Binaural Pulse Modulation (BPM) as Adjunctive Treatment for Anxiety

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Article

Binaural Pulse Modulation (BPM) as Adjunctive Treatment for Anxiety

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Abstract: Background: Several decades of feedback research with EEG signals have shown that participants can be trained to influence the amplitude or topography of specific components of scalp electric activity. However, it has been very difficult to influence specific mental states or treat psychiatric disorders with EEG-based neurofeedback, probably because of its low spatial specificity and difficulties associated with the poor signal-to-noise ratio provided by single trial-based EEG. For this reason, tuned sound may be a viable alternative. Objective: Our objective in this pilot study was to examine the possibility of using a Binaural Pulse-Mode-Modulation-type (BPM) device to restore an effective psycho-emotional state by activating the endogenous methods of self-regulation to activate the processes of recovery from anxiety and mood disorders. We desired to evaluate if emotional distress would be altered (reduced) or regulated by means of BPM-type systems. Methods: Sixty adult participants were studied with self-reported measures of distress (Generalized Anxiety Disorder 7, Covid-Stress Scale, PTSD Checklist for DSM-5, Beck Depression Inventory-II) were completed before, after, four weeks, and 12 weeks post-treatment. This BPM produced two frequencies combined to create a binaural pulse through differential auditory tone presentations and the user response adjusted to the appropriate target tone for effective treatment. Each individual calibrated the binaural pulse to increase the level of emotion experienced while imagining an experience with a similar emotional valence or while engaged in a cognitive function while also listening to the sound. "Treatment" was based on the individual's control of the binaural pulses to achieve the desired state. The training focused on specific aspects of their psychological difficulties while listening to an auditory tone, turning a knob until the sound increased the desired emotional state. Another knob was turned to intensify the emotional state associated with distress reduction. Results: On self-report measures, the BPM treatment group was significantly better than the sham treatment and control groups. These findings indicate that over the four-week intervention period, BPM was similarly effective to standard treatment approaches for anxiety, PTSD, and stress. Conclusions: BPM appears to result in at least a temporary change in self-reported levels of distress during treatment. Limitations of the study are reviewed and directions for further research are offered.

Keywords: Binaural pulse modulation; neurofeedback; anxiety; distress; stress; PTSD; qEEG; fMRI

Introduction

Psychological interventions for mental disorders are commonly validated for their clinical rather than their biological effects. However, it is increasingly recognized that a better understanding of the neural changes accompanying successful psychotherapy may have considerable benefits. For example, if we can identify pathological activation patterns in relation to psychiatric symptoms, and if these patterns normalize after intervention, we may use this information in the development of new treatment protocols targeting the functional correlates of specific brain networks. This we have

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already demonstrated in a clinical study [1]. To take the matter one step further, we might even be able to target these pathological networks directly, through neurofeedback or related technologies [1,2]. Several decades of feedback research with EEG signals have shown that participants can be trained to influence the amplitude or topography of specific components of scalp electric activity [3]. However, it has been very difficult to influence specific mental states or treat psychiatric disorders with EEG-based neurofeedback, probably because of its low spatial specificity and difficulties associated with the poor signal-to-noise ratio provided by single trial-based EEG. For this reason, tuned sound may be a viable alternative.

A little-known function of the ear is transforming stimuli from our environment into energy. The ear is a generator for the nervous system and brain [4]. The vestibule, a part of the ear that contributes to hearing, not only listens to signals and sends them to the brain, but it also transforms body movements into energy [5].

With auditory stimulation, frequency information is transmitted to the auditory cortex through direct inputs to the fourth layer of neurons, and beat, modulating in character, projects to the auditory cortex through the modulating inputs of the second and third neural layers [6]. The features of the frequency-time structure of auditory signals, which is like the frequency-time structure of impulsive flows of neurons and anatomical conditionality of the affective processing of sound indicate that the mechanisms of the potential therapeutic influence of sound supports synchronization between afferent influences and endogenous neurodynamic processes including potentially emotional state [7].

BPM may be a promising novel method for modifying affective-cognitive function, and the altering of emotional state. Auditory Beat Stimulation (ABS) in general and BPM can be of significant influence in a broad array of clinical applications. It has been suggested that related technologies such as ABS can be used to modulate cognition [8] to reduce anxiety levels [9], as well as providing treatment for the effects of traumatic brain injury [10] and attention deficit hyperactivity disorder [11]. There have been mixed results reported in the literature concerning appropriate auditory beat frequencies [12].

BPM can occur when either sine or square waves of closely related frequencies, and stable amplitudes are presented binaurally simultaneously. For example, when a 440 Hz tone is presented to the right ear and a 414 Hz tone to the right, a beat of 26 Hz will be perceived, subjectively localized to the head of the participant. This effect was initially observed by H. W. Dove in 1839 and noticed again a while back by [13] and by Oster [14] who reported that BPM modulation could be perceived when there was a carrier frequency less than 1000 Hz. We can conclude from this early work that one requires a beat carrier frequency to be significantly low for cortical encoding.

In attempting to employ BPM for anxiety reduction in those suffering from related disorders, be they trait or state types, Padmanabhan and associates [15] examined the effects of binaural beat audio on individuals manifesting pre-operative anxiety reactions. Measuring anxiety with the State-Trait Anxiety (STA-I) questionnaire, those patients having received binaural beat demonstrated a 26.3 reduction in the scores obtained on the STA-I when compared to the 11.8 reduction in STA-I scores in a placebo group. Weiland and associates [16] studied the effects of binaural beat on anxiety by providing natural sound with and without an embedded 10 Hz binaural beat. STA-I scores in this study also demonstrated a significant reduction in anxiety levels in those individuals receiving binaural beats compared to those who did not. Le Scouarnec et al., [17] examined individuals suffering from anxiety disorders and also demonstrated a significant reduction in anxiety scores as compared to those control patients not being exposed to binaural beat. Numerous similar effects have been found in the use of binaural beats in positively affecting mood states [18,19].

It is well known that a coincidence of frequencies exists between neural and musical rhythms) [1,20–23]. Musical rhythms and low-frequency thalamocortical activity have been reported to entrain [22]. Much attention in the literature has been given to the synchronicity of neurodynamic processes and the physiological significance of this phenomenon. It has been demonstrated that synchronization phenomena exert a significant influence on the mechanisms of higher integrative brain functions [24]. This applies to both endogenous neurodynamic processes and neural activity

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evoked by external stimuli. For example, the development of conditioned reflex is possible at a certain level of synchronization (combination] of external stimuli: conditional and unconditional [25].

The time factor or temporal coincidence of different activations is considered the most important condition for long-term changes in synaptic efficiency [26–28]. An example of the importance of endogenous synchronization is the message that the activation of attention and consciously predicted arbitrary movements are accompanied by synchronized discharges of neurons of the nonspecific and motor thalamus. The processes associated with the synchronization of neural activity are considered to be one of the important mechanisms of thalamocortical integration [29,30]. Synchronization of endogenous neural activity with external stimuli is essential for the brain – an information and stimulation-seeking organ [31,32]. The literature supports the notion that afferent impulses, combined with certain phases of spontaneous neural activity can lead to a restructuring of the bioelectric activity of the brain.

BPM can serve as a non-typical biofeedback device that, using audio tones, stimulates the nervous system. The sound is calibrated by each individual to increase the level of emotion (positive or negative) experienced while imagining an experience and while also listening to the sound from the device. Our objective in this pilot study was to examine the possibility of using a BPM-type device to restore an effective psycho-emotional state by activating the endogenous methods of self-regulation to activate the processes of recovery from anxiety and mood disorders. We desired to evaluate if emotional distress would be altered (reduced) or regulated by means of BPM-type systems.

Methods and Methodology

Participants

Sixty participants partook in the study (28 males, and 32 females aged between x and y (M=47.1 years s.d. 7.47). Each of the participants was diagnosed with major depression and/or anxiety and evaluated by a psychiatrist and or psychologist. None of the individuals examined presented with a history of neurological disease or disorder, history of seizures, or trauma either psychological or physical. Each of the participants had physical examinations that ruled out hypothyroidism or hyperthyroidism or any form of cancer. Each participant was medication-free including corticosteroids or appetite suppressants. None of the individuals studied presented with or suffered from potentially co-morbid conditions such as asthma.

Institutional Approval:

The Institutional Review Board of the Institute for Neurology and Neurosurgery in Havana, Cuba, approved this project after careful review of informed consent and all ethical issues. The file is available for inspection upon reasonable request to Dra. Yanin Machado-Ferrer (dra.yaninmachado@gmail.com).

Clinical Trial Registration:

As the current investigation was a pilot study, FDA registration was not obtained at this point.

Inclusion Criteria: Each participant presented or met the criteria for diagnosis of an anxiety disorder, and/or symptoms of Post-Traumatic Stress Disorder (PTSD), and/or presenting with a high level of distress associated with anxiety based on an objective screening measure. None of the individuals in the experimental group or control groups were taking any prescribed medication of any kind before and during the study.

Exclusion Criteria: None of the individuals studied suffered from a primary psychiatric complaint that was a non-anxiety diagnosis, a diagnosis such as pervasive developmental disorder (PDD) or Developmental Coordination Disorder (DCD), an active or inactive psychotic or thought disorder, active substance abuse or dependence excluding nicotine, caffeine or cannabis, hearing impairment, epilepsy or generalized seizure disorder, cerebral palsy, traumatic brain injury, or history of brain surgery, neurologic abnormalities such as autism spectrum disorder (ASD), dyslexia, metabolic illness, autoimmune disease, vascular disorder, history of cancer, and not presently breastfeeding.

Procedure

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Depression/Anxiety evaluation:

Each participant was evaluated at the outset of the study, at the end of the four-week treatment phase, four weeks post-treatment phase, and twelve weeks post-treatment phase after the study. Participants completed the following standardized instruments Beck Depression Inventory-II (BDI-II) [33] or Geriatric Depression Scale, the Generalized Anxiety Disorder test (GAD-7) [34], the Covid Stress Scale (CSS] [35], and/or the PSTD Checklist for DSM-5 (PCL-5) [36].

BPM Administration:

The Binaural Pulse Modulator (BPM) is not a typical biofeedback device, rather using auditory frequencies, it stimulates the nervous system. The sound is calibrated by each individual to increase the level of emotion (positive or negative) experienced while imagining an experience while also listening to the sound from the device.

Apparatus:

The BPM provides auditory stimulation in the range between 0-350 Hz. The auditory stimuli were adjusted in volume for each ear separately and as well as in the range. The main auditory frequency adjustment control knob (frequency) controls range from 0-330 Hz and the secondary auditory frequency adjustment control knob (disruptor) controls an additional offset range from 0-20 Hz. This difference is what is perceived/combined in the brain as the binaural pulse. Wired over ear-headphones were used.

Intervention procedure with BPM:

The participants were introduced to the BPM device and were given an explanation of how it is used and how the volume controls work separately for each ear. Participants were informed how to set and adjust the frequency and disruptor control knobs. The participants were then instructed to put on the headphones and to turn on the device to a setting of 2 on the frequency and 2 on the disruptor. They then listened to the tone for a few minutes to acclimatize and become comfortable with the tone. They adjusted the volume and control knob until they found a frequency with which they were most comfortable. When this was achieved, they were told to turn the BPM off to hear the next step. Then they were required to identify and describe a target relaxing or positive experience, thought, and associated image. Then the participants were instructed to attempt to continue to engage in focusing on the target experience by continuing to think about it and the image and then turn on the BPM while they wore the headphones and heard the tone. The participants were instructed to adjust the frequency control knob until they felt a slight intensification of the feeling of relaxation. Then the participants continued to focus on the feeling while they slowly adjusted the disruptor control knob until they felt an even stronger increase in the feeling or at least did not reduce the feeling. The participant was instructed to continue to continue listening to the auditory stimuli for 15-20 minutes, with the option for a break followed by a second 15–20-minute treatment session. Treatment was twice per week for four weeks.

Results

Analysis of Variance tests were used to evaluate for differences between groups, time, and interactions for each of the measures to determine if self-reported emotional distress was significantly reduced in the BPM treatment group relative to other groups. Reflected in Table 1 on the GAD-7, differences were present between groups (F 6.30, $p < 0.01$), over time (F=8.75, $p < 0.01$), and between groups over time (F 2.99, $p < 0.01$). Table 2 presents the medium effect size between groups (partial eta 2 = 0.06), which for time was medium (partial eta 2 = 0.11), and for the interaction between time and group was medium (partial eta 2 = 0.11). On the GAD-7 the significant group difference was between the experimental treatment group and the waitlist control group, with the waitlist group having a higher mean score (-2.16, $p<0.01$). On the GAD-7 the significant difference over time was between measures before treatment and at the end of treatment with the average on the GAD-7 score at the end of treatment being lower (2.79, $p<0.01$) and reflected in Table 3. Table 4 provides the results of the interaction between groups over time showing a statistically significant difference between the experimental treatment group to all the other groups at the end of treatment, with the experimental treatment group having a lower mean GAD-7 score at the end of treatment. Additionally, the effect

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was limited, and at both 4- and 12-weeks post-intervention the results show a return to higher GAD-7 mean values. The effect was limited, as seen in Table 5, and at both 4- and 12-weeks post-intervention the results show a return to higher GAD-7 mean values.

Table 1. Type 3 Tests of Fixed Effects on the GAD-7.

Effect	Num DF	Den DF	F Value	Pr > F
Group	3	15	6.30	0.0056
time	4	60	8.75	<.0001
time*Group	12	60	2.99	0.0025

Table 2. Effect Size on the GAD-7.

Obs	Effect	partial_eta_2
1	Group	0.06077
2	time	0.10733
3	time*Group	0.11237

Table 3. GAD-7 differences prior to and at the end of treatment.

Obs	Effect	time	Group	_time	_Group	Estimate	StdErr	DF	tValue	Probt	Adjustment	Adjp
1	Group	_	A	_	B	-0.6900	0.5412	15	-1.28	0.2217	SMM	0.7404
2	Group	_	A	_	C	-1.2000	0.5102	15	-2.35	0.0328	SMM	0.1669
3	Group	_	A	_	D	-2.1600	0.5102	15	-4.23	0.0007	SMM	0.0042
4	Group	_	B	_	C	-0.5100	0.5412	15	-0.94	0.3609	SMM	0.9125
5	Group	_	B	_	D	-1.4700	0.5412	15	-2.72	0.0159	SMM	0.0854
6	Group	_	C	_	D	-0.9600	0.5102	15	-1.88	0.0794	SMM	0.3604

Table 4. Interaction between the experimental treatment group compared to all the other groups at the end of treatment, with the experimental treatment group having a lower mean GAD-7 score at the end of treatment.

Obs	Effect	Time	Group	_Time	_Group	Estimate	StdErr	DF	tValue	Probt	Adjustment	Adjp
1	time	BL		END		2.7875	0.5880	60	4.74	<.0001	SMM	0.0001
2	time	BL		END+12		-0.1375	0.5880	60	-0.23	0.8159	SMM	1.0000
3	time	BL		END+4		0.8000	0.5880	60	1.36	0.1787	SMM	0.8460
4	time	BL		PRE		3.13E-14	0.5880	60	0.00	1.0000	SMM	1.0000
5	time	END		END+12		-2.9250	0.5880	60	-4.97	<.0001	SMM	<.0001
6	time	END		END+4		-1.9875	0.5880	60	-3.38	0.0013	SMM	0.0126
7	time	END		PRE		-2.7875	0.5880	60	-4.74	<.0001	SMM	0.0001
8	time	END+4		PRE		-0.8000	0.5880	60	-1.36	0.1787	SMM	0.8460
9	time	END+12		END+4		0.9375	0.5880	60	1.59	0.1161	SMM	0.6908
10	time	END+12		PRE		0.1375	0.5880	60	0.23	0.8159	SMM	1.0000

Table 5. Limited effect size at both 4- and 12 weeks post-intervention. Results demonstrate a return to higher GAD-7 mean values.

Effect	time	Group	_time	_Group	Estimate	StdErr	DF	tValue	Probt
time*Group	END	A	END	B	-4.5000	1.2101	60	-3.72	0.0004
time*Group	END	A	END	C	-5.0000	1.1409	60	-4.38	<.0001
time*Group	END	A	END	D	-7.6000	1.1409	60	-6.66	<.0001
time*Group	END	A	END+12	A	-7.2000	1.1409	60	-6.31	<.0001
time*Group	END	A	END+4	A	-4.8000	1.1409	60	-4.21	<.0001
time*Group	END	A	PRE	A	-7.4000	1.1409	60	-6.49	<.0001

On the CSS, represented in Table 6, no significant differences were found between groups ($F=1.68$, $p>0.05$), a significant difference was present over time ($F=5.87$, $p<0.01$), and the groups appeared to behave similarly over time ($F=0.47$, $p>0.05$). The effect size for the difference over time

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was medium (partial eta 2 = 0.075). With differences between initial screening as well as baseline and end of treatment and four weeks after the end of treatment.

Table 6. CSS test data between groups.

Obs	Effect	time	Group	_time	_Group	Estimate	StdErr	DF	tValue	Probt	Adjustment	Adjp
1	time	BL		END		14.3000	4.3809	65	3.26	0.0018	SMM	0.0172
3	time	BL		END+4		14.3833	4.3809	65	3.28	0.0017	SMM	0.0163
7	time	END		PRE		-15.4208	4.3809	65	-3.52	0.0008	SMM	0.0079
8	time	END+4		PRE		-15.5042	4.3809	65	-3.54	0.0007	SMM	0.0074

On the PCL-5, reflected in Table 7, no significant differences were present between groups (F 0.75, $p > 0.5$), and no significant differences were present over time (F=0.91, $p > 0.1$); however, significant differences were present in the interaction between groups over time (F 2.34, $p < 0.05$). The effect size for the interaction between time and group was medium (partial eta 2 = 0.09). Table 8 presents the results of the interaction between groups over time showing a statistically significant difference between the experimental treatment group to all the other groups at the end of treatment, with the experimental treatment group having a lower mean PCL-5 score at the end of treatment. Table 9 demonstrates that the effect was limited and 12 weeks post-intervention the results show a return toward higher PCL5 mean values.

Table 7. PCL-5 results with tests of fixed effects.

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Group	3	17	0.75	0.5393
time	4	63	0.91	0.4617
time*Group	12	63	2.34	0.0149

Table 8. PCL-5 results of the interaction between groups over time. The experimental treatment group demonstrates a lower mean PCL-5 score at the end of treatment.

Obs	Effect	partial_eta_2
1	Group	0.007608
2	time	0.012400
3	time*Group	0.090299

Table 9. The effect on the PCL-5 was limited and 12 weeks post-intervention with the results showing a return toward higher PCL-5 mean values.

Obs	Effect	time	Group	_time	_Group	Estimate	StdErr	DF	tValue	Probt
11	time*Group	END	A	END	B	-17.8333	7.5941	63	-2.35	0.0220
12	time*Group	END	A	END	C	-18.9167	8.4905	63	-2.23	0.0295
13	time*Group	END	A	END	D	-25.6667	8.4905	63	-3.02	0.0036
14	time*Group	END	A	END+12	A	-23.6667	7.5941	63	-3.12	0.0028

On the BDI-II represented in Table 10, no significant differences were found between groups (F=2.38, $p>0.05$), over time (F=1.54, $p>0.05$), or in the interaction between groups and time (F=0.42, $p>0.05$).

Table 10. BDI-II results for group v. time.

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Group	3	55	2.38	0.0792
time	4	220	1.54	0.1920
time*Group	12	220	0.42	0.9540

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Discussion

While many studies have examined binaural pulse modulation, many up to now have reported contradictory or inconclusive results. Some studies, consistently report a diminishing impact of BPM on anxiety over time, with the underlying mechanisms yet to be understood and how it is that the BPM is produced, and which cortical networks are most involved. Knowing the basis of the effect will support the BPM stimulation optimization as a potentially powerful therapeutic tool with a capacity to modulate cognitive and mood states [37]. We have already performed such a pilot study examining electrophysiological and fMRI changes as a consequence of BPM stimulation that is consistent with the psychometric findings [1]. Additional research, with more precise reporting of research methodologies, in particular including studies performed in clinical environments, will aid in the clarification of BPM effects on anxiety, mood, PTSD, and other behavioral aberrations. Numerous considerations may impact the efficacy of BPM, including the duration of the implied stimulus carrier, frequencies chosen, and background noise that could potentially impact the results. Frequencies may also play a role as well as the addition of background, white, or pink noise which may amplify the beat frequency, having already been subjectively noted to vary the results, with a more robust effect noted at 432 Hz rather than 440 Hz.

A study of the effects of aging showed that independent of age, a BPM in the gamma range of the EEG could be detected, but with less accuracy by older individuals [38]. Some investigations also reported gender differences concerning BPM perception and alterations in auditory perception during the menstrual cycle [39] but gender differences have been ruled out under normal circumstances [40]. Other studies suggest that attending to the stimulus [41] may play a role as numerous additional variables may affect the efficacy of BPM Most importantly, electrophysiological investigations comparing the effects of auditory beats under different stimulation conditions and parameters are still rare. Such studies are required, to allow the development of effective hypotheses explaining the clinical and behavioral outcomes of BPM.

Conclusions

Results of the BPM treatment group were similar to the treatment as usual group which included either psychiatric medication or psychotherapy. Furthermore, on the self-report measures (GAD-7, PCL5, CSS) the BPM treatment group was statistically better than the sham treatment and the waitlist control groups. These findings indicate that over the four-week intervention period, the BPM as used in this study, was similarly effective to the standard treatment approach for anxiety, PTSD, and stress. Due to the self-directed nature of this treatment approach and the beneficial results, without the costs and side effects from medication or psychotherapy, BPM intervention appears to provide a potentially significant tool in the ongoing treatment of anxiety, stress, and Post Traumatic Stress Disorders. With the increased presence of psychiatric and psychological complaints, the potential benefit of this intervention as an adjunctive therapeutic tool may be profound. Additionally, with concerns of medication side effects, short and long-term, this intervention may provide a benefit in reduced severity and perhaps even reduce reliance on long-term medication use for anxiety, stress, and PTSD.

Declarations:

Author Contributions: GL: Conceptualization, Analysis, Writing-Original draft preparation, Visualization, Investigation, Supervision, Writing-Reviewing, and Editing; JW: Writing- Original draft preparation, Visualization, Analysis, Writing-Reviewing, and Editing; YM-F: Supervision, Data Curation, Data Collection, Data Analysis; MA-C: Data Curation, Data Collection, Data Analysis; AGM: Conceptualization, Writing-Original draft preparation, Writing-Reviewing, and Editing; RL: Conceptualization, Writing-Original draft preparation, Writing-Reviewing, and Editing; SD: Writing-Original draft preparation, Writing-Reviewing, and Editing.

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Informed Consent and Ethics Approval: Ethics approval and consent to participate received and available through the Institutional Review Board of the Institute for Neurology and Neurosurgery, Havana, Cuba

Declaration of Patient Consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the journal. The patient understands that his/her name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Declaration of Competing Interest: The authors declare that they have no known competing financial interests or personal relationships with the funding source or elsewhere that could have appeared to influence the work reported in this paper.

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