

Pilot Study: Measuring Relaxation Response to the iLs Dreampad

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Abstract

Well over 70% of people in the US report that they regularly experience physical and psychological symptoms caused by stress. An estimated 50-70 million US adults have sleep or wakefulness disorder. Anxiety disorders are the most common mental illness in the U.S., affecting 40 million adults in the United States age 18 and older. This pilot project was designed as a first step in determining the efficacy of the Integrated Listening Systems' (iLs) Dreampad™ in engaging the parasympathetic branch of the autonomic nervous system. HFC is representative of synchronous coupling between heart rate variations and respiration. The more synchronous these signals, the healthier the autonomic nervous system. It has been associated with vagal tone, and improved HFC may indicate parasympathetic dominance, which will promote a more favorable internal environment for resting/sleeping. Subjects in the pilot study relaxed for 15 min without and then with the Dreampad while data, including HFC data, were collected. 82% of subjects saw significant improvement in HFC while using the Dreampad. Further research with additional populations is in progress.

Pilot Study Background and Design

This pilot project was designed as a first step in determining the efficacy of the Integrated Listening Systems' (iLs) Dreampad in engaging the parasympathetic branch of the autonomic nervous system. The Dreampad delivers low frequency-rich music through vibration, which is carried internally by the cranium to the cochlea. Feedback from clinicians since the 2012 release of the original iLs Pillow (re-designed and re-named as the Dreampad in 2013) regarding the relaxing effect of the device implies engagement of the parasympathetic nervous system via the vagus nerve, via afferent fibers connecting to the ear drum and outer ear. The observed symptoms of relaxation and calm have been consistent across varied populations, including those with sleep, attention, trauma and developmental challenges.

The SleepImage system was chosen to measure a marker of sleep quality and relaxation called heart

rate variability (HRV), the most widely accepted measure of parasympathetic nervous system activity.

Thirteen healthy adults having no anxiety-related symptoms were chosen for the pilot. HRV measures were taken from each person for a 15-minute baseline period and then again while using the Dreampad. For both periods, the subject sat in the same semi-reclined position looking out a window with a tranquil view of the mountains. Complete data sets were collected from 11 out of 13 subjects.

Data from all subjects was uploaded from the SleepImage device directly to their password protected, web-based interface and securely maintained on an external server. Analysis of the data was performed by the SleepImage clinical team (PhD).

Summary of Results

The use of the Dreampad showed significant improvement in HFC which may equate to improved autonomic function and balance. Specifically, High Frequency Coupling (HFC) is representative of synchronous coupling between heart rate variations and respiration. The more synchronous these signals, the healthier the autonomic nervous system. Because

the oscillations between sympathetic and parasympathetic drive. During healthy rest and sleep, parasympathetic drive predominates. At rest, this is associated with decreased anxiety and increased calm. During sleep, this represents non-rapid eye movement (NREM) sleep. During rapid eye movement (REM) sleep, sympathetic nervous system

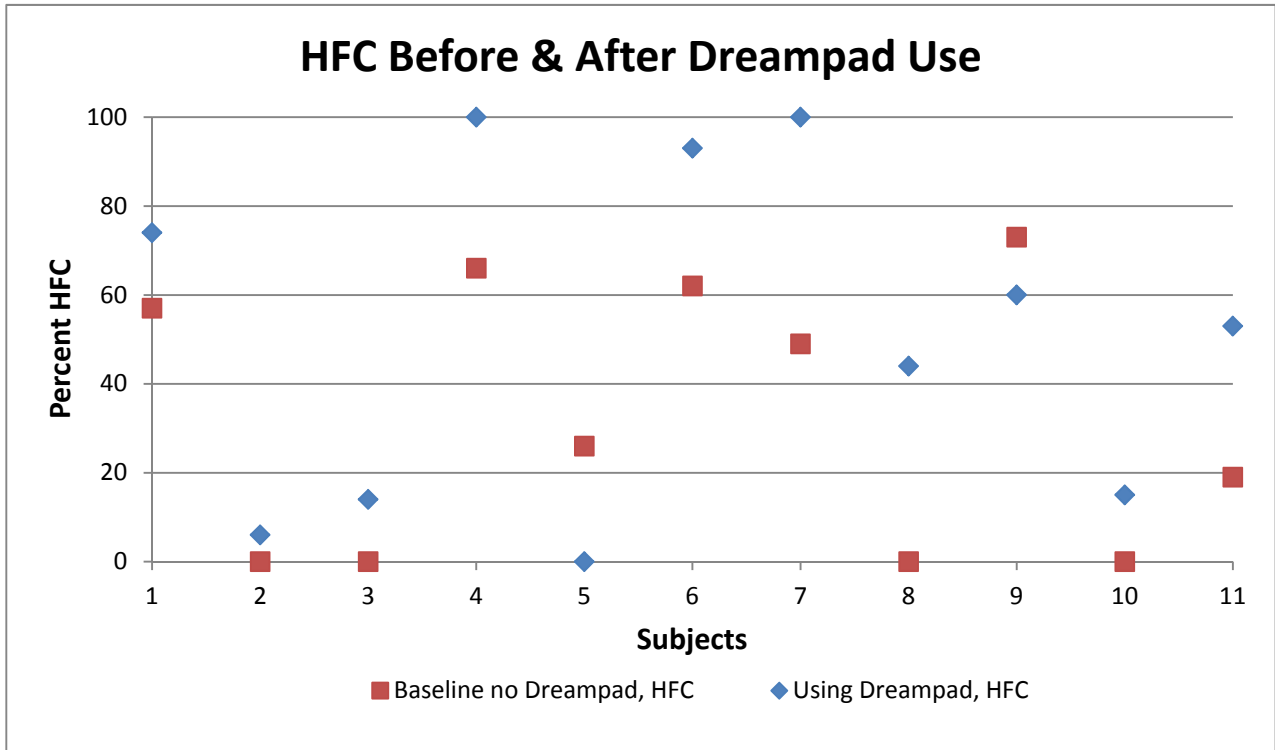


Figure 1: There was a statistically significant improvement in HFC with use of the Dreampad when compared to baseline (without the Dreampad), $p < 0.05$

HFC has been associated with vagal tone, improved HFC (from baseline to treatment or in the present study, before Dreampad use and during) may indicate parasympathetic dominance, which will promote a more favorable internal environment for resting/sleeping.

Heart Rate Variability

The changes between R-peaks in an electrocardiogram (ECG) is the foundation of heart rate variability (HRV). Heart rate variability is representative of autonomic function in particular,

function predominates. Respiration is further influenced by restful stages and sleep phases, becoming deep and slow during slow wave sleep, while speeding up and becoming more shallow during REM and periods of wake. **As such, HRV has become known as one of the most reliable methods to examine autonomic influence over cardiac function.** To capture HRV, both time and frequency can be observed in tandem to provide a physiological overview of autonomic function. Quantitatively, the frequencies typically measured are very low (0.01-0.04 Hz), low (0.04-0.15 Hz) and high (0.15-0.4 Hz).

Researchers have discovered that high frequency is representative of parasympathetic activity, while low frequency is more indicative of a mix between sympathetic and parasympathetic functioning. A predominance of low frequency has been associated with increased sympathetic influence on the heart, thereby increasing heart rate. To that end, high and low frequencies have therefore become suitable physiological markers for sympathetic and parasympathetic influence on cardiovascular function.

Cardiovascular influences on rest and sleep have been studied previously and collectively identified as playing a critical physiological role in both states. Therefore, it is the autonomic modulation of cardiac function that takes jurisdiction over peaceful resting states and sleep health. How is this influence measured? Using a new method of biorhythm capture called Cardiopulmonary Coupling.

Cardiopulmonary Coupling

Cardiopulmonary coupling (CPC) describes the synchronicity of heart rate and breathing rate. Heart rate and HRV are derived from a single lead electrocardiogram (ECG), while respiration, used to assess breathing dynamics, is calculated via changes in the QRS-complex. Both internal and external factors influence the coupling of these biological rhythms. For example, immune upregulation, good or bad stress (i.e. increased cortisol release at night), biochemical imbalances, behavioural issues (i.e. ADHD, ADD, etc.) and apneas, may all contribute to the uncoupling of heart and breathing rates, manifesting in large part as fitful rest and poor sleep quality.

Cardiac and respiratory rhythms are of particular importance in sleep as harmonious coupling of these signals represent stable, NREM sleep, while a disharmonious connection is indicative of unstable, NREM sleep. To that end, the more asynchronous the two signals are, influenced in part by conditions previously mentioned, the poorer the quality of sleep.

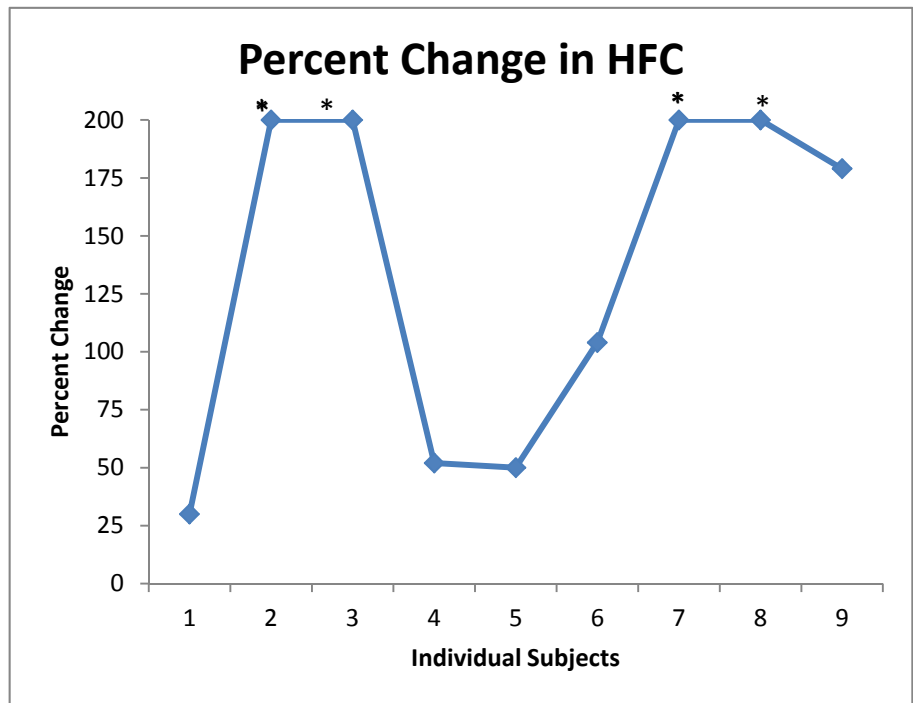


Figure 2: Percent change (pre- vs. during Dreampad use) in HFC in 9 subjects who showed improved HFC during Dreampad use, when compared to baseline (without the Dreampad; 30%, 200+%, 200+%, 52%, 50%, 104%, 200+%, 200+%, 179% percent improvement, respectively) Note: '*' denotes values greater than 200%.

Sleep Quality

Sleep quality can be efficiently assessed by quantifying autonomic activity. Autonomic activity influences heart rate while ECG-derived breathing dynamics are directly influenced by cardiac activity. The variability in heart rate and ECG-derived respiration provide representative markers of sleep physiology. This combined method of examining sleep quality, called Cardiopulmonary coupling, is an accurate and simple representation of dynamic changes in both healthy and pathological sleep conditions.

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