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Reducing Sleep Disorder and Insomnia Related Symptoms with Haptic Technology

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ABSTRACT

There are several diseases that are associated with sleep disorders and many current pharmacological approaches have been shown to have significant side effects. Sleep issues are widely prevalent in the US, with an estimate of 50-70 million people having chronic, or ongoing, sleep disorders. The importance of sleep health significantly impacts overall physical health, behavioral health, wellness, and safety and should not be underestimated or ignored. Identifying alternative treatments, including non-invasive and non-pharmacologic options and that are safe, efficacious, and have reduced and limited side effect profiles, will provide options that may be preferred over conventional therapies and how clinicians treat sleep disorders.

Ongoing research focusing on different brain centers has shown that areas of the brain can respond to external stimuli. Haptic vibrotactile trigger technology (VTT) is designed and theorized to target the pathways and influence these brain centers. The technology has been incorporated into non-invasive, non-pharmacological topical patches and other routes of delivery.

The purpose of this IRB-approved, blinded, minimal-risk observational study was to evaluate patients' experiences and/or perceptions and patient response for those who received a haptic vibrotactile trigger technology (VTT) embedded non-pharmacologic, non-invasive, over-the-counter sleep patch (REM Sleep Patch with VTT; Super Patch Company, Srysty Holding Co, Toronto, Canada) with those who received a control patch without the embedded VTT technology.

Methods: *Baseline, 7- and 14-day data were recorded in one hundred thirteen (133) adult subjects (87 females and 46 males) with a mean age of 53 years (Treatment Group) and 60 years (Control Group) who presented with sleep- or insomnia- related issues or associated symptoms. The study evaluated changes in overall sleep quality and insomnia severity scores via validated scales including the PSQI (Pittsburgh Sleep Quality Index) and the ISI (Insomnia Severity Index), changes in nighttime awakenings, the use of prescription and OTC medications, patient satisfaction, and any side effects reported while using the patches.*

Results: *After using the VTT embedded sleep patch, results showed statistically significant decreases in time to fall asleep, an increase in number of hours of sleep, improvement in the quality of sleep, and reduction in global PSQI Score. After 14 days, the vast majority of patients in the Treatment Group reported a reduction of usage of oral medications, that the patch was convenient and easy to use, and preferred the patch over oral and other medications for sleep. Results also showed positive outcomes in Quality of Life (QoL) components with improvements in daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, and mood. After 14 days for those subjects assigned to the Control Group using a patch not embedded with VTT technology, there were no improvements in time to fall asleep, number of hours of sleep, improvement in the quality of sleep, change in use of oral medications, change in daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, and mood.*

Conclusions: *Study results indicate that this non-pharmacologic, non-invasive, haptic vibrotactile trigger technology (VTT) embedded topical patch improves sleep quality, duration, and quality-of-life components and may reduce the use of concurrent medications, including prescribed and other oral medication for adult patients with sleep or insomnia-related symptoms compared to those subjects using a patch not embedded with VTT. Results reported support the use of this non-pharmacological, VTT-embedded, topical sleep patch to the current approaches and treatments of noninvasive and nonpharmacological sleep therapies.*

Keywords
Haptic vibrotactile trigger technology, Insomnia, Sleep management, PSQI, ISI, REM SLEEP PATCH, VTT.

Introduction
In the US, approximately 50 to 70 million Americans have sleep disorders, and a third of the adult population (about 84 million people) do not routinely get the recommended amount of uninterrupted sleep they need to protect their health. Sleep issues can greatly impact quality of life, morbidity and mortality, and imparts a significant personal and societal burden [1]. Evidence supports the importance of sleep health to overall physical health, behavioral health, wellness, and safety [2]. Several diseases have been associated with sleep disorders and duration including depression [3,4], diabetes [5], obesity [6,7], hypertension [8], and cardiovascular events [9,10]. However, serious health concerns can arise if individuals do not address and ignore their sleep issues and symptoms [11].

There are many pharmacological treatments but few non-pharmacological treatments for insomnia and sleep related disorders that attempt to assist with sleep onset, maintenance, consolidation, or quality. Treatments may include cognitive therapy, sleep-inducing medication, a combination of both [12], or sleep-assist devices, such as positive airway pressure (PAP) devices. Conventional pharmacological approaches have been associated with undesirable and serious side effects, even life-threatening, limiting the effectiveness and desirability of the treatment [12]. Herbal medicine, homeopathy, dietary supplements and other over the counter products also have been shown to have adverse side effects and limited scientific evidence of efficacy [13]. In light of potential serious adverse events, there has been an effort to minimize the use of pharmacologic treatments as first line therapy in recent years. Several medical associations, including the National Sleep Foundation (NSF) and the American Academy of Sleep Medicine (AASM) have suggested and developed guidelines for sleep disorders and recommend treatments that include non-invasive and non-pharmacological therapies as a first line treatment before consideration of other approaches [14].

There are known networks of neuronal pathways and circuits along with "neurosignature" patterns of nerve impulses generated by a widely distributed neural network in the brain. These neurosignature patterns may be triggered by inputs such as tactile sensations. In 2021, two scientists were awarded the Nobel Prize in Medicine for their work in identifying and understanding the roles of different receptors responsible for temperature and touch [15]. Tactile perception is an innate mechanism for human survival and allows for the adaptive ability to apprehend information via haptics – the active touch for object recognition and perception by higher centers of the brain [15-18]. The scientists identified two important ion channel receptors, PIEZO1 and PIEZO2 (after *piesi*, Greek for "pressure"). These ion channels have been shown to be involved in our somatosensory experience and tactile sensation of light touch, pressure, and pain, as well as showing sensitivity to external mechanical stimuli. Piezo2 has essential roles in sensory processes, such as gentle touch sensation [19-20]. The vibration one feels from text or a call on your mobile phone is a form of haptic feedback. These neuronal signals have been measured by the electroencephalogram (EEG) [16,21-23], and EEG research has shown that haptic technology, specifically haptic vibrotactile trigger technology (VTT), can influence and modulate brain centers and neuronal pathways [22]. Existing and ongoing research on how networks of neuronal pathways and the interaction with brain centers responds to sensory (nociceptive) stimulation has supported the incorporation of haptic feedback technology into novel, non-pharmacological treatment options to assist with addressing various sleep and other disorders [24-27]. Haptic vibrotactile trigger technology is theorized to target various pathways in your body that connect to the brain centers that control sleep, pain, and anxiety.

In this pilot HARMONI (Health Assessments: Reviewing, Measuring, and Observing Neuromatrix Interaction) minimal risk, observational study, IRB-approved study, we compared and evaluated an over the counter, non-invasive, non-drug, sleep-supporting patch (REM Sleep Patch with VTT; Super Patch Company, Srysty Holding Co, Toronto, Canada) that incorporates haptic-vibrotactile trigger technology (VTT) with a patch that did not contain VTT in patients with sleep or insomnia related symptoms. This study evaluated study subject responses to validated tools including The Pittsburgh Sleep Quality Index (PSQI) and Insomnia Severity Index (ISI) to assess patient-reported changes in sleep quality and interference scores and change in the use of sleep medications at 7- and 14-days following treatment. Data presented here are for both treatment and control groups.

Methods
Study Design
This study was a prospective, Institutional Review Board-approved, blinded Observational Study aimed at evaluating patients' experiences and/or perceptions and patient response for those who have received a haptic vibrotactile trigger technology (VTT) embedded patch (REM Sleep Patch with VTT; Super Patch Company, Srysty Holding Co, Toronto, Canada) or an inactive sleep patch, without VTT, by their clinician.

Baseline Demographic and Clinical Characteristics of Patients
A total of 133 patients (87 females, 46 males) at 3 US investigator sites were enrolled in the treatment (n=113) and control (n=20) arms of the study and completed the baseline, day 7, and day 14 surveys. Demographic results were similar for gender and age at the baseline survey for all groups of patients. The mean age at baseline was 53 years for the treatment group and 61 years for the control group.

Study subjects were given surveys that included validated sleep and insomnia measurement and symptom scales (e.g., The Pittsburgh Sleep Quality Index (PSQI) and Insomnia Severity Index (ISI)) as well as additional survey questions regarding patient satisfaction, patient quality of life, and resumption of their normal activities.

Patients who met the eligibility criteria and who were treated with the sleep patch comprised the study's treatment group (TG) and patients given a similar-looking patch without the embedded VTT were assigned to the control group (CG). For the treatment group, patient inclusion criteria were as follows: 1) ages 18 to 85 years, inclusive; 2) ability to provide written informed consent; 3) received the active VTT embedded study patch; and 4) had been diagnosed with sleep or insomnia related symptoms. Patients who had had a history of use drug or alcohol abuse, patients who had an implantable pacemaker, defibrillator or other electrical devices, or patients who were pregnant, were ineligible to participate in the study. Inclusion and exclusion criteria were the same for the control group except the patch given to subjects did not contain the VTT technology. Patients were blinded and were unaware of which patch was given to them. Patches were identified by a number on the external package and after being given to each patient was recorded and tracked by the CRO's compliance team for future data analysis.

For each enrolled study subject, patients were identified by an identification number, and a confidential file containing the informed consent forms and patient identification numbers were kept and maintained in a secured cabinet only accessible to the principal investigator and authorized personnel. Patient survey responses were provided with no identifying patient information. Patients could withdraw from this study at any time with the assurance of no unfavorable impact on their medical care. All diagnostic tests and treatment decisions were made at the discretion of clinicians, with no tests, treatments, or investigations performed as part of this study. Patients were provided the patches at no cost and were not compensated for their participation in the study.

The study protocol was approved by ADVARRA institutional review board and was performed in full accordance with the rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the principles of the declaration of Helsinki and the international council of Harmonisation/GCP. All patients gave informed and written consent.

Topical Intervention

The active, non-invasive, 2 x 2-inch non-pharmacological patches are embedded with proprietary sensory pattern imprints and incorporate haptic vibrotactile trigger technology (VTT). The active patches contain no drug or energy source. There is an adhesive backing on one side of the active patch. Patients in the treatment group were instructed to wear one patch on their forearm and replace the patch each day (Figure/Photo 1). The non-active patches look similar to the active patches but do not incorporate the haptic vibrotactile trigger technology (VTT).

Study Procedures and Assessments

Following enrollment, all study subjects were asked to complete surveys of the PSQI and ISI at baseline (day 0) and follow-up on days 7 and 14 of the study period. The surveys were comprised of questions to address and document sleep length, quality, and impact and level of interference that their sleep- or insomnia-related symptoms have on their quality-of-life components and in their daily lives. Any reported side effects were also documented. Study participants were instructed to wear a patch on their forearm before going to bed and patch placement was the same for the active and non-active treatment arms.

Figure/Photo 1

The PSQI is widely used in the field of sleep medicine and is considered an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, in addition to daytime dysfunction [28]. The Insomnia Severity Index (ISI) is a brief instrument that was designed to assess the severity of both nighttime and daytime components of insomnia. It is considered a validated and efficient measure suitable for evaluating sleep quality in a variety of patient and research populations. The seven-item questionnaire asks respondents to rate the nature and symptoms of their sleep problems. Questions relate to subjective qualities of the respondent's sleep, including the severity of symptoms, the respondent's satisfaction with his or her sleep patterns, the degree to which insomnia interferes with daily functioning, how noticeable the respondent feels his or her insomnia is to others, and the overall level of distress created by the sleep problem [29].

Patients were also asked to indicate their preference between the patch they were given and any other medications that they had been taking for sleep relief at the time of the baseline, day 7, and day 14, as well as their satisfaction and ease of use of the patch.

Study end points

The primary endpoints included changes in patient responses to The Pittsburgh Sleep Quality Index (PSQI) and Insomnia Severity Index (ISI) scores among the treatment group, control group, differences between the treatment and control groups, as well as preference in the use of prescription and OTC medications. We

also assessed patient satisfaction with patch treatment and any side effects reported by patients during the trial.

Statistical analysis

For all variables, descriptive statistics were calculated, including frequencies and percent for categorical variables and means with standard deviation (SD) for continuous variables. The maximum sample size available was used for each statistical analysis. Changes from baseline to day 7, and to day 14, in PSQI and ISI scores were analyzed using the paired *t*-test to identify any statistically significant differences within the treatment and control groups. Each survey collected responses to questions regarding patient satisfaction and side effects of assigned treatment. Descriptive statistics were used to determine patient satisfaction with the sleep patch within the treatment and control group. Descriptive statistics were also used to report any side effects experienced by patients. A two-tailed alpha was set to 0.05 for all statistical comparisons. SPSS v. 27 was used for all analyses.

Results

For both the treatment and control groups, only patients that completed 14 days of treatment were included in the analysis.

Global PSQI Score and ISI Severity Score

For the treatment group, after 14 days, the mean Global PSQI score decreased 55% (12.5 to 5.5/21;P< .001) and mean ISI Severity score decreased 57% (18.7 to 8.1;P< .001). Results also showed positive outcomes in all measured ISI Quality of Life (QoL) components with reductions in daytime fatigue, and improvements in mood, ability to function at work/daily chores, concentration, and memory after use of the sleep patch. For the control group, there were no improvements noted in either the PSQI or the ISI (Figure 2 and Figure 3).

Changes in Time to Fall Asleep and Duration of Sleep

In the treatment group, the mean number of minutes that it took a person to fall asleep at baseline was 69.1 (SD 32.5), reducing to 47 minutes (SD 22.7) at day 7, and 36 minutes (SD 23.7) at day 14 while wearing the patch (Table 1). This correlates to study subjects falling asleep almost 50% faster while using the sleep patch. The mean actual number of hours a person slept at baseline, before the introduction of the sleep patch was 5.25 (SD 1.27), increasing to 6.04 hours (SD .94) after 7 days and 6.51 hours (SD .90) after 14 days (Table 3), representing an increase of 25% of sleep duration after 14 days of patch use. For the control group, there were no reported improvements (Table 2 and Table 4).

Table 1: Treatment Group.

Statistic	Baseline	Day 7	Day 14
Mean, SD	69.1, 32.5	47.0, 22.7	36.6, 23.7
Median	60.0	45.0	30.0
Min	2.0	10.0	5.0
Max	210.0	150.0	180.0

- Each difference is statistically significant at $p<0.001$
- *"How long (in minutes) has it usually taken you to fall asleep each night?"*
- n=113 for each of Baseline, Day 7 and Day 14, matched data

Table 2: Control Group.

Statistic	Baseline	Day 7	Day 14
Mean, SD	57.3, 13.2	61.5, 8.3	60.8, 5.9
Median	60.0	60.0	60.0
Min	45	45	45
Max	90	90	75

Table 3: Treatment Group.

Statistic	Baseline	Day 7	Day 14
Mean, SD	5.25, 1.27	6.04, 0.94	6.51, 0.90
Median	5.0	6.0	7.0
Min	3.0	4.0	4.0
Max	8.5	8.0	8.0

- Each difference is statistically significant at $p<0.001$
- *"How many hours of actual sleep did you get at night?"*
- N=113 for each of Baseline, Day 7 and Day 14, matched data

Table 4: Control Group.

Statistic	Baseline	Day 7	Day 14
Mean, SD	4.1, 0.7	3.9, 0.5	3.9, 0.5
Median	4	4	4
Min	3	3	3
Max	5	4.5	4.5

Changes in Awakenings during Night

One of the PSQI questions asks the patient "*How often have you had trouble sleeping because you wake up in the middle of the night or early morning?"* At baseline for the treatment group, over 83% of study participants indicated that they had trouble sleeping at least once or twice (41.6%) or three or more (41.6%) times a week during the past month. After 7 days of incorporating the sleep patch with VTT, only 31% of subjects reported trouble sleeping and waking up either once or twice (18.6%) or three or more times (12.4%) during the past week, and after 14 days of using the sleep patch, only 22% of subjects reported trouble sleeping due to waking up either once or twice (11.5%) or three or more times (10.6%) during the past week (Table 5). For the control group of patients, the patch without the embedded VTT did not result in any improvements.

Table 5: Treatment Group.

Response	Baseline	Day 7	Day 14
Not during the past month (week)	5, 4.4%	25, 22.1%	50, 44.2%
Less than once a week	14, 12.4%	53, 46.9%	38, 33.6%
Once or twice a week	47, 41.6%	21, 18.6%	13, 11.5%
Three or more times a week	47, 41.6%	14, 12.4%	12, 10.6%

- How often have you had trouble sleeping because you wake up in the middle of the night or early morning?
- n=113 for each of Baseline, Day 7 and Day 14, matched data, n, %

Almost 70% of subjects in the treatment group and all subjects in the control group indicated that they had trouble sleeping because they had to use the bathroom during the night up to three or more times per week. After 14 days, only 15% of subjects in

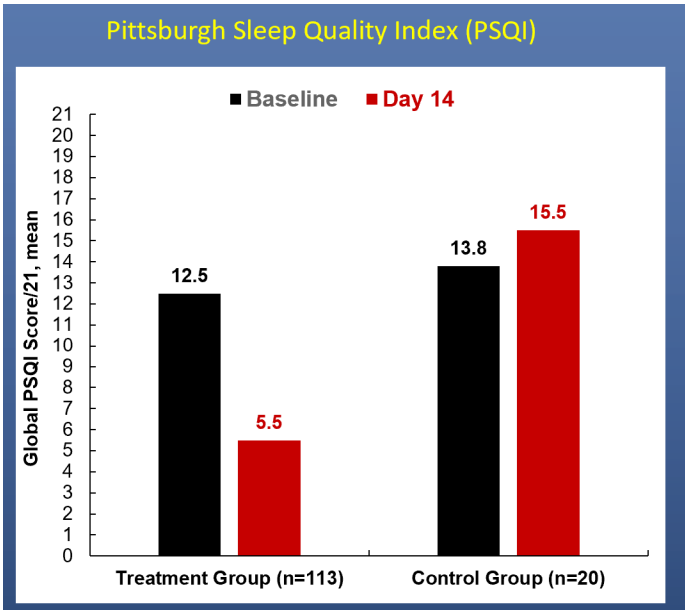

Figure 2 Baseline and Day 14 Global Pittsburgh Sleep Quality Index (PSQI) Score/21 within the Treatment and Control Groups
*95% Confidence Interval of the difference, paired *t*-test.

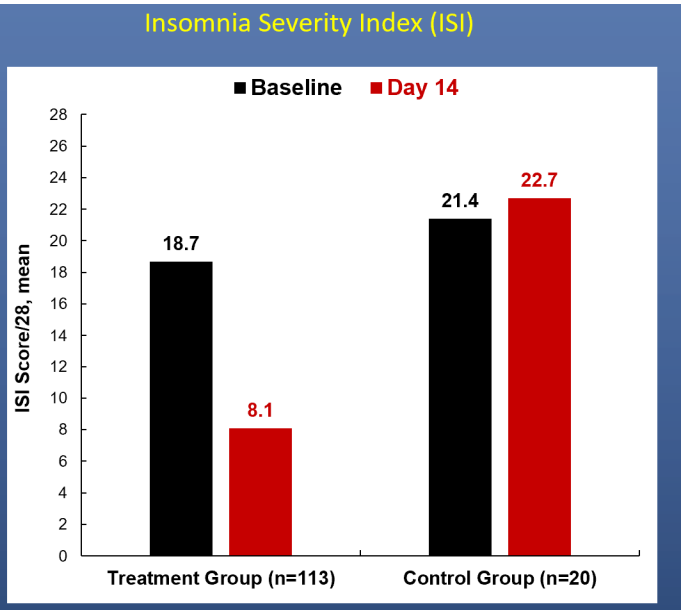

Figure 3 Baseline and Day 14 Insomnia Severity Index (ISI) Score/28 within the Treatment and Control Groups
*95% Confidence Interval of the difference, paired *t*-test.

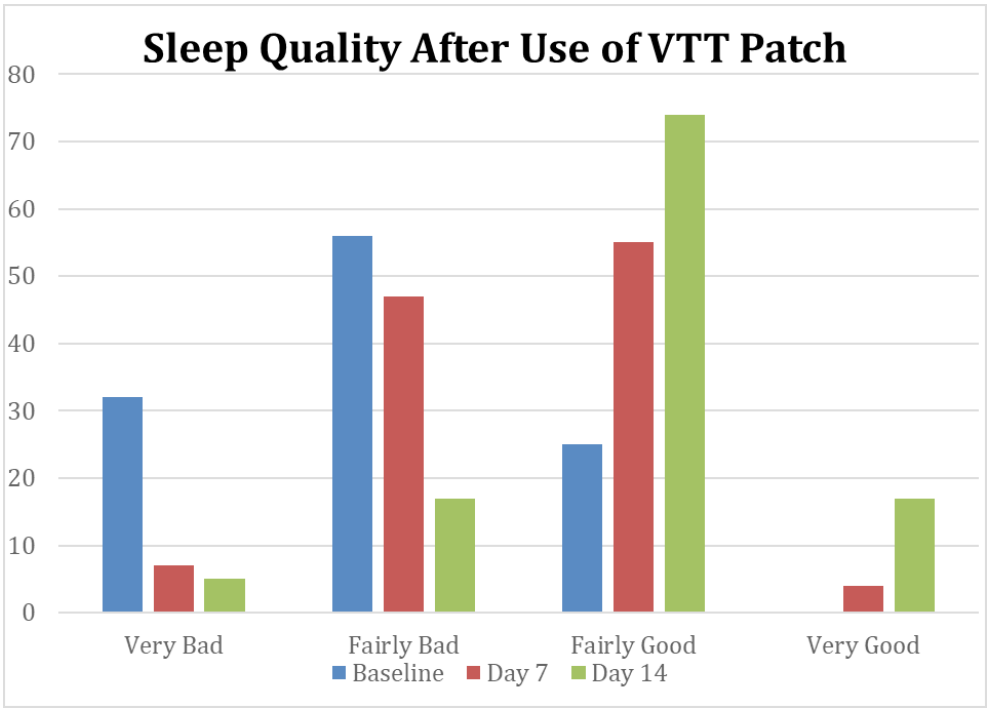

Figure 4:

the treatment group indicated that they had trouble sleeping due to getting up to use the bathroom at night. This is a reduction of almost 80%. There was no improvement reported in the control group of patients.

Changes in Sleep Quality

At baseline, 78% of patients in the treatment group indicated that during the month prior to using the sleep patch, they categorized their quality of sleep as either 'fairly bad' (38.1%) or 'very bad' (31%). Only after 7 days of patch use, 7 patients (6%) of patients indicated that their sleep was 'very bad.' After 14 days of patch use, this was further reduced to only 5 subjects indicating that their sleep was 'very bad.' In comparison, at baseline, only 25% of subjects indicated that they had 'fairly good' sleep in the month before patch use. After 14 days of using the active patch, over 90% of patients indicated that they had either 'fairly good' or 'very good' sleep (Figure 4). There were no reported improvements in the control group (Table 6).

Table 6: Control Group.

CONTROL GROUP			
Response	**Baseline**	**Day 7**	**Day 14**
Very good	---	---	---
Fairly good	---	---	---
Fairly bad	16, 80%	17, 85%	15, 75%
Very bad	4, 20%	3, 15%	5, 25%

The summary of all outcomes is illustrated below (Figure 5).

Changes From Baseline to Day 7 and Baseline to Day 14 in the Use of Concurrent Sleep Medications

During the month prior to enrollment, over 56% of patients (n=63) in the treatment group indicated that they took either prescription of over-the counter (OTC) medications to help them sleep at least once or twice a week, with 57% (n=36) of those patients indicating that they took medications three or more times per week. After 7 days of patch use, only 12 patients (10.6%) indicated that they took medications to help them sleep, an 81% reduction. And after 14 days of patch use, only 10 patients indicated that they took medications to help them sleep, a reduction of 85% from baseline. Further, after 14 days of patch use, 80% of patients (n=90) indicated that they did not take any medication during the past week to help them sleep, compared to only 35% (n=40) at baseline. After 14 days, there was no reported changes in concurrent medication usage for the control group.

Use and Preference of the sleep patch

Subjects were queried on specific satisfaction rating aspects regarding use of the sleep patch (scale: 0 = N/A, 1 = Strongly disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly agree). At day 14, approximately 90% of patients in the treatment group and all patients in the control group 'agreed' or 'strongly agreed' that the patch was "easy to apply" (n=101 (TG); CG; n=20 (CG)) and "convenient" (n=100 (TG), 20 (CG)), and approximately 70% of patients in the treatment group 'agreed' or 'strongly agreed' that they "preferred the patch over pills and other oral medication" (n=76 (TG)) and "preferred over other sleep-relieving treatments" (n=75 (TG)). In the treatment group, the vast majority of patients were highly satisfied with the patch embedded with VTT. However, in the control group, not one subject indicated that they were satisfied with the non-VTT-embedded patch.

Safety

Patients reported no serious adverse events while being treated with the active or inactive patch. In the treatment group, there were 5 reports (5/113) of side effects including: lucid dreams (1), insomnia (1), itching (1), sleeplessness (1), and adhesive irritation (1). There were no reported side effects in the control group.

	TREATMENT GROUP	**CONTROL GROUP**
Global PSQI Score	Over 14 days, the mean score decreased 56% (12.5 to 5.5/21; p<.001)	Over 14 days, the mean score increased 11% (13.8 to 15.5/21; p<.001)
ISI Severity Score	Over 14 days, the mean score decreased 57% (18.7 to 8.1; p< .001)	Over 14 days, the mean score increased 6% (21.4 to 22.7; p= .011)
	Results also showed positive outcomes in all measured ISI Quality of Life (QoL) components with reductions in daytime fatigue, and improvements in mood, ability to function at work/daily chores, concentration, and memory after use of the sleep patch.	No Change
Time to Fall Asleep	After 14 days, Study subjects fell asleep almost 50% faster	No Significant Change
Length of Sleep	After 14 days, Study subjects showed an increase of 25% of sleep duration after 14 days	No Significant Change
Sleep Quality		
At Baseline	78% indicated "Fairly Bad/Very Bad"	100% indicated "Fairly Bad/Very Bad"
After 14 days	>90% indicated "Fairly Good/Very Good"	No Change
Changes in Awakenings During Night		
At Baseline	Over 83% indicated that they had trouble sleeping at least once, twice, or three or more times a week	All patients indicated that they had trouble sleeping at least once, twice, or three or more times a week
After 14 days	Only 22% of subjects reported trouble sleeping due to waking up once, twice, or three or more times a week	No Change
Changes in Getting Up to Use the Bathroom		
After 14 days	There was a Reduction of over 80%	No Change

Figure 5: Sleep Outcome Summary between Treatment and Control Groups.

Discussion

Here we report the final results of this HARMONI study, a prospective, blinded, non-randomized observational study evaluating the safety and efficacy of the REM Sleep Patch with VTT in patients presenting with sleep or insomnia-related symptoms compared to a control group of patients who received a patch without the embedded technology. For the treatment group, results showed reductions in Global PSQI and ISI Severity scores and a preference for the patch over other sleep medications from baseline to day 7, and to day 14. There were improvements in time to fall asleep, length of sleep, reductions in awakening during the night, and reductions in getting up at night to use the bathroom. In the control group, no improvements were reported in any of the areas studied (Figure 5).

There has been a significant amount of research over the past several years regarding haptics to gain a better understanding of how it interacts with different brain centers and its potential role in helping patients across a wide variety of therapeutic areas [24-32]. When a person is exposed to VTT, published research has shown that there are changes in their EEG patterns [22,23]. In addition, researchers have advanced their theoretical understanding and how neural networks are impacted by VTT [22-27,33]. Brain centers have been shown to be responsive to external stimuli that incorporate the VTT technology and have produced positive outcomes in balance and stability measurements [22,35].

Ronald Melzack first proposed and hypothesized that specific regions of the brain communicate with networks of neurons in "large loops", as a way to explain the cognitive, emotional, and motor modalities through which humans experience sensations [33,36]. He theorized and described 3 distinct looping pathways: 1) a traditional sensory pathway with neural projections routed through the thalamus, 2) one that follows a path through the brainstem and parts of the limbic system, and 3) one associated with pathways that are routed through different Brodmann Areas (BA), particularly the somatosensory cortex. Neuroimaging techniques, such as functional analysis using magnetic resonance imaging (fMRI), have been evaluated to illustrate changes in EEG patterns. The sensory patterns within the studied VTT patches are designed and thought to be in close symmetry between known EEG patterns and their role in modulating EEG and neuronal circuits within higher brain centers [36].

There are many undesirable and well documented harmful and potentially life-threatening serious side effects that are associated with conventional pharmacological treatments for sleep disorders [37]. These include heart risks, dizziness, nausea, hallucinations, depression, a higher risk for confusion, and falls [38-41]. The American Academy of Sleep Medicine (AASM) has noted that even non-prescription drugs, including over-the counter sleeping aids and herbal/nutritional agents were not recommended due to lack of demonstrated efficacy as well as safety concerns [14]. Although non-pharmacological approaches, such as Cognitive Behavioral Therapy (CBT), has shown success in treating patients with sleep disorders [42], there remains a significant unmet need for alternative treatment options for those patients experiencing sleep-related symptoms and issues that do not respond to CBT. Gaining a better understanding of how the brain interacts with external stimuli, such as through VTT, may lead to viable, safe and effective, non-invasive, drug-free treatment options, with limited or no side effects. In this analysis, subjects in the treatment group of HARMONI reported a longer length of sleep, a better quality of sleep, and reduced awakenings during the night. This is perhaps due to the VTT patch's ability to influence the brain centers and to allow a deeper level of sleep. As continued positive outcomes are reported by patients and clinicians after use of haptic vibrotactile trigger technology, future research that incorporates more comprehensive measurements, obtained through tools such as wearables, sensors, or other monitoring devices, is encouraged to confirm and document real-time changes and support the use of VTT for a variety of conditions. Careful selection of treatment for sleep disorders and related symptoms are needed and novel, non-pharmacologic and non-invasive therapies fulfill an unmet need for additional safe and effective treatment strategies and options for patients [39].

Limitations

This was a nonrandomized, blinded, observational study based on a sample of patients attending diverse clinical settings for the treatment of sleep- or insomnia-related symptoms who consented to participate in this study. This analysis reported on a group of 113 patients who were treated with the VTT embedded study patch and a control group of 20 patients that were given a patch without embedded VTT.

The data of those patients who did not complete the follow up surveys after baseline, or patients who indicated that they did not use the patch after the baseline visit were removed from evaluation. Due to patients having different sleep symptoms and differences in how they report their sleep patterns and quality, overall generalization and consistency of results may be impacted due to the differences in sleep issues, the amount of time the patient utilized the patch, and subjective self-reporting by the patient. Although there were shown to be significant and positive outcomes in those subjects in the treatment group and significant differences were illustrated between the treatment group and the control group, the limited size of the control group compared to the size of the treatment group makes it difficult to draw absolute conclusions about the effects of the VTT embedded patch. We have attempted to accurately evaluate and provide the most detailed reporting of the data while considering these limitations. Further research and randomized control, double-blinded trials are suggested to reinforce, confirm, and support the use of this novel VTT technology.

Conclusion

Study results indicate that this non-pharmacologic, non-invasive, haptic vibrotactile trigger technology (VTT) embedded topical patch improves sleep quality, sleep duration, and quality-of-life components and may reduce the use of concurrent medications,

including prescribed and other oral medication for adult patients with sleep or insomnia-related symptoms. Results reported suggest that this widely available OTC sleep patch supports inclusion to current first-line noninvasive and nonpharmacological sleep therapies and as part of a multimodal treatment approach.

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Disclosure

Paul Doghramji MD has received compensation from Clarity Science LLC for his role as principal investigator and for providing protocol-required services for the study. Janet Fason DO was compensated for her role as a study investigator. Peter L Hurwitz is President of Clarity Science LLC. The authors report no other disclosures.

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