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Feelmore Labs

Modulating the Interoceptive Network through Mechanical Dermal Stimulation

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Presenter Biographies

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Sahithi Garikapati

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She received a M.Sc. degree in Biomedical Engineering from Johns Hopkins University in 2017. Her research interests include signal processing of electrophysiological signals and the application of neural instrumentation. Currently her research includes proprietary noninvasive neuromodulation techniques.

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Gina Sensale

Research Assistant

She received a B.S. degree in Psychology, from the University of Connecticut in 2018. She is interested in studying psychological and neurological dysfunction through neuroimaging, signal processing, and behavior. She plans to continue studying noninvasive neuromodulation therapies and their effect on the brain and behavior.

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Gina Distefano

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She received a B.S. degree in Psychology from Union College in 2017. Her general interest in neuroscience, human behavior and healthcare, led her to the Feelmore Labs team. She has contributed to their research in the EEG lab and is excited to continue exploring noninvasive therapeutic techniques and their impact on the brain.

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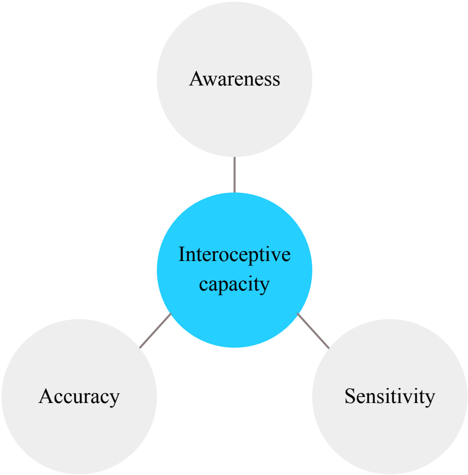
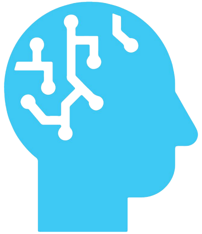
Interoception





Interoception is the perception of sensations originating in the body. Most are preconscious but some somatic interoceptive signals, especially those related to emotion, are often perceived consciously.

The conscious perception of the internal bodily state can be broken into three domains: **overall awareness, sensitivity to interoceptive changes, and accuracy in assessing interoceptive signals.**

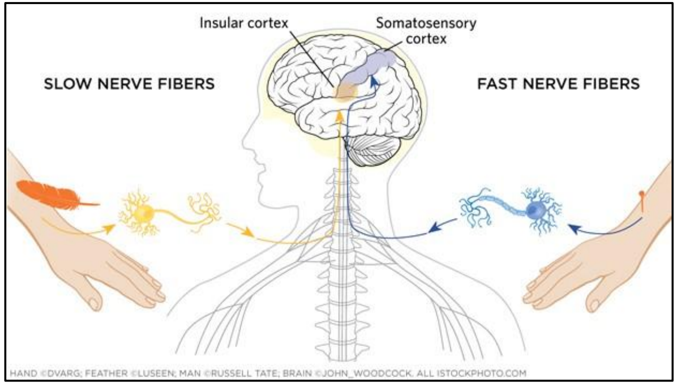
Interoception can become dysregulated. Awareness may lapse, sensitivity to change can become blunted or magnified and/or assessments become inaccurate. Interoceptive dysregulation has emerged as a significant component of stress and many affective disorders.

[2][3][4]

C-Tactile Afferent Neurons (CTAs) and Affective Touch

Mammals, including humans, are hardwired for receiving and processing affective (slow, light) touch via specialized mechanoreceptors, CTAs, found in all hairy skin.

Affective touch, in turn, is associated with feelings of calm, relaxation and social connectedness, all **related to improved interoceptive regulation.**



The **insular cortex**, where information from CTAs is processed, is a primary area for **interoceptive processing**[1], particularly as related to emotional responses and empathy.

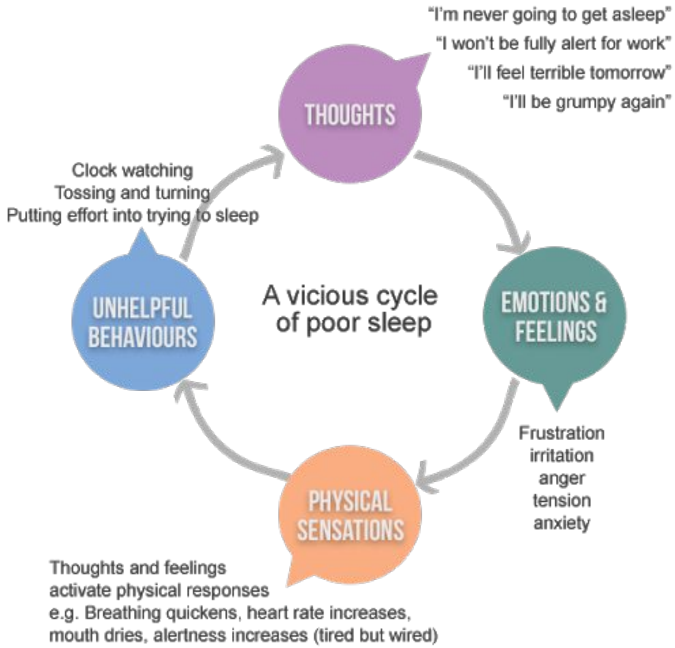
Affective Touch and Interoception

- Affective touch network imposes a high evolutionary cost.
  - Specialized skin/brain network
- Affective touch generates positive emotion, a sense of belonging and activates areas of the brain associated with empathy.
  - Improves interoceptive regulation
- As affective (social) touch recedes in a technologically outward looking society, this regulatory network atrophies.
- Interoception becomes dysregulated without CT Afferent input.
  - Increased anxiety
  - Reduced empathy
  - Sleep disorders

Interoception can be strengthened and re-regulated

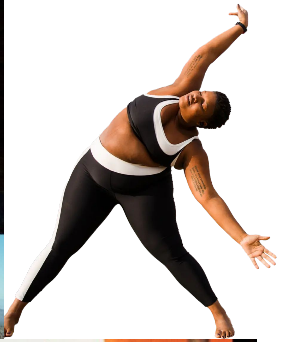
Interoception and Sleep

- Research studies have found that interoceptive sensitivity and awareness may disrupt several processes during sleep initiation and sleep. [2][3][4]
- Dysregulated interoception is being investigated and even treated for a variety of psychiatric disorders, such as affective disorders, eating disorders and others (Khalsa).
- Similarly, **dysregulated interoception may be an underlying mechanism for some common problems with sleep** and other stressors.
- Dysregulated interoception is developing as a novel therapeutic target.



Interoception and Sleep Interventions

- In the last decade, an estimated **83 million adults in the United States reported suffering from insufficient sleep**. [7]
- Few non-drug therapeutic interventions exist that are both low-side effect and effective in treating sleep-related disorders.
- Multiple studies suggest practices that improve interoception can improve sleep. [12]
  - Mindfulness
  - Yoga
  - Extreme sports/exercise



Research Objective

- Develop a device designed to stimulate the interoceptive system via the affective touch pathway

- 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).

Mechanical Stimulation Device

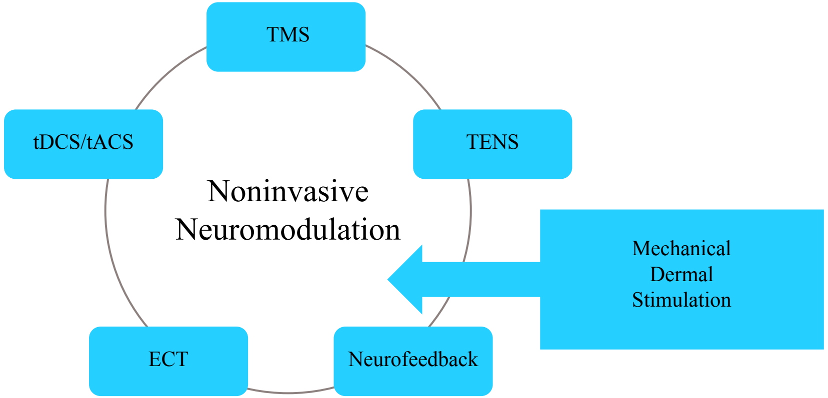
Mechanical Stimulation

Device Development

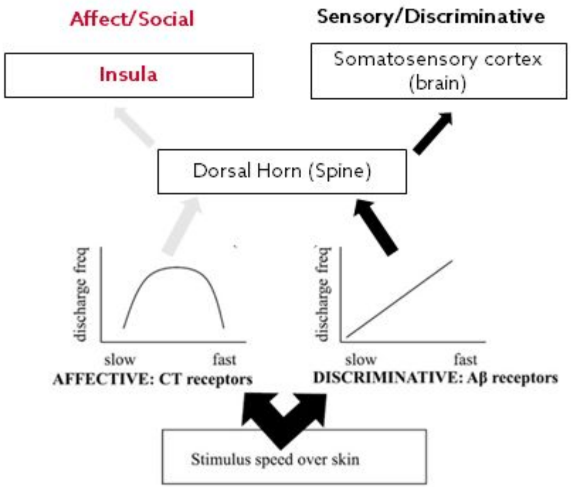
Device Prototype

Mechanical Stimulation

- Non-invasive option for accessing and activating the sensory system via skin contact and mechanoreceptors. [10]



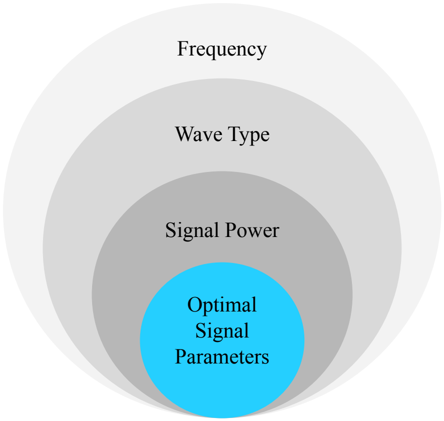
- **Mechanical stimulation can be altered (frequency & amplitude) in order to specifically target a variety of tactile afferents. [11]**



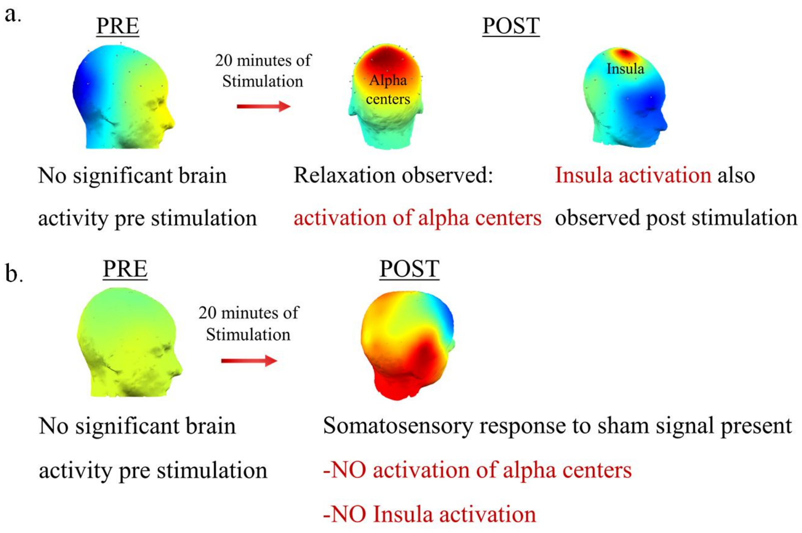
C-Tactile Afferent mechanoreceptors respond to characteristics of touch - mainly low intensity and low frequency (~10 Hz) stimulation. [1]

Device Development

For over 2 years **we studied changes in brain activity pre and post mechanical dermal stimulation**, using EEG, testing different variables such as frequency, intensity, and duration of stimulation.



The specific waveform was derived from a combination of empirical study (changes in alpha power pre/post stimulation) and known response characteristics of the CTA mechanoreceptors (low intensity, low frequency ~10 Hz).



- N = 600+ participants (~270 Active signal, ~425 Sham)
- The Feelmore signal generated a relaxed state, with increased alpha activity.
- Stimulated with different signals (sham), there was NO increase in alpha activity

Device Prototypes

Prototype used in present study

2016 → 2020

We developed a novel mechanical stimulation device, targeting the affective touch pathway, designed to improve interoceptive regulation.

Study Procedures

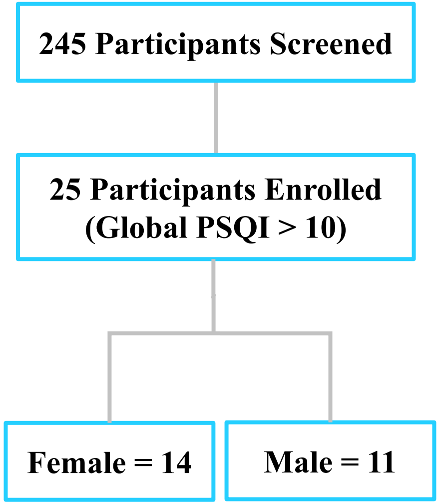
Study Sample

Detailed Study Procedure and Participant Responsibilities

Measures Used

Study Participants

Participants were recruited via digital and print advertisements.



Pittsburgh Sleep Quality Index (PSQI) = 19-item self-report measure for assessing sleep quality, where a Global PSQI score of 5 or above is considered to indicate poor sleep. [6]

Demographics

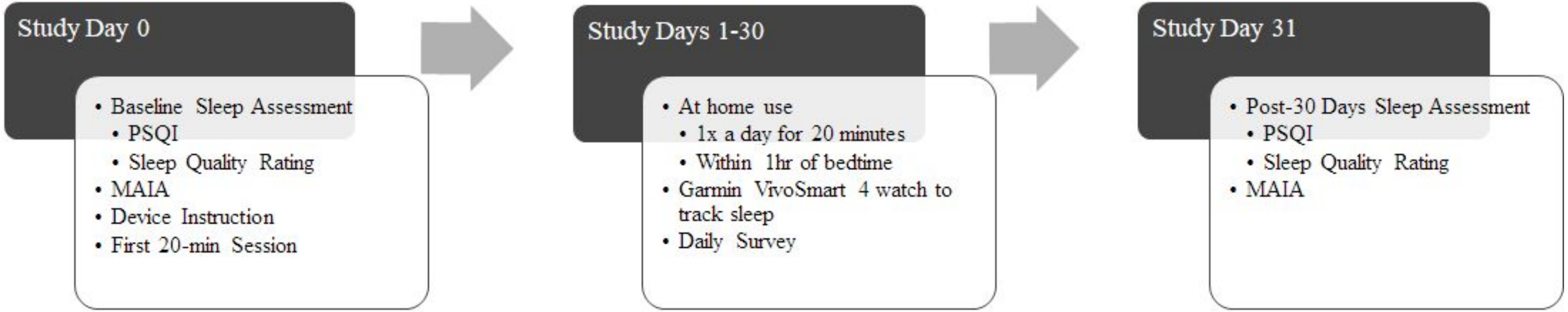
	(N=25)
Mean Age (± SD*)	35 (± 10.2)
Ethnicity	***n***
Asian / Pacific Islander	7
Black or African American	5
Hispanic	2
White / Caucasian	9
Mixed Race	2
Prefer not to say	1
Education	***n***
Some college	3
Associate’s degree	1
Bachelor’s degree	16
Master’s degree	4
Doctorate level degree	2

*SD = Standard Deviation

Study Procedure

- All participants (n=25) reviewed inclusion & exclusion criteria and were formally consented.
- Once participants have been consented, they then completed baseline assessments, learned how to use the device, and went through a calibration process to find their appropriate intensity level.
- They completed their first 20-minute session in-lab, to ensure proper training.
- All participants were instructed to use the device ONCE a day, within an hour of bedtime, for 30 days.

30 Day Study Flow:



All study procedures were reviewed and approved by an ethical board (Solutions IRB, #: FWA00021831) [9]

Pittsburgh Sleep Quality Index (PSQI)

19-item self-report measure assessing sleep quality and disturbances over a 1-month period of time. [6]

The 19 items are separated into 7 components, each scored on a scale of 0 - 3 (0 = normal function, 3 = severe dysfunction).

The 7 component scores are then summed to produce a Global PSQI score ranging from 0 to 21, where a score of 5 or above is considered to indicate poor sleep quality. [6]

Improvement in sleep is indicated by a decrease in scores over a 1-month period.

PSQI Sleep Components

1. Subjective Sleep Quality
2. Sleep Latency
3. Sleep Duration
4. Habitual Sleep Efficiency
5. Sleep Disturbances
6. Use of Sleep Medications
7. Daytime Drowsiness

Sleep Quality Rating

1-Item self-report rating scale assessing sleep quality the previous night.

Participants rate their previous night's sleep on a scale of 1 - 5, where an increase in sleep quality rating represents an improvement in sleep quality.

Participants rated their sleep quality prior to and after using the device for 30 days, as well as in the form of a daily survey throughout the study.

Sleep Quality Rating Scale

5	Great – no problem falling or staying asleep
4	Occasional waking
3	Tossing and turning
2	Frequent and extended periods of wakefulness
1	Little to no sleep at all

Garmin - Sleep Hours

Sleep hours were assessed using a commercial wrist photoplethysmography (PPG) device: Garmin VivoSmart 4.

This PPG device was chosen as it was most reliable for sleep time in earlier studies.

A subset of participants (n=13) wore the PPG device nightly throughout the 30-day study period.

Garmin VivoSmart 4

Multidimensional Assessment of Interoceptive Awareness (MAIA)

32-Item self-report questionnaire assessing interoceptive awareness across 5 main dimensions.

Participants are instructed to indicate how often each statement applies to them in their general daily life on a scale of 0 to 5 (0 = never, 5 = always).

Items are grouped into 8 subcategories, which can then be grouped into 5 main dimensions of interoceptive awareness, described in the figure to the right. [8]

MAIA Dimensions of Interoceptive Awareness

Awareness of Body Sensations

- **Noticing**: awareness of uncomfortable, comfortable, and neutral body sensations

Emotional Reaction and Attentional Response to Sensations

- **Not Distracting:** Tendency to ignore or distract oneself from sensations of pain or discomfort
- **Not Worrying:** Emotional distress or worry with sensations of pain or discomfort (reversed)

Capacity to Regulate Attention

- **Attention Regulation:** Ability to sustain and control attention to body sensation

Awareness of Mind-Body Integration

- **Emotional Awareness:** Awareness of the connection between body sensations and emotional states
- **Self-Regulation:** Ability to regulate psychological distress by attention to body sensations
- **Body Listening:** Actively listens to the body for insight

Trusting Body Sensations

- **Trusting**: Experiences one's body as safe and trustworthy

Results

3 participants were excluded from analysis due to lack of compliance with the study protocol (i.e., device usage, completing the study).

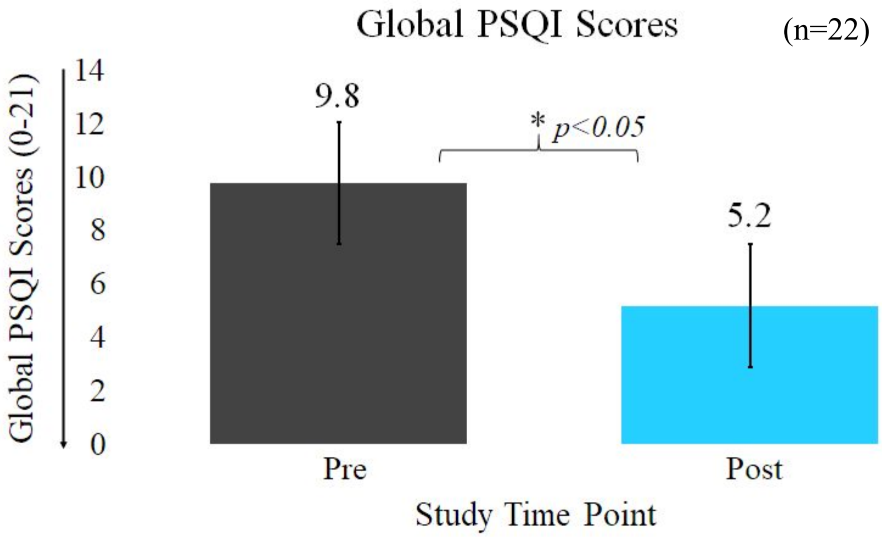
Pittsburgh Sleep Quality Index

Sleep Hours

Sleep Rating Scale

Multidimensional Assessment of Interoceptive Awareness

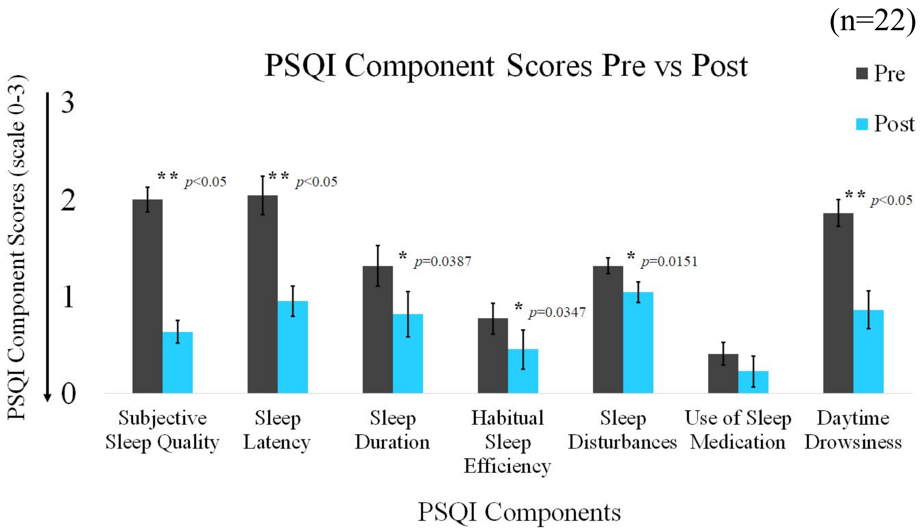
Pittsburgh Sleep Quality Index (PSQI)



On average there was an 43% decrease in PSQI scores from pre to post.

Higher scores represent greater sleep dysfunction and a decrease in score means improved sleep.

Pittsburgh Sleep Quality Index (PSQI)

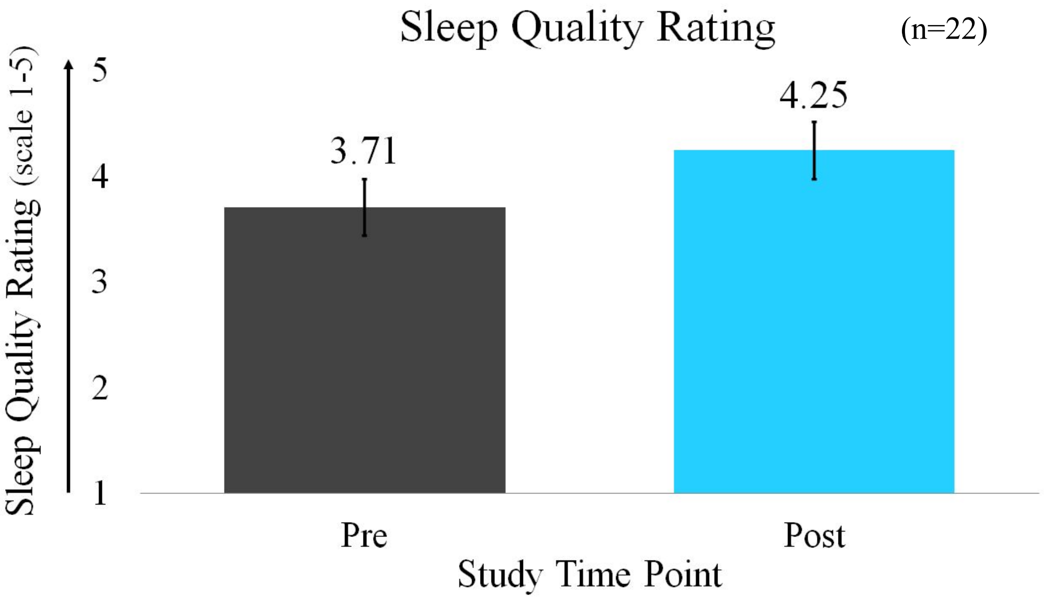


After 30 days of device use, there was an **overall improvement across the 7 components of sleep**, represented by an average decrease in PSQI Component Scores.

The most significant improvements were seen in the following components (on average across subjects):

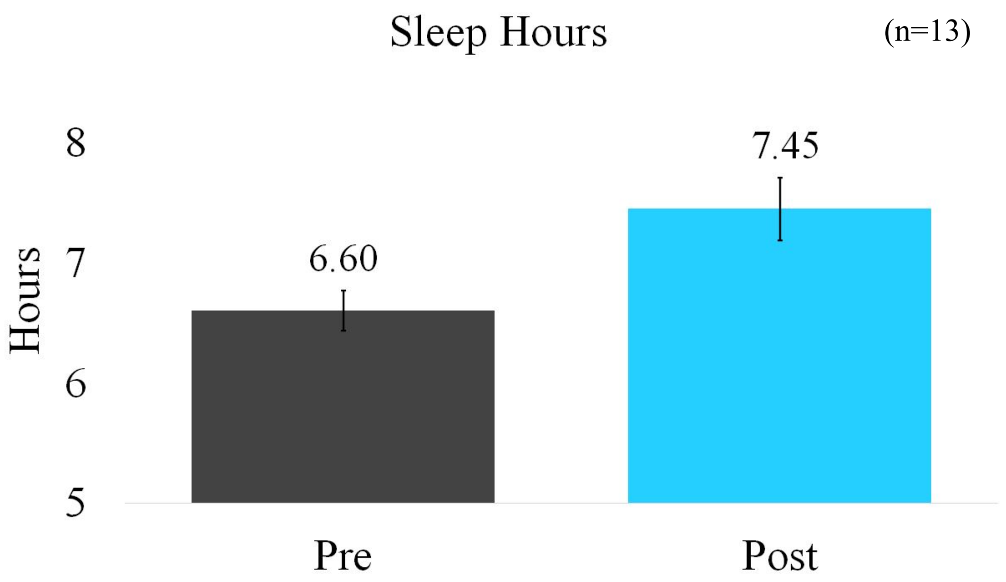
- **Subjective Sleep Quality improved** by 1.4 points
- **Sleep Latency improved** by 1.1 points
- **Daytime Drowsiness improved** by 1 point

Sleep Quality Rating Scale



Self-reported **sleep quality improved** after 30 days of device use.

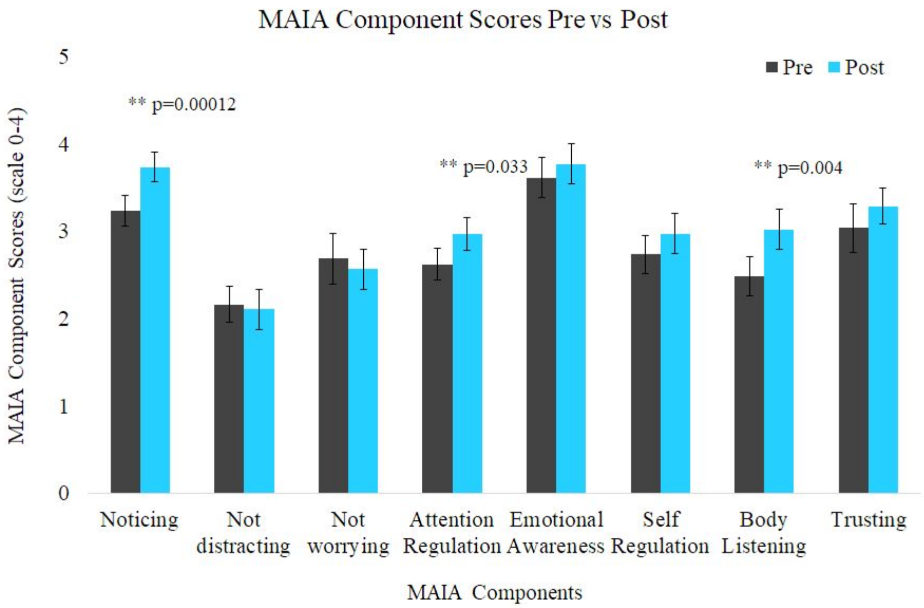
Sleep Hours



A subset of participants (n=13) used a Garmin wristwatch, to track sleep during the study.

Sleep hours increased 65 minutes on average, assessed via Garmin VivoSmart 4.

Multidimensional Assessment of Interoceptive Awareness (MAIA)



After 30 days of device use, there was a significant improvement on these MAIA subscales:

- 18% increase in **Noticing**
- 22% increase in **Attention Regulation**
- 31% increase in **Body Listening**

These results suggest that the participants experienced **improvements in interoceptive regulation**.

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, proposing a potential **new, non-drug, therapeutic intervention for sleep-disordered populations.**
- The success of our trial can help pave a path for future studies and **explore different applications of modulating the interoceptive system** through mechanical dermal stimulation.
- A confirmatory Randomized Control Trial (RCT) is underway and will be completed in late 2021.

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