals were completed daily for the duration of the study. Telephone interviews allowing participants to describe their experiences and impressions using the SleepWave device were conducted on days 7 and 14 of the study. An online questionnaire was provided as an alternative for participants who could not complete the

interviews by telephone. A final questionnaire was conducted upon completion of the 30-day study, examining sleep habits, frequency of the SleepWave device use and use of alternative interventions (medications or other) during the study and a post-study ISI.

## Results

In total, 105 participants were enrolled into the study. Five participants (all female) withdrew within the first week of data collection. Of the 5, 3 reported an inability to tolerate treatment and 2 withdrew after 7 days without giving a reason. Mean age in years (n=86) was 43.8 (SD  $\pm 10$ ). Gender data were available for 91 participants (59/91 female), resulting in a 2:1 female:male ratio. Sleep journal data showed that the device was initiated once per night during 61% of the nights; twice per night during 11% of the nights; 3 or more times 4% of nights and not used at all 24% of the total nights (n=2525).

ISI scores were collected from 89/105, confining pre/post-analysis to 85% of the sample population. Comparing pre- and post-ISI scores, as a measure of treatment effectiveness, a statistically significant improvement was shown in this study sample (Wilcoxon Signed Ranks test,  $p < .001$ ). Additionally, the scores were converted to the corresponding classifications: 0-7 = No clinically significant insomnia; 8-14 = Sub-threshold insomnia; 15-21 = Clinical insomnia (moderate severity); 22-28 = Clinical insomnia (severe). The distributions of ISI categories differed significantly between study intervals (Figure 1, McNemar Test,  $p < 0.001$ ), showing a significant improvement of the group ISI scores pre- and post-intervention; mean (SD) 17.8 (4.0) and 11.8 (5.4) respectively.

Seven-day baseline sleep journal data were collected from 43/105 confining pre/post analysis to 41% of the sample population. Measures of participant recorded sleep variables demonstrated statistically significant improvement in SOL, TST, WASO and SE% between baseline and 30 days (Table 2). As baseline data limited the analysis of this study population, a comparison between subjects with and without baseline data was explored for recorded sleep onset latency measures to determine whether the reported improvement was comparable between groups. A mixed model was performed including the between-subjects with or without baseline data, and the repeated measures factor of time (weeks 1-4). No significant

difference was observed between those with baseline and those without ( $p=.983$ ). Furthermore, there was no significant interaction between subject group and time ( $p=.933$ ), suggesting that the change in sleep onset latency over time did not differ significantly between participants with and without baseline information.

### Discussion

This study provides new evidence supporting electrical vestibular nerve activation as a promising therapeutic intervention for chronic insomnia.

One potential limitation of this study is the absence of sleep data derived by polysomnography. Therefore, the findings were entirely reliant on subjective assessment. Also, the sample population from which the study cohort was obtained and the resulting number of participants who provided complete data sets for analysis, was limited and may have created bias.

It is important to note that this study employed a purely “as needed” therapy regimen. Giving individuals complete autonomy to determine whether or not to activate the SleepWave device resulted in variable use of the medical device by participants in this study. While it is common for

prescription medication management to be of a fixed nightly dose, participants did not necessarily feel the need to use the SleepWave device every night. This is possibly due to the waxing and waning nature of insomnia symptoms and appears to be beneficial compared to that of fixed dosing, as it empowers individuals to manage their own symptoms. Although this study was open-label and uncontrolled, it has been suggested that “optimal trial conditions (efficacy) misrepresents the real world (effectiveness) where variations in clinical skills, the intensity and duration of interventions, patient adherence and local resources influence outcomes”.<sup>24</sup> Considering this, and the limitation of current treatments, a non-invasive ‘as required’ treatment, such as the SleepWave device, may prove to be an effective solution with limited risks or side-effects,<sup>25</sup> and one that does not require intensive resources.

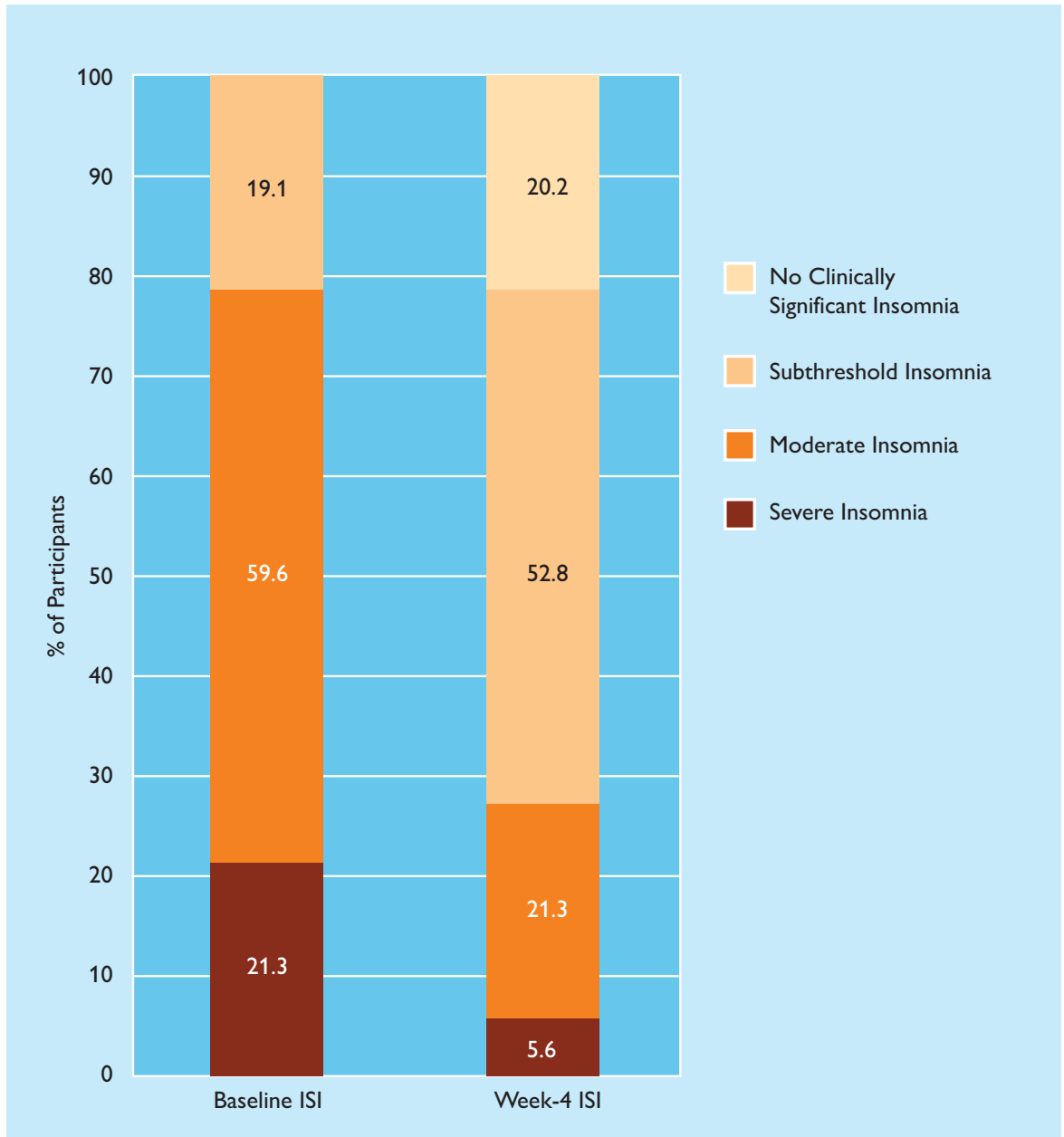
### Conclusion

At the completion of this 30-day open-label, uncontrolled study of chronic insomniacs, all sleep parameters improved significantly. Considering the ISI as a measure of treatment outcome, results suggest that using the SleepWave device as a form of therapy is effective in individuals with chronic insomnia symptoms.

**Table 1: Inclusion /exclusion criteria**

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• Age 21 – 65</li> <li>• Ability to provide consent</li> <li>• Self-reported history of difficulty falling asleep, maintaining sleep, or waking up prematurely at least once per week for a minimum of 1 month prior to enrollment</li> </ul>	<ul style="list-style-type: none"> <li>• Serious medical illness that may interfere with study participation or use of device</li> <li>• Unstable or untreated psychiatric illness</li> <li>• Use of any medications, including over-the-counter and herbal products, which may affect sleep/wake function unless used to promote sleep (which were monitored for the duration of study)</li> <li>• Diagnosis or suspected diagnosis of a sleep disorder that is unstable or untreated</li> <li>• Pregnancy or suspected pregnancy</li> <li>• Pre-existing medical condition contraindicated for vestibular nerve activation</li> <li>• Any disorder initiating seizures</li> <li>• Electronic implanted device</li> <li>• Cochlear implant or hearing aid</li> <li>• Current electrical monitoring for any medical conditions</li> <li>• History of falls</li> <li>• Previously participated in a vestibular nerve activation study</li> </ul>

**Figure 1: Distribution of Insomnia Severity Index (ISI) Class by Study Interval**



ISI scores were collected from 89/105, confining pre/post analysis 85% of the sample population.

<b>Table 2. Mean ± Standard Deviation (Median) summaries for recorded and sleep measures before and after intervention with formal assessment for all individuals with complete data sets (n=43)<sup>#</sup></b>				
<b>Sleep measures</b>	<b>Baseline</b>	<b>Day 30</b>	<b>Day 30 - Baseline</b>	<b>p value</b>
Recorded Sleep onset latency (mins) †	46.6 ± 28.5 (40.8)	28.3 ± 21.1 (22.5)	-18.3 ± 22.1 (-17.7)	<.001
Recorded total sleep time (mins) †	376.9 ± 63.3 (378.8)	415.6 ± 62.2 (413.6)	38.7 ± 67.1 (42.0)	=.001
Calculated total sleep time (mins) π	371.5 ± 72.8 (373.7)	418.0 ± 65.0 (420.9)	46.5 ± 69.4 (44.5)	<.001
Recorded wake after sleep onset (mins) †	30.5 ± 21.9 (26.3)	13.2 ± 15.7 (9.3)	-17.3 ± 23.2 (-13.1)	<.001
Recorded sleep efficiency†	0.8 ± 0.1 (0.8)	0.9 ± 0.1(0.9)	0.1 ± 0.1 (0.1)	<.001
Calculated sleep efficiency π	0.8 ± 0.1 (0.8)	0.9 ± 0.1(0.9)	0.1 ± 0.1 (0.1)	<.001

<sup>#</sup> For the majority of the endpoints, distributions of the paired differences exhibited a departure from the normality; therefore, change from baseline was assessed using the non-parametric Wilcoxon Signed Ranks test.

† Participant documented times in sleep journal.

π Investigator calculations from time stamps recorded by participants in sleep journals.

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