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QEEG Individualized Protocols for the Treatment of Alcohol Use Disorder

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Throughout United States history, alcohol use disorder (AUD) continues to be a national health concern. Within the last few years, pandemic stressors may also increase the potential for relapse in individuals struggling with AUD (Da et al., 2020). Medical professionals are imploring helping professionals to stay aware of this rising concern and to enhance AUD treatment options. Whereas treatments such as psychotherapy and pharmacology can be efficacious for AUD, there are also limitations to these types of interventions. AUD affects brain wave activity; while the prior mentioned treatments do not directly target brain activity, one treatment that does is neurofeedback. Neurofeedback is well documented for helping individuals with AUD, and other addiction concerns, to reach an enhanced state of regulation (Sokhadze et al., 2008).

After IRB approval and participant recruitment, my supervisor and I created qEEG individualized protocols while also considering Peniston and Kulkosky's (1989, 1990) seminal neurofeedback studies that recommend certain brain wave parameters for AUD protocols. In addition, we also referred to the Scott-Kaiser modification (Scott & Kaiser, 1998) of the Peniston Protocol. The Peniston Protocol uses alpha/theta training and seeks to reduce states of stress and anxiety, while the Scott-Kaiser modification (e.g., SMR-beta modulation) aims to reduce impulsivity tendencies by remedying cognitive issues (Dousset et al., 2020). Participants were asked to complete pre and post qEEG and heart rate variability (HRV) measures along with self-report assessments of pre, post, and follow-up measures of the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993), and repeated measures of a craving desire assessment after every neurofeedback session. Also, participants were asked to attend twice-weekly neurofeedback sessions for 6 weeks or at least twelve 10- to 25-minute sessions. University student clinicians and neurofeedback clinicians administered the neurofeedback sessions. Due to the pandemic and subsequent limiting factors (i.e., COVID concerns or lack of money for transportation), participants were allowed remote neurofeedback. Only one participant asked to utilize remote services.

The primary purpose of this study was to determine if qEEG individualized neurofeedback protocols helped participants regulate their brain activity and reduce AUD cravings. Secondary purposes included comparing physiological data to self-report data and exploring neurofeedback session-to-session changes with a single-subject approach. This poster presentation will include pre and post qEEG *z*-score comparisons from NeuroGuide and pre and post HRV comparisons from BioTrace. Further, I will explore individual changes over time according to participants' neurofeedback protocols using single-case research design methods and participants' individual craving desire changes. The presentation will also entail implications for future research.

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Comparison Between Audiovisual and Visual Beta Neurofeedback for Attention Enhancement

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EEG neurofeedback therapy (EEG-NFT) allows modulation of brain signals by either inhibiting or enhancing them and, consequently, improving the cognitive domain. One such domain is attention or peak performance, which is targeted by enhancing the beta frequency. The adult attention span has a duration of 20 minutes on average (Chaney, 2005). In Pakistan, inattention and hyperactivity among medical students shows 29.6% prevalence (Hamid et al., 2020). Most neurofeedback studies check efficacy for attention by visual feedback (Jurewicz et al., 2018). Visual and motor protocols are effective for task-based attention (Thomas et al., 2013) and auditory EEG-NFT, for meditation (Hunkin et al., 2021). No such comparison between the audiovisual and visual stimuli for attention enhancement exists, hereby creating a need for such study. We anticipated that beta EEG-NFT leads to changes in cognitive behavior. The objective is to compare the impacts of visual and audiovisual feedback on the subjects' behavioral, psychometric, and neurological aspects of attention. We have conducted a pilot study for attention enhancement with two groups: audiovisual NFT (10 subjects) and visual NFT (2 subjects) targeting the beta band (15–22 Hz). Six neurofeedback sessions, with five blocks per session, have been conducted on alternate days. This study has shown an increase in the mean beta power post-NFT followed by the psychometric and behavioral scores. The audiovisual feedback exhibited an increase of 36.15% mean beta power on average, while visual feedback showed an increase of 35.88%. This increase in beta power indicates an increase in attention. The proposed study is an extension of our pilot study to further validate the effect of EEG-NFT for improving attention with increased number of sessions. It consists of a pre-NFT qEEG recording in eyes-opened and eyes-closed conditions, for 2 min each, using a Mistar NVX52 DC amplifier, with 40 channels. ELAS and MAAS questionnaires and Stroop Test are conducted for pre-NFT and post-NFT. The EEG-NFT sessions are initiated with a baseline recording of 2 min in eyes-opened condition, using an EMOTIV EPOC+ 14-channel device. This baseline determines the threshold value for the feedback which, in this study, is set to be 10% of the baseline. The active feedback electrode is FC5, covering the right frontal and central region of the brain. The feedback mechanism works by video pausing itself when the beta power fails to cross the threshold value. The results of pilot study show a significant difference between the mean beta powers at the time prebaseline was recorded and during the NFT sessions ($p < .001$). Increase in prebaseline of all the subjects was evident from regression results. There was a significant difference between the pre-NFT and the post-NFT Stroop test response times ($p = .04828$). The results show successful attention enhancement. A reference for the experiments has yet to be set to find out whether audio plays a vital role along with the visual feedback and if the visual feedback on its own is sustainable enough to enhance the attention. The limitation of the ongoing study is the smaller number of participants and sessions.

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Dynamics of the Psycho-Emotional State and fMRI Neuroimaging During Biofeedback Training Course

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Background and hypotheses. Functional magnetic resonance imaging (fMRI) allows development of new insights about biofeedback mechanisms. The study was aimed at investigation of the specifics of the central processes during the game-based autonomic biofeedback and analysis of the psycho-emotional state of a trainee in the process of mastering the skills of self-regulation. Research hypotheses predicted that (a) the psycho-emotional state changes during biofeedback training will be featured by lower anxiety, decreased neuropsychic tension and the general improvement of emotional state, and (b) the fMRI data will allow to visualize the underlying cerebral network as a set of voxels in the areas of activation (AA).

Materials and methods. The study was conducted on 20 healthy volunteers aged 18 to 30 years, with high personality and situational anxiety and high scores on the neurotic scale (based on Eysenck, Spielberger-Khanin, SHAS, Taylor, and Zung Self-Rating Depression questionnaires). Training course included 10 sessions of heart rate biofeedback using the “BOS-Pulse” system “Vira!” game. Pre- and post-training course, 12 subjects participated in the fMRI-study of biofeedback effects.

Results. By the end of the training the ability for long-term volitional efforts, working capacity, and self-regulation skills increased. As a result of the training the level of neuro-psychic tension decreased significantly (p < .001). The situational anxiety decreased after the biofeedback training (p < .001) and scores on the scale of subdepression and depressed mood also significantly decreased (p < .01). The analysis of the dynamics of autonomic indices during biofeedback matched to the fMRI data allowed visualization of the underlying cerebral network as a set of voxels in the AA. It was shown that the “epicenters” of the AAs were prone to shift into the cerebellum and the brainstem during optimal cognitive strategy used by subjects. The growth of the AAs volume indicated the successive involvement of several networks. The architectonic areas of the cortex included the 37 Brodmann areas (BA) during the first stage, and BA 2, 7, 39, and 44, with the second and the third stages characterized by further involvement of the cortical structures of BA 6, 9, 19, 22, and 40. During the subsequent stages, the activation volumes declined, and AAs were maintained in the BA 6, 7, 37, and 40.

Conclusion. The course of heart rate biofeedback helps to reduce situational anxiety, improve mood, reduce neuropsychic stress, and increase the activity of mental activity (i.e., positively affects the general mental state). The integrative brain activity related to the course of the biofeedback media training points to the fact that developing of the skills of physiological functions self-regulation is accompanied by the activation of the sensory and associative (prefrontal and parietal) cortical areas, subcortical regions (the cerebellum) and is not limited to the cerebral structures that are traditionally considered as cognitive ones. During the learning to self-regulate the heart-rate AAs shifted to the sensory brain areas.

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Real-Time fMRI-EEG Neurofeedback for Stroke Rehabilitation

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In this study poststroke patients performed motor-imagery task and received feedback signal based on mu-rhythm desynchronization and functional activation in supplementary motor area (SMA) and dorsal premotor cortex (PreM) in the 6-session fMRI-EEG neurofeedback treatment course. The patients were enrolled within the period of 1.5–24 weeks from the stroke onset. The inclusion criteria were (a) right-handedness patients aged over 45 years; (b) verified stroke-related hand function impairment; (c) ability to tolerate tests in the MRI; scanner and lie still within the training sessions; (d) mild cognitive impairment allowing them to understand instructions; and (e) while featuring no other severe condition. An ischemic stroke was verified with neuroimaging and other clinical criteria (i.e., MoCA scores, Ashworth scale scores, lower and upper limbs paresis scores, etc.). The study aimed to test the effectiveness of fMRI-EEG neurofeedback. Both control and experimental group patients were admitted to the hospital for 2–3 weeks and were subject to standard medical rehabilitation procedures. At the beginning and end of the treatment course, diagnostic fMRI-EEG sessions were recorded, including structural MR-tomography, resting-state condition, motor-execution and motor-imagery tasks. Patients from the experimental group have participated in six neurofeedback sessions, consisted of two 10-min runs with eight regulation blocks. Each block began with a 20-s rest, then the patients were given 40 s for a motor imagery trial, and then feedback on a scale of 0 to 100 demonstrated for 10 s. SMA and PreM contralateral to the injured hand were chosen as fMRI targets, and desynchronization in mu (8–13 Hz) and beta (18–26 Hz) frequency band for C3 and C4 electrodes as EEG targets. OpenNFT software was used for collecting, preprocessing, and modelling of real-time fMRI data. In the EEG case, data were cleaned of scanner and cardioballistic artifacts using RecView (Brain Products) software. The fMRI-EEG data have been collected for eight patients of the experimental group (five – left, two – right hemiparesis, one was excluded later due to artifacts) and six of the control group (three left and right). In the experimental group on average significant ($p < .05$) positive percent signal change of fMRI signal in PreM is revealed for 45% of neurofeedback sessions and 51% in SMA. Despite a positive linear trend in total fMRI-EEG feedback scores for four patients from seven over the treatment course, there is no group differences in this value between sessions. There were (a) significant interaction between time and group factor on the Kinesthetic and Visual Imagery Questionnaire (KVIQ) scale ($F = 5.849$, $p = .034$) using a repeated measures ANOVA with 2x2 design, and (b) significant Spearman correlation coefficient of session number with box-n-blocks test dynamic in the experimental group ($r = 0.986$, $p < .001$). More patients are required for the better statistical results. In addition, dynamic causal modelling is needed for investigation of effective connectivity before and after intervention.

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Braingomo: An Innovative Smartphone-Based Neurofeedback Platform

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Neurofeedback is the brain training during which individuals learn to regulate the brain activity voluntarily for the side effect free treatment of many neurological and psychological conditions (Marzbani et al., 2016). For example, a large body of clinical research, including meta-analyses, has consistently shown that neurofeedback serves as an effective treatment for attention-deficit/hyperactivity disorder (ADHD) with its standard training protocols and long-term treatment outcomes (Arns et al., 2014; Cortese et al., 2016; Van Doren et al., 2018). Considering the continuously increasing acceptance of neurofeedback and its profound treatment outcomes, we aim to further contribute to the field by developing the Braingomo platform. The Braingomo platform is an innovative smartphone-based neurofeedback platform that provides home-based brain training under the supervision of a clinician, thus bringing neurofeedback to anyone, anywhere, and anytime. Braingomo is composed of a mobile EEG system with dry electrodes as the hardware, and a smartphone app and a web server as the software. We acknowledge that good brain training needs good data quality. Accordingly, the main part of the Braingomo innovation comes from our self-designed and self-manufactured dry electrodes that provide high-quality data. We have developed copper and conductive polymer-based electrodes that both have high electrical conductivity based on the microvolt range of human brain waves (Chen et al., 2014). The copper electrodes have good conductivity throughout the scalp (e.g., occipital region), due to the diagonal pins that pass through any amount of hair, thus recording brain activity from any scalp region. The polymer-based electrodes have softer pins, thus suitable for sensitive skins. Both electrodes have a high life span and a high signal-to-noise ratio but low production costs. Moreover, they are compatible with any standard cable due to their connections through standard snap buttons. The prototypes have shown promising results with a high potential to be improved further by coatings as well as better design and production path. We also acknowledge that treatment outcomes depend on several neurofeedback parameters such as training intensity and repetition as well as psychological factors including individualization of the training and coaching that further affect the motivation and adherence to the training (Kadosh & Staunton, 2019). Accordingly, as another innovation, we implement all these parameters into the Braingomo platform by combining the software's smartphone app and web server. Smartphone app receives brain activity and analyses it in real time for brain training anywhere and anytime, thus providing flexibility in training time and place. Moreover, it has many appealing game options with a reward system, thus increasing the motivation and adherence to the training. The connection between the smartphone app and the web server provides supervision and control by clinicians over training sessions and training reports, thus providing supervised and individualized training outside of clinics. We consider that the Braingomo platform offers a novel neurofeedback approach that has a high potential to decrease the accessibility limit of neurofeedback, thus contributing further to the widening of the neurofeedback applications, acceptance, and treatment outcomes (Bussalb et al., 2019).

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QEEG-Guided sLORETA Neurofeedback Effects on Event-Related Potentials and Cognitive Performance on a Stroke Sufferer: A Case Study

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Cognitive and motor impairments are highly prevalent and persistent in stroke survivors. Network disruptions caused by a stroke event on brain regions implicated in the different aspects of cognition can significantly impact the quality of life. Accordingly, targeting both focal cortical tissue damage and nonfocal global changes in brain function should be considered when developing therapeutic strategies to improve brain dysregulation, recovery rate, and cognitive performance of brain injury survivors. In this regard, the use of standardized low-resolution electromagnetic tomography analysis (sLORETA) *Z*-Score neurofeedback (sLZNFB) is a promising approach to target dysregulation in networks on deep cortical locations. The present study aimed to explore the effects of sLZNFB on brain electrophysiology and cognitive performance for a 67-year-old male who suffered a stroke in the left hemisphere (speech difficulty and right hemiparesis were presented at intake). The study used a pre-experimental design with pre–post comparison. To this end, sLZNFB (surfaces plus coherence training) was applied to affected brain areas for 15 sessions. An eyes-open training approach was conducted as the patient showed low engagement/arousal at the initial stages of recovery. Baseline and post measurements were made on qEEG metrics, event-related potentials at Pz (oddball paradigm), attention, memory, executive function, reaction time, and cognitive flexibility. Clinical improvements were found in attention, memory, and reaction time after 15 sessions of sLZNFB on computerized cognitive tasks. QEEG Z-score maps show positive changes on frontal high frequencies and left posterior delta. Improvement in connectivity variables was observed across all frequencies. Greater discrimination and less latency for auditory stimulus were also found on P300 ERP component analysis at Pz after the intervention. In addition, significantly improved speech and motor function were also observed at session #8. These findings suggest the potential effectiveness of sLZNFB on cognitive performance improvement among stroke sufferers. Further studies with a larger number of patients and control groups may be required to evaluate the full potential of this type of training in stroke patients.

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Effect of TMS on EEG Biomarker in a Patient with PTSD Performance on a Stroke Sufferer: A Case Study

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Background. A large majority of the United States population will experience at least one traumatic event in their lifetime, and 5–10% will go on to develop posttraumatic stress disorder (PTSD; Yehuda et al., 2015). Trauma-focused therapy is the recommended treatment for PTSD, but 30–50% of patients do not respond (Jonas et al., 2013). There is significant interest in using focal neuromodulation, such as transcranial magnetic stimulation (TMS), to induce functional brain changes as a potential treatment for psychiatric disorders (Zandvakili et al., 2019). Quantifying TMS's functional and neurophysiological effects and their link to symptom severity change is essential to understanding TMS's neural mechanisms and developing more effective and individualized TMS therapies. This study

explores an electrophysiological biomarker by comparing electroencephalography (EEG) signals before and after 10 days of TMS in patients with PTSD symptoms.

Method. Four female patients (age 36.5 ± 16.3) with PTSD symptoms underwent our TMS study procedures consisting of 20 sessions (1800 pulses each) of 1 Hz to the right dorsolateral prefrontal cortex (DLPFC). We assessed the patient's PTSD symptom severity using the PTSD checklist for DSM-5 (PCL-5) before and after the 10-day treatment. Additionally, we recorded EEG signals using a 14-channel wireless EEG headset (Emotiv, San Francisco, CA) with a 128 Hz sampling rate for 6 min at these time points. The 14 channels include AF3, AF4, F3, F4, F7, F8, FC5, FC6, T7, T8, P7, P8, O1, and O2 (Duvinage et al., 2013). We segmented each session of EEG signal into 5-s nonoverlapping epochs. Next, for each epoch, we extracted spectral power features including theta (5–8 Hz), alpha (9–12 Hz), and beta (13–30 Hz) of both pre- and post-TMS for each contact. We trained a five-fold nested cross-validation logistic regression (LR) with elastic net regularization (ENR) to classify pre- and posttreatment states based on the spectral power feature of each contact separately. The receiver operating characteristic (ROC) of the cross-validation and area under the curve (AUC) was used to measure the classifier performance (Sendi et al., 2021). Finally, we used ENR as a feature learning method to find the feature with the most contribution in the classification.

Results. In this study, we only analyzed data from one patient who showed a 40% reduction in PTSD symptom severity after a 20-session TMS treatment. We found that frontal contact, including AF3 and F3, were the top two contacts separating the pre- and posttreatment conditions with an AUC value of 0.78 ± 0.09 and 0.68 ± 0.13, respectively. Additionally, we found that the AF3 beta and F3 theta power have the highest contribution in classifying pretreatment and posttreatment conditions ($p < .001$).

Conclusions. This $N = 1$ study shows that frontal contacts significantly separate pre- and post-TMS conditions and change in PTSD symptoms, suggesting its relevance for TMS response biomarker in PTSD. Data collection and analysis is ongoing and future study is needed to explore other EEG features across multiple patient data.

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Loreta *Z*-Score Neurofeedback in Nine Clients with Anxiety and Posterior Cingulated Deviations

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Loreta *Z*-score neurofeedback training (LZNFB) is an individualized method of neurofeedback. This method trains specific brain hubs and networks towards $Z = 0$, which are the most deviant for each individual client and the most likely linked to their symptomatology. Studies investigating the efficacy of LZNFB are promising in that they often show a significant decrease in symptoms. However, too few studies report qEEG changes among their outcome measures. The aim of this pilot study is to bridge this gap in LZNFB research, investigating results in a subgroup of clients with anxiety and posterior cingulate gyrus abnormalities.

Participants. Nine adult clients (five men, four women, age $M = 32.72$, $SD = 10.73$) with mental health complaints filled in the Brief Symptom

Inventory (BSI-53) before and after their neurofeedback therapy. They all reported anxiety as a main symptom and had significant deviation in the posterior cingulate gyrus before LZNFB.

Method. All clients started with an intake and qEEG assessment, guiding their LZNFB protocol. Before the first training session patients filled out the BSI-53 in order to clarify symptoms related to the physiological profile. Each LZNFB session lasted between 30 and 40 minutes. The training protocols were designed to target a neural network, that has a significant role in the client's symptomatology and includes the posterior cingulate gyrus. Since this study was made in a clinical setting, each client did a number of sessions limited to their financial possibilities. After their last session, they filled the BSI-53 again.

Results. The participants did 16 sessions on average (SD = 3.87). On average, the global BSI-53 scores before neurofeedback (M = 3.96, SE = 0.73) were higher than after neurofeedback (M = 0.78, SE = 0.35). This difference, 3.18, was significant, $t(8)$ = 4.02, $p < .01$, and represented a very large effect size of d = 2.45. The scores on the anxiety scale of the BSI-53 was also better after neurofeedback (M = 0.76, SE = 0.46) than before neurofeedback (M = 4.25, SE = 0.62). This difference, 3.49, was significant, $t(8)$ = 4.49, $p < .01$, and also represented a very large effect size of d = 3.35. The average standard deviation (across all frequencies left and right) in Brodmann area (BA) 31 decreased from a mean of 0.83 (SE = 0.08) before neurofeedback to a mean of 0.60 (SE = 0.74) after neurofeedback. This difference, 0.23, was significant, $t(8)$ = 3.17, p = .01, and also represented a large effect size of d = 1.05. The only noticeable side effect was fatigue, which subsided within a day after each session. Interestingly, there was a significant correlation (r = 0.71, p = .03) between difference in anxiety scores and difference in BA31 deviation.

Conclusion. LZNFB shows promise to improve anxiety in a subgroup of patients with posterior cingulate gyrus abnormalities. The more the posterior cingulate gyrus normalized through LZNFB, the more the anxiety score decreased. This could confirm both the working mechanism of LZNFB (bringing subjective progress through changes in brain activation patterns), and the role of the posterior cingulate gyrus in anxiety symptoms. These findings and the conclusions that it could bring, remain to be confirmed in a larger sample.

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The Application of Biofeedback and Neurofeedback in Underserved Children and Adolescents in Pediatric Neurology

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Mental health issues represent a major global economic burden and affect 21% of adults in the U.S. each year. According to the Centers for Disease Control and Prevention, 1 in 5 children living below the United States federal poverty line has a mental, behavioral, or developmental disorder.

As underserved communities lack resources and access to medical and mental health care, their social and environmental difficulties, as well as their cultural, systematic, and individual barriers, are magnified. The need for a comprehensive approach to reduce disruptive mental disorders in children from minority populations is therefore imperative. Despite the wide avenue of treatments available, these children and families are less likely to seek and receive such services. Biofeedback therapy and electroencephalography (EEG) biofeedback are noninvasive therapeutic techniques that have been shown to regulate brain activity and improve clinical symptomology of neurological conditions including depression, anxiety, and migraine. Although there is indeed a wealth of studies that regard strong evidence of the therapeutic effects of biofeedback training on mental health problems, nationally representative evidence on minority individuals in these studies remains scarce. To date, the biofeedback framework has been built without enough appreciation of pertinent factors such as race, ethnicity, and culture and their underlying determinants of health. This is especially true for children and adolescents living in underserved communities which represent a high-risk population aggravated by network inadequacy in healthcare. Therefore, it is imperative and a growing urgency to study the effectiveness of these therapies in children living in historically marginalized communities. While there are only a handful of studies that have tried to shed light on this knowledge gap, most of them were performed and carried out in nonclinical settings. Our ongoing study aims to investigate the application of biofeedback and neurofeedback in underserved children and adolescents, ages 7 to 21, treated at an outpatient site at the Vanderbilt Clinic in New York-Presbyterian Hospital at Columbia University. We will present a thorough analysis of results and demographics gathered from approximately 50 underserved patients, primarily Hispanic and Black, during intervention sessions. Patients initially presented negative symptoms associated with either anxiety, depression, or migraine. An intervention treatment plan of biofeedback or neurofeedback was tailored for each patient prior to the commencement of the first session. Our preliminary data suggest clinically significant improvement in most of the symptom-related outcome variables. We will discuss thoroughly the limitations and challenges of the current study. To our knowledge, this is the first research study exploring the implementation of biofeedback and neurofeedback in ethnic minority groups in the United States, especially children and adolescents. This study will highlight the meaningful incorporation of biofeedback and neurofeedback services in pediatric neurology practices to provide underrepresented populations access to this health service, who would otherwise not receive it. We understand the significance of bridging this gap for health equity in clinical practice and biomedical research representation, and we aim to encourage others to join these efforts.

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Power Spectrum Analysis in a SMR/Theta Neurofeedback Protocol Using Different Behavioral Strategies

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The literature reports that it is possible to modify the pattern of electroencephalographic (EEG) activity from neurofeedback techniques; however, such findings continue to have limitations. One of the most widely used clinical protocols consists of increasing sensorimotor rhythm (SMR) and simultaneously decreasing theta activity with the aim of increasing attentional performance and reducing hyperactive and impulsive behaviors. The SMR band is characterized by a frequency of 12–15 Hz and is the expression of synchronized oscillatory activity, reflected in the sensory motor cortex; it is associated with body movement and the ability to concentrate (Gruzelier et al., 2010). SMR neurogenesis emanates from the ventrobasal nucleus of the thalamus which is generally related to the conduction of somatosensory information (Gruzelier et al., 2010). The protocols that train SMR/theta report the use of different behavioral strategies to favor the production of trained rhythms; however, there is no consensus regarding the use of which strategies are more effective. On the other hand, there are SMR/theta protocols that are not combined with any behavioral strategy, and participants are successful in the protocol. (Binsch et al., 2017; Crivelli et al., 2019; Dessy et al., 2020; Gonçalves et al., 2018; Jirayucharoensak et al., 2019; Lee et al., 2019; Shtark et al., 2018; Skottnik et al., 2019; Pei et al., 2018; Wood, Brickwedde, et al., 2019).

The objective is to analyze the effect of the following behavioral strategies: guided imagery, mindfulness, or heart rate variability (HRV) during a neurofeedback protocol on absolute SMR/theta power in healthy volunteer participants. In this study, 25 healthy volunteer participants between 21 and 50 years old were assigned to four groups: (a) Comparison group: NRA, *n* = 8; (b) Intervention group 1: NRA + HRV, *n* = 6; (c) Intervention group 2: NRA + guided imagination, *n* = 5; and (d) Intervention group 3: NRA + mindfulness, *n* = 6. The absolute power of each of the frequency bands was analyzed with the continuous wavelet transform. Likewise, the contribution factor of the area under the curve of each brain frequency was compared. The nonparametric Spearman's Rho test was performed to assess the degree of correlation between the contribution factor of the SMR/theta frequency bands and the number of training sessions.

The behaviors observed both in the contribution factor and in the power indicate that the behavioral strategies used to train the SMR/theta rhythms differ in their effect, so it is important to standardize the strategies proposed in the SMR/theta protocols.

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Effect of Transcutaneous Electrical Nerve Stimulation of the Auricular Branch of the Vagus Nerve for the Treatment of Anxiety

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Background. Vagus nerve stimulation is a known technique to modulate autonomic function (Clancy et al., 2014) and is FDA approved for the treatment of certain diseases like depression and epilepsy. However, traditional stimulation methods are invasive, require an implant, and are reserved for severe or drug-resistant cases and approval for use in anxiety-related diseases has yet to be achieved.

Objective. The purpose of this study was to assess the safety and efficacy of transcutaneous auricular vagus nerve stimulation (taVNS) compared to a sham taVNS in patients with anxiety using a novel neurostimulation device.

Methods. A randomized, sham-controlled approach was used to investigate the effects of active or sham taVNS on state-anxiety in 24 participants as scored by the State-Trait Anxiety Inventory (STAI). Participants completed a stress-inducing task before and after using a sham or active neurostimulation device at a target site over the proximal lateral cervical region containing the auricular vagus nerve. The STAI was used to measure anxiety before and after each stress-inducing task was completed. Upon completion of the tasks and treatment, the safety and tolerability of the device were assessed. EEG and physiological measures were recorded throughout the study tasks. Results were examined to compare the change in anxiety levels, EEG, physiology, task performance, and safety and tolerability measures before and after treatment with the P57 ONE (sham vs. active).

Results. A Fisher's Exact Test was used to quantify the relationship between immediately after and 24 hours after safety reports (yes or no) of discomfort, dizziness, blurred vision, headache, skin irritation, relaxation, and distraction from the stimulation protocols (sham vs. stimulation). An unpaired *t*-test was used to compare average levels (1–10) of comfort, discomfort, dizziness, blurred vision, headache, skin irritation, relaxation, and distraction ratings immediately after stimulation and at least 24 hours after stimulation between each protocol group. An unpaired two-tailed *t*-test was used to compare the difference (post and pre) in state-anxiety, EEG, physiology, and task performance between active and sham stimulation groups. Analyses for safety and tolerability ratings found no significant differences between active and sham users immediately after or 24 hours after stimulation. Compared to the sham group, the active treatment group reported the experience as relaxing more frequently ($p = .001$) and a greater level of relaxation ($p = .002$). Analysis of STAI, EEG, physiology, and performance data is ongoing; these results will be presented during the poster session.

Conclusion. This study provides preliminary evidence in support of using taVNS to elicit a beneficial effect on relative anxiety via increased relaxation. Stimulation of the target site with a novel neurostimulation device was found to be both safe and tolerable. Analysis of STAI, EEG, physiology, and performance data will be presented to address efficacy aims. This technique of noninvasive stimulation could be a new effective method to quickly reduce anxiety without having to resort to pharmaceutical or invasive intervention.

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