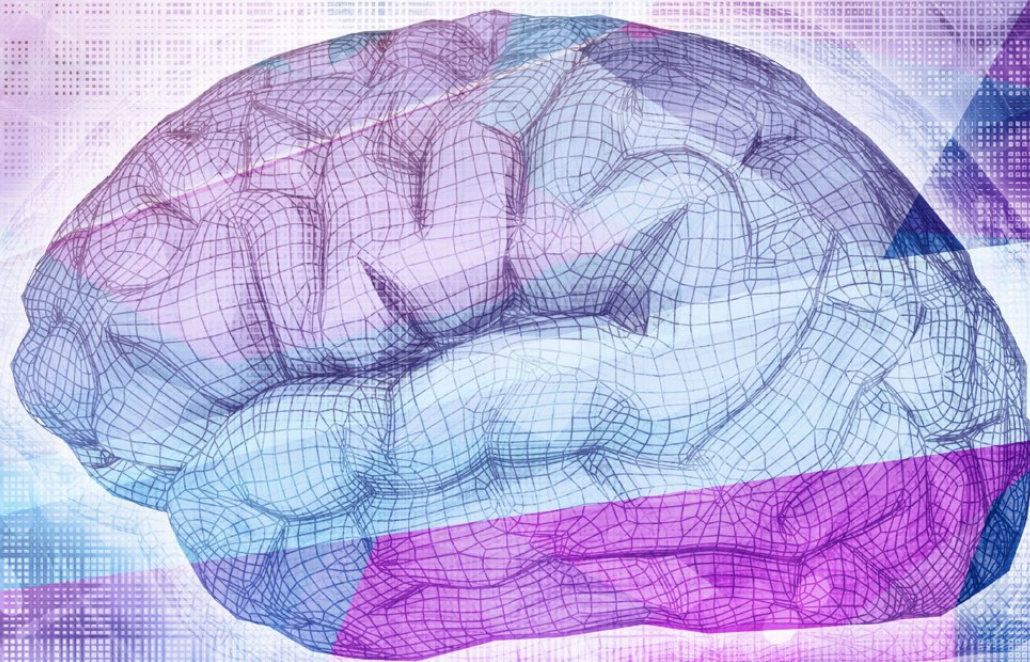




An Analysis of the Novel NuCalm Device for Anxiety and Depression Treatment

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Abstract

Solace Lifesciences, Inc., the makers of NuCalm, have introduced an innovative version of their transcutaneous Vagus Nerve Stimulation (tVNS) using proprietary electromagnetic biosignal processing discs placed near the wrist. This frequency delivery device, conceived by Dr. Blake Holloway, has been examined in a study involving 60 depressed subjects and 60 individuals suffering from anxiety. The research aimed to assess the proprietary biosignal processing disc's effectiveness in treating anxiety and depression. The results demonstrate the device's potential to restore normalcy in individuals with these syndromes post-treatment.



Introduction

Electrical pulses have been used to influence neuronal activity for decades. This therapy was historically employed, and continues to be, in the form of electroconvulsive therapy for severe depression. More recently, electrical stimulation of the vagus nerve or vagal nerve stimulation (VNS) has gained FDA approval for treating refractory depression and epilepsy, and has shown promise in addressing various psychological, psychiatric, and cardiac disorders.

VNS impacts various brain regions, including the thalamus, cerebellum, orbitofrontal cortex, limbic system, hypothalamus, and medulla, as confirmed by neuroimaging studies (Schachter & Saper, 1998; Ben-Menachem, 2002; Grimm & Bajbouj, 2010). Traditionally, VNS involved implanting a neurostimulating device connected to an electrode near the vagus nerve. However, this procedure had drawbacks, including coughing during stimulation, hoarseness, and surgical risks.

To mitigate these issues, transcutaneous Vagus Nerve Stimulation (tVNS) was introduced, which applied gel electrodes to the neck below the earlobe. This method, exemplified by the previous NuCalm device, was both FDA-approved and found to be a safe method for consumer use. Ear lobe vagal stimulation is generally well-tolerated without adverse effects. However, it does result in modulating effects on various physiological parameters like heart rate, blood pressure, and peripheral microcirculation during the stimulation procedure. This effect is achieved by applying electrodes near both the right and left ear lobes, facilitating afferent and efferent induction, especially noteworthy because the right vagus nerve contains efferent fibers leading to the heart. It is crucial to emphasize that using the device is contraindicated during pregnancy and in individuals with metal implants such as pacemakers, ventricular assist devices, or brain and cochlear implants.

Innovation in this field came from Dr. Blake Holloway, who proposed a more practical and effective approach. His idea involved a compact disc, approximately 4 cm in diameter, placed just four fingers width from the wrist, eliminating the need for connecting cables and simplifying the procedure. The NuCalm biosignal processing discs enhance relaxation responses by activating the GABAergic system through a direct connection with the Pericardium 6 acupressure point on the left arm. These biosignal processing discs function like batteries, emitting specific electromagnetic frequencies, such as GABA and L-Theanine, which travel to the heart and brain, interrupting stress responses and promoting relaxation. It's important to note that these biosignal processing discs transmit only frequencies and biosignals, not chemical or transdermal elements, to achieve their effects.

The previous tVNS method utilized two gel electrodes attached to the neck near the earlobes, connected to a device. Dr. Holloway's innovation replaces this setup with a single electromagnetic biosignaling processing disc, significantly enhancing convenience and ease of use. The objective of this study is to assess the effectiveness of the newly introduced biosignal processing discs and compare them to the previously established tVNS method, which had previously demonstrated its efficacy.

Alongside the use of the new biosignal processing disc is NuCalm's neuroacoustic software which is designed to restore harmony and synchronization within the human mind and body. It achieves this through a complex process involving binaural signal processing, isochronic waveforms, and proprietary techniques, ultimately guiding the brain into specific frequency ranges (Alpha and Theta) associated with relaxation, creativity, and healing. This technology, backed by a patented method and scientific studies, aims to help users achieve mental states conducive to relaxation, clarity, and creativity.

Materials and Methods

Solace Lifesciences, the makers of NuCalm, provided NuCalm biosignal processing discs and neuroacoustic software via the NuCalm mobile app for the study, which involved two groups: 60 participants with clinical depression and 60 participants with clinical anxiety. The subjects were assessed using diagnostic criteria from the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). They were divided into groups based on their anxiety and depression symptomatology, as measured by the Hamilton Anxiety Scale (HAM-A) and the Hamilton Depression Scale (HAM-D). All subjects were between 25 and 45 years old and provided informed consent.

In accordance with the 1996 Task Force Standards established by the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, we followed specific subject selection criteria, excluding those individuals already diagnosed with other well-established pathologies, as outlined in detail in reference. Tachograms were acquired using finger plethysmography (PG) and were consistently compared to ECG-derived tachograms, factoring in Pulse Wave Transit Time (PWTT). Each subject underwent concurrent recording of GSR in tone and phase values for a duration of thirty minutes. Additionally, an electroencephalogram (EEG) was conducted both with and without treatment during this half-hour session. This comprehensive approach allowed us to assess heart rate variability (HRV), galvanic skin response (GSR), and EEG patterns before, during, and after tVNS application.

To analyze the physiological data, we employed various methods, including the Fast Fourier Transform (FFT) spectrum analysis, which facilitated the estimation of VLF, LF, HF, and total power as indicators of the frequency domain representation of the autonomic nervous system modulation. The standard methodology involves re-sampling the original NN interval series followed by FFT analysis. The VLF band is defined within the frequency range of 0.003 to 0.04 Hz, the LF band spans from 0.04 to 0.15 Hz, and the HF band is characterized by frequencies between 0.15 and 0.4 Hz. The VLF spectral component (0.003-0.05 Hz) is believed to be associated with long-term regulatory mechanisms like the renin-angiotensin system, peripheral blood flow regulation, and hormonal systems. The LF spectral component primarily relates to sympathetic modulation and baroreceptor activity, while also encompassing parasympathetic contributions. Lastly, the HF spectral band reflects parasympathetic (vagal) activity. We observed dysfunction in the modulation of the autonomic nervous system (ANS) affecting heart rhythm and altered EEG values in individuals with depression and anxiety. Following treatment with the new NuCalm devices, ANS function returned to normal, and subjective conditions improved.

Participants experienced two distinct phases of data collection and treatment conditions. In the initial phase, they used the biosignal processing disc without neuroacoustic software. In the subsequent phase, participants utilized the biosignal processing disc along with the neuroacoustic software. Physiological measurements for all participants were recorded before, during, and after both conditions.

Results

EEG Results Summary:

An EEG (Electroencephalogram) records the electrical activity of the brain, providing insights into brain function and detecting abnormal patterns associated with various neurological conditions.

Results are reported for different brain wave frequencies: beta, alpha, theta, and delta.

We initially analyzed the EEG results for individuals with anxiety, at rest and without any treatment. In the right frontal electrode, the mean beta activity was 2.4+-, while in the left frontal electrode, it was 2.2+-; for the right temporal electrode, it was 1.8+-, and for the left temporal activity, it was 1.4. Regarding alpha activity, we observed 3.6+- in the right temporal and 3.3+- in the left frontal electrodes, with a value of 4.00+- in the right temporal and 2.9 in the left temporal activity. In terms of theta activity, we recorded a result of 2.09 in the right temporal and 4.1 in the left frontal electrodes, with a value of 2.9 for the right temporal and the same for the left temporal. Delta activity yielded a result of 2.9, 6.3, 2.9, and 2.4 for the right frontal, left frontal, right temporal, and left temporal electrodes, respectively.

Synchronization values were found to be $F1/F2 = 44.1$ for the frontal electrodes, $T5/T6 = 17.5$ for the temporal electrodes, and $F1/T5 = 23.8$ and $F2/T6 = 21.3$ for the combined frontal/temporal electrodes.

For individuals with depression, we initially observed beta activity values of 2.2+- for the right frontal electrode, 2.00 for the left frontal electrode, 7.8 for the right alpha electrode, and 7.7 for the left alpha electrode. Theta activity registered 5.9 for the right electrode and 5.8 for the left electrode. Delta activity resulted in 7.3 for the right electrode and 6.9 for the left electrode. For the temporal electrodes, beta activity was 1.8 for the right and 1.7 for the left, alpha activity was 8.4 for the right and 7.3 for the left, and delta activity was 4.4 for the right and 4.3 for the left. Synchronization values were $F1/F2=67.3$, $T5/T6=36.9$, $F1/T5=34$, and $F2/T6=46.6$.

After using the biosignal processing disc alone, beta activity showed $F1=F2=1.9+-$, $T5=2.1$, $T6=1.9$. Alpha activity exhibited enhanced values with $F1=6.3$, $F2=6.1$, $T5=6.1$, and $T6=5.8$. Theta activity yielded $F1=5.2$, $F2=5.1$, $T5=3.3$, and $T6=2.8$, while delta activity showed $F1=7.9$, $F2=7.8$, $T5=3.2$, and $T6=3.1$. Synchronization values were $F1/F2=66.4$, $T5/T6=21.1$, $F1/T5=17.1$, and $F2/T6=16.6$. Notably, a further enhancement of approximately 30% was observed when the same subjects underwent a combined treatment of thirty minutes using the biosignal processing disc and neuroacoustic software.

EEG Table:

EEG Activity Parameters	Anxiety (Before Treatment)	Depression (Before Treatment)	After Biosignal Processing Disc Only
Right Frontal Beta Activity (F1)	2.4+-	2.2+-	1.9+-
Left Frontal Beta Activity (F2)	2.2+-	2.00	1.9+-
Right Temporal Beta Activity (T5)	1.8+-	7.8	2.1
Left Temporal Beta Activity (T6)	1.4	7.7	1.9
Right Temporal Alpha Activity (F1)	3.6+-	8.4	6.3
Left Frontal Alpha Activity (F2)	3.3+-	7.3	6.1
Right Temporal Alpha Activity (T5)	4.00+-	Not specified	6.1
Left Temporal Alpha Activity (T6)	2.9	Not specified	5.8
Right Temporal Theta Activity (F1)	2.09	Not specified	5.2
Left Frontal Theta Activity (F2)	4.1	Not specified	5.1
Right Temporal Theta Activity (T5)	2.9	Not specified	3.3
Left Temporal Theta Activity (T6)	2.9	Not specified	2.8
Right Frontal Delta Activity (F1)	2.9	Not specified	7.9
Left Frontal Delta Activity (F2)	6.3	Not specified	0.8
Right Temporal Delta Activity (T5)	2.9	Not specified	3.2
Left Temporal Delta Activity (T6)	2.4	Not specified	3.1
Frontal Synchronization (F1/F2)	44.1	67.3	66.4
Temporal Synchronization (T5/T6)	17.5	36.9	21.1
Frontal/Temporal Synchronization (F1/T5)	23.8	34	17.1
Frontal/Temporal Synchronization (F2/T6)	21.3	46.6	16.6

In summary, the table presents EEG activity parameters for individuals with anxiety and depression before and after using the biosignal processing disc alone. An additional enhancement of approximately 30% was observed when subjects underwent a combined treatment of thirty minutes using the biosignal processing disc and neuroacoustic software.

GSR Results:

GSR (Galvanic Skin Response) measures changes in the electrical conductance of the skin, typically reflecting variations in emotional arousal and stress levels. Higher conductance levels suggest heightened emotional responses, while lower levels may indicate relaxation or reduced stress.

Depressed subjects had GSR values of 343 (Kohm) and anxious subjects had values of 373 (Kohm) with high sympathetic activity (indicated by phase values). After treatment with the biosignal processing disc and disc + neuroacoustic software, GSR values normalized to around 700 and 800, respectively, demonstrating a significant reduction in sympathetic activity.

Galvanic Skin Response:

Condition	GSR Mean Tone Before Treatment (Kohm)	GSR Mean Tone After Treatment (Kohm)
Depressed	343	700
Anxiety	373	800

HRV Results:

In the case of heart rate, we observed a mean value of 74.86 ± 6.51 Bpm, accompanied by a standard deviation of 50.11 msec. Additionally, the total power exhibited a mean of 2540.30 ± 537.52 , while the VLF component measured 954.60 ± 491.60 . The LF and HF values were as follows: $LF = 818.00 \pm 134.99$ and $HF = 698.90 \pm 235.1$, all measured in msec^2/Hz . In normalized units, LF and HF were 0.55 ± 0.08 and 0.45 ± 0.08 , respectively, and the LF/HF ratio was 1.28 ± 0.38 . These results pertain to the condition involving the use of the biosignal processing disc alone.

When considering the combination of the biosignal processing disc and neuroacoustic software, we noted a heart rate of 72.86 ± 5.51 bpm, accompanied by a standard deviation of 52.33 msec. The total power averaged 2469.94 ± 549.58 , and the VLF component showed a mean of 944.60 ± 497.56 . Furthermore, the LF and HF values were recorded as follows: $LF = 800.00 \pm 139.99$ and $HF = 725.50 \pm 224.10$, measured in msec^2/Hz . In normalized units, LF and HF remained consistent at 0.55 ± 0.08 and 0.45 ± 0.08 , respectively, with the LF/HF ratio at 1.10 ± 0.38 . These findings are associated with the condition involving the use of both the biosignal processing and neuroacoustic software.

For subjects experiencing anxiety, the heart rate exhibited an average of 99.75 ± 9.51 bpm, with a standard deviation of 30.23 msec. In terms of spectral power, the total power, VLF, LF, and HF showed values of 2398.35 ± 73 , 754.34 ± 385.60 , 1265.00 ± 394.22 , and 389.01 ± 198.21 , respectively. Additionally, the normalized units revealed $LF = 0.76$, $HF = 0.24$, and a ratio of $LF/HF = 3.21$.

In the case of depression, the heart rate averaged 89 ± 8.71 bpm, with a standard deviation of 29.22 msec. The VLF component measured 500.01 ± 104 , while LF and HF values were 610.12 ± 232 and 250.05 ± 102 , respectively, with a total power of 1360.18. In normalized units, LF was 0.71, HF was 0.29, and the LF/HF ratio was 2.44.

Heart Rate Variability Metrics (Pre-Treatment/Baseline)

Condition	Heart Rate (Bpm)	Standard Deviation (msec)	Total Power (msec ² /Hz)	VLF (msec ² /Hz)	LF (msec ² /Hz)	HF (msec ² /Hz)	LF (Normalized)	HF (Normalized)	LF/HF Ratio
Anxiety	99.75 ± 9.51	30.23	-	754.34 ± 385.60	1265.00 ± 394.22	389.01 ± 198.21	0.76	0.24	3.21
Depression	89 ± 8.71	29.22	-	-	610.12 ± 232	250.05 ± 102	0.71	0.29	2.44

Heart Rate Variability Metrics (Treatment Conditions)

Condition	Heart Rate (Bpm)	Standard Deviation (msec)	Total Power (msec ² /Hz)	VLF (msec ² /Hz)	LF (msec ² /Hz)	HF (msec ² /Hz)	LF (Normalized)	HF (Normalized)	LF/HF Ratio
Biosignal Processing Disc Only	74.86 ± 6.51	50.11	2540.30 ± 537.52	954.60 ± 491.60	818.00 ± 134.99	698.90 ± 235.1	0.55 ± 0.08	0.45 ± 0.08	1.28 ± 0.38
Biosignal Processing Disc + Neuroacoustic software	72.86 ± 5.51	52.33	2469.94 ± 549.58	944.60 ± 497.56	800.00 ± 139.99	725.50 ± 224.10	0.55 ± 0.08	0.45 ± 0.08	1.10 ± 0.38

Note:

- “-” indicates that specific data was not provided for a particular condition or measurement.
- Values are presented as mean $\pm$ standard deviation for heart rate and standard deviation columns, and mean $\pm$ standard deviation for other measurement columns.
- Total Power, VLF, LF, and HF are all presented in units of msec²/Hz.
- LF and HF are also presented in normalized units, which do not have standard deviations as they are normalized values.

In our study, we also investigated several parameters related to non-linear heart rate variability (HRV) analysis, which includes Approximate Entropy (ApEn), Sample Entropy (SamEn), and Detrended Fluctuations Analysis (DFA) for subjects affected by anxiety and depression. We also examined the effects of two treatments: biosignal processing disc and biosignal processing disc + neuroacoustic software. Below, is a summary of findings:

It is first important to consider the nature of non-linear HRV analysis and how it relates to nervous system regulation.

Approximate Entropy (ApEn):

What it does: ApEn acts like a detective that looks for how predictable or unpredictable your heartbeats are.

How we use ApEn to interpret heartbeat data:

- If ApEn is low, it means your heartbeats follow a pattern, like a drumbeat in a song.
- If ApEn is high, it means your heartbeats are irregular, like random drumming.

Approximate Entropy (ApEn):

- For anxiety-afflicted subjects, the ApEn value was $\text{ApEn} = 1.368 \pm 0.973$.
- Subjects with depression exhibited an ApEn value of $\text{ApEn} = 1.388 \pm 0.901$.
- After exposure to the biosignal processing disc, the ApEn value was $\text{ApEn} = 1.099 \pm 0.956$.
- With the addition of the neuroacoustic software, the ApEn value became $\text{ApEn} = 1.010 \pm 0.931$.

Table summarizing the Approximate Entropy (ApEn) values:

BEFORE NUCALM

Condition (pre-treatment)	ApEn Value	Range
Anxiety	1.368	± 0.973
Depression	1.388	± 0.901

AFTER NUCALM

Condition (pre-treatment)	ApEn Value	Range
After Biosignal Processing Disc	1.099	± 0.956
After Biosignal Processing Disc + Neuroacoustic software	1.010	± 0.931

Sample Entropy (SamEn):

-What it does: SamEn is another detective that checks for patterns in your heartbeats.

How we use SamEn to interpret heartbeat data:

- If SamEn is low, it means your heartbeats are following a clear pattern, like a simple dance.
- If SamEn is high, it means your heartbeats are chaotic, like people dancing in all directions at once.

Sample Entropy (SamEn):

- For those suffering from anxiety, the SamEn value was $\text{SamEn} = 1.337 \pm 0.121$.
- Subjects with depression had a SamEn value of $\text{SamEn} = 1.287 \pm 0.131$.
- When exposed to the Biosignal Processing Disc, the SamEn value became $\text{SamEn} = 1.479 \pm 0.100$.
- For subjects subjected to Biosignal Processing Disc + Neuroacoustic software, the SamEn value was $\text{SamEn} = 1.690 \pm 0.140$.

Table summarizing the Sample Entropy (SamEn) values:

BEFORE NUCALM		
Condition (pre-treatment)	SamEn Value	Range
Anxiety	1.337	± 0.121
Depression	1.287	± 0.131
AFTER NUCALM		
Condition (pre-treatment)	SamEn Value	Range
After Biosignal Processing Disc	1.479	± 0.100
After Biosignal Processing Disc + Neuroacoustic software	1.690	± 0.140

The values are provided with their respective ranges ($\pm$) for each condition.

Detrended Fluctuations Analysis (DFA):

What it does: DFA is like an artist's tool that measures how smooth or wiggly your heartbeats are.

How we use DFA to interpret heartbeat data:

- If DFA says your heartbeats are wiggly (α^2 close to 0), it means they change a lot from beat to beat, like a shaky line.
- If DFA says your heartbeats are smooth (α^2 close to 1), it means they change more predictably, like a smoother line.

Detrended Fluctuations Analysis (DFA):

- For individuals with anxiety, alpha 1 was found to be 1.508 ± 0.872 , indicating a smoother time series.
- Alpha 2 for anxiety was 0.513 ± 0.100 , indicating anti-persistence and alternating values in the R-R time series.
- Similar findings were observed for subjects with depression, with alpha 1 near 1 and alpha 2 near 0.6.
- However, exposure to the Biosignal Processing Disc and Biosignal Processing Disc + Neuroacoustic software normalized these values, resulting in alpha 1 values of 0.977 ± 0.099 and 0.912 ± 0.0789 , and alpha 2 values of 0.473 ± 0.0987 and 0.497 ± 0.0546 , respectively.

Table summarizing the Detrended Fluctuations Analysis results for alpha 1 and alpha 2:

BEFORE NUCALM		
Condition (pre-treatment)	Alpha 1 Value	Alpha 2 Value
Anxiety	1.508	0.513
Depression	~1 (near to 1)	~0.6 (near to 0.6)
AFTER NUCALM		
Condition (pre-treatment)	Alpha 1 Value	Alpha 2 Value
After Biosignal Processing Disc	0.977	0.473
After Biosignal Processing Disc + Neuroacoustic software	0.912	0.497

The values for alpha 1 and alpha 2 are provided for each condition, along with their respective ranges ($\pm$) where applicable. The descriptions of the alpha values' interpretations are also provided in the table.

Standard Deviations (SD1 and SD2):

SD1 (Standard Deviation 1):

- What it does: Imagine you have a bunch of dots on a piece of paper, and you want to see how spread out they are along a line from the bottom left to the top right of the paper.
- How we use SD1 to interpret heartbeat data: SD1 tells us how much our heartbeats are jumping around from one beat to the next in a short time, like a few seconds. If SD1 is big, it means our heartbeats are changing a lot in a short time, which can be a good thing because our body is reacting to different situations quickly.

SD2 (Standard Deviation 2):

- What it does: Now, imagine you're looking at those same dots on the paper, but instead of checking how they spread out along the line, you're looking at how they spread out sideways, away from that line.
- How we use SD1 to interpret heartbeat data: SD2 shows us how our heart rate changes over a longer time, like a few minutes. If SD2 is big, it means our heart rate is changing a lot over a longer time, which is also usually a good thing because our body can adapt well to different situations.

So, in simple terms:

- SD1 tells us about quick changes in our heart rate over a short time.
- SD2 tells us about slower changes in our heart rate over a longer time.

Both SD1 and SD2 can help you understand how our body is doing and if it's responding well to different situations and stresses.

The mean values for SD1 and SD2 in various subject groups are as follows:

For individuals affected by anxiety, $SD1 = 36.1 \pm 4.0$ msec and $SD2 = 36.9 \pm 9.00$ msec. In the case of depression, $SD1 = 14.32 \pm 1.32$ msec, and $SD2 = 35.00 \pm 7.18$ msec. For subjects using Biosignal Processing Disc alone, $SD1 = 75.00 \pm 11.00$ msec, and $SD2 = 101.01 \pm 8.07$ msec. Conversely, for those using Biosignal Processing Disc + Neuroacoustic software, $SD1 = 14.9 \pm 2.25$ msec, and $SD2 = 33.5 \pm 4.9$ msec. The ratio of SD1 to SD2 yielded the following results: $SD1/SD2 = 0.978$ for Anxiety, $SD1/SD2 = 0.409$ for Depression, $SD1/SD2 = 0.742$ for Biosignal Processing Disc, and $SD1/SD2 = 0.377$ for Biosignal Processing Disc + Neuroacoustic software. The ratio of SD1 to SD2 ($SD1/SD2$) was calculated and found to be as follows: $SD1/SD2 = 0.978$ for Anxiety, $SD1/SD2 = 0.409$ for Depression, $SD1/SD2 = 0.742$ for Biosignal Processing Disc, and $SD1/SD2 = 0.377$ for Biosignal Processing Disc + Neuroacoustic software.

Condition	SD1 (msec)	SD2 (msec)	SD1/SD2	Approximate Entropy (ApEn)	Sample Entropy (SamEn)	Detrended Fluctuations Analysis (Alpha 1)	Detrended Fluctuations Analysis (Alpha 2)
Anxiety	36.1 ± 4.0	36.9 ± 9.00	0.978	1.368 ± 0.973	1.337 ± 0.121	1.508 ± 0.872	0.513
Depression	14.32 ± 1.32	35.00 ± 7.18	0.409	1.388 ± 0.901	1.287 ± 0.0131	Alpha 1 Near 1	Alpha 2 Near 0.6
Biosignal Processing Disc	75.00 ± 11.00	101.01 ± 8.07	0.742	1.099 ± 0.956	1.479 ± 0.100	0.977 ± 0.099	0.473 ± 0.0987
Biosignal Processing Disc + Neuroacoustic software	14.9 ± 2.25	33.5 ± 4.9	0.377	1.010 ± 0.931	1.690 ± 0.140	0.912 ± 0.0789	0.497 ± 0.0546

These findings suggest that the treatments, particularly the combination of the use of the NuCalm system with the biosignal processing disc and neuroacoustic software, had a notable impact on the physiological parameters and entropy measures, indicating potential benefits for individuals with anxiety and depression.

Summarized Results:

For anxiety subjects, EEG results showed altered beta, alpha, theta, and delta activities before treatment. After treatment with the new NuCalm system, these values normalized. GSR indicated elevated sympathetic activity in anxious subjects, which also returned to normal levels post-treatment. HRV analysis showed decreased LF/HF ratios and most particularly notable increases in high frequency (HF), indicating improved ANS function. There were also dynamic shifts in non-linear HRV metrics that indicate notable changes in nervous system regulation after treatment.

Depressed subjects exhibited similar EEG abnormalities, GSR responses, and LF/HF ratio elevations before treatment. These factors improved significantly after using the new NuCalm system.

Combined treatment with the biosignal processing discs and neuroacoustic software further enhanced results by approximately 30%.

Conclusion

In our study, we assessed 120 individuals with anxiety and depression who underwent a novel treatment involving the use of a new, innovative technology that stimulates vagal functioning and allows for autonomic nervous system reset. This technology consists of a wrist-worn biosignal processing disc, devoid of pharmaceutical agents, and instead comprised solely of therapeutic electromagnetic waves/frequencies that respond directly to resonance and biomodulation. It was found that these electromagnetic waves interfaced with the brain's own electromagnetic activity, replicating the therapeutic effects previously achieved through traditional tVNS or, even more historically, via implantation of a neurostimulating device connected to an electrode along the cervical branch of the vagus nerve.

Remarkably, the results demonstrated that this biosignal processing disc not only replicated the functions of the traditional tVNS device but also offered significantly enhanced benefits. Individuals exhibiting evidence of sympathetic (fight-or-flight) arousal via an elevation of the LF/HF ratio of 2.44 (depression participants) and/or 3.21 (anxiety participants) experienced a reduction to a value of 1.28, indicative of significant sympathetic (fight-or-flight) reduction. Additionally, subjective symptoms improved notably after treatment with the biosignal processing disc alone and in combination with neuroacoustic software.

It is worth highlighting that our investigation focused on changes in heart rate variability (HRV), specifically highlighting alterations in high-frequency power, which serves as a marker for parasympathetic activity within the autonomic nervous system. Intriguingly, we observed a twofold amplification in power among participants experiencing anxiety, while those experiencing depression exhibited a threefold increase. These findings provide compelling evidence that NuCalm's innovative biosignal processing disc, in conjunction with their advanced neuroacoustic software, possesses the ability to dynamically modulate the functioning of the nervous system. This modulation ultimately translates into an elevated relaxation response, underscoring the potential therapeutic benefits of this technology.

Furthermore, analysis of Galvanic Skin Response (GSR) revealed a normalization of sympathetic activity in subjects with elevated levels during treatment. Fourier transform analysis of EEG waves showcased a restoration of altered values post-treatment. Consequently, we argue that this NuCalm technology could extend its therapeutic benefits to related pathologies, as well as conditions involving pain, stress, psychological disorders, ear ailments, and bruxism.

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(Note: Only a selection of references has been included for clarity.)

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