Mechanical Dermal Stimulation to Modulate the Interoceptive Network in Sleep-disordered Populations

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***Abstract*— More than 80 million adults are affected by insufficient sleep in the United States, yet effective, drug-free therapies with few or no side effects are lacking. A 30-day open-label study was conducted, in which participants (n=25) reporting poor sleep (assessed via Pittsburgh Sleep Quality Index) were recruited to test a novel wearable mechanical neuromodulation device. The device was designed to modulate the interoceptive system via the affective touch network. 86% of participants showed an overall improvement in sleep after 30 days of device use.**

Keywords-sleep; neurostimulation; interoception.

I. INTRODUCTION

There is growing evidence that humans are hard-wired for receiving and processing affective (slow, light) touch via unmyelinated C-Tactile Afferent neurons (CTAs). Neuroimaging studies have found information from CTAs is primarily processed in the insula cortex, not the somatosensory cortex where myelinated inputs are processed [1]. This distinction is important to note when considering the growing evidence in support of the fundamental role of the insula in interoceptive processing. Affective touch, in turn, is associated with feelings of calm, relaxation and social connectedness, all related to improved interoceptive regulation.

Interoception is recognized as the processing of internal bodily signals such as changes in physiological states, via the Central Nervous System (CNS) [2][3]. Information is continuously exchanged through ascending and descending pathways between the CNS and the periphery, allowing for interoceptive information such as a change in temperature, to influence various physiological systems and processes, including sleep [3][4]. Furthermore, research has shown that interoceptive sensitivity and awareness may disrupt several processes, during sleep initiation and while asleep [2][3][4]. Dysregulated interoception, a mismatch between perceived and actual bodily states, is a hallmark of affective disorders and may be an underlying mechanism for sleep-related disorders. In a 2016 report, an estimated 83 million adults in the United States suffered from insufficient sleep; however, few drug-free therapeutic interventions exist that have few side effects and are effective in treating sleep-related disorders [7]. We developed a novel mechanical stimulation device, targeting the affective touch pathway, and thereby modulating the interoceptive system to improve sleep.

The objective of this research is to develop a device designed to stimulate the interoceptive system via the affective touch pathway, and then test the technology in the real world, targeting symptoms associated with dysregulated interoception. Here, we targeted poor sleep, measured by the Pittsburgh Sleep Quality Index (PSQI) [6].

The rest of this paper is organized as follows. Section II outlines study methods, including a description of the participant sample and the device technology used, an ethics statement, participant responsibilities, and measures used to assess sleep quality. Section III contains the detailed results of the present study and Section IV closes out the paper with the conclusion.

II. METHODS

A. Participants

25 adults (14 females, 11 males), out of a total of 245 screened, were enrolled in the study after meeting the criteria for poor sleep, measured by the PSQI (Global PSQI $\geq$ 10). Ages ranged from 24 to 60 years old (mean=35).

B. Mechanical Stimulation Device

A simple headband with small piezoelectric actuators at the distal ends, seen in Figure 1, was developed to deliver short bursts of very low intensity, low frequency mechanical stimulation, targeting CTAs associated with the affective touch pathway. The actuators were positioned behind the ears, on the mastoid, for convenience.

Figure 1. Mechanical Stimulation Device Prototype.

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The specific wave form was derived from a combination of empirical study (changes in alpha power pre/post stimulation in in-lab studies over 2 years) and known response characteristics of the CTA mechanoreceptors (low intensity, low frequency ~10 Hz).

C. Study Procedure

All study procedures were reviewed and approved by an ethical board (Solutions IRB, #: FWA00021831) [8]. The 25 participants who consented to the study were familiarized with the device, instructed in its use, and the device was donned by participants. A researcher, with feedback from the participant, reduced the intensity to the lowest perceivable level for that individual. Participants could increase/decrease the intensity throughout the 30-day study. The device logged usage time and intensity. The participant then had their first 20-minute session in our lab to assess any side effects and ensure competence in using the device. They were instructed to use the device for 20 minutes every day, within an hour of their normal bedtime. In addition, participants wore a wrist device to track sleep (Garmin VivoSmart 4).

D. Measures

Changes in sleep quality were assessed via PSQI, a 1-Item Sleep Quality Rating Scale, and the Garmin VivoSmart 4 wrist device. The PSQI is a self-report measure assessing sleep quality and disturbances over a 1-month timeframe. The 1-Item Sleep Quality Rating Scale is a self-report measure utilizing a scale of 1 to 5, where 1 represents little to no sleep at all, and 5 represents great sleep (no problems falling or staying asleep).

III. RESULTS

In the sample of 25 participants, 3 participants were excluded from analysis due to lack of compliance with the study protocol (i.e., device usage, completing the study). The following results will be reported as Mean ± standard deviation. 86% of compliant participants (n=22) reported an overall improvement in sleep, measured by Global PSQI scores shown in Figure 2, where lower scores indicate improvement in symptoms. Global PSQI scores improved by 43% on average (Pre: 9.8 ± 3.0, Post: 5.2 ± 2.6).

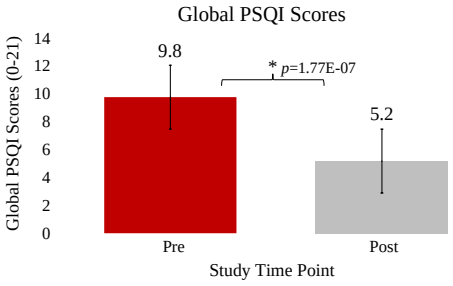

Figure 2. Global PSQI scores decreased on average, after 30 days of device use, representing an improvement in sleep.

More specifically, 91% of participants reported improvement in sleep quality, 77% reported falling asleep faster, and 68% reported a reduction in daytime drowsiness, shown in Figure 5, displaying average PSQI component scores pre and post 30 days of device use. Similarly, sleep hours increased 65 minutes on average (Pre: 6.60 ± 0.29, Post: 7.45 ± 0.45), shown in Figure 3, and self-reported sleep quality, shown in

Figure 4, improved significantly (Pre: 3.71 ± 0.31, Post: 4.25 ± 0.10). Sleep hours were assessed via a commercial wrist Photoplethysmography (PPG) device (Garmin VivoSmart 4, chosen as it was most reliable for sleep time in earlier studies). No devices appeared, in our assessment, to accurately measure sleep stages, nor is PPG a suitable substitute for a hypnogram.

Subjects rated the device as simple and easy to use. There were no known adverse effects and some minor transient side-effects (headache, skin irritation) that subsided with use.

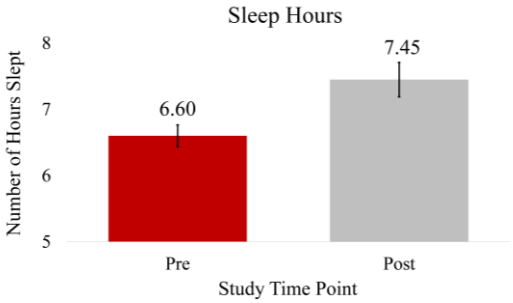

Figure 3. Sleep Hours increased on average, after 30 days of device use (measured by Garmin VivoSmart 4).

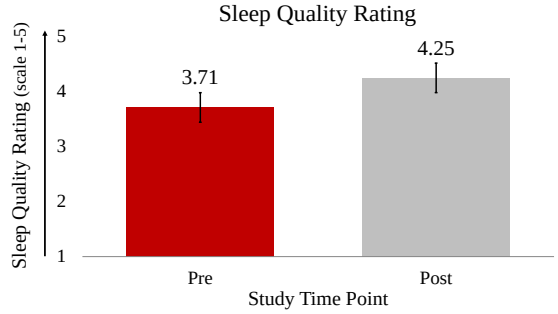

Figure 4. Sleep Quality Rating increased on average, after 30 days of device use.

IV. CONCLUSION AND FUTURE WORK

This is the first human study to evaluate mechanical stimulation of the affective touch pathway in a sleep-disordered population. Although the trial is small, open-label, and used early prototypes, the results were significant and participants clearly thought they benefited from the use of the device. A confirmatory Randomized

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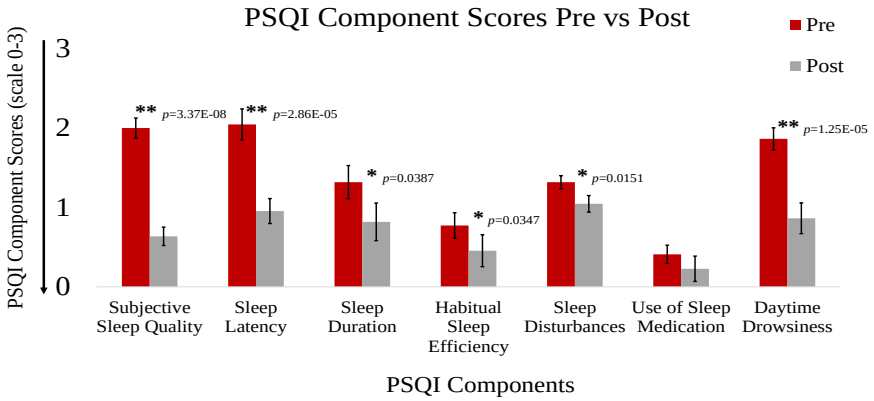

Figure 5. PSQI Component Scores before and after 30 days of device use, representing an overall improvement across 7 dimensions of sleep on average, most notably in Subjective Sleep Quality, Sleep Latency, and Daytime Drowsiness.

Control Trial (RCT) is underway to address limitations such as sample size and inclusion of a control group, which will be completed in late 2021.

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